THE CHEMICAL AND PHARMACEUTICAL INNOVATION REPORT 2013

FINNEGAN

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About Finnegan

With more than 350 intellectual property lawyers, Finnegan is one of the largest IP law firms in the world. From offices in Washington, DC; Atlanta, Georgia; Boston, Massachusetts; Palo Alto, California; Reston, Virginia; London, United Kingdom; Shanghai; Taipei; and Tokyo, the firm practices all aspects of patent, trademark, copyright, and trade secret law, including counseling, prosecution, licensing, and litigation. It also represents clients on IP issues related to international trade, portfolio management, the Internet, e-commerce, government contracts, antitrust, and unfair competition. For additional information on the firm, please visit www.finnegan.com. Follow us on LinkedIn or on Twitter.

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Table of Contents

I. Introduction

With the historic reforms of the America Invents Act ("AIA") shaping 2012 and 2013, this was a good time to update *Finnegan's Biotechnology Innovation Report 2004* and *The Chemical and Pharmaceutical Innovation Report 2006*. As we begin this new chapter under the AIA, it will be important to understand how the changes under the AIA shape jurisprudence and the innovation behind the jurisprudence. At this time, *The Chemical and Pharmaceutical Innovation Report 2013* benchmarks the state of the U.S. patent system from 2006 to 2012 in the chemical and pharmaceutical areas by using certain measures.

As with previous years' *Reports*, we review patent-prosecution trends and survey the changes that are occurring in the courtroom at the district court and appellate levels in the chemical and pharmaceutical areas. In the *Report 2013*, those sections include coverage and analysis that look into the patenting of the top fifteen chemical and pharmaceutical companies. The litigation sections further provide insight into win rates by method of disposition (i.e., bench trial, jury trial, summary judgment, or post-trial motion) and a detailed look at the subject matter of today's chemical and pharmaceutical cases. Given the broad reach of the AIA, we included a section describing the major changes. Summary charts and tables are provided to understand the impact and identify considerations in developing strategies under the AIA. Finally, the *Report 2013* surveys the Federal Circuit case law from 2006 to 2012 in the chemical and pharmaceutical areas. This survey not only includes summaries of relevant decisions, but also categorizes the decisions in this time period by subject matter in order to provide a finding tool.

By benchmarking now, the *Report 2013* captures pre-AIA data and will be subsequently updated in order to fully capture and understand the post-AIA patent world and its implications from a chemical and pharmaceutical perspective.

We welcome your comments and suggestions as this *Report* evolves.

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II. Patenting and Application Publication Trends

By examining patenting and application publication trends, we can get a better understanding of not only the chemical and pharmaceutical industries today (by looking at the patents that grant), but also we can get a preview of the industries' future (by looking at the applications that are publishing). Here, we survey the past decade to see what trends emerge to provide an understanding of today's as well as tomorrow's future.

The trend analysis detailed below seeks to answer the following questions:

- What is the health of the chemical and pharmaceutical industries?
- What patent activities are on the rise in the chemical and pharmaceutical industries?
- What emerging claim terms appear?
- What claim terms are on the decline?
- What are the patenting and filing trends of some of the *Fortune 500* chemical and pharmaceutical companies?

A. Patenting

1. Methodology

Using the United States Patent and Trademark Office ("PTO") Patent Full-Text Databases for issued patents and published patent applications, we used specific search terms to compare the relative patenting activity among various technologies within the chemical and pharmaceutical industries. In order to compare "apples to apples," we normalized the results of the number of patents or published patent applications containing the search terms to the total number of issued patents or published applications per thousand. For example, for issued patents, the patents per thousand ("PPT") number was the number of patents in a particular year containing a particular search term divided by the total number of patents issued that year, multiplied by 1000. Similarly, for published patent applications, we measured "application share" in published applications per thousand ("PAPT").

Figures 2-3 and 2-4 exemplify our methodology. These charts show patenting activity based on the search terms "pharmaceutical" and "compound or composition" found in claims of issued patents and published patent applications over the time period 2002-2012. Figure 2-3 illustrates patenting activity based on changes in PPT over the last decade. Similarly, Figure 2-4 demonstrates patenting activity based on changes in PAPT over the last decade.

2. Results

In general, the results of our search show that the number of issued patents, although fluctuating from year to year, has dramatically increased from 2002 to 2012 (Figure 2-1). The fluctuation pattern of the issued patents over the past ten years somewhat coincides with the timing of administration changes in the PTO. Compared to 2002, the number of issued patents in 2012 has a 50% increase (Figure 2-2). It appears, however, almost all of that increase took place in the past four years while David Kappos was at the helm of the PTO.

Overall, the number of published applications did not suffer a year-to-year fluctuation. Instead, it has been steadily increased from 2002 to 2012 (Figure 2-1), reflecting a continued feverish public interest in procuring patent rights. Compared to 2002, the number of published applications in 2012 has an over 65% increase (Figure 2-2). But, of note, there is a slight dip in 2011. That may be a delayed reflection of the most recent economic recession, as patent publications are generally published eighteen months from the priority date.

The above general trend is not reflected in pharmaceutical patents. As shown in Figure 2-3, the appearances of general terms such as "compound" and "composition" in issued patent claims have been tapering off slightly over the past several years, while the appearance of "pharmaceutical" has been kept nearly constant. The trends of these terms in claims of published applications are also similar (Figure 2-4).

Figure 2-1: Issued Patents and Published Applications from 2002-2012

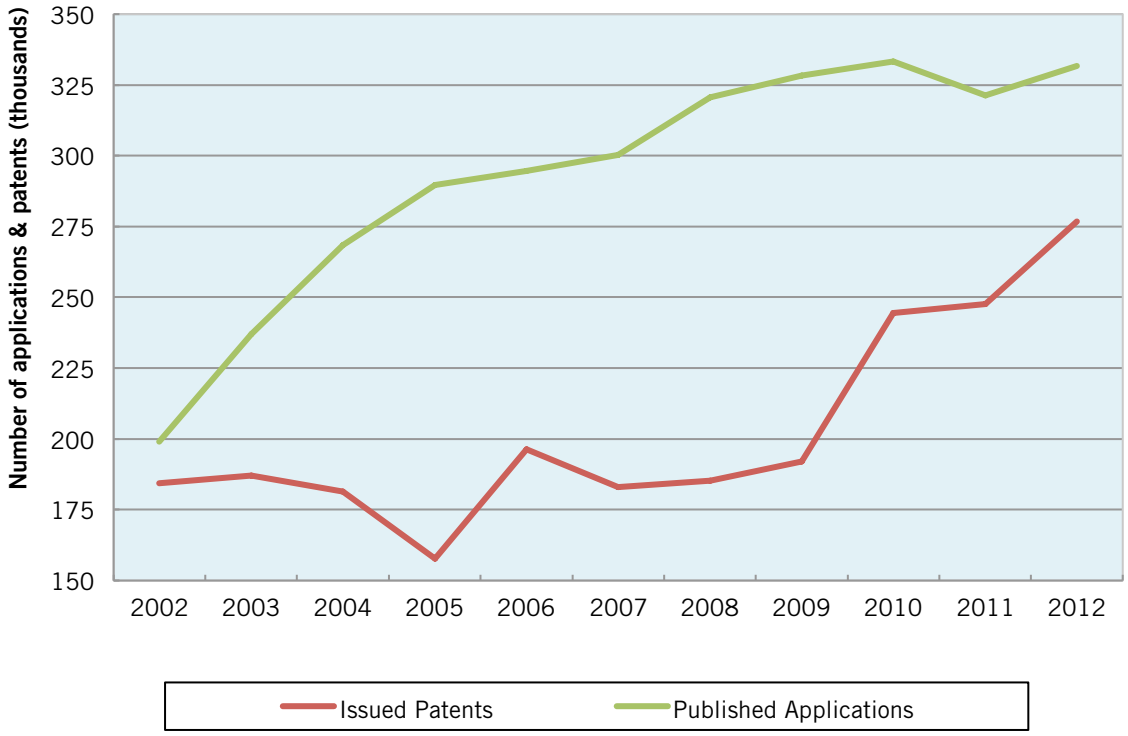


Figure 2-2: % Change in Total Issued Patents & Published Patent Applications from 2002-2012

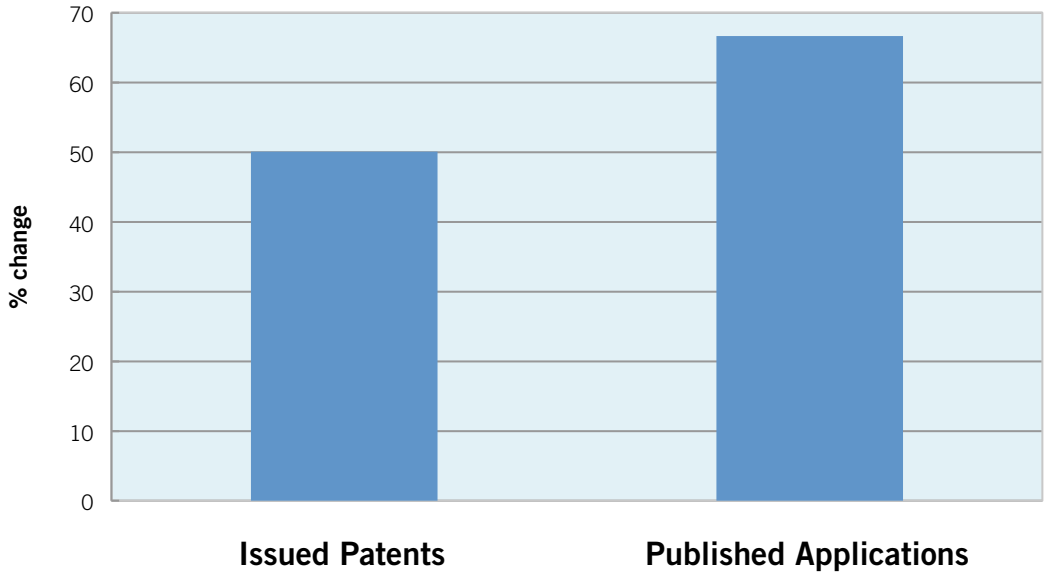


Figure 2-3: Pharmaceutical/Chemical Trends (Claims of Issued Patents)

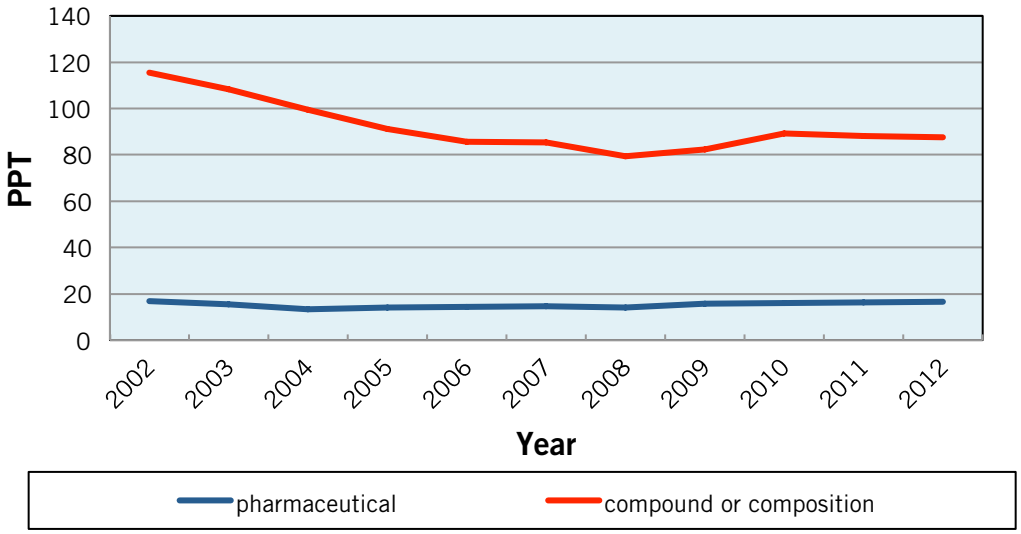
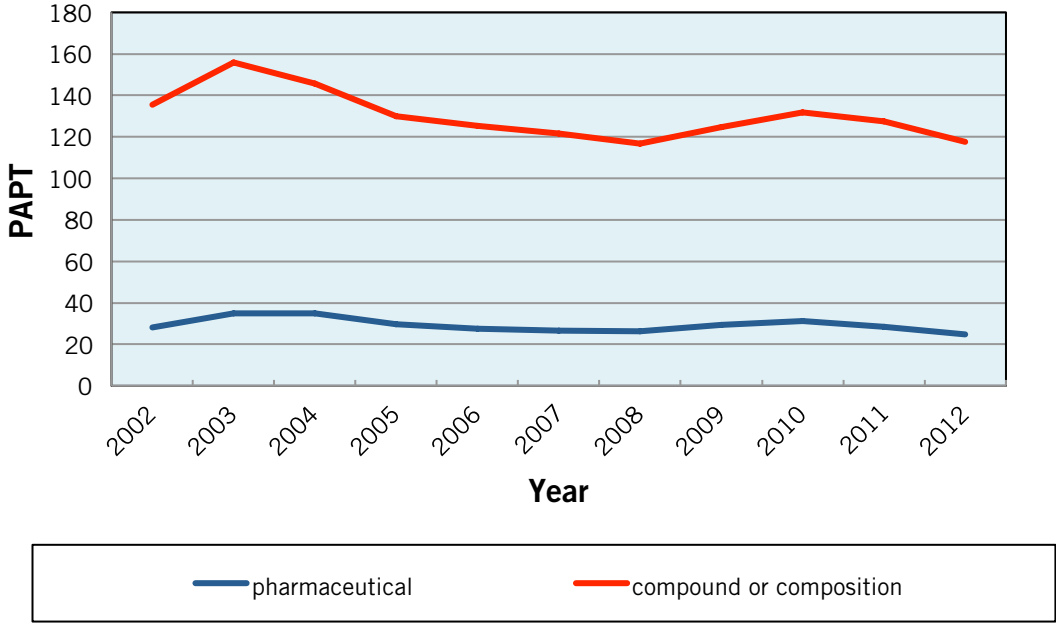


Figure 2-4: Pharmaceutical/Chemical Trends (Claims of Published Patent Applications)



3. A Closer Look at Pharmaceutical and Chemical Activity

We will now take a closer look a patenting activity in the pharmaceutical and chemical areas. By looking at the trends of certain claim terms, the identification of trends emerges (e.g., what patent activities are on the rise in the pharmaceutical and chemical industries, what emerging claim terms appear, or what claim terms are on the decline).

In Figures 2-5 and 2-6, we see comparative data for pharmaceutical and chemical terms more closely for the time period 2002 to 2012 for issued patents and published patent applications. In Figure 2-5, despite significantly more patents which recited "compound" or "composition" in the claims, we see that the appearance of "pharmaceutical" in the claims remains generally stable over time, and "treat or treating or treatment" experiences a slight decline.

All three terms show a decline beginning in 2010 in the claims of published patent applications in Figure 2-6.

Figure 2-5: Pharmaceutical/Chemical Terms in Claims of Issued Patents

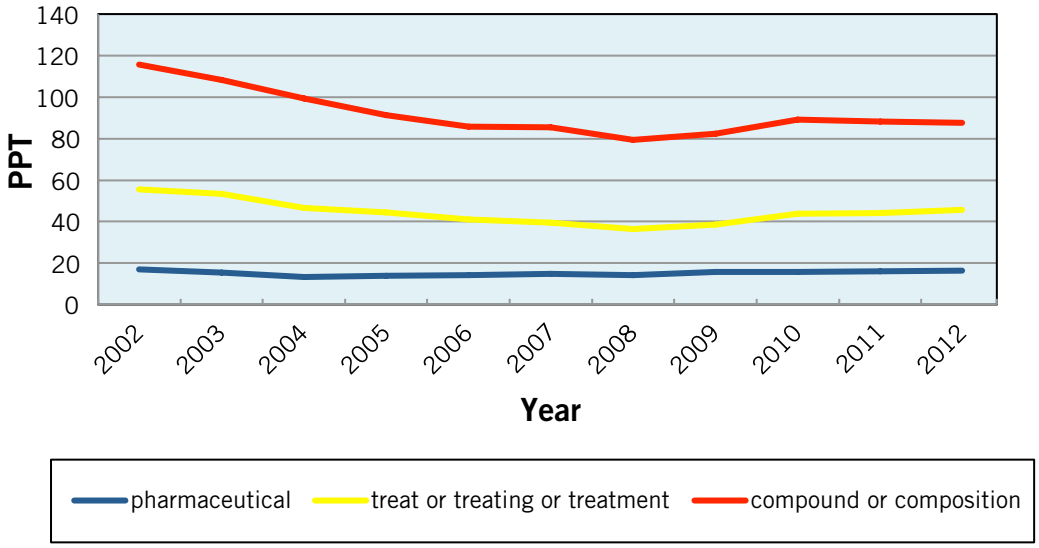
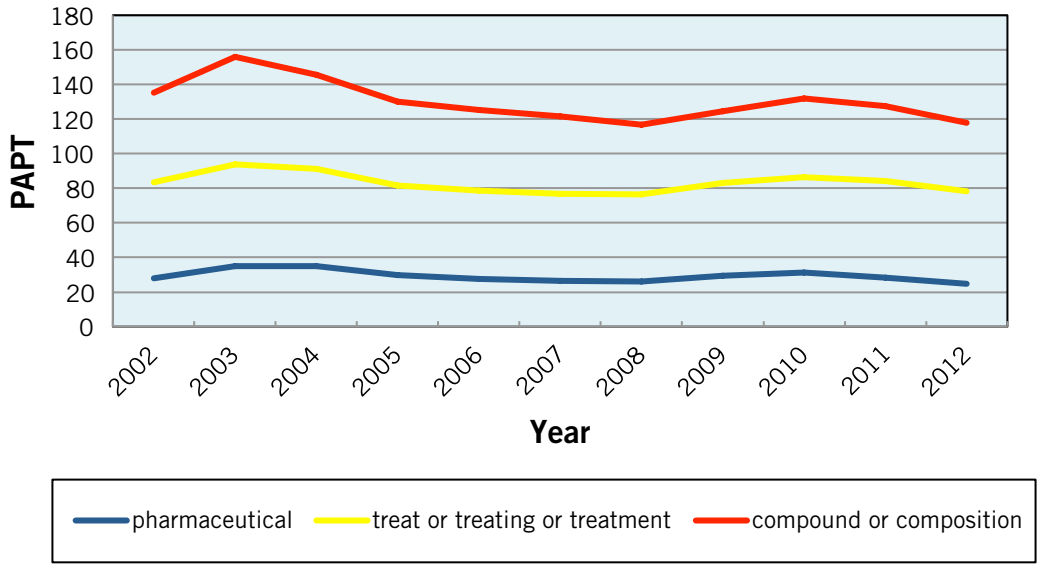


Figure 2-6: Pharmaceutical/Chemical Terms in Claims of Published Patent Applications



Figures 2-5 and 2-6 represent pharmaceutical and chemical search terms in the claims of issued patents and published patent applications, respectively, as a function of time. The results were converted to PPT and PAPT for comparison.

Figures 2-7a and 2-7b show the overall percentage change in the appearance of pharmaceutical and chemical terms in the claims of issued patents from 2002 to 2012. Notably, in Figure 2-7a, "green technology" and "miRNA" do not show a corresponding growth change; in 2002, neither term appeared in any claims of issued patents. In 2012, "green technology" appeared in one claim of an issued patent, and "miRNA" appeared in sixty-two claims.

Figure 2-7a: Change from 2002-2012
In Key Terms in Claims of Issued Patents

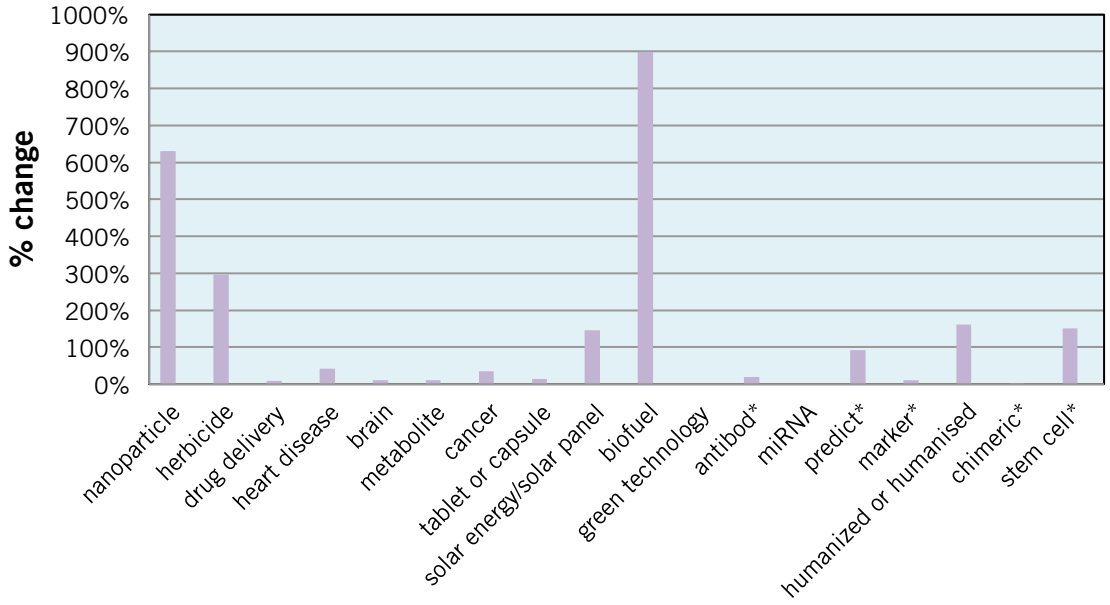
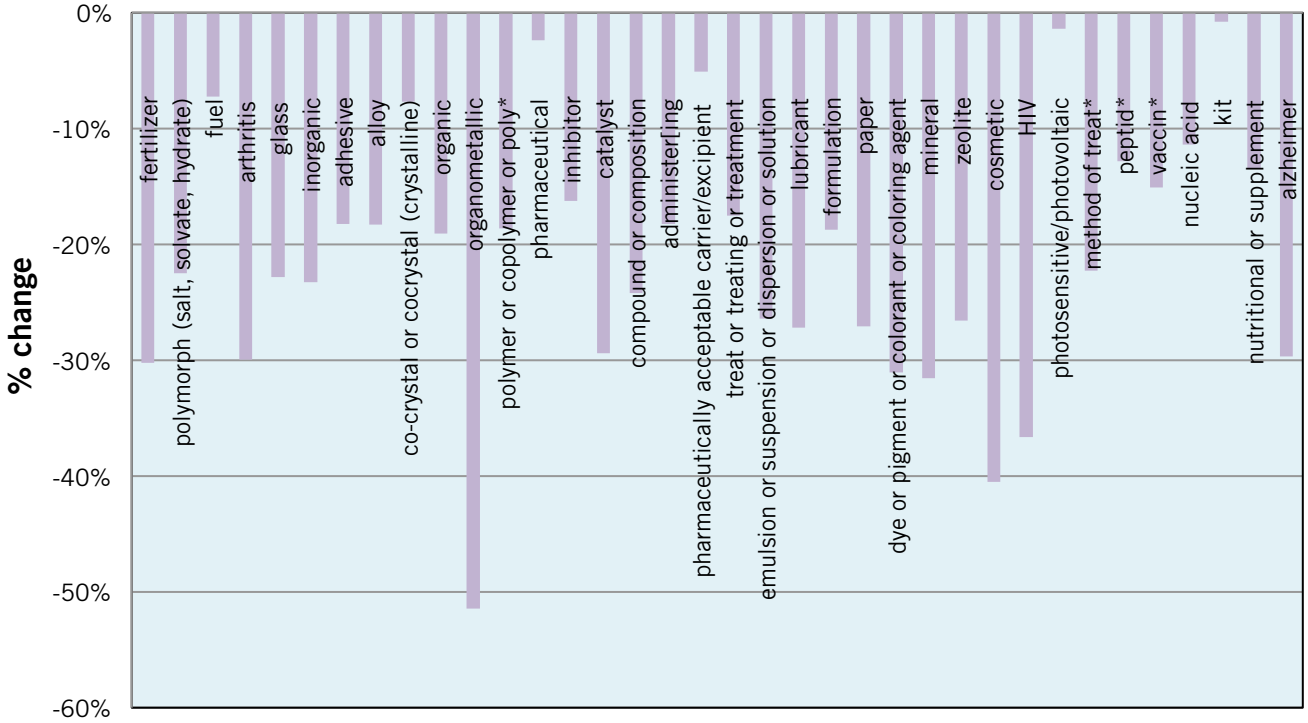


Figure 2-7b: Change from 2002-2012 In Key Terms in Claims of Issued Patents



Figures 2-7a and 2-7b show the change (both positive and negative changes, respectively) in selected pharmaceutical and chemical terms in the claims of issued patents from 2002 to 2012.

Similarly, Figures 2-8a and 2-8b show the corresponding change in the appearance of pharmaceutical and chemical terms in the claims of published patent applications from 2002 to 2012. Similar to Figure 2-7a, "green technology" does not show a corresponding growth change. In 2002, "green technology" did not appear in any claims, and in 2012, the term appeared in two claims.

Figure 2-8a: Change from 2002-2012 in Key Terms in Claims of Published Patent Applications

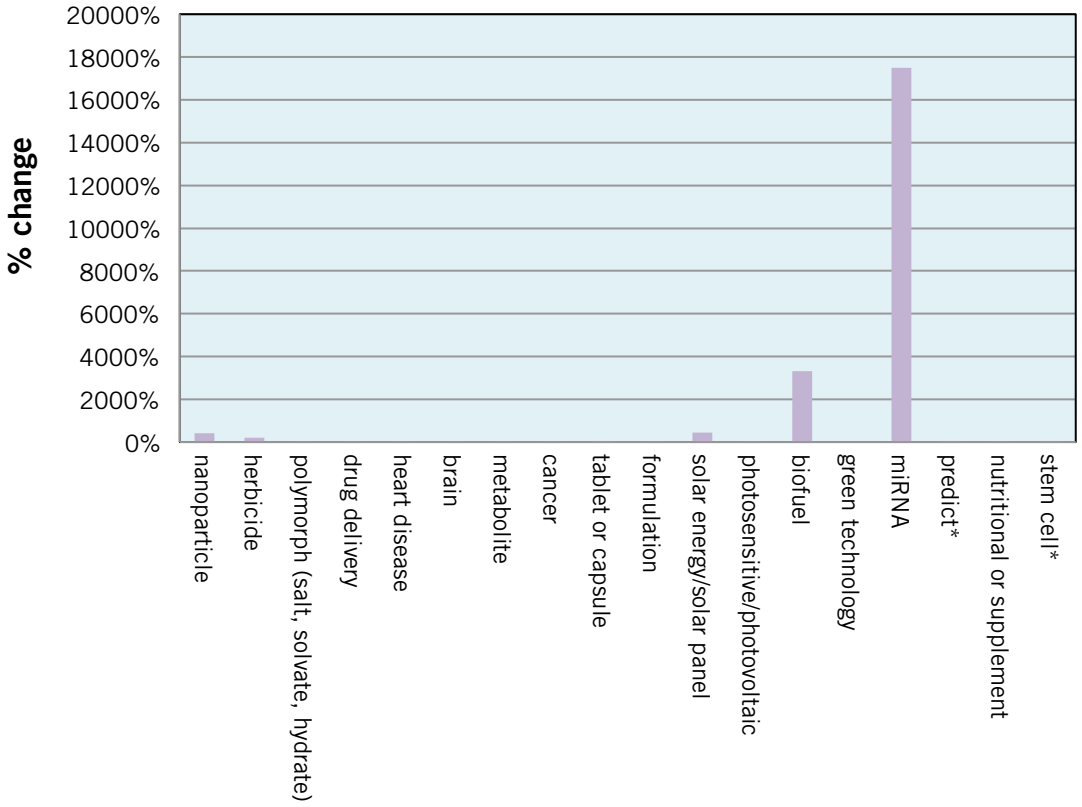
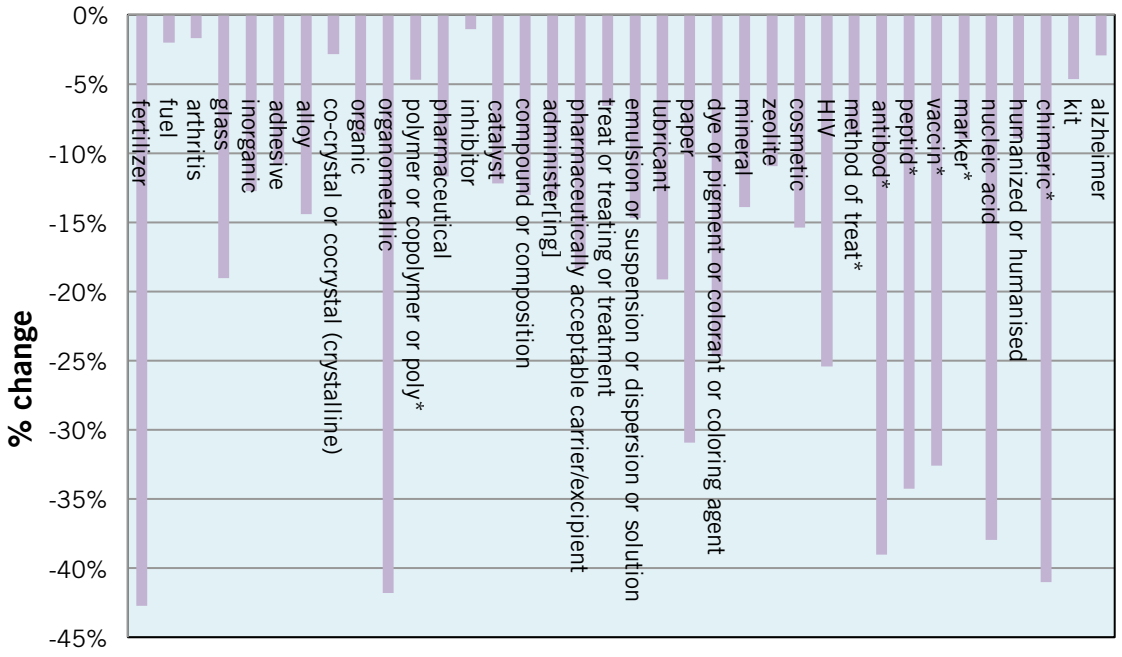


Figure 2-8b: Change from 2002-2012 in Key Terms in Claims of Published Patent Applications



Figures 2-8a and 2-8b show the percentage change (both positive and negative changes, respectively) in selected pharmaceutical and chemical terms in the claims of published patent applications from 2002 to 2012.

Figures 2-9a and 2-9b show the ratio of issued pharmaceutical patents (using the search term "pharmaceutical") to chemical patents (using the search terms "compound" or "composition") from the time period 2002 to 2012.

Figure 2-9b explicitly excludes those patents that have the term "pharmaceutical" from the data for "compound or composition." Regardless, little difference is seen between Figures 2-9a and 2-9b.

Figure 2-9a: Ratio of Patent Share of "Pharmaceutical" to "Compound or Composition" in Issued Patents

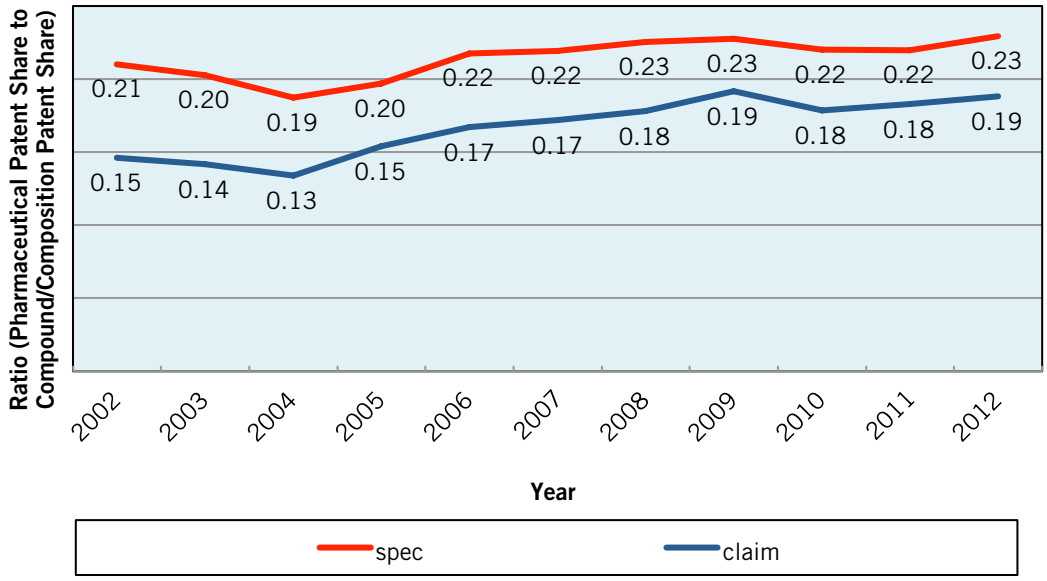
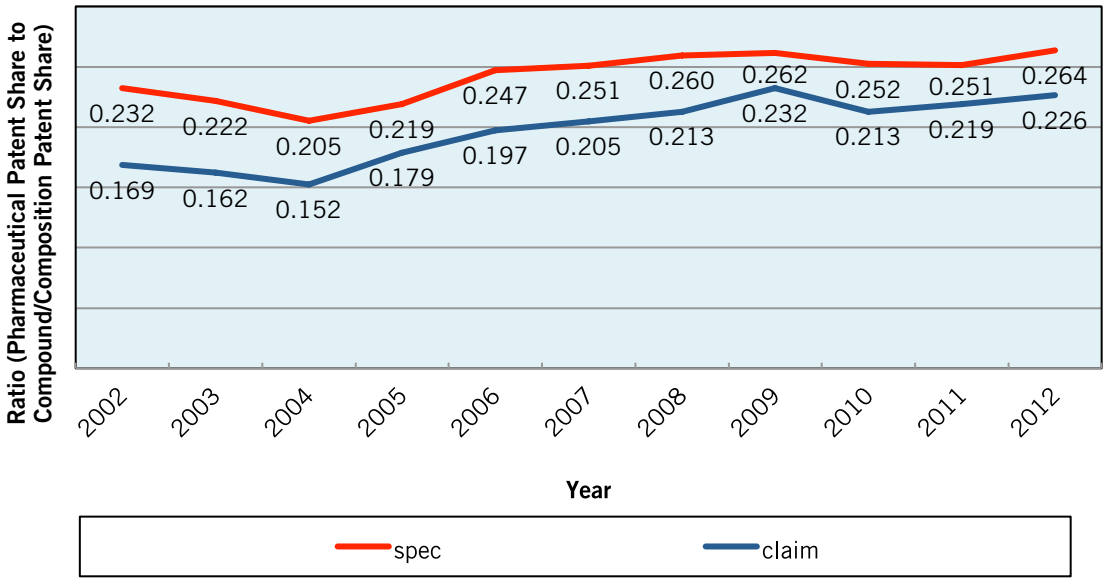


Figure 2-9b: Ratio of Patent Share of "Pharmaceutical" to "Compound or Composition" Excluding the Term "Pharmaceutical" in Issued Patents



Figures 2-9a and 2-9b show the ratio of issued pharmaceutical to chemical patents from 2002 to 2012.

Figure 2-10 shows trends in pharmaceutical diagnostic and research tools. Here, we queried the PTO database with either "pharmaceutical" or "compound or composition" in the specification and any of "kit," "detect or detection or detecting," or "screen or screening" in the claims of issued patents. We see that the combination of "compound or composition" in the specification and "detect or detection or detecting" in the claims is at a much higher level than the other combinations. Further, combinations with the terms "compound or composition" are generally at a higher level than the "pharmaceutical" combinations. This is consistent with the high level of "compound or composition" activity we have seen in the preceding charts.

Figure 2-10: Pharmaceutical Diagnostic and Research-Tool Patenting Trends

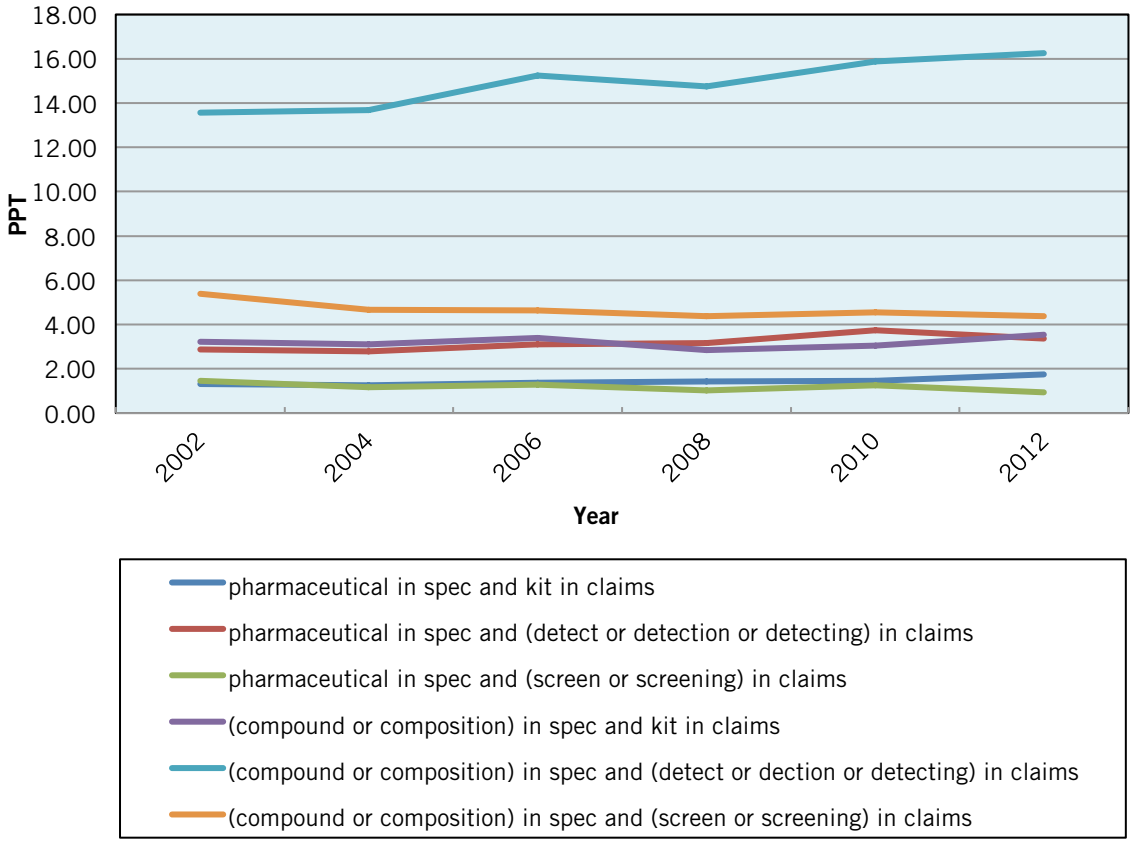


Figure 2-10 plots patent share of selected diagnostic and research terms in the specification and claims of issued patents from 2002 to 2012.

4. Patenting Trends in Therapeutic Areas

Figures 2-11, 2-12, and 2-13 show the results in terms of trends over time as well as the percentage change in activity from 2002 to 2012 in six therapeutic areas: arthritis, heart disease, cancer, HIV, Alzheimer's disease, and the brain. In Figure 2-11, we see the greatest increase in the appearance of the term "cancer" in claims of issued patents. Overall, we a see a general increase since 2008 in the appearance of those terms in claims of issued patents.

Figure 2-11: Therapeutic Area Patenting Trends in Issued Patents: Terms in Claims

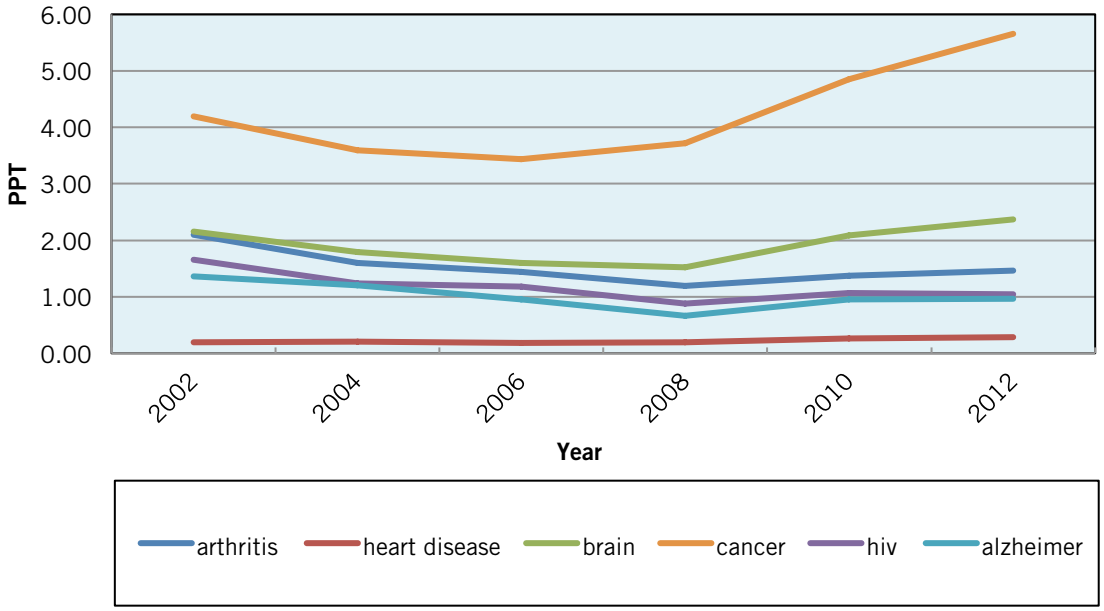


Figure 2-11 charts the trend in appearance in claims of issued patents from 2002 to 2012.

In Figure 2-12, we see that, although several therapeutic terms appear in fewer claims in 2012 than 2002, all terms are present in the specification in greater numbers in 2012 across the board. Notably, although Figure 2-11 shows that the therapeutic term "heart disease" captured the lowest patenting activity, Figure 2-12 shows that the term "heart disease" experienced the greatest overall percentage change in appearance in issued patents.

In Figure 2-13, we see that the therapeutic term "HIV" experienced a decrease in appearance in both the specification and the claims in published patent applications from 2002 to 2012. Although both "heart disease" and "cancer" increased, the term "cancer" showed a relatively higher increase in the claims versus specification than that of "heart disease."

Figure 2-12: Change from 2002-2012: Therapeutic Terms in Issued Patents

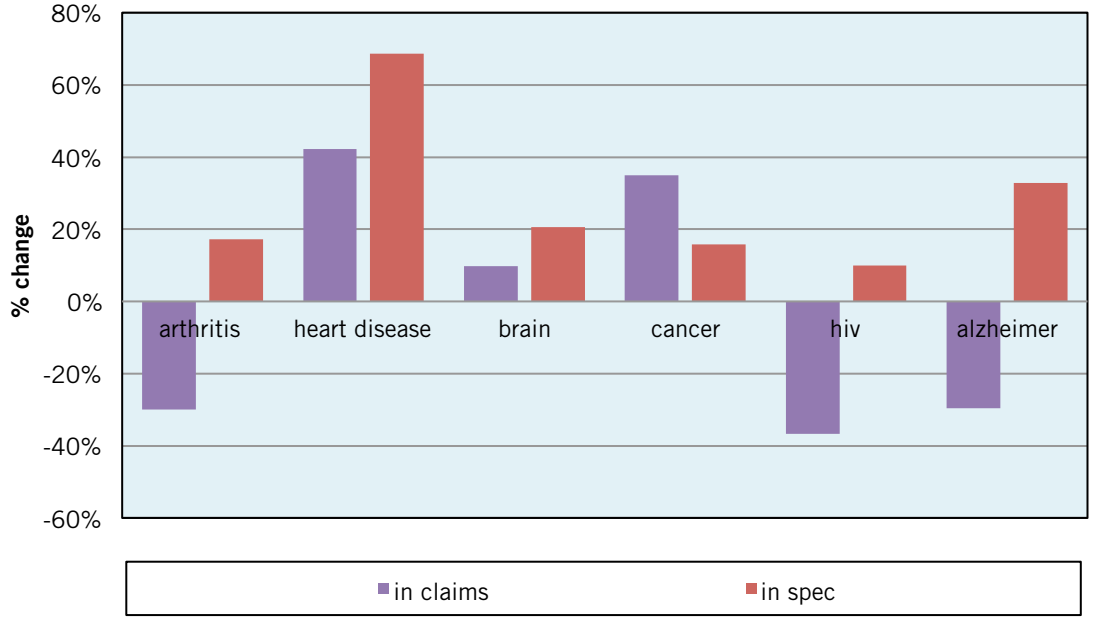
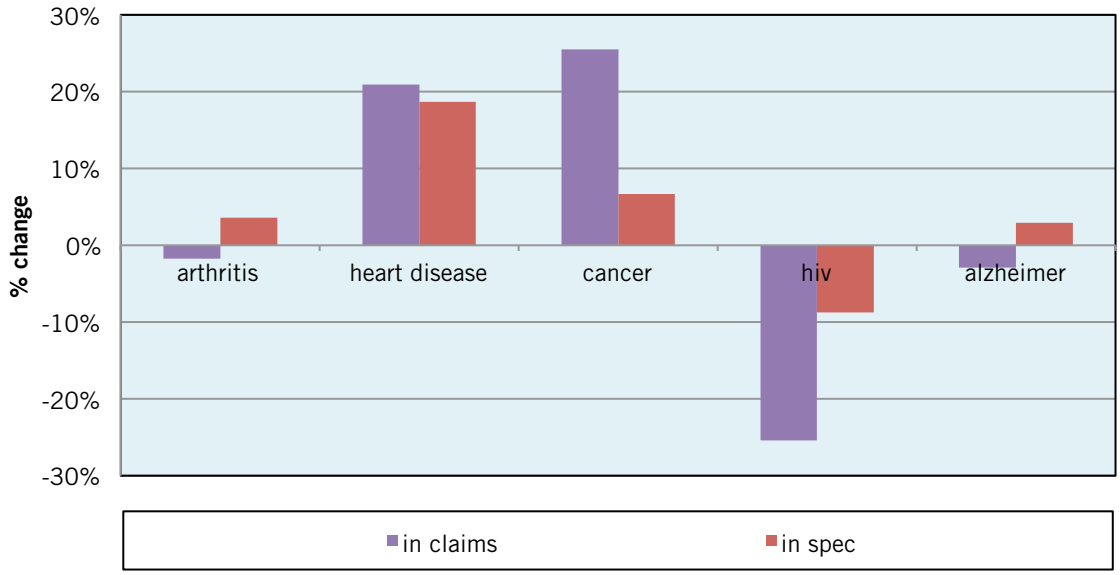


Figure 2-13: Change from 2002-2012: Therapeutic Terms in Published Patent Applications



Figures 2-12 and 2-13 show the percentage change in both the claims and the specifications of issued patents and published patent applications, respectively, from 2002 to 2012.

5. Ownership Trends from 2002 to 2012 (Issued Patents and Applications Filed)

Ownership trends for the decade extending from 2002 to 2012 were analyzed by searching the PTO database for the number of patents issued and applications published in 2002 and 2012, which list as assignee on their face one of the top fifteen chemical companies or top fifteen pharmaceutical companies, based on the 2012 Fortune 500 list. As an additional data point, the number of patents issued and applications published in 2007—the midpoint between 2002 and 2012—listing as assignee on their face one of the top fifteen chemical companies or top fifteen pharmaceutical companies, was also obtained. The resulting data illustrate the number of patents issued and applications published to each of the companies relative to each other, as well as indicating an overall, generalized trend by company for the decade.

Notably, some of the companies identified below may have holding companies or may use alternative company names/designations for patent assignment purposes. Thus, the assignment search results based on the listed company name below may not be reflective of the actual number of assigned patents and published applications. Moreover, the assignment data used to generate the charts below are based on information at the time of patent grant and at the time of publication of the patent application. Subsequent updates in assignment information are not taken into consideration.

a. Top Fifteen Chemical Companies

The list of top fifteen chemical companies used for this analysis was generated by filtering the 2012 Fortune 500 list by the industry category "Chemicals." Table 1 provides the names of the top fifteen chemical companies; their respective 2012 Fortune 500 rank; the respective number of patents issued and applications published to each in 2002, 2007, and 2012; and the overall percent change calculated using the 2002 and 2012 data points.

Table 1: Number of patents and published applications assigned to the Top 15 Chemical Companies, 2002-2012.

Top 15 Chemical Companies	Fortune 500 Rank (2012)	Issued Patents			2002-2012 Percent Change (%)	Published Applications			2002-2012 Percent Change (%)
		2002	2007	2012		2002	2007	2012	
Dow Chemical	47	119	8	3	-97	12	6	4	-67
DuPont	72	59	45	40	-32	13	38	40	208
PPG Industries	180	67	51	72	7	0	34	62	-
Monsanto	224	48	195	406	746	24	43	151	529
Huntsman	237	38	19	26	-32	19	23	44	132
Praxair	238	78	45	52	-33	1	0	2	100
Air Products & Chemicals	265	70	68	81	16	0	14	69	-
Mosaic	268	1	2	0	-100	3	1	2	-33
Sherwin-Williams	293	8	4	9	13	0	8	16	-

Top 15 Chemical Companies	Fortune 500 Rank (2012)	Issued Patents			2002-2012 Percent Change (%)	Published Applications			2002-2012 Percent Change (%)
		2002	2007	2012		2002	2007	2012	
Ashland	307	50	33	8	-84	3	17	5	67
Eastman Chemical	346	98	57	53	-46	18	19	117	550
Ecolab	365	51	31	92	80	16	31	135	744
Avery Dennison	367	64	51	62	-3	11	23	73	564
Celanese	368	28	18	29	4	2	12	86	4200
CF Industries Holdings	402	0	0	0	-	0	0	0	-
Total		**779**	**627**	**933**	**20**	**122**	**269**	**806**	**561**

These data presented in Table 1 are graphically illustrated in Figures 2-14a and 2-14b.

Figure 2-14a: Patents Issued to Top 15 Chemical Companies: 2002, 2007, and 2012

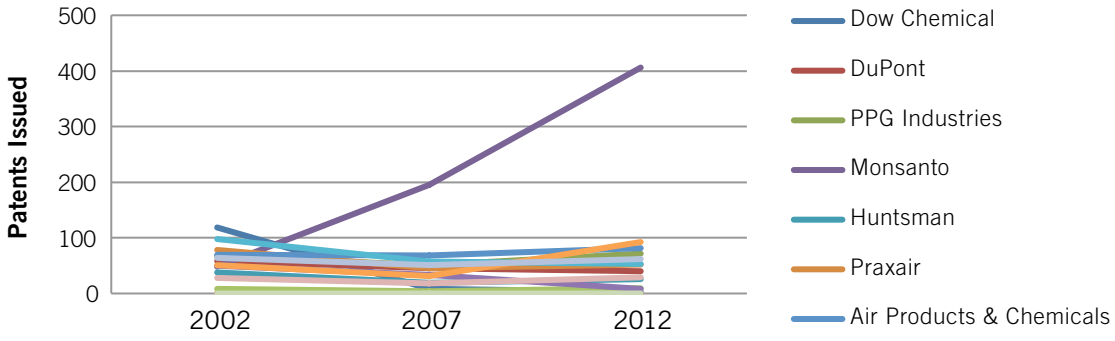
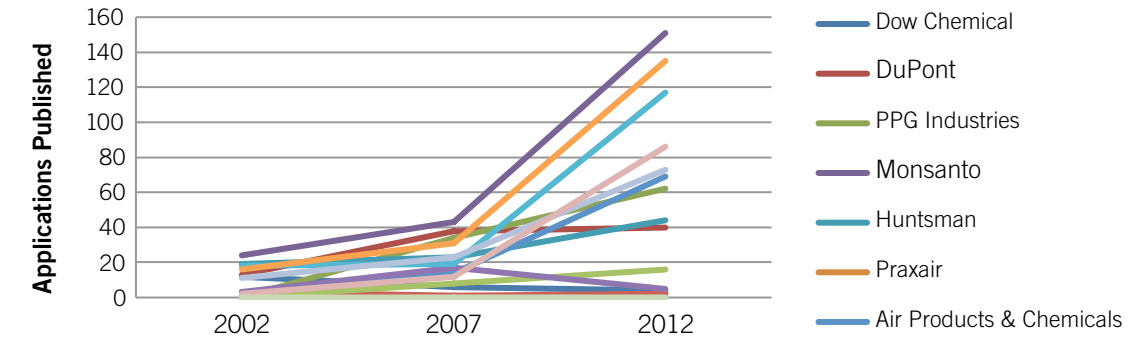


Figure 2-14b: Applications Published to Top 15 Chemical Companies: 2002, 2007, and 2012



As illustrated by Table 1 and Figure 2-14a, with the exception of outliers such as Monsanto, the general trend for patents issued over the past decade to the top fifteen chemical companies is roughly steady, with a total percent increase of 20% for the group from 2002 to 2012. Table 1 and Figure 2-14b demonstrate that the general trend for applications published over the past decade to the top fifteen chemical companies is positive, with a total percent increase of 561% for the group from 2002 to 2012.

b. Top Fifteen Pharmaceutical Companies

The list of top fifteen pharmaceutical companies used for this analysis was generated by filtering the 2012 Fortune 500 list by the industry category "Pharmaceuticals." Because fewer than fifteen companies appeared on the list, the "Pharmaceuticals" list was combined with the list for the "Medical Products and Equipment" industry, with the top fifteen overall by Fortune 500 rank making the final list. Table 2 provides the names of the companies making this final list; their respective 2012 Fortune 500 rank; the respective number of patents issued and applications published to each in 2002, 2007, and 2012; and the overall percent change calculated using the 2002 and 2012 data points.

Table 2: Number of patents and published applications assigned to the Top 15 Pharmaceutical Companies, 2002-2012.

Top 15 Pharmaceutical Companies	Fortune 500 Rank (2012)	Issued Patents			2002-2012 Percent Change (%)	Published Applications			2002-2012 Percent Change (%)
		2002	2007	2012		2002	2007	2012	
Pfizer	40	193	119	84	-56	42	120	104	148
Johnson & Johnson	42	0	0	0	-	0	0	0	-
Merck	57	335	235	292	-13	104	75	245	136
Abbott Laboratories	71	115	58	195	70	2	54	210	10400
Eli Lilly	119	131	72	70	-47	0	39	40	-
Bristol-Myers Squibb	134	140	188	119	-15	3	169	105	3400
Medtronic	164	236	317	581	146	120	339	591	393
Amgen	168	30	55	90	200	33	72	87	164
Baxter Int'l	195	56	33	97	73	18	26	114	533
Gilead Sciences	306	17	8	43	153	12	14	35	192
Stryker	308	23	27	94	309	7	49	59	743
Becton Dickinson	333	99	50	90	-9	25	68	101	304
Boston Scientific	335	27	156	477	1667	13	275	436	3254
Mylan	396	0	1	8	-	0	5	5	-
St. Jude Medical	437	22	32	119	441	17	19	80	371
Total		**1424**	**1351**	**2359**	**66**	**396**	**1324**	**2212**	**459**

These data presented in Table 2 are graphically illustrated in Figures 2-15a and 2-15b.

Figure 2-15a: Patents Issued to Top 15 Pharmaceutical Companies: 2002, 2007, and 2012

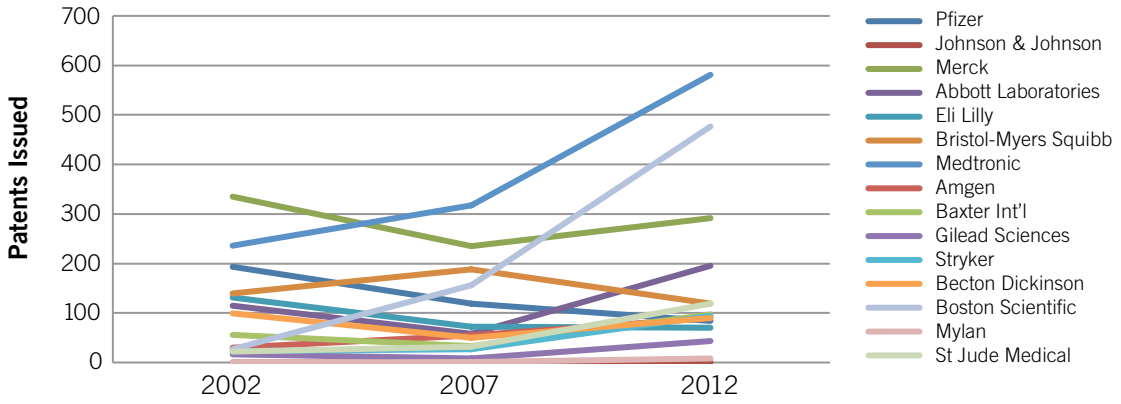
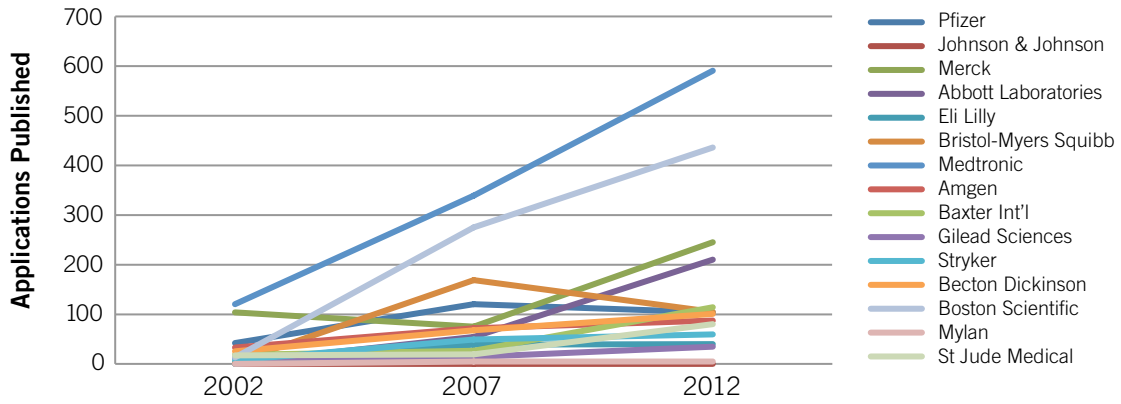


Figure 2-15b: Applications Published to Top 15 Pharmaceutical Companies: 2002, 2007, and 2012



As illustrated by Table 2 and Figure 2-15a, the general trend for patents issued over the past decade to the top fifteen pharmaceutical companies is positive, with a total percent increase of 66% for the group from 2002 to 2012. Table 2 and Figure 2-15b demonstrate that the general trend for applications published over the past decade to the top fifteen pharmaceutical companies is also positive, with an overall percent increase of 459% for the group from 2002 to 2012.

The ownership trend analysis therefore shows that over the past decade, the number of patents issued and applications published to both the top fifteen chemical companies and top fifteen pharmaceutical companies is increasing overall.

III. District Court Litigation

Litigation is always a hot topic of conversation when discussing patents, and particularly true, in the pharmaceutical industry. Here, we look at federal district court decisions from chemical and pharmaceutical patent cases to determine trends. We compare the number of final decisions reached in chemical and pharmaceutical patent cases to those in other technology sectors, such as automotive, transportation, semiconductor, and internet in the last decade (i.e., from 2002 to 2012). Next, we dive into those final district court decisions to provide further insight to identify trends. For example, we detail how those final decisions were reached (bench trial, jury trial, summary judgment, or post-trial motion), win rates, and win rates in ANDA ("Abbreviated New Drug Application") litigations. Other questions we seek to answer based on our survey of final district court decisions include:

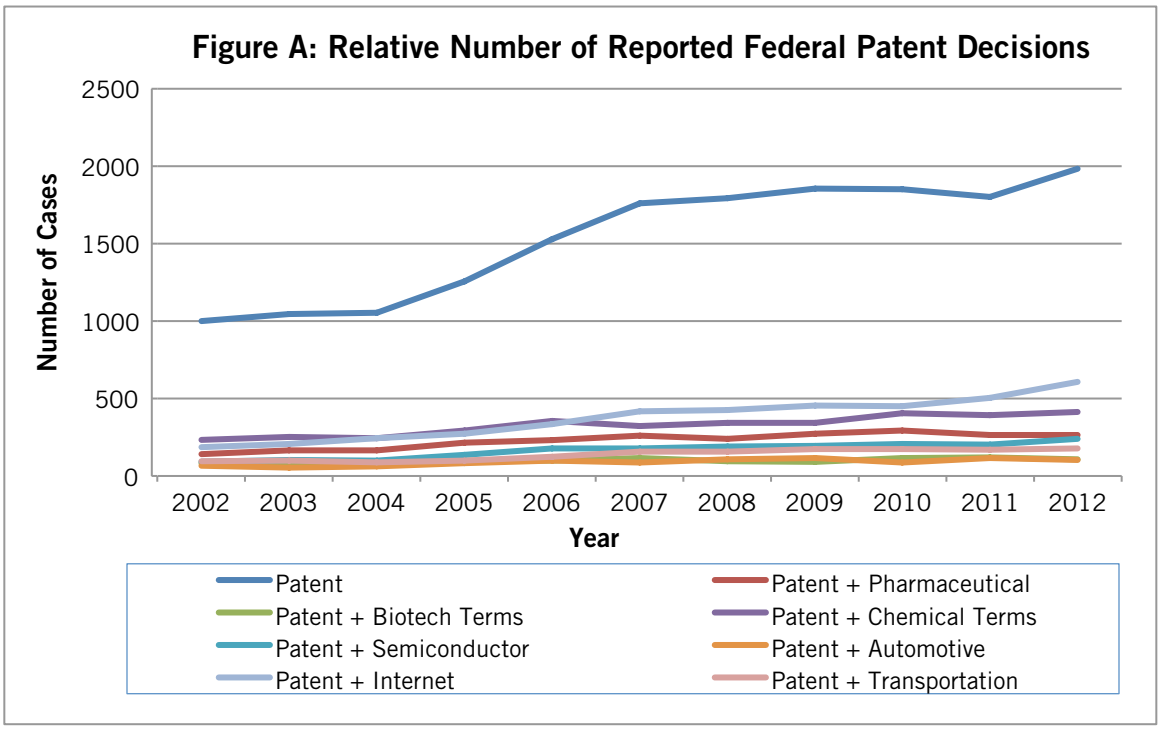
- What jurisdictions have the most patent cases in this technology area?
- How often does the patentee win in those jurisdictions?
- How long does it take to reach a final decision in the most popular jurisdictions?
- What type of technology is involved in those final decisions? And, what type of technology is involved in the ANDA cases?

A. District Court Pharmaceutical, Biotech, and Chemical Patent Cases, 2002-2012

1. Litigation Trends and Methodology

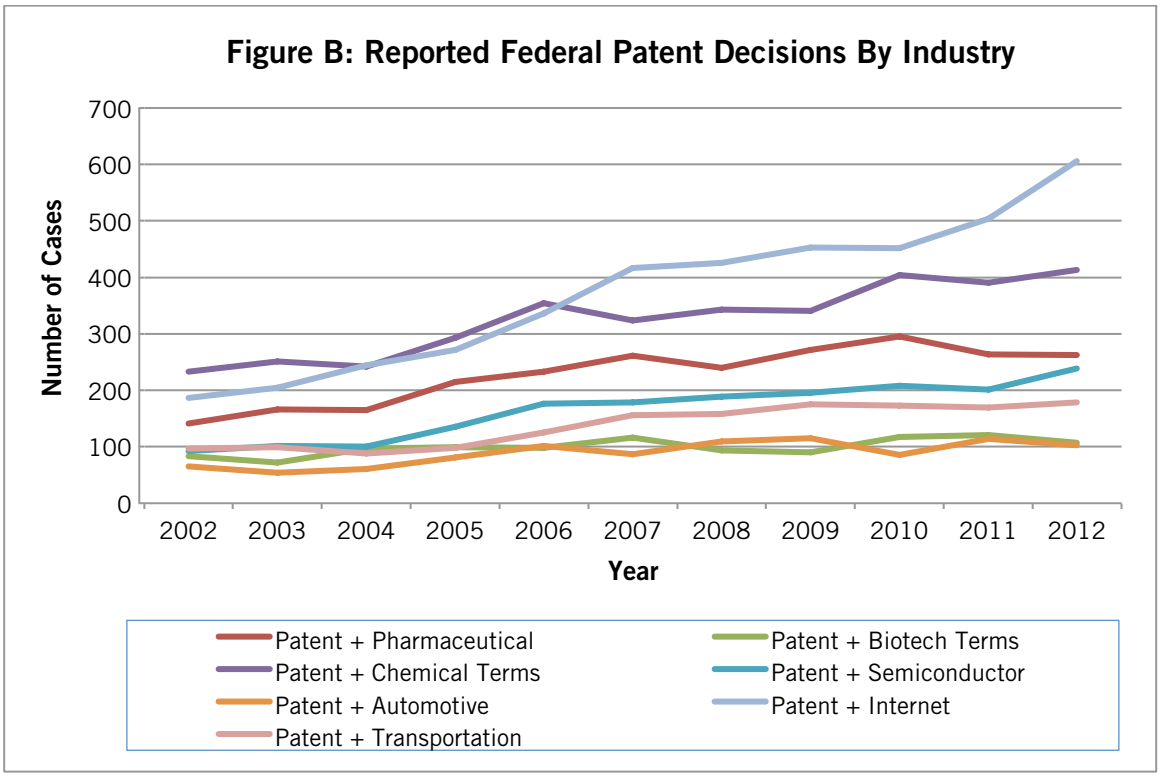
In this chapter, we present data and trends from reviewing pharmaceutical, biotech, and chemical patent cases decided by U.S. district dourts from 2002 to 2012. To initially gather the cases, we queried the Federal Patent Cases database on WestlawNext® using our search terms + year. We then prepared an industry-by-industry comparison of trends in U.S. district court patent decisions, as shown in the figures below.

In Figure A, we charted the results of querying the Federal Patent Cases database on WestlawNext® to compare patent-litigation activity across various fields of technology, including a comparison to all fields of technology as a whole. The trends reveal a continuing rise in patent litigation generally, although it appears to have somewhat slowed over the 2007-2010 period before picking up again in 2011-2012.



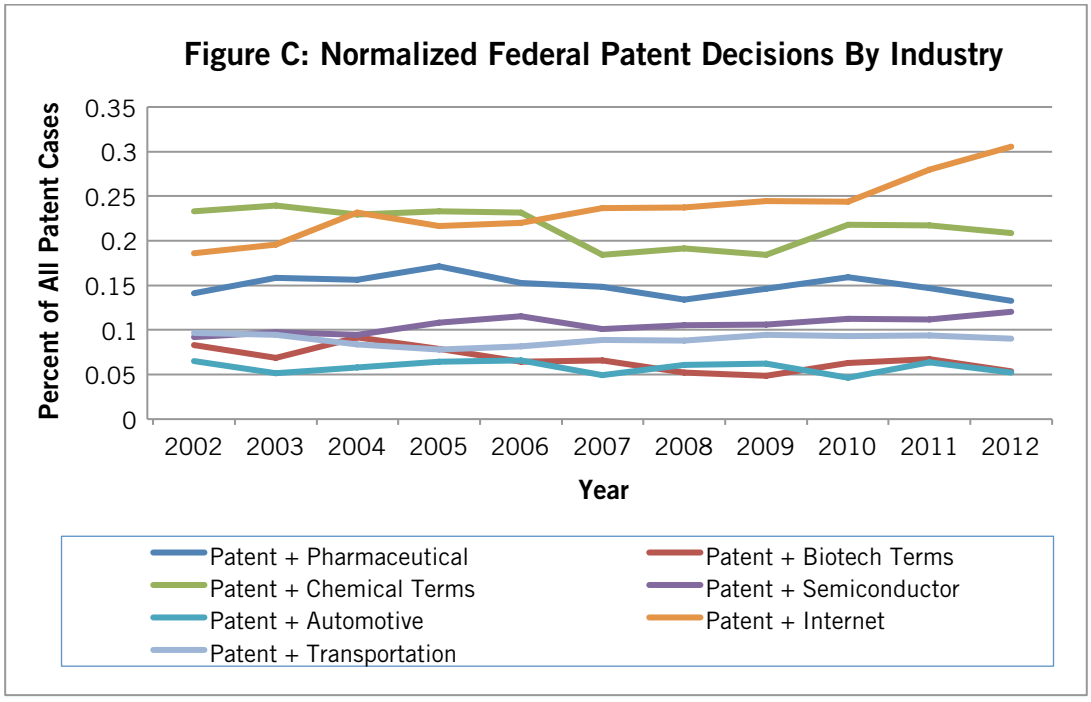
For Figure A, we queried the WestlawNext® Federal Patent Cases database with the search term "patent" alone, and "patent" in combination with "pharmaceutical," "semiconductor," "automotive," "internet," and "transportation." We also queried the database with the search term "patent" in combination with the biotech terms: nucleotide or "nucleic acid" or "amino acid" or peptide or antibody or protein. We also ran "patent" in combination with the chemical terms: "chemical formula" or "compound or composition." Figure A shows the results of absolute numbers of decisions as a function of year.

In Figure B, we provide a more detailed comparison of patent-litigation activity in various specific fields of technology by omitting the "patent" trend line relating to all fields of technology as a whole. In closer detail, it appears that in addition to Internet technology, litigation in the chemical and semiconductor fields continued to grow over the 2002-2012 time period, with a relatively strong rise in the 2011-2012 period. Meanwhile, biotech patent litigation has remained somewhat flat since 2006, and pharmaceutical litigation has slowed somewhat in recent years after a strong increase from 2008 to 2010.



For Figure B, we queried the WestlawNext® Federal Patent Cases database with the search term "patent" in combination with "pharmaceutical," "semiconductor," "automotive," "internet," and "transportation." We also queried the database with the search term "patent" in combination with the biotech terms: nucleotide or "nucleic acid" or "amino acid" or peptide or antibody or protein. We also ran "patent" in combination with the chemical terms: "chemical formula" or "compound or composition." Figure B shows the results of absolute numbers of decisions as a function of year in greater detail by omitting the results from searching "patent" alone.

Figure C also shows a comparison of patent-litigation activity in various technology fields, with the data normalized to a percentage of the total number of patent cases per year. These data put the strong growth of Internet patent litigation in perspective, as litigation in all fields of technology except for semiconductor patent litigation have declined as a percentage of total patent litigation. For example, the recent steady levels of pharmaceutical patent litigation from Figure B has sharply decreased as a percentage of total patent litigation, given the strong recent growth in Internet patent litigation and the moderate growth in many other fields of technology, as illustrated in Figure B, above.



For Figure C, we queried the WestlawNext® Federal Patent Cases database with the search term "patent" in combination with "pharmaceutical," "semiconductor," "automotive," "internet," and "transportation." We also queried the database with the search term "patent" in combination with the biotech terms: nucleotide or "nucleic acid" or "amino acid" or peptide or antibody or protein. We also ran "patent" in combination with the chemical terms: "chemical formula" or "compound or composition." Figure C shows the results normalized to the total number of patent decisions per year, calculated by dividing the absolute number of cases in each technological field by the total number of patent decisions for each year.

2. Analysis of 2010-2012 Final Decisions in the Pharmaceutical, Biotech, and Chemical Fields

Based on querying the WestlawNext® Federal Patent Cases database with the "patent" search term in combination with "pharmaceutical," the biotech terms, and the chemical terms for the years 2010-2012, we collected 2375 total search results. We reviewed these results to select only the U.S. district court decisions and to screen out the nonfinal decisions and decisions unrelated to patent infringement, validity, and/or enforceability of pharmaceutical, biotech, and chemical patents. We determined that 103 of these results were final decisions.

Figure D: Final decisions from U.S. district courts from 2010-2012 directed to pharmaceutical, biotech, and chemical patents.

Year	Total Search Hits	Total # of Final Decisions
2010	816	40
2011	776	32
2012	783	31
Overall	**2375**	**103**

We defined a final decision as a decision on the merits, where infringement or validity (or both) was resolved. Thus, if the court found at least one patent claim valid and infringed, we counted it as a final decision. Similarly, if the court rendered a decision on invalidity and infringement was conceded, we counted the decision as final. Also, if the court found the asserted claims noninfringed or invalid, we counted the decision as final. We did not include decisions granting motions to dismiss as final decisions, because these opinions did not analyze patent infringement or validity.

The methods of disposition for the 103 final decisions are shown below in Figure E, illustrating that jury trials are relatively rare in pharmaceutical, biotech, and chemical patent litigation.

Figure E: Methods of disposition for final decisions from U.S. district courts from 2010-2012 directed to pharmaceutical, biotech, and chemical patents.

Method of Disposition	Total # of Final Decisions	Percentage of Final Decisions
Bench Trial	51	49%
Jury Trial	11	11%
Summary Judgment	39	38%
Post-Trial Motion	2	2%
Overall	**103**	**100%**

3. Win Rates in Pharmaceutical, Biotech, and Chemical Patent Litigation

We analyzed the 103 final decisions (as defined above) to determine the relative success rates of patentees and accused infringers in litigation. We counted a patentee "win" as a case in which the court determined that at least one claim was valid, enforceable, and infringed. When a court found the claims invalidated, unenforceable, or not infringed, we counted the case as a patentee "loss."

Figure F: Win rates, year by year, for final decisions from U.S. district courts from 2010-2012 directed to pharmaceutical, biotech, and chemical patents.

Year	Total # of Final Decisions	Patentee Wins	Patentee Win %
2010	40	16	40%
2011	32	15	47%
2012	31	15	48%
Overall	**103**	**46**	**45%**

Our year-by-year comparative results are shown in Figure F, above. Although the total number of final decisions has fallen, perhaps as a result of decreased litigation activity and comparatively fewer cases filed during the 2008-2010 period, the percentage of patentee "wins" has increased from 40% to 48%. When analyzed by method of disposition, however, it appears that patentees generally do quite well when litigation advances to trial, particularly before juries. Meanwhile, accused infringers have a very high rate of success on summary judgment.

Figure G: Win rates by method of disposition for final decisions from U.S. district courts from 2010-2012 directed to pharmaceutical, biotech, and chemical patents.

Method of Disposition	Total # of Final Decisions	Percentage of Final Decisions	Patentee Wins	Patentee Win Rate
Bench Trial	51	50%	32	63%
Jury Trial	11	11%	8	73%
Summary Judgment	39	38%	5	13%
Post-Trial Motion	2	2%	1	50%
Overall	**103**	**100%**	**46**	**45%**

These trends bear out in Abbreviated New Drug Application ("ANDA") litigation as well, as shown in Figures H, I, and J, below. Although jury trials appear very rarely for ANDA litigation, patentees win over two-thirds of bench trials, while accused generics win the vast majority of the time on summary judgment.

Figure H: Win rates by method of disposition for ANDA litigation from 2010.

Type of Disposition	Total # of Final Decisions	Percentage of Final Decisions	Patentee Wins	Patentee Win Rate
Bench Trial	11	61%	6	55%
Summary Judgment	6	33%	2	33%
Jury Trial	0	0%	0	N/A
Post-Trial Motion	1	6%	1	100%
Overall	**18**	**100%**	**9**	**50%**

Figure I: Win rates by method of disposition for ANDA litigation from 2011.

Method of Disposition	Total # of Final Decisions	Percentage of Final Decisions	Patentee Wins	Patentee Win Rate
Bench Trial	19	83%	13	68%
Summary Judgment	1	4%	0	0%
Jury Trial	2	9%	1	50%
Post-Trial Motion	1	4%	0	0%
Overall	**23**	**100%**	**14**	**61%**

Figure J: Win rates by method of disposition for ANDA litigation from 2012.

Type of Disposition	Total # of Final Decisions	Percentage of Final Decisions	Patentee Wins	Patentee Win Rate
Bench Trial	19	83%	13	68%
Summary Judgment	4	17%	1	25%
Jury Trial	0	0%	0	N/A
Post-Trial Motion	0	0%	0	N/A
Overall	**23**	**100%**	**14**	**61%**

B. Pharmaceutical, Biotech, and Chemical Patent Litigation by Jurisdiction

In Figure K, below, we show the breakdown of final decisions in pharmaceutical, biotech, and chemical patent litigation by U.S. district court jurisdiction. In these technological fields, parties most often litigate in the District of Delaware, the District of New Jersey, and the Southern District of New York. Yet with win rates ranging from 38% to 52%, these jurisdictions do not appear to clearly favor patentees who file suit there. Other jurisdictions, such as the Eastern District of Texas, appear more patentee-friendly, although these jurisdictions try a far fewer number of pharmaceutical, biotech, and chemical patent cases.

Figure K: Cases and win rate by jurisdiction from 2010-2012.

Tribunal	Total # of Final Decisions	Percentage of Final Decisions	Patentee Wins	Patentee Win Rate
D. Del.	33	32%	17	52%
D.N.J.	21	20%	8	38%
S.D.N.Y.	10	10%	5	50%
N.D. Ill.	5	5%	1	20%
E.D. Tex.	4	4%	4	100%
E.D. Pa.	3	3%	0	0%
S.D. Cal.	3	3%	1	33%
C.D. Cal.	2	2%	0	0%
E.D. Va.	2	2%	1	50%
M.D. Tenn.	2	2%	1	50%
N.D. Cal.	2	2%	0	0%
S.D. Fla.	2	2%	2	100%
S.D. Ind.	2	2%	2	100%
D. Mass.	1	1%	0	0%
D. Neb.	1	1%	1	100%
D. Nev.	1	1%	1	100%
D.N.H.	1	1%	1	100%
E.D. Mich.	1	1%	0	0%
M.D.N.C.	1	1%	0	0%
N.D. Ga.	1	1%	0	0%
N.D. Ohio	1	1%	0	0%
W.D. Mich.	1	1%	0	0%
W.D. Wash.	1	1%	0	0%
W.D.N.C.	1	1%	0	0%

C. Average Time to Disposition

Out of the 103 final decisions analyzed, the average time to final decision in pharmaceutical, biotech, and chemical patent cases was about 35.8 months. Among the most popular jurisdictions, the average time to final decision varied greatly, from 29.0 months to 52.7 months, as shown in Figure L.

Figure L: Average time to final decision in most popular jurisdictions.

Tribunal	Average Time to Final Decision (months)
D. Del.	34.7
D.N.J.	35.9
N.D. Ill.	52.7
E.D. Tex.	42.6
E.D. Pa.	52.7
S.D. Cal.	29.0

D. Patent Subject Matter

A further breakdown of the patent subject matter at issue in the 103 final decisions reviewed reveals that the healthcare and pharmaceutical fields comprise the majority of district court cases. In particular, ANDA litigation is very prevalent, with those cases most often involving pharmaceutical products and treatments for cardiac and musculoskeletal disorders. Pharmaceuticals and other healthcare technology similarly comprise the most frequent categories of non-ANDA litigation. Industrial chemical products and processes, meanwhile, are the most litigated non healthcare technology. Figure M, shown below, displays the total number of district court cases by patent subject matter.

Figure M: Patent subject matter in pharmaceutical, biotech, and chemical patent litigation from 2010-2012.

Technology	No. of Cases
Pharmaceuticals	7
Other Healthcare	10
Genetics	3
Electrical Materials	3
Environmental technology	3
Food & Nutrition	5
Industrial Chemistry	8

Technology	No. of Cases
ANDA – Allergy	3
ANDA – Anesthesia	2
ANDA – Antibiotics	4
ANDA – Cancer	4
ANDA – Formulations	5
ANDA – Cardiology	8
ANDA – Hormones	4
ANDA – Musculoskeletal	7
ANDA – Ophthalmology	3
ANDA – Psychiatric	5
ANDA – Urology/Reproductive	5
ANDA – Other	13

IV. Appellate Litigation

In a similar manner to the district court trends, we reviewed chemical and pharmaceutical patent decisions by the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") from 2010 to 2012. In particular, we identify the total number of decisions and affirmance rates by year, and provide a breakdown of the cases by tribunal (district court, PTO, or International Trade Commission) and by issue.

A. Pharmaceutical, Biotech, and Chemical Cases at the Federal Circuit, 2010-2012

1. Methodology

In this chapter, we examine trends in pharmaceutical, biotech, and chemical patent appeals decided by the U.S. Court of Appeals for the Federal Circuit from 2010 to 2012. Based on the search criteria discussed above in Chapter III, we reviewed all of the patent appeals decided by the Federal Circuit in the pharmaceutical, biotech, and chemical fields of technology. We selected only those appeal cases pertaining to infringement, validity, or enforceability of pharmaceutical, biotech, and chemical patents. This encompassed appeals involving related issues having significant bearing on infringement, validity, or enforceability, such as claim construction. Through this screening process, we were left with ninety-nine total appellate decisions. The Federal Circuit received eighty of these appeals from U.S. district courts, eighteen from the U.S. Patent and Trademark Office ("PTO"), and one from the International Trade Commission ("ITC").

Figure N: Pharmaceutical, biotech, and chemical Federal Circuit decisions by year.

Year	Total Appellate Decisions	From U.S. District Courts	From PTO	From ITC
2010	39	34	4	1
2011	26	23	3	0
2012	34	23	11	0
Total	**99**	**80**	**18**	**1**

2. Analysis of Federal Circuit Trends

Of the ninety-nine appellate decisions we collected, the Federal Circuit affirmed in fifty-two decisions for an affirmance rate of 52%. The Federal Circuit affirmed-in-part in an additional twenty-seven decisions, which raises this adjusted affirmance rate to 80%. A year-by-year breakdown of the Federal Circuit's affirmance rates, however, shows that the rate varies greatly from one year to the next.

Figure O: Federal Circuit affirmance rates by year.

Year	Affirmed	Reversed/ Vacated	Affirmed-in-Part & Reversed/ Vacated-in Part	Clean Affirm %	Affirm-in-Part %	Clean Reversal %	Reversal-in-Part %
2010	15	14	10	38%	64%	36%	62%
2011	13	4	9	50%	85%	15%	50%
2012	24	2	8	71%	94%	6%	29%
Total	**52**	**20**	**27**	**53%**	**80%**	**20%**	**47%**

We defined a "clean" affirmance as a decision in which the Federal Circuit affirmed the lower tribunal's decision on all patent grounds. We similarly defined a "clean" reversal as a decision in which the Federal Circuit reversed or vacated the lower tribunal's decision on all patent grounds. Any decision that was affirmed at least in part, including "clean" affirmances, we included within the category of decisions affirmed-in-part. Meanwhile, any decision that was reversed at least in part, including "clean" reversals, we included within the category of decisions reversed/vacated-in-part. For the joint category of decisions affirmed-in-part/reversed/vacated-in-part, we counted any decision that was not a "clean" affirmance or reversal.

Further analysis shows that the Federal Circuit cleanly affirms decisions by the PTO at a much higher rate than decisions by U.S. district courts. The Federal Circuit's affirmance rate held fairly steady regardless of whether it reviewed a PTO decision following patent prosecution, patent reexamination, or interference. This discrepancy in affirmance rates might in part be explained by the Federal Circuit's deference to certain aspects of PTO decision making, as well as the different standards applied by the PTO and U.S. district courts on many issues, such as claim construction, presumption of patent validity, etc. The discrepancy might be further explained by the cleaner issues typically presented by the PTO's decisions, which are often comparatively more streamlined than U.S. district court decisions implicating a wide variety of patent- and litigation-related considerations. Indeed, the difference between the clean affirmance rate and the affirmance-in-part rate is large for U.S. district courts, but rather small for the PTO,

perhaps reflecting the narrower issues typically addressed in the PTO's decisions. Meanwhile, the affirmance-in-part rates are similar for U.S. district court and PTO decisions.

Given the Federal Circuit's high clean affirmance rate of PTO decisions as compared to district court decisions, litigants may wish to take advantage of the new administrative trial procedures created by the America Invents Act ("AIA") to request review of patentability of issued patents rather than engaging in district court litigation. These procedures include post-grant review and inter partes review. A more detailed discussion of these proceedings can be found in Section V(D), (E).

Figure P: Federal Circuit's affirmance rates by tribunal.

Tribunal	Clean Affirm %	Affirm-in-Part %	Clean Reversal %	Reversal-in-Part %
District Court	48%	79%	21%	53%
PTO	72%	83%	17%	28%
ITC	100%	100%	0%	0%

We defined a "clean" affirmance as a decision in which the Federal Circuit affirmed the lower tribunal's decision on all patent grounds. We similarly defined a "clean" reversal as a decision in which the Federal Circuit reversed or vacated the lower tribunal's decision on all patent grounds. Any decision that was affirmed at least in part, including "clean" affirmances, we included within the category of decisions affirmed-in-part. Meanwhile, any decision that was reversed at least in part, including "clean" reversals, we included within the category of decisions reversed/vacated-in-part.

We also analyzed the Federal Circuit's affirmance rates by issue, as shown in Figure P above. The Federal Circuit often affirms decisions on issues such as anticipation, obviousness, enablement, written description, and infringement. Yet the Federal Circuit reverses lower tribunals' claim constructions close to 50% of the time, and reverses on claim indefiniteness and patent eligibility at a very high rate. The Federal Circuit also affirmed lower tribunals' best-mode decisions, although best mode will cease to provide a means for invalidating patents in litigation under the new provisions of the AIA, as discussed above in Section V(A).

Figure Q: Federal Circuit's affirmance rates by issue.

Issue	Affirmed	Reversed/ Vacated	Affirmed-in-Part & Reversed/ Vacated-in-Part	Clean Affirmance %	Overall Affirmance %
Claim Construction	11	9	1	52%	57%
Infringement/Noninfringement	21	9	0	70%	70%
§ 101 Patentability	0	3	3	0%	50%
§ 102 Anticipation	16	1	4	76%	95%
§ 103 Obviousness	28	10	5	65%	77%
§ 112 Enablement	6	3	0	67%	67%
§ 112 Written Description	9	4	0	69%	69%
§ 112 Best Mode	3	1	0	75%	75%
§ 112 Indefiniteness	1	5	0	17%	17%
Inequitable Conduct	6	2	0	75%	75%

V. The America Invents Act

On March 16, 2013, the U.S. patent system underwent a historic transition from a first-to-invent ("FTI") to a first-inventor-to-file ("FITF") system, completing a transition that has been ongoing since September 16, 2011, when President Obama signed the America Invents Act ("AIA") into law. Given this historic transformation and its many implications, we provide below capsule summaries for some of the key AIA provisions.

In particular, we summarize and highlight considerations for the following AIA provisions:

- Best Mode
- Derivation Proceedings
- First-Inventor-to-File
- Inter Partes Review
- Post-Grant Review
- Pre-issuance Submissions
- Supplemental Examination

A. Best Mode[1]

The AIA added 35 U.S.C. § 282(3)(A), which provides that failure to comply with the best-mode requirement is no longer a basis to hold a patent claim canceled, invalid, or unenforceable. AIA, sec. 15. Thus, 35 U.S.C. § 112, first paragraph, still requires that the patent specification "shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention." It, however, will no longer be a basis to invalidate a patent. From a prosecution perspective, the PTO announced that it will continue to examine applications for compliance with the best-mode requirement (http://www.uspto.gov/aia_implementation/best-modememo.pdf), but acknowledged that "[i]t is extremely rare that a best mode rejection properly would be made in ex parte prosecution." Manual of Patent Examining Procedure ("MPEP") § 2165.03. The changes to the best-mode requirement took effect on September 16, 2011, and apply to all cases filed on or after that date.

1 Excerpt of: How Will Patent Reform Affect the Software and Internet Industries?, *The Computer & Internet Lawyer*, December 2011, Yoches, E. Robert , Lim, Esther H., Schultz, Christopher S., Thayer, Linda J., Arner, Erika Harmon.

B. Derivation Proceedings

To accommodate the new FITF system of the AIA, patent interference proceedings will be phased out and replaced by derivation proceedings. The principle function of the derivation proceeding is to ensure that under a FITF system, the true inventor is the one who obtains the patent. An inventor who believes that an earlier patent applicant derived his invention from the inventor and without the inventor's authorization filed the earlier patent application may file a derivation proceeding.

1. Eligibility

As in the former interference proceedings, a derivation determination can be pursued in a civil-court action (among two or more patentees) or in a PTO proceeding. Civil-court actions are reserved for derivation proceedings involving issued patents of both the plaintiff and defendant. 35 U.S.C. § 291. The claims of the plaintiff's patent must be the same as the defendant's claims, and the defendant's patent must not be cited in the plaintiff's patent. Also, the plaintiff's patent must be granted within one year of the earlier patent. *Id.*

Derivation proceedings before the PTO concern derivation challenges between a patent application and a previously published patent or patent application. An applicant may file a petition in the PTO to institute a derivation proceeding for relief against the owner of an earlier-filed application as long as the invention claimed in the earlier-filed application was derived from the petitioning applicant. 37 C.F.R. § 42.402. The petitioner must file his petition within one year of the publication of a claim to an invention that is the same or substantially the same as the petitioner's claim to the invention. 37 C.F.R. § 42.403.

2. Petition Requirements

In addition to showing that the respondent's claimed invention is the same or substantially the same as the petitioner's claimed invention, the petitioner must provide information supporting a showing of derivation, including:

(1) sufficient information to identify the application or patent for which the petitioner seeks a derivation proceeding;

(2) demonstrating that a claimed invention was derived from an inventor named in the petitioner's application, and that the inventor from whom the invention was derived did not authorize the filing of the earliest application claiming such invention;

(3) why the claimed invention is the same or substantially the same as the invention disclosed to the respondent;

(4) identify how the claim is to be construed; and

(5) substantive evidence, including at least one affidavit addressing communication of the derived invention and lack of authorization that, if unrebutted, would support a determination of derivation.

37 C.F.R. § 42.405.

Petitioner must also serve the respondent with the petition by mailing it to the respondent's address of record, or parties may agree to electronic service. 37 C.F.R. § 42.406. If the PTO determines that a petition meets the requisite standards, the Director then has final and non-appealable discretion to institute a derivation proceeding. 35 U.S.C. § 135(a); 37 C.F.R. § 42.408.

Derivation proceedings are conducted by the newly minted Patent Trial and Appeal Board ("Board" or "PTAB"). The Board has significant discretion to defer action on a petition or stay a proceeding until termination of ex parte reexamination, inter partes review ("IPR"), or post-grant review ("PGR"). 35 U.S.C. § 135(c).

The rules allow derivation proceedings to be terminated by a settlement between the parties as long as the PTAB does not find it inconsistent with the evidence of record, in which case the settlement will not terminate the derivation proceeding. 37 C.F.R. § 42.409. Parties may also use binding arbitration to determine inventorship and derivation. 37 C.F.R. § 42.410.

3. Evaluation of Evidence

To prevail in a derivation proceeding, the inventor of the later-filed application must prove, with substantial evidence, not only that he invented the common subject matter but also that he communicated the invention to the earlier applicant and that the earlier applicant filed a patent application to that invention without authorization. With the implementation of derivation proceedings on March 16, 2013, the case law will develop to show what constitutes sufficient particularity and substantial evidence. Since derivation proceedings will likely incorporate—or at least start with—existing § 102(f) case law, the PTAB is expected to require a petitioner to prove by clear and convincing evidence the two-part test for derivation, namely, that (1) the petitioner first conceived of the invention, and (2) that the petitioner communicated his invention to the alleged deriver with enough particularity to enable the claimed invention. *Brand v. Miller*, 487 F.3d 862, 869-70 (Fed. Cir. 2007). Merely stating that the petitioner previously published an enabling research article is likely insufficient to meet the proposed threshold because, under current § 102(f) case law, access to information alone is not enough to prove derivation. *Hedgewick v. Ackers*, 497 F.2d 906, 908 (C.C.P.A. 1974).

4. Pros and Cons

Interference practice was cumbersome and expensive by virtue of providing full discovery and a two-stage process of first determining patentability and then determining priority. These proceedings were based on a "count," simulating the alleged common subject matter. Showing prior invention in interference proceedings required proof of conception, reduction to practice, and, possibly, diligence, as well as proof that the invention has not been abandoned, suppressed, or concealed. Interference and the new derivation proceedings have one common element—conception.

The elements of proof required to show prior invention, other than conception, in interference proceedings are often difficult, time-consuming, and very expensive. Derivation proceedings require showing only conception, communication, and unauthorized filing. The elements of proof are fewer and more simplistic than in interference proceedings. But with the requirement that an inventor prove that an earlier patent applicant derived the claimed invention from the inventor, not many requests for derivation proceedings are expected to be filed nor have been filed to date.

Procedurally, the new derivation proceeding is far more limited than the old interference practice. Discovery is more limited. Whereas interference practice evolved into permitting full discovery and extensive substantive motions practice, at the expense of time and resources to both the parties and the Board of Patent Appeals and Interferences ("BPAI"), derivation proceedings will involve only limited discovery and a more streamlined process. All of the new trial-type proceedings (derivation, PGR, and IPR) will be subject to the Board's rules of practice. These rules limit discovery to the relevant facts at issue and provide for additional discovery only for good cause shown.

Proceeding	Pros	Cons
Derivation	• Much less complex and expensive than an interference • Streamlined procedures: limited discovery, submission of evidence, and hearing • Reduced expense relative to interference practice	• Much more limited availability than interference • Requires proof of: (1) prior conception, (2) communication, and (3) unauthorized filing • Limited window—within one year of publication of claim • Requires a pending application and can be filed only against a prior-filed application or patent • Substantial PTO fees

C. First Inventor to File

One of the most historic changes under the America Invents Act ("AIA") is the conversion of the U.S. patent system from a "first-to-invent" ("FTI") system to a "first-inventor-to-file" ("FITF") system. The new FITF rules apply to U.S. patents with claims having an effective filing date on or after **March 16, 2013**.

1. "Effective Filing Date"

The relevant date of a claimed invention for patentability purposes under the AIA is the "effective filing date" of the claimed invention as defined in new 35 U.S.C. § 100(i). This is defined as the earlier of:

(A) The actual filing date of the patent or the application for the patent containing a claim to the invention; or

(B) The filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority under U.S.C. § 119, 365(a), or 365(b) (e.g., foreign application) or to the benefit of an earlier filing date under § 120, 121, or 365(c) (e.g., nonprovisional application. *See* 35 U.S.C. § 100(i).

The new AIA prior-art rules will apply to any application that contains or contained at any time a claim to a claimed invention with an effective filing date on or after March 16, 2013, and all applications claiming priority to that application and any patent issuing thereon. If even one claim has an effective filing date on or after March 16, 2013, the entire application will be examined under the new AIA prior-art rules. Moreover, once the new AIA prior-art rules apply to an application, it is not possible to return to pre-AIA prior-art principles in that application or any other application claiming benefit of that application; this is true even if the claims with a post March 16, 2013, effective filing date are eventually canceled.

2. Prior Art

In general, the AIA expands the scope of prior art in the United States by removing certain geographical, temporal, and language limitations. New 35 U.S.C. § 102(a) defines the new universe of prior art, and new 35 U.S.C. § 102(b) sets forth the exceptions. The chart below compares the old and new subsections of 35 U.S.C. § 102.

<table>
<tr><th colspan="5">First-to-Invent ("FTI") System
(before March 16, 2013)</th><th colspan="5">First-Inventor-to-File ("FITF") System
(on or after March 16, 2013)</th></tr>
<tr><td colspan="5"><u>Section 102(a) and (b)</u>
(Reliance on Patent/Publication Date of a Reference)</td><td colspan="5"><u>Section 102(a)(1) and (b)(1)</u>
(Reliance on Patent/Publication Date of a Reference)</td></tr>
<tr><th>Section</th><th>Who</th><th>What</th><th>Where</th><th>When</th><th>Section</th><th>Who</th><th>What</th><th>Where</th><th>When</th></tr>
<tr><td>102(a)</td><td>Others</td><td>Known or used</td><td>U.S.</td><td>Before Date of Invention</td><td>102(a)(1)</td><td>Anyone</td><td>Known or used</td><td>Anywhere</td><td>Before EFD</td></tr>
<tr><td>102(a)</td><td>Others</td><td>Described in a patent</td><td>Anywhere</td><td>Before Date of Invention</td><td>102(a)(1)</td><td>Anyone</td><td>Described in a patent</td><td>Anywhere</td><td>Before EFD</td></tr>
<tr><td>102(a)</td><td>Others</td><td>Described in a publication</td><td>Anywhere</td><td>Before Date of Invention</td><td>102(a)(1)</td><td>Anyone</td><td>Described in a publication</td><td>Anywhere</td><td>Before EFD</td></tr>
<tr><td>102(b)</td><td>Anyone</td><td>Used or on sale</td><td>U.S.</td><td>More than one year before filing date</td><td>102(a)(1)</td><td>Anyone</td><td>Used or on sale</td><td>Anywhere</td><td>Before EFD</td></tr>
<tr><td>102(b)</td><td>Anyone</td><td>Described in a patent</td><td>Anywhere</td><td>More than one year before filing date</td><td colspan="5" rowspan="2">EXCEPTIONS under § 102(b)(1)
A disclosure made one year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if –
(A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
(B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.</td></tr>
<tr><td>102(b)</td><td>Anyone</td><td>Described in a publication</td><td>Anywhere</td><td>More than one year before filing date</td></tr>
</table>

<table>
<tr><th colspan="5">First-to-Invent (“FTI”) System
(before March 16, 2013)</th><th colspan="5">First-Inventor-to-File (“FITF”) system
(on or after March 16, 2013)</th></tr>
<tr><th colspan="5">Section 102(c)</th><th colspan="5">Replaced with New Section 102(c)</th></tr>
<tr><td colspan="5">A person is barred from obtaining a patent if he/she has abandoned the invention.</td><td colspan="5">Common ownership/Joint Development Agreement EXCEPTIONS under § 102(c):
(1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, one or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;
(2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
(3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.</td></tr>
<tr><th colspan="5">Section 102(d)</th><th colspan="5">Section 102(d) Removed</th></tr>
<tr><td colspan="5">A person is barred from obtaining a U.S. patent when the invention was filed or patented abroad more than twelve months before the filing of the application in the United States.</td><td colspan="5">REMOVED</td></tr>
<tr><th colspan="5">Section 102(e)
(Reliance on Filing Date of a Reference)</th><th colspan="5">Section 102(a)(2) and (b)(2)
(Reliance on Filing Date of a Reference)</th></tr>
<tr><th>Section</th><th>Who</th><th>What</th><th>Where</th><th>When</th><th>Section</th><th>Who</th><th>What</th><th>Where</th><th>When</th></tr>
<tr><td>102(e)(1)</td><td>Others</td><td>Described in a published application.
PCT application filed after Nov. 29, 2000 can be used as a reference under this section IF the U.S. is designated and the publication is in English.</td><td>U.S.</td><td>Before date of invention</td><td>102(a)(2)</td><td>Others</td><td>Described in a published application.
PCT applications must designate the U.S., but are no longer required to be in English to permit reliance on the filing date of the PCT application or earlier priority application.</td><td>Anywhere</td><td>Before EFD</td></tr>
<tr><td>102(e)(2)</td><td>Others</td><td>Described in an issued patent.
PCT does not count because not issued in U.S.</td><td>U.S.</td><td>Before date of invention</td><td>102(a)(2)</td><td>Others</td><td>Described in an issued patent
PCT does not count.</td><td>Anywhere</td><td>Before EFD</td></tr>
<tr><td colspan="5"></td><td colspan="5">EXCEPTIONS under § 102(b)(2)
(A) the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;
(B) the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
(C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.</td></tr>
</table>

First-to-Invent ("FTI") System (before March 16, 2013)	First-Inventor-to-File ("FITF") system (on or after March 16, 2013)
Section 102(f) (Derivation)	**Replaced by New Section 135**
A person is barred from obtaining a U.S. patent if he did not himself invent the subject matter to be patented.	Replaced by 35 U.S.C. § 135, Derivation Proceedings
Section 102(g) (Prior Invention by Another)	**Section 102(g) Removed**
A person is barred from obtaining a U.S. patent if the invention was made in the U.S. by another who has not abandoned, suppressed, or concealed it.	REMOVED

D. Inter Partes Review

The America Invents Act ("AIA") also altered the substantive law of post-grant examination and created new post-grant mechanisms, including inter partes review ("IPR") and post-grant review ("PGR"), replacing inter partes reexamination as the only proceedings allowing third parties to participate in validity challenges to issued patents. This section first focuses on the differences between new IPR procedures and previous reexamination procedures, and concludes with a discussion of potential advantages and disadvantages of choosing IPR over district-court litigation.

IPR procedures differ substantially from prior reexamination procedures. Potential parties should be aware of how these changes affect their legal rights and business interests. Some noteworthy differences between IPR and prior reexamination procedures include the point in time when it is available, the threshold showing for initiating a proceeding, the time given to the United States Patent and Trademark Office ("PTO") to reach a final determination, available invalidity arguments, and the trier of the determination.

Summary of ex parte reexamination, inter partes reexamination, post-grant review, and inter partes review.

	Ex Parte Reexamination	Inter Partes Reexamination	Post-Grant Review (PGR)	Inter Partes Review (IPR)
Availability	After grant	After grant (not available after Sept. 16, 2012)	Within 9 months of grant	After 9 months of grant, or after termination of PGR, if PGR has been initiated (available on Sept. 16, 2012)
Threshold Showing	SNQ	Reasonable likelihood of success with respect to at least one claim (was SNQ)	More likely than not, at least one claim is unpatentable or novel legal question	Reasonable likelihood of successful ("RLS") with respect to at least one claim

	Ex Parte Reexamination	Inter Partes Reexamination	Post-Grant Review (PGR)	Inter Partes Review (IPR)
Anonymity	Yes	No	No	No
Estoppel	None	Issues raised or could have been raised	Issues raised or could have been raised	Issues raised or could have been raised
Time to Completion	Potentially multiple years	Potentially multiple years	1-1½ years	1-1½ years
Appeal	Only patentee can appeal to PTAB and then Federal Circuit	Both parties can appeal to PTAB and then Federal Circuit	Both parties can appeal to Federal Circuit	Both parties can appeal to Federal Circuit
Basis of Invalidity	Only patents and printed publications considered	Only patents and printed publications considered	Most grounds–can argue prior art; utility and patent eligibility, written description, definiteness	Novelty and obviousness only over patents and printed publications
Before Whom	CRU	CRU	PTAB	PTAB

SNQ = Substantial New Question of Patentability
PTAB = Patent Trial and Appeal Board
CRU = Central Reexamination Unit

1. Availability

IPR becomes available after nine months of the patent grant or after the expiration of a PGR proceeding, if initiated. PGR proceedings fall within the first nine months after the patent grant. IPR only occurs after PGR or the opportunity thereof has expired. Petitioners party to a litigation in another forum must file within one year of being served a complaint alleging infringement to remain eligible for IPR. AIA § 315(b). The AIA, however, does not allow a petitioner to file an IPR or PGR request if he has previously filed a declaratory civil action challenging a patent's validity. AIA §§ 315(a)(1), 325(a)(1). Further, a civil action challenging validity filed by a petitioner on or after the date an IPR or PGR is filed will be automatically stayed unless (1) the patent owner moves to lift the stay, (2) the patent owner files an action or counterclaim for infringement, or (3) the petitioner moves to dismiss the civil action. AIA §§ 315(a)(2), 325(a)(2). Notably, a counterclaim of invalidity does not qualify as a civil action challenging validity. 35 U.S.C. § 317(b).

2. Threshold Showing

To institute an IPR proceeding, the petitioner must show a "reasonable likelihood of success that the petitioner would

prevail" with respect to at least one claim. 35 U.S.C. § 314(a). This "reasonable likelihood of prevailing" ("RLP") threshold replaces the "substantial new question of patentability" (SNQ) threshold required in inter partes reexamination. The congressional record states, "The present bill dispenses with the test of 'substantial new question of patentability,' a standard that currently allows 95% of all requests to be granted. It instead imposes thresholds that require petitioners to present information that creates serious doubts about the patent's validity. Under section 314(a), inter partes review will employ a reasonable-likelihood-of-prevailing threshold, and under section 324(a), post-grant review will use a more-likely-than-not-invalidity threshold." Cong. Rec. Mar. 8, 2011, S1375 (Senator Kyl). The new threshold of RLP is higher than the current SNQ threshold applied to reexamination. A precise level of the RLP threshold continues to be determined in this inaugural year of implementation.

Adding to the challenge of meeting the threshold, IPR procedure, unlike inter partes reexamination, allows the patent owner an opportunity to respond to the petition before the PTO decides whether the threshold is met. 35 U.S.C. § 313. The patent owner may also disclaim claims after the petition is filed to avoid IPR over the disclaimed claims, but may not amend the claims.

3. Anonymity

A petitioner for PGR or IPR must identify all real parties in interest, including those entities in privity with the petitioner. 35 U.S.C. §§ 312(a)(2), 322(a)(2). Under the AIA, ex parte reexamination remains the only PGR proceeding that may be initiated by an anonymous petitioner.

4. Estoppel

Estoppel applies to "any ground that the petitioner raised or reasonably could have raised" during a PGR or IPR proceeding. Estoppel will have legal effect in further proceedings before the PTO, federal courts, and the International Trade Commission, 35 U.S.C. §§ 315(e), 325(e). Litigants who have finished proceedings outside the PTO have no estoppel in PGR, IPR, or ex parte reexamination.

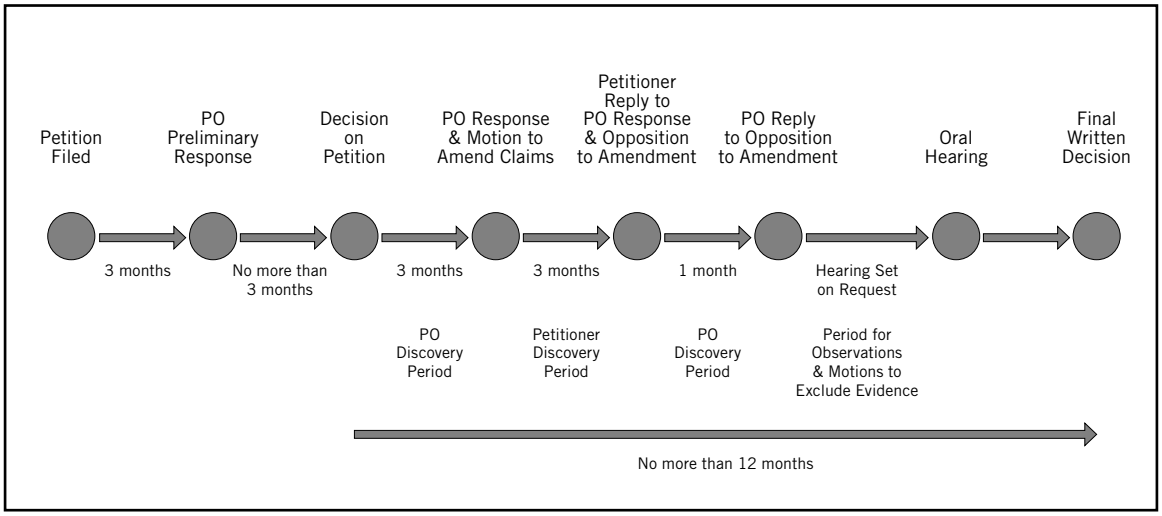
In the event of settlement, no estoppel attaches to the petitioner when the IPR is terminated. *See* 35 U.S.C. § 317(a).

Not just the petitioner is subject to estoppel in IPR. The patent applicant or owner is precluded from taking action inconsistent with the adverse judgment, including obtaining in any patent: (1) a claim that is not patentably distinct from a finally refused or canceled claim; or (2) an amendment of a specification or of a drawing that was denied during the trial proceeding, but this provision does not apply to an application or patent that has a different written description. AIA § 42.73(d)(3).

5. Time to Determination

The AIA requires a final determination in any PGR or IPR proceeding to be issued within one year from the date the petition is granted. The PTO may, only in the event that good cause can be shown, extend that time by up to an additional six months. The new timeline allows a much quicker determination than inter partes reexamination, which generally took years of examination before that Central Reexamination Unit ("CRU"), frequently followed by appeal to the Board of Patent Appeals and Interferences ("BPAI").

The chart below, provided by the PTO's Trial Practice Guide, summarizes a representative timeline for IPR and PGR proceedings.



6. Appeal

In prior reexamination proceedings, any appeal from the CRU went to the BPAI. Any subsequent appeal would then go to the United States Court of Appeals for the Federal Circuit. Now, both PGR and IPR proceedings may be directly appealed to the Federal Circuit.

7. Basis of Invalidity

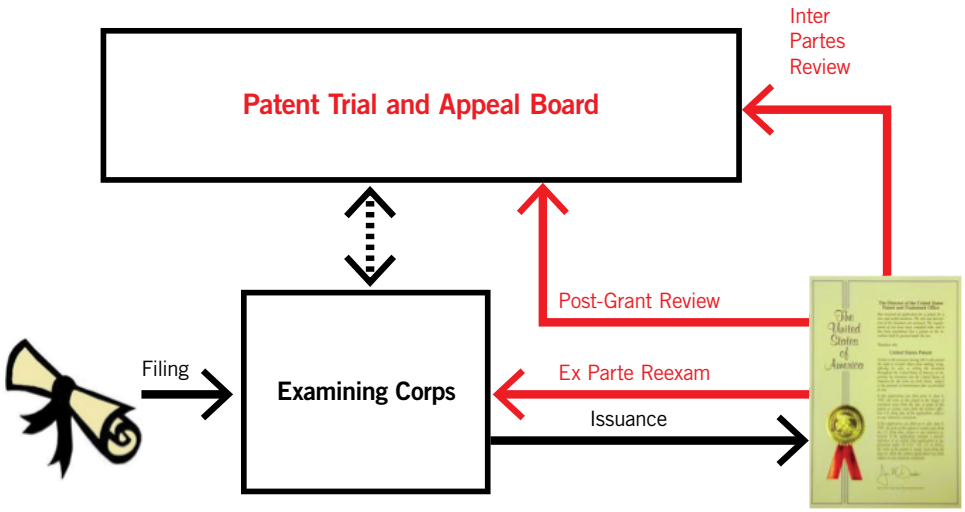
In an IPR proceeding, the PTO will consider only novelty or obviousness arguments based on patents or printed publications. 35 U.S.C. § 311(b). Prior requests for inter partes reexamination were based on patents and printed publications, but there were no explicit prohibitions of challenging the patent on grounds other than novelty and obviousness. In prior inter partes reexamination practice, parties could still challenge the patent under other legal theories such as obvious-type double patenting. M.P.E.P. § 2658. By contrast, IPR is strictly limited to theories of

novelty and obviousness, and only on the basis of prior art consisting of patents and printed publications. Other legal theories are reserved for PGR, which allows challenges of any kind.

8. Before Whom

IPR proceedings occur before judges at the Patent Trial and Appeal Board ("PTAB" or "Board") instead of examiners at the CRU as was the practice for inter partes reexamination. Ex parte reexamination proceedings continue to be before the PTO's CRU.

The flowchart below shows who evaluates the various post-grant review proceedings at the PTO.



9. Choosing Between Inter Partes Review and District Court

To develop effective use of the new IPR proceedings, potential parties should consider how IPR differs from traditional district court litigation. Some important differences between the IPR and district court litigation include the time to completion, basis of invalidity, the decision maker, discovery, page limits, claim interpretation, burden of proof, anonymity, estoppel, cost, and options for appeal.

a. Time to Completion

	Ex Parte Re exam	Post Grant Review	Inter Partes Review	District Court
Time to Completion	Several years	1-1½ years	1-1½ years	1 year to ?

IPR has a strict time limitation for completion, which will make it faster, with a set schedule, than district court. According to the AIA, a final determination for IPR and PGR will issue within twelve to eighteen months, while district court litigation can conclude quickly or slowly, depending on the jurisdiction. The Eastern District of Virginia, the Eastern District of Texas, and the Northern District of California typically conclude patent cases quickly, within approximately one to two years, and the Southern District of West Virginia, the Eastern District of Arkansas, and the Middle District of Florida often take more than three years to finish a case. Cases before the International Trade Commission ("ITC") typically take around sixteen months to complete from complaint to final decision, but the ITC only applies to patent disputes involving imported products. Parties who desire a quick determination on validity should consider the timing advantages of IPR.

Before the AIA, infringement suits often followed a dual-track approach with a suit in district court and an inter partes reexamination at the PTO. IPR and PGR, replacing inter partes reexamination, are much quicker than pre-AIA reexamination proceedings, which were notably slow at reaching a final determination. Plus, IPR decisions are appealed directly to the Federal Circuit, which bypasses the old inter partes reexamination procedure of mandatory appeal to the BPAI. The new IPR and PGR procedure and timing restrictions speed up the overall time of dispute for parties with actions in multiple forums.

b. Basis of Invalidity (Arguments That Are Available)

	Ex Parte Reexam	Post-Grant Review	Inter Partes Review	District Court
Basis of Invalidity	Novelty and obviousness: only patents and printed publications considered	Most grounds: can argue prior art; utility and patent eligibility; enablement, written description, definiteness	Novelty and obviousness: only patents and printed publications	All grounds

The AIA limits the basis for invalidity in IPR to novelty and obviousness issues related to patents and printed publications. 35 U.S.C. § 311(b). In district court litigation, on the other hand, any basis for invalidity may be raised, and parties can offer any kind of admissible evidence before the court to show invalidity. Limiting IPR to patents and printed publications hinders a showing of invalidity for the statutory provisions of "public use, on sale, or otherwise available to the public" in 35 U.S.C. § 102(a)(1), which are typically established by evidence other than patents or printed publications. But, the limited basis and evidence also limits the amount of estoppel (issues raised and could have been raised) that applies to petitioners in IPR. After IPR, a petitioner can still seek invalidity over novelty and obviousness in other forums by presenting evidence excluded from IPR, such as prior sales, as well as raise invalidity contentions of eligibility, enablement, written description, and definiteness. Careful consideration of the potential basis for invalidity and the types of evidence available or likely to be available to show invalidity will help parties choose

between IPR and district court.

c. Before Whom – Who Is the Decision Maker?

	Ex Parte Reexam	Post-Grant Review	Inter Partes Review	District Court
Before Whom	Central Reexamining Unit (CRU)	Patent Trial and Appeal Board (PTAB)	Patent Trial and Appeal Board (PTAB)	Judge or jury

The outcome of any patent case can vary depending on the person deciding the case and the level of experience in patent law the decider possesses. In IPR, cases are decided by judges at the PTAB. In district court, cases go before a judge or jury. PTAB judges overseeing IPR all have experience with patent law, whereas only some judges in district court have patent-law experience and juries have no knowledge of the patent system. Because PTAB judges all have experience with patent law, parties could have greater certainty that evaluation of the issues will be more predictable and accurate than in many district courts.

d. Discovery – What Is Available?

	Ex Parte Reexam	Post-Grant Review	Inter Partes Review	District Court
Discovery/ Evidence?	Declaration	Declaration and limited discovery	Declaration and limited discovery	Full discovery

Discovery is available in IPR, but limited in comparison to the full discovery offered in district court. In IPR, discovery is limited to (1) deposition of witnesses submitting affidavits or declarations; and (2) what is otherwise necessary in the interest of justice. 35 U.S.C. § 316(a)(5). IPR also includes "routine discovery" provisions, which allow discovery of any exhibit cited in a paper or in testimony, cross-examination of affidavit testimony, and relevant information that is inconsistent with a position advanced by the party during the proceeding concurrent with the filing of the documents or things that contains the inconsistency. 37 C.F.R. § 42.51(b)(1). Routine discovery, however, "does not make discoverable anything otherwise protected by legally recognized privileges such as attorney-client or attorney work product." *Id.*

In some circumstances, "additional discovery" is permitted in IPR upon showing that it is in the "interests of justice." 37 C.F.R. § 42.51(b)(2)(i). To make this showing, the moving party must show, based on a totality of the relevant circumstances, that it was fully diligent in seeking discovery and that there is no undue prejudice to the nonmoving

party. *See* Resp. to Comment 132, 77 Fed. Reg. 48,612, at 48,641 (Aug. 14, 2012).

For exchange and submission of confidential information, protective orders are available in IPR for "good cause." A petitioner may file a motion to seal with the proposed protective order. The patent owner must then agree to the protective order to access sealed information. *See* 35 U.S.C. § 326(a)(7).

The PTAB may also impose sanctions for abuse of discovery, improper use of IPR, harassment, unnecessary delay, or increase in cost.

e. Page Limits

	Ex Parte Reexam	Post-Grant Review	Inter Partes Review	District Court
Page Limits	No	Yes (80)	Yes (60)	Varies by jurisdiction

Petitions and patent-owner responses, including claim charts, are limited to sixty pages. While page limits in district court vary by jurisdiction, district court will generally allow more pages, which allows parties to make more arguments to the judge or jury. The sixty-page limit (double spaced in size 14 point font) could make it difficult to challenge patents with numerous claims. Potential parties should consider whether petitions should be filed for certain subsets of claims leading to multiple petitions.

f. Claim Interpretation

	Ex Parte Reexam	Post-Grant Review	Inter Partes Review	District Court
Claim Interpretation	Broadest reasonable construction	Broadest reasonable construction	Broadest reasonable construction	Based on canons of construction, prosecution history

In IRP, claims are construed much more broadly than in district court. In district court, claims are construed narrowly to preserve their validity. *See Atl. Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 824, 846 (Fed. Cir. 1992) ("During litigation determining validity or infringement … the courts must consult the specification, prosecution history, prior art, and other claims to determine the proper construction of the claim language."). Defendants offer invalidating claim constructions often find themselves at a disadvantage. In a proceeding at the PTO, by contrast, the claims are construed according to "the broadest reasonable interpretation consistent with the specification." MPEP § 2111 (Director Kappos has stated

"The USPTO has chosen to employ a single standard, the broadest reasonable interpretation standard, for proceedings before the USPTO."). Thus, evidence excluded as prior art in district court because of narrow claim construction could be applied in IPR to show invalidity of the claims.

g. Burden of Proof

	Ex Parte Reexam	Post-Grant Review	Inter Partes Review	District Court
Burden of Proof	Preponderance of the evidence	Preponderance of the evidence	Preponderance of the evidence	Clear and convincing evidence

IPR petitioners need only establish invalidity by a preponderance of the evidence. AIA §§ 316(e), 326(e). District court applies a much higher burden of proof; patents are given a presumption of validity, even those that were erroneously issued. 35 U.S.C. § 282. The courts interpret the presumption to require defendants to establish invalidity under a "clear and convincing" standard for all grounds of invalidity, even ones that were never considered by the PTO during prosecution. *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012). In district court, the burden of proof for establishing invalidity clearly favors the patentee. IPR provides a forum in which defendants or potential defendants to an infringement suit can challenge the patent without having to overcome the presumption of validity. Petitioners will still need to overcome the "likelihood of prevailing" threshold for instituting an IPR, but once that threshold is met, invalidity may be established by a preponderance of the evidence. IPR, like prior inter partes reexamination, is an attractive form for defendants seeking to circumvent the presumption of validity.

h. Estoppel

	Ex Parte Reexam	Post-Grant Review	Inter Partes Review	District Court
Estoppel	None	Issues raised or could have been raised	Issues raised or could have been raised	Various estoppel doctrines. No post-grant challenge if you lose in district court.

Estoppel applies to "any ground that the petitioner raised or reasonably could have raised" during IPR proceedings. Estoppel after IPR will have legal effect in further proceedings before the PTO, federal courts, and the ITC. Estoppel in IPR should properly be seen as having a claim-by-claim effect, not by the patent as a whole. In district court, on the other hand, estoppel does not apply to invalidity contentions raised or could have been raised in district court. Issues raised or could have been raised in district court can still be argued in IPR.

i. Cost

	Ex Parte Reexam	Post-Grant Review	Inter Partes Review	District Court
Total Filing Fee	$12,000	$30,000 (request + post-institutional fees)	$23,000 (request + post-institutional fees)	Nominal

The total IPR filing fees are substantially higher than the nominal fee for filing a complaint in district court. But the legal fees for IPR could be less because the eligible issues raised, discovery, and page limits are all limited in comparison to district court litigation.

j. Appeal – Who Can Appeal and to Whom Is the Decision Appealed?

	Ex Parte Reexam	Post-Grant Review	Inter Partes Review	District Court
Appeal	Only patentee can appeal to PTAB and then Federal Circuit	Both parties can appeal to Federal Circuit	Both parties can appeal to Federal Circuit	Both parties can appeal to Federal Circuit

IPR differs from the old reeexamination proceedings and current ex parte reexam proceedings in that an appeal goes to the Federal Circuit instead of the PTAB (or old BPAI). For both IPR and district court litigation either party can appeal directly to the Federal Circuit. However, it still remains unclear whether the denial of a petition for IPR is appealable, and to whom the decision would be appealed.

10. Summary of IPR Advantages

- Lower burden of proof than litigation
- Lower cost than litigation

- Filing not time-limited once past nine months of patent issuance, except if sued (one year)
- Final determination within one to one-and-one-half years
- Broad claim construction (broadest reasonable interpretation)

11. Summary of IPR Disadvantages

- Requires higher threshold than current ex parte reexamination procedures (RLP versus SNQ)
- Grounds limited to invalidity for novelty and obviousness (patents or publications only)
- Must identify the real parties in interest
- Estoppel on arguments raised or reasonably could have been raised
- Limited discovery

E. Post-Grant Review

Post-Grant Review ("PGR") is a new trial proceeding to review the patentability of one or more claims in a patent. *See* 35 U.S.C. § 321; *see also* 37 C.F.R. § 42.200. With PGR, the U.S. Patent and Trademark Office ("PTO") provides a quasijudicial proceeding that delivers quality outcomes without the broad discovery and expense of district court litigation.

1. Summary

The Table below provides a summary of the requirements and costs of PGR. Each of the topics listed in the Table will be discussed in more detail below.

Eligibility	Basis for Request	Threshold	Timing	Costs	Processing Time by PTO
Third parties	Any ground related to patent invalidity under 35 U.S.C. § 282 (except best mode)	Preponderance of the evidence	File within 9 months of the issue date of the patent	$30,000 (request + post-institutional fees)	12-18 months

2. Eligibility

PGR became available on September 16, 2012, but applies only to patents granted on an application filed on or after March 16, 2013. This means that there will likely not be a PGR before 2014.

The petition for PGR must identify all real parties in interest. That is, a request for PGR cannot be filed anonymously.

3. Timing

PGR must be requested within nine months of the issue date of the patent.

4. Requirements

PGR may be requested based on any ground related to patent invalidity under 35 U.S.C. § 282. That is, PGR may be requested based on utility under 35 U.S.C. § 101, novelty under 35 U.S.C. § 102, obviousness under 35 U.S.C. § 103, and enablement, written description, and definiteness under 35 U.S.C. § 112, but not best mode.

PGR must include an identification of each claim challenged, the grounds for each challenge, and the evidence supporting the challenge. Such evidence may include patents, printed publications, affidavits, and declarations.

The requesting party must establish the basis of its request to a preponderance of the evidence. A preponderance of the evidence means "more likely than not." The Director must determine whether the information presented in a request shows that it is more likely than not that at least one of the claims challenged in the petition is unpatentable.

5. Costs

There is a graduated scale of fees increasing with the number of claims requested for review. In addition, there is an eighty-page limit to the PGR request.

6. Processing of PGR

Once a PGR request is filed, the patent owner has one opportunity to file a response to the request. The Director must then decide whether or not to grant the request within three months of the patent owner's response.

Once granted, the parties may request an oral hearing, and there may be some discovery. The patent owner will have one opportunity to amend or cancel claims (but the amendment cannot broaden a claim). The patent owner will also have one chance to respond to the PGR request, including any factual evidence and expert opinions on which the patent owner relies. The third party will have another opportunity to file written comments after the patent owner files the response.

For PGR, discovery is available for "relevant evidence directly related to factual assertions advanced by either party in the proceeding." The PTO rules provide routine discovery of exhibits cited in a paper or testimony and provide for cross-examination of affidavit testimony without the need to request authorization from the Patent Trial and Appeal Board ("PTAB or "Board"). There is provision for agreed-upon mandatory discovery and additional discovery, as well as a motion procedure if there is no agreement between the parties.

By statute, PGR should be complete within twelve to eighteen months. Either party may appeal the PTAB's decision. The appeal is to the Court of Appeals for the Federal Circuit. If the PTAB decision has resulted in an amended claim, there may be intervening rights by a third party who was not infringing the original claim but is now infringing the amended claim. If so, the intervening rights are treated the same as if it was a U.S. reissue patent.

7. Advantages

a. Cost/Timing

PGR costs much less and provides faster results than litigation.

b. Burden of Proof

The "burden of proof" standard in PGR (preponderance of the evidence) is lower than the "clear and convincing" evidence standard applicable in district court.

8. Disadvantages

a. Estoppel

The third party requesting PGR will be estopped from raising "any ground that the petitioner raised or reasonably could have raised during that post-grant review" in a later proceeding before the PTO, district court, or the International Trade Commission. Under the AIA, estoppel for PGR becomes effective with a written PTAB decision with respect to any ground that the petitioner raised or reasonably could have raised. However, settlement agreements are allowed, which create no estoppel.

b. Relationship Between PGR and Litigation

A third party who files a civil action in court (requesting a declaratory judgment of invalidity) cannot then file a request for PGR. If a patent owner files an infringement suit within three months of the patent issuing, the court may not stay motion for preliminary injunction on the basis that a PGR request was filed or a PGR instituted. If a third party files a civil action on or after the request for PGR is filed, the civil action is automatically stayed unless:

(1) The patent owner moves to lift the stay;

(2) The patent owner files an action or counterclaim for infringement; or

(3) The third party moves to dismiss the civil action.

F. Preissuance Submissions

The preissuance-submission provision of the America Invents Act ("AIA") expands the options available for members of the public to make validity challenges to pending applications at the U.S. Patent and Trademark Office ("PTO"). Before the AIA, interested third parties could submit relevant prior art to challenge pending patent applications, but the submissions were limited to a maximum of ten documents and the third parties were not allowed to comment on the documents submitted. The AIA removed the maximum limit of documents that may be submitted and requires third parties to provide "a concise description of the asserted relevance of each item identified in the document list." 37 C.F.R. § 1.290(d)(2).

1. Eligibility

The new preissuance submission took effect on September 16, 2012, and applies to all applications before, on, or after September 16, 2012. Any "third party is permitted to submit patents, published patent applications or printed publications." 35 U.S.C. § 122(e). No other types of evidence are permissible. Third-party submitters remain anonymous and receive no estoppel effects from the prior art submitted nor the comments made in the submission. 37 C.F.R. § 1.290(a), (c). Preissuance submissions do not apply to reissue applications and reexaminations.

2. Timing

Preissuance submissions are only permitted within a specific time period of prosecution. The third party must make the submission the earlier of a notice of allowance, or the later of six months after publication by the PTO (does not apply to WIPO or foreign publications) or a first office action rejecting claims (not including restriction requirements). 37 C.F.R. § 1.290(b). Notably, the largest possible window for filing a preissuance submission extends only to six months after publication of the pending patent application. Parties interested in making preissuance submissions need to remain alert of new publications and file submissions as soon as possible to avoid missing the window of opportunity.

3. Requirements

- List of Items
- Concise Description of Relevance

- Concise Description of Relevance
- Legible Copy of Non-U.S. Patent or Published Application
- Translations
- Statement of Compliance with Statute and Rule
- Fees

Section 1.290(d) requires a list identifying the submitted documents; a concise description of the asserted relevance of each item; a legible copy of each; an English language translation of any non-English language item; a statement by the submitter that the party has no duty to disclose information (i.e., is a true third party); and a statement that the submission complies with the statutory and regulatory requirements.

The final rule set forth by the PTO suggests that the description of asserted relevance can be a "narrative description" or a "claim chart." By way of example, the PTO stated that "a description that includes an introductory paragraph describing the field of technology of a document and a claim chart that maps portions of the document to different claim elements" would likely qualify. Third-party filers, however, cannot participate in prosecution nor propose rejections based on the submitted documents.

4. Consideration by the Examiner

After submission, the examiner will consider the documents as part of the next office action similar to the way he would consider an Information Disclosure Statement ("IDS"). The examiner reviews the documents and makes rejections over the documents he considers prior art. Once the preissuance submission is filed, the third-party submitter cannot respond to any office action or response by the applicant.

Applicants address any rejections in an office action over references provided in a preissuance submission, but need not reply to the preissuance submission itself. For instance, applicants are not required to file an IDS containing the documents cited in the preissuance submission.

5. Advantages

a. Cost

The costs of filing a preissuance submission are significantly less than other challenges to validity available to third parties such as post-grant review ("PGR") and inters partes review ("IPR"). The fee is akin to filing an IDS, and no fee applies, if the first and only submitted list contains three items or fewer. 37 C.F.R. § 1.290(f).

b. Comments Allowed

The ability to submit a description of relevance allows third parties greater participation in challenging patents before they issue. While somewhat limited, the description of relevance still permits summaries of the technology and claim charts linking claim elements to relevant portions of the submitted documents. Connecting the prior art with the claim elements should increase the likelihood that the examiner will apply the relevant references properly in the office action.

c. No Estoppel

Third-party submitters remain anonymous and receive no estoppel effects from both the prior art submitted and the comments made in the submission. Other patent challenges made at the PTO such as PGR and IPR apply estoppel for issues raised and could have been raised, and severely limits the third-party challenger from seeking invalidity in other forums after a final decision.

d. No Threshold Showing

There is no threshold showing for challenging patents with a preissuance submission, whereas reexamination, PGR, and IPR all have a threshold showing that a relevant issue will be raised to challenge the patent. With preissuance submissions, third parties may submit any document they choose–documents need not be prior art. Furthermore, third parties have no duty to disclose the most relevant documents. Parties may choose to submit less relevant documents to the examiner in hopes that such documents will be sufficient to invalidate or significantly limit the scope of the claims before the examiner, while keeping the most relevant documents for other proceedings.

6. Disadvantages

a. No Participation

Participation of the third party is extremely limited. The examiner may overlook relevant references or not properly ascertain the connections between the references and the claim elements. Moreover, limitations to the comments submitted prevent third parties from communicating theories of obviousness or inherency to the examiner.

b. Overcoming Prior Art May Strengthen Patent

If the prior art submitted in the preissuance submission is overcome during prosecution, the resultant patent will be more resilient to future attacks. In district court, patents are given a presumption of validity, which requires a showing of clear and convincing evidence that the patent is invalid. If the examiner "blesses" the patent over the prior art submitted in the preissuance submission, it will be more difficult for challengers to establish a clear and convincing case that the patent is invalid over the submitted references. *See Al-Site Corp. v. VSI Int'l., Inc.*, 174 F.3d 1308, 1323 (Fed. Cir.

1999) (burden of showing invalidity "especially difficult" when the challenger attempts to rely on prior art that was before the examiner).

In other proceedings before the PTO such as ex parte reexamination, PGR and IPR, the resultant patent is not given a presumption of validity, so the patent may not be strengthened by overcoming the prior art from the preissuance submission, but having the prior art already considered may make it more difficult for the third-party challenger to overcome the threshold for instituting one of these proceedings before the PTO. For example, a party seeking to challenge a patent in ex parte reexamination may fail to show a substantial new question of patentability over prior art submitted in a preissuance submission because it was already considered by the examiner. And notably, the standard for instituting an ex parte reexamination is the lowest of standards among post-grant proceedings at the PTO.

G. Supplemental Examination

Supplemental examination is a new mechanism introduced by the America Invents Act ("AIA") to access ex parte reexamination. Supplemental examination allows a patent owner to request the U.S. Patent and Trademark Office ("PTO") to consider, reconsider, or correct any information the patent owner considers to be relevant to the patent. *See* 35 U.S.C. § 257. This is meant to offer patent owners a possible means of purging a potential inequitable conduct problem discovered after issuance but before litigation. The incentive to the patentee to use supplemental examination is that the patentee is insulated in subsequent litigation from inequitable-conduct allegations for claims that are patentable after the PTO considers and/or reconsiders the submitted information and/or corrected information.

1. Summary

The Table below provides a summary of the basic requirements and costs of supplemental examination. Each of the topics listed in the Table will be discussed in more detail below.

Eligibility	Timing	Basis for Request	Cost	Processing Time by PTO
Only patent owners	File during the period of enforceability of the patent	Any information (not just patents and publications) that the patent owner considers to be relevant to patentability. There is a limit of 12 items of information per supplemental exam request, but no limit on the number of supplemental exam requests that can be filed.	$16,500 (request + reexam, if reexam ordered as a result of the supplemental examination)	3 months

2. Eligibility

Supplemental examination became available on September 16, 2012, but it can be used for any patent that issued before, on, or after September 16, 2012.

Only a patent owner may file a request for supplemental examination; a third party is not permitted to seek a supplemental examination. All parties having an ownership interest in the patent must act together in seeking supplemental examination.

3. Timing

A patent owner may file a supplemental examination of any patent during the period of enforceability of the patent.

4. Requirements

A request for supplemental examination must contain:

(1) a list of each item of information that is requested to be considered, reconsidered, or corrected;

(2) an identification of each claim of the patent for which supplemental examination is requested;

(3) a separate explanation of the relevance and manner of applying each item of information to each claim of the patent for which it was identified;

(4) a summary of the relevant portions of any submitted document, other than the request, that is over fifty pages in length; and

(5) fees totaling $16,500, broken down as (i) a fee of $4,400 for processing and treating a request for

supplemental examination; and (ii) a fee of $12,100 for ex parte reexamination ordered as a result of a supplemental examination proceeding.[2]

In addition, a request for supplemental examination must be accompanied by any applicable document-size fees.

a. "Item of Information"

An item of information includes a document containing information believed to be relevant to the patent that the patent owner requests the PTO to consider, reconsider, or correct. An item of information is not limited to patents and printed publications, and may include, for example, a sales receipt or invoice. If the information is not, at least in part, contained within or based on any document filed as part of the request, the discussion within the body of the request relative to the information will be considered to be an "item of information."

There is a limit of twelve items of information per supplemental exam request, but no limit on the number of supplemental exam requests that can be filed.

5. Processing of a Request for Supplemental Examination

Once a request for supplemental examination is made, the PTO has three months to determine whether any of the items of information filed with the request raises a substantial new question of patentability ("SNQ"). The SNQ is triggered when there is a substantial likelihood that a reasonable examiner would consider an item of information important in determining the patentability of the claimed invention. If a SNQ is found for any item of information, then the PTO will order an ex parte reexamination of the patent. The ex parte reexamination will be conducted in accordance with the existing rules governing ex parte reexamination proceedings except that: (1) the patent owner will not have the right to file a patent-owner statement and (2) the PTO will address each substantial question of patentability without regard to whether it is raised by a patent or printed publication.

The PTO will conclude a supplemental examination by issuing a certificate of supplemental examination. The certificate will indicate the results of the PTO's determination as to whether any item of information filed by the patent owner in the request raised a SNQ.

6. Advantages

a. Not Limited to Patents and Publications

Unlike ex parte reexaminations, supplemental examination can be used to raise any issue based on any information believed to be relevant to a patent.

2 The fee of $12,100 for ex parte reexamination ordered as a result of a supplemental examination proceeding will be refunded if the supplemental examination certificate indicates that no SNQ was raised by any of the items of information properly submitted as part of the request and reexamination is not ordered.

b. PTO Makes the Judgment Regarding Questions of Patentability

With supplemental examination, the patent owner only needs to point to an item of information that is believed to be relevant to patentability. This is a subjective standard based on the patent owner's belief. Making a request for supplemental examination should not be characterized as an admission of materiality to patentability. *See* 235 U.S.C. § 257(c). Indeed, once a request for supplemental examination is made, the PTO makes the judgment as to whether the submitted material raises an SNQ. This helps the patent owner avoid prosecution-history issues.

c. Removing Inequitable-Conduct Issues

A request for supplemental examination provides a patent owner with a mechanism to cure any issues that may make the patent subject to inequitable-conduct allegations. Further, by filing a request for supplemental examination, the patent owner can immunize his/her patent against allegations of inequitable conduct. Information considered, reconsidered, or corrected during supplemental examination cannot be the basis for rendering a patent unenforceable for inequitable conduct so long as the supplemental examination and any resulting ex parte reexamination are completed before the civil action is brought.

7. Disadvantages

The main disadvantage of supplemental examination is cost. While the PTO will return $12,100 if ex parte reexamination is not ordered, the supplemental examination fee, the ex parte examination fee, and any applicable document-size fees must be paid with the initial supplemental-examination request.

VI. Summary of Chemical and Pharmaceutical Federal Circuit Cases from 2006 to 2012

From Federal Circuit decisions between 2006 and 2012, we identified and compiled the chemical and pharmaceutical decisions regardless of issue. We present those decisions in various chart forms below. All the charts include a date of the decision, a case number, an origin of the case, a case name, and a brief description of the case. The case charts are useful finding tools when looking for particular case law in the chemical and pharmaceutical areas.

To begin with, the first set of charts is organized by category. Those categories include:

- Subject Matter - 35 U.S.C. § 101
- Novelty - 35 U.S.C. § 102
- Obviousness - 35 U.S.C. § 103
- Infringement
- Written Description, Enablement, Definiteness - 35 U.S.C. § 112
- Inventorship
- Inequitable Conduct
- Patent Term
- Interference
- Jurisdiction
- Priority
- Prosecution History Estoppel/ Doctrine of Equiavlence
- Reexamination
- Safe Harbor
- Claim Construction
- Double Patenting
- Hatch-Waxman
- Other

Next, we provide a year-by-year review of Federal Circuit cases generally in intellectual property. We provide a similar year-by-year review of the chemical and pharmaceutical cases.

Finally, the chemical and pharmaceutical Federal Circuit decisions are organized by year. For each year, we provide a case summary of the relevant decisions along with a summary chart of the remaining cases for that year.

Notably, the case summaries provided below are reprinted from previously published issues of Finnegan's newsletter *Last Month at the Federal Circuit*. If you would like to subscribe to *Last Month at the Federal Circuit*, please email info@finnegan.com.

A. Subject Matter - 35 U.S.C. § 101

Date	Case No.	Origin	Case Name	Brief Description
2008-10-30	2007-1130	PTO	*In re Bilski*	To be patentable under § 101, a process must be tied to a machine or transform an article into a different state or thing
2009-09-17	2008-1403	DCT	*Prometheus Labs., Inc. v. Mayo Collaborative Servs.*	Claims to methods of optimizing therapeutic efficacy are patent-eligible subject matter under 35 U.S.C. § 101
2010-12-17	2008-1403	SC	*Prometheus Labs., Inc. v. Mayo Collaborative Servs.*	Eligibility of claims previously held valid under machine-or-transformation test reaffirmed
2011-08-31	2006-1634, -1649	SC	*Classen Immunotherapies, Inc. v. Biogen IDEC*	Majority holds § 101 does not exclude claims directed to a specific, tangible application
2012-08-16	2010-1406	SC	*Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*	Claims to isolated DNA and screening method are patent eligible, but claims to analyze and comparing methods are not

B. Novelty - 35 U.S.C. § 102

Date	Case No.	Origin	Case Name	Brief Description
2006-11-09	2006-1021, -1022, -1034	DCT	*Abbott Labs. v. Baxter Prods., Inc.*	Inherent feature in prior art was anticipating even though not previously appreciated
2006-11-20	2005-1313	DCT	*Impax Labs., Inc. v. Aventis Pharm. Inc.*	The enablement requirement of § 102, unlike § 112, does not require proof of efficacy or utility
2006-12-08	2006-1613	DCT	*Sanofi-Synthelabo v. Apotex*	Patent covering Plavix® drug not anticipated and grant of preliminary injunction upheld
2007-04-23	2004-1562, -1563, -1589	DCT	*In re Omeprazole Litig.*	Prior art disclosing only product ingredients can inherently anticipate a process claim
2008-10-03	2007-1513	DCT	*Impax Labs., Inc. v. Aventis Pharm. Inc.*	Prior art patent's dosage guidelines failed to provide sufficient guidance to prescribe a treatment regimen and did not enable claimed invention so as to anticipate patent-in-suit
2008-10-07	2008-1029	DCT	*Cohesive Techs., Inc. v. Waters Corp.*	Novelty analysis is separate and distinct from nonobviousness analysis
2008-12-12	2007-1438	DCT	*Sanofi-Synthelabo v. Apotex, Inc.*	Prior disclosure of a racemic mixture of a compound does not anticipate or render obvious a claim to an isolated enantiomer having unpredictable properties

Date	Case No.	Origin	Case Name	Brief Description
2009-03-26	2008-1453	PTO	*In re Gleave*	A reference that lists every fifteen-base sense oligodeoxynucleotide in a known nucleic acid sequence anticipates claims to specific antisense sequences having particular properties
2009-03-31	2008-1003	DCT	*Cordis v. Boston Scientific*	The mere fact that a document is distributed without a legal obligation of confidentiality is not in and of itself sufficient to render the document a "printed publication" under 35 U.S.C. § 102(b)
2009-09-14	2008-1306	DCT	*Fresenius USA, Inc. v. Baxter Int'l, Inc.*	Structural and functional analysis of disclosed and prior art elements are required when means-plus-function limitations are at issue
2009-11-19	2009-1018	DCT	*Iovate Health Scis., Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*	Claims are invalid because an advertisement disclosed the invention in a printed publication before the critical date
2010-08-02	2009-1437	DCT	*King Pharm., Inc. v. Eon Labs, Inc.*	The Federal Circuit invalidated the "advising" and "informing" claims for lack of novelty under the printed-matter doctrine. The act of administering metaxalone to patients was known, and the "advising" or "informing" steps, while new as a factual matter, could not render the claims novel as a legal matter
2011-03-28	2010-1019	PTO	*In re Jung*	Prima facie case established when examiner sufficiently articulates statutory basis of rejection and identifies references relied upon
2011-12-01	2011-1091	DCT	*Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP*	Proving prior invention does not require that the prior inventor appreciated the subject matter using the same words of the claim
2012-02-17	2011-1078	DCT	*ClearValue, Inc. v. Pearl River Polymers, Inc.*	Broad range in prior art anticipates narrow range in claims
2012-05-08	2011-1376	PTO	*In re Montgomery*	Actual reduction to practice is not required for inherent anticipation of a therapeutic method
2012-06-22	2011-1140	DCT	*Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC.*	A reference may anticipate even if it requires a person of ordinary skill to pick items from lists of components to assemble the invention
2012-11-28	2011-1576	DCT	*The Fox Grp., Inc. v. Cree, Inc.*	Invalidation under § 102(g) does not require prior conception if there was prior reduction to practice

C. Obviousness - 35 U.S.C. § 103

Date	Case No.	Origin	Case Name	Brief Description
2006-06-22	2005-1433	DCT	*Abbott Labs. v. Andrx Pharm., Inc.*	Preliminary injunction should not issue where substantial questions of validity exist
2006-09-06	2006-1019	DCT	*Alzo Corp. v. Mylan Labs., Inc.*	Motivation to combine prior art teachings need not be found in the art
2006-10-03	2006-1088	DCT	*DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*	The test for obviousness does not require an explicit suggestion in a particular reference to combine references
2006-12-26	2005-1396, -1429, -1430	DCT	*Eli Lilly & Co. v. Zenith Coldline Pharm., Inc.*	Structurally similar chemical compounds alone do not render a compound obvious
2007-03-22	2006-1261	DCT	*Pfizer, Inc. v. Apotex, Inc.*	A prima facie case of obviousness was found over the same prior art references considered by the examiner during the prosecution
2007-06-28	2006-1329	DCT	*Takeda Chem. Indus., Ltd. v. Alphapharma Pty., Ltd.*	A new compound is not prima facie obvious over an old compound absent a suggestion in the prior art to make specific molecular modifications
2007-08-29	2006-1507	PTO	*In re Sullivan*	PTO must consider rebuttal evidence of nonobviousness
2007-09-11	2006-1530, -1555	DCT	*Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*	Isolation of the most therapeutically active ingredient was obvious where the ingredient was present in a mixture in the prior art
2007-09-12	2006-1564	DCT	*Daiichi Sankyo Co. v. Apotex, Inc.*	Appropriate level of ordinary skill in the art pertaining to a patent for a method for treating ear infections is that of a person with experience in pharmaceutical formulations, not just a pediatrician or general practitioner
2007-09-27	2006-1489	PTO	*In re Buszard*	Board's finding of obviousness reversed because prior art rigid foam that is crushed could not reasonably be construed to be a flexible foam reaction mixture
2008-03-31	2007-1223	DCT	*Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*	Claim term "and" meant "or," and invention was not obvious because infringer was relying on hindsight to show obviousness
2008-11-03	2008-1120	PTO	*In re DBC*	During ex parte reexamination, evidence that sales were a direct result of the unique characteristics of the claimed invention was necessary to demonstrate nonobviousness based on commercial success
2009-01-15	2008-1073	DCT	*Boston Scientific Scimed, Inc. v. Cordis Corp.*	Court finds obviousness based on adjacent figures in a single prior art reference
2009-01-30	2008-1247	DCT	*Sud-Chemie, Inc. v. Multisorb Techs., Inc.*	The district court erred in granting summary judgment of obviousness and by not taking into account evidence of secondary considerations

Date	Case No.	Origin	Case Name	Brief Description
2009-04-03	2008-1184	PTO	*In re Kubin*	The "obvious to try" rationale may provide the basis for an obviousness rejection after *KSR*
2009-04-24	2008-1528	DCT	*Ritchie v. Vast Res., Inc.*	Patent for a device containing an "appreciable amount of an oxide of boron to render it lubricious and resistant to heat, chemicals, electricity and bacterial absorptions" is invalid for obviousness, since patent's reference to "appreciable amounts" of oxide of boron simply claims use of glass that has amount of boron oxide usually found in borosilicate glass
2009-05-13	2008-1404, -1405, -1406	DCT	*Procter & Gamble Co. v. Teva Pharm. USA, Inc.*	Positional isomer not obvious where compounds are unpredictable and general teaching would not have provided a reasonable expectation of success
2009-08-05	2008-1282	DCT	*Bayer Schering Pharma AG v. Barr Labs. Inc.*	A drug formulation is obvious if there are a finite number of options for making the formulation
2010-02-24	2009-1270	PTO	*In re Chapman*	Board's misunderstanding of prior art calls into question conclusions on obviousness and constitutes harmful error
2010-06-09	2009-1423	DCT	*Trimed, Inc. v. Stryker Corp.*	Court reverses summary judgement of invalidity and orders assignment to new judge to preserve appearance of justice; a federal district court invoking common sense or any other basis for extrapolating from prior art to conclusion of obviousness must articulate its reasoning with sufficient clarity for appellate review
2010-09-09	2009-1538	DCT	*Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*	Lost profits not awarded where the patentee corporation did not sell any patented products and patentee's parent and sister companies were not owners or exclusive licensees of the patent
2010-09-09	2009-1511	DCT	*Daiichi Sankyo Co., v. Matrix Labs., Ltd.*	Selection of and motivation to modify a lead compound follows from the possession of useful properties, not mere structural similarity
2011-01-05	2010-1141	PTO	*In re Glatt Air Techniques, Inc.*	Single embodiment is sufficient evidence to show commercial success
2011-05-13	2010-1307	PTO	*In re Huai-Hung Kao*	Evidence of secondary considerations can be commensurate with the scope of the claims without testing or selling every conceivable embodiment of the claims, but there must be a nexus to the novel aspects of the claimed invention
2011-05-19	2010-1102	DCT	*In re Brimonidine Patent Litig.*	A combination of ingredients from two separate solutions previously used together as part of an overall treatment regimen is not necessarily obvious
2011-06-06	2010-1411	PTO	*In re Klein*	Nonanalogous prior art cannot support an obviousness rejection

Date	Case No.	Origin	Case Name	Brief Description
2011-06-22	2010-1513	DCT	*Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*	Prior-art range encompassing the claimed invention creates a rebuttable presumption of obviousness
2011-08-25	2010-1006	DCT	*Unigene Labs., Inc. v. Apotex, Inc.*	Functional and pharmaceutical properties of a lead compound can be more relevant than chemical structure when judging the obviousness of a patented formulation designed to mimic an FDA-approved formulation
2011-08-26	2010-1183	DCT	*Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*	Speculative and tentative disclosures in the prior art may not sufficiently direct or instruct a skilled artisan
2012-01-09	2010-1547	DCT	*Celsis In Vitro, Inc. v. CellzDirect, Inc.*	Market need properly linked to the invention can be probative of long-felt need and supportive of nonobviousness
2012-04-16	2011-1399	DCT	*In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*	Federal Circuit reaffirms broad and expansive obviousness inquiry, rejecting a formal burden-shifting framework
2012-05-17	2011-1073	PTO	*In re Baxter Int'l, Inc.*	Court affirms Board's decision of unpatentability despite previous affirmance of earlier declaration of validity by district court
2012-08-08	2011-1455	DCT	*Alcon Research, Ltd. v. Apotex Inc.*	The concentration range in an independent claim must include the concentrations in the dependent claims
2012-09-21	2011-1600	PTO	*In re Droge*	Obviousness by combination of references is not undermined by inventor's declarations to the contrary
2012-11-30	2011-1638	DCT	*Arcelormittal France v. AK Steel Corp.*	Commercial success of embodiments having features not recited in the claims may be considered when determining obviousness

D. Infringement

Date	Case No.	Origin	Case Name	Brief Description
2006-09-20	2005-1414, -1420	DCT	*Kim v. ConAgra Foods, Inc.*	Whether subject matter was surrendered is determined by an objective observer
2007-07-20	2006-1122	DCT	*Benitec Australia, Ltd. v. Nucleonics, Inc.*	A patentee's dismissal of its infringement claims may destroy the "immediacy and reality" required under the declaratory judgment act for jurisdiction over counterclaims of invalidity or unenforceability

Date	Case No.	Origin	Case Name	Brief Description
2007-09-05	2007-1059	DCT	*Forest Labs., Inc. v. IVAX Pharm., Inc.*	Party supplying abbreviated new drug applications ("ANDA") filer with data may be enjoined along with the filer if they will be joint participants in commercialization, but an injunction may not extend beyond the product described in the ANDA
2007-09-21	2006-1572	DCT	*In re Gabapentin Patent Litig.*	Comparative quantitative testing not necessary when testing provides sufficient evidence of infringement
2007-10-04	2006-1472	DCT	*Monsanto Co. v. Syngenta Seeds, Inc.*	Multistep process not infringed when the patentee performed some of the claimed steps, and claims were not enabled when a patent was filed before transformation of cells covered by the claims was possible
2008-02-05	2007-1104	DCT	*Monsanto Co. v. David*	Planting seed containing a gene sequence infringes a patent covering that sequence
2008-07-21	2007-1397, -1398	DCT	*Eisai Co v. Dr. Reddy's Labs., Ltd.*	In the chemical arts, *KSR*'s focus on "identified, predictable solutions" may present a difficult hurdle
2008-08-20	2007-1414	DCT	*In re Omeprazole Patent Litig.*	Court upholds findings of infringement and validity for Prilosec® patents
2008-10-02	2007-1530	DCT	*Johns Hopkins Univ. v. Datascope Corp.*	Infringement judgment reversed where expert's testimony did not address claim limitation
2008-12-18	2007-1560	DCT	*Rentrop v. Spectranetics Corp.*	Failure to notify the district court of a change in law constituted a waiver on appeal
2009-06-01	2008-1240	DCT	*Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*	Evidence of copying in a case of direct infringement is relevant only to *Seagate*'s second prong, as it may show what the accused infringer knew or should have known about the likelihood of its infringement
2009-06-09	2008-1228	DCT	*Ecolab, Inc. v. FMC Corp.*	Federal Circuit upholds high standards for prosecution history disclaimer and induced infringement
2010-08-12	2010-1058	DCT	*Baran v. Med. Device Techs.*	Means-plus-function element having two functions must be construed to include both functions, regardless of placement of modifier
2011-04-20	2009-1374	DCT	*TiVo Inc. v. EchoStar Corp.*	En banc court establishes new test for contempt proceedings in infringement cases
2011-09-21	2010-1068	DCT	*Monsanto Co. v. Bowman*	Planting seed containing a gene sequence infringes a patent covering that sequence
2012-02-09	2011-1182	DCT	*AstraZeneca Pharm. LP. v. Apotex Corp.*	Abbreviated new drug application seeking to market a drug for unpatented uses cannot infringe method of use patents under 35 U.S.C. § 271(e)(2)
2012-04-16	2011-1143	DCT	*Bayer Schering Pharma AG. v. Lupin, Ltd.*	No liability for induced infringement where drug label does not instruct the patented method of use

Date	Case No.	Origin	Case Name	Brief Description
2012-06-14	2010-1510	DCT	*Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*	Federal Circuit issues new standards for determining willfulness
2012-08-03	2012-1062	DCT	*Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*	The § 271(e)(1) safe harbor covers generic qualitycontrol batch testing even after FDA approval
2012-08-15	2011-1329	DCT	*Meyer Intellectual Props. Ltd. v. Bodum, Inc.*	SJ of infringement of a patented method is inappropriate where plaintiff offers no evidence of actual use of the method
2012-08-31	2009-1372, -1380, -1416, -1417, 2010-1391	DCT	*Akamai Techs., Inc. v. Limelight Networks, Inc.*	En banc court holds that a party can show induced infringement of method claims where inducer and induced party each perform some of the steps
2012-09-28	2011-1584	DCT	*Pozen Inc. v. Par Pharm., Inc.*	Doctrine of equivalents not foreclosed where qualitative claim limitation is given a quantitative construction

E. Written Description, Enablement, Definiteness, and Best Mode - 35 U.S.C. § 112

Date	Case No.	Origin	Case Name	Brief Description
2006-04-16	2005-1363, -1461	DCT	*Concor, Inc. v. Energy & Envtl. Int'l, L.C.*	Numerical ranges of a preferred embodiment do not limit claim language
2006-11-15	2006-1118	DCT	*Abraxis Bioscience, Inc v. Mayne Pharma (USA) Inc.*	Listing of salts in specification limits the term "derivatives" to salts
2007-01-19	2006-1102	DCT	*Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs, Ltd.*	A claim reciting a single weight ratio of "about 1:5" is limited to encompass a "range of ratios no greater than 1:36 to 1:71"
2008-10-30	2008-1079	PTO	*In re Alonso*	Insufficient written description under representative number-of-species test where only one species was identified
2008-09-08	2007-1267, -1266	DCT	*Carnegie Mellon Univ. v. Hoffman-La Roche Inc.*	A claim to a genus described in functional terms was not supported by the specification's disclosure of species that were not representative of the entire genus
2009-03-13	2008-1077	DCT	*ICU Med., Inc. v. Alaris Med. Sys., Inc.*	Federal Circuit affirms award of attorneys' fees for litigation misconduct
2009-06-04	2008-1466	DCT	*Agilent Tech., Inc. v. Affymetrix, Inc.*	When a party challenges written description support for a copied claim in an interference, the claims are construed in light of the originating disclosure

Date	Case No.	Origin	Case Name	Brief Description
2009-09-22	2009-1006	DCT	*Edwards Lifesciences LLC. v. Cook, Inc.*	Written description and prosecution history may trump the plain language of the claims and the doctrine of claim differentiation during claim construction
2009-09-25	2008-1594	DCT	*In re '318 Patent Infringement Litig.*	Patent claiming a method of treatment was not enabled where it failed to establish utility
2010-09-01	2010-1005	DCT	*Eli Lilly & Co. v. Teva Pharm. USA, Inc.*	The Federal Circuit upholds Eli Lilly and Company's Evista® franchise to 2014
2010-09-07	2009-1455	DCT	*Green Edge Enters., LLC v. Rubber Mulch Etc., LLC*	Misidentifying best mode did not warrant summary judgment and trademark counterclaims met case or controversy standard
2010-03-08	2009-1081	ITC	*Ajinomoto Co., v. Int'l Trade Comm'n*	Patents invalidated for failing to disclose best mode
2010-03-22	2008-1248	DCT	*Ariad Pharm., Inc. v. Eli Lilly & Co.*	En banc court confirms existence of writtendescription requirement separate from enablement
2010-03-26	2009-1281	DCT	*Enzo Biochem, Inc. v. Applera Corp.*	Language of magnitude can be definite without reference to a precise numerical range if the intrinsic evidence provides sufficient comparative information
2010-04-07	2008-1577	PTO	*Yorkey v. Diab*	Court affirms board's interference ruling after finding claims satisfied written description requirement
2010-04-07	2008-1578	PTO	*Yorkey v. Diab*	Court affirms board's finding of adequate written description and reverses board's finding of failure to establish actual reduction to practice in an interference
2010-04-26	2009-1058	DCT	*Medtronic Navigation, Inc. v. Brainlab Medizinische Computersysteme GmbH*	Absent misrepresentation, a party may rely on a favorable judgment as a matter of law determination and jury verdict as objective evidence that its infringement claims are not frivolous
2010-04-26	2009-1350	DCT	*ALZA Corp. v. Andrx Pharm., LLC.*	Ordinary skill cannot substitute for disclosure of an invention's novel aspects to satisfy the enablement requirement
2010-09-07	2009-1156	PTO	*Goeddel v. Sugano*	Claimed subject matter that can be "envisioned" from the specification fails to meet the writtendescription requirement
2011-02-23	2010-1144	DCT	*Centocor Ortho Biotech, Inc. v. Abbott Labs.*	Claims to antibodies with specific properties are not always fully described by disclosing the protein
2011-04-29	2010-1249	DCT	*Wellman, Inc. v. Eastman Chem. Co.*	Claims invalidated because specification does not set forth the best mode as contemplated by at least one of the inventors
2011-04-29	2010-1401	DCT	*Billups-Rothenberg, Inc. v. Associated Reg'l & Univ. Pathologists, Inc.*	Claims to a method of detecting a genetic disorder not adequately described where the gene sequence or its specific disease-causing mutations were not disclosed

Date	Case No.	Origin	Case Name	Brief Description
2011-06-07	2010-1230	DCT	*Boston Scientific Corp. v. Johnson & Johnson*	State of the art could not fill the gaps in disclosure for writtendescription support where the specifications indicated unpredictability and a lack of knowledge in the art
2012-09-04	2010-1360	DCT	*Santarus, Inc. v. Par Pharm., Inc.*	A negative claim limitation has adequate written description if the specification provides a reason to exclude the limitation

F. Inventorship

Date	Case No.	Origin	Case Name	Brief Description
2006-01-17	2005-1291	DCT	*Stern v. Trs. of Columbia Univ.*	Medical student presented insufficient evidence to corroborate his claim of coinventorship
2008-07-16	2008-1075	DCT	*Serdarevic v. Advanced Med. Optics, Inc.*	Inventorship claim was barred by laches, and related unjustenrichment and fraud claims were barred by statute of limitations
2010-04-09	2009-1258	DCT	*Vanderbilt Univ. v. ICOS Corp.*	Plaintiff university fails to provide clear and convincing evidence of joint inventorship where the parties' respective stories are "equally plausible"
2010-10-13	2009-1161	DCT	*Solvay S.A. v. Honeywell Int'l, Inc.*	Reproducing an invention in the united states does not constitute inventorship under 35 U.S.C. § 102(G)(2)
2012-11-14	2011-1540	DCT	*Hor v. Chu*	For correction of inventorship under 35 U.S.C. § 256, the laches period begins when the patent issues

G. Inequitable Conduct

Date	Case No.	Origin	Case Name	Brief Description
2006-02-01	2004-1189	DCT	*Purdue Pharma L.P. v. Endo Pharm., Inc.*	There is little basis to infer intent to deceive when materiality is low
2006-02-15	2005-1284	DCT	*Ferring B.V. v. Barr Labs., Inc.*	Failure to disclose relationship between declarants and applicant affirmed to be inequitable conduct

Date	Case No.	Origin	Case Name	Brief Description
2006-09-25	2005-1479	DCT	*Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*	District court did not abuse its discretion in finding low materiality of a prior-art reference and no intent to deceive
2007-02-14	2006-1265	DCT	*Cargill, Inc. v. Canbra Foods, Ltd.*	Omission of test data related to the issue which bedeviled the examiner is evidence of an intent to deceive the PTO
2007-05-28	2006-1517	DCT	*McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*	Nondisclosure of prior art rejection from copending application results in finding of inequitable conduct
2008-01-25	2007-1109	DCT	*Monsanto Co. v. Bayer Bioscience N.V.*	Nondisclosure of notes describing a poster at a conference rendered patent-in-suit and related patents unenforceable
2008-05-14	2007-1280	DCT	*Aventis Pharma S.A. v. Amphastar Pharm., Inc.*	Intent to deceive was sufficient to establish inequitable conduct
2009-03-24	2007-1487	DCT	*ClearValue, Inc. v. Pearl River Polymers, Inc.*	Withholding relevant test results of an accused product is sanctionable misconduct
2009-08-04	2006-1491	DCT	*Exergen Corp. v. Wal-Mart Stores, Inc.*	Allegations of inequitable conduct must set forth particular factual bases to satisfy Rule 9(b)
2008-08-25	2007-1448	DCT	*Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*	The elevated standard of proof in the inequitable conduct context remains paramount
2009-09-25	2008-1480	DCT	*Astrazeneca Pharm. LP v Teva Pharm. USA, Inc.*	Failure to provide unpublished information about less similar compounds is not inequitable conduct
2010-01-25	2008-1511	DCT	*Therasense, Inc. v. Becton, Dickinson & Co.*	Federal Circuit finds inequitable conduct based on applicant's conflicting statements made to the European Patent Office
2010-11-09	2010-1204	DCT	*Cancer Research Tech. & Schering v. Barr Labs.*	Court clarifies the prejudice requirement for prosecution laches and the intent requirement for inequitable conduct
2011-05-25	2008-1511, -1512, -1513, -1514, -1595	DCT	*Therasense, Inc. v. Becton, Dickinson & Co.*	Federal Circuit en banc tightens the standards for inequitable conduct for both intent and materiality
2012-04-09	2011-1018	DCT	*Aventis Pharma S.A. v. Hospira, Inc.*	An inventor's lack of credibility can lead to a conclusion of intent to deceive and a finding of inequitable conduct
2012-12-14	2010-1460	DCT	*AstraZeneca v. Aurobindo*	No inference of deceptive intent where it is "equally plausible" that patent owner believed prosecution requirements had been met

H. Patent Term

Date	Case No.	Origin	Case Name	Brief Description
2007-03-29	2006-1401	DCT	*Merck & Co. v. Hi-Tech Pharmacal Co.*	Hatch-Waxman patent term extension may be applied to a patent subject to a terminal disclaimer
2007-10-04	2007-1447	DCT	*Somerset Pharm., Inc. v. Dudas*	The PTO can only extend a patent term in the interim under 35 U.S.C. § 156(e)(2) when the patent would expire before a denial of an extension under § 156(d)(1)
2010-01-07	2009-1120	DCT	*Wyeth v. Kappos*	PTO incorrectly calculated patent term adjustments in situations of overlapping PTO delays
2010-05-10	2009-1393	DCT	*PhotoCure ASA v. Kappos*	New and improved drug product eligible for patent term extension pursuant to 35 U.S.C. § 156
2010-05-10	2009-1362	DCT	*Ortho-McNeil Pharm., Inc. v. Lupin Pharm., Inc.*	Distinct enantiomers are different "drug products" and properly subject to statutory term extensions

I. Jurisdiction

Date	Case No.	Origin	Case Name	Brief Description
2007-10-11	2007-1019	DCT	*Abbott Labs. v. TorPharm, Inc.*	A district court has subject matter jurisdiction to conduct contempt proceedings in an abbreviated new drug application ("ANDA") litigation, but filing of a second ANDA does not violate an injunction where the injunction does not prohibit such a filing
2007-11-13	2006-1522	DCT	*HIF Bio, Inc. v. Yung Shin Pharm. Indus. Co.*	Federal Circuit lacked jurisdiction to review a district court remand declining supplemental jurisdiction over statelaw claims
2008-08-15	2007-1524	DCT	*Prasco, LLC v. Medicis Pharm. Corp.*	"Reasonable apprehension of suit" test revived as one of several ways to establish declaratory judgment jurisdiction
2008-09-09	2007-1163	DCT	*Medical Solutions, Inc. v. C Change Surgical LLC*	No personal jurisdiction because display of accused infringing device at a trade show held not to be an infringing "use" in the forum state
2011-06-24	2010-1445	DCT	*Creative Compounds, LLC v. Starmark Labs.*	"Competing patents" not sufficient to confer declaratory-judgment jurisdiction

Date	Case No.	Origin	Case Name	Brief Description
2011-08-23	2010-1264	DCT	*Genetics Inst., LLC v. Novartis Vaccines And Diagnostics, Inc.*	Expiration of patent does not divest a court of jurisdiction in a § 291 interference proceeding
2012-04-16	2011-1507	DCT	*Dey Pharma, LP. v. Sunovion Pharm. Inc.*	DJ jurisdiction exists even if the action may later become moot

J. Priority

Date	Case No.	Origin	Case Name	Brief Description
2006-02-03	2005-1179	DCT	*Medichem, S.A. v. Rolabo, S.L.*	Inventors' priority testimony must be independently corroborated
2007-08-08	2006-1434	PTO	*Boston Scientific v. Medtronic Vascular*	Foreign priority requires nexus between inventor and foreign applicant at the time the foreign application was filed
2007-08-20	2006-1154	PTO	*Frazer v. Schlegel*	Australian application provided priority date despite later discovery and unpredictable technology
2007-12-05	2007-1221	PTO	*In re Garner*	A patent specification is not "new evidence" when submitted as evidence of priority
2009-03-18	2008-1447	PTO	*Henkel Corp. v. Proctor & Gamble Co.*	Factual findings supporting award of priority reviewed for substantial evidence

K. Prosecution History Estoppel/Doctrine of Equivalents

Date	Case No.	Origin	Case Name	Brief Description
2006-12-29	2006-1074	DCT	*Ventana Med. Sys., Inc. v. BioGenex Labs., Inc.*	General statements in specification describing improvement over prior art did not act as disclaimer
2007-10-12	2007-1074	DCT	*Schwarz Pharma, Inc. v. Paddock Labs., Inc*	An exclusive licensee has standing to appeal on its own if the patentee was a party in the district court, and prosecution history estoppel bars application of doctrine of equivalents when a narrowing amendment is directly related to the range of equivalents sought to be recaptured
2008-02-28	2006-1334, -1452, 2007-1202	DCT	*Regents of the Univ. of Cal. v. Dakocytonation Cal., Inc.*	Tangential exception applied to prevent prosecution history estoppel

Date	Case No.	Origin	Case Name	Brief Description
2008-04-18	2006-1602	DCT	*Honeywell Int'l, Inc. v. Hamilton Sundstand Corp.*	Rewriting dependent claims into independent form resulted in a narrowing amendment leading to prosecution history estoppel and a bar to doctrine of equivalents
2008-05-06	2007-1512	DCT	*PSN Ill., LLC v. Ivoclar Vivadent, Inc.*	Unasserted or cancelled claims may provide "probative evidence" that an embodiment is not within the scope of an asserted claim
2008-07-09	2008-1021	DCT	*Roche Palo Alto LLC v. Apotex, Inc.*	The equitable scope of a claim under reverse doctrine of equivalents is determined by the specification, prosecution history, and the prior art
2010-08-04	2009-1568	DCT	*Intervet Inc. v. Merial Ltd.*	Prosecution history estoppel does not bar application of doctrine of equivalents for patent directed to DNA encoding
2010-12-09	2008-1425	DCT	*Erbe Elektromedizin GmbH v. Canady Tech. LLC.*	Prosecution history estoppel from distinguishing argument overcomes claim differentiation based on facially narrower dependent claim
2011-02-24	2010-1145	DCT	*Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*	Burden of proof for infringement under the doctrine of equivalents is not heightened in cases of separate patentability
2011-07-21	2010-1419	DCT	*Duramed Pharma v. Paddock Labs*	Disclosure of a less-than-ideal use of a priorart compound is sufficient to render it foreseeable for purposes of prosecution history estoppel
2012-09-28	2011-1516	PTO	*In re Abbott Diabetes Care Inc.*	A "clear disavowal" in a patent specification is not required to disclaim claim scope

L. Reexamination

Date	Case No.	Origin	Case Name	Brief Description
2008-08-19	2008-1130	DCT	*Cooper Techs. Co. v. Dudas*	PTO's interpretation that "original application" as used in the inter partes reexamination statute includes continuation applications filed after November 29, 1999, is reasonable
2008-09-04	2007-1534	PTO	*In re Swanson*	Neither consideration during prior litigation nor consideration during initial examination by the PTO precluded the use of a reference during reexamination where it raised a substantial new question of patentability

M. Safe Harbor

Date	Case No.	Origin	Case Name	Brief Description
2007-07-27	2002-1052	SC	*Integra Lifesciences I, Ltd. v. Merck KGaA*	FDA "safe harbor" provision applied to experiments not ultimately submitted to the FDA
2008-03-07	2007-1271	DCT	*Pfizer, Inc. v. Teva Pharm. USA, Inc.*	Safe harbor of § 121 applies to divisionals only, not continuations-in-part
2008-08-05	2007-1428	DCT	*Proveris Scientific Corp. v. Innovasystems, Inc.*	Safe harbor provision of 35 U.S.C. § 271(e)(1) does not apply to patented inventions that are not themselves subject to FDA regulation
2009-09-15	2009-1020	DCT	*Amgen, Inc. v. F. Hoffman-La Roche, Ltd.*	35 U.S.C. § 121 safe harbor from double patenting rejections does not apply to continuation applications
2010-01-25	2009-1032	DCT	*Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*	Safe-harbor provision of 35 U.S.C. § 121 applies to a divisional of a divisional—even one filed voluntarily, claiming several nonelected inventions
2012-08-03	2012-1062	DCT	*Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*	The § 271(e)(1) safe harbor covers generic qualitycontrol batch testing even after FDA approval

N. Claim Construction

Date	Case No.	Origin	Case Name	Brief Description
2006-02-24	2004-1522	DCT	*SmithKline Beecham Corp. v. Apotex Corp.*	Product-by-process claims not limited by claimed process steps for purposes of anticipation
2007-01-26	2005-1434, 2006-1009	DCT	*Andersen Corp. v. Fiber Composities, LLC*	Product claim limited by process steps because process steps are essential for practicing invention
2009-02-02	2007-1340	DCT	*Kinetic Concepts, Inc. v. Blue Sky Medical Grp., Inc.*	District court's failure to construe a disputed claim term considered harmless error
2009-05-18	2007-1400, -1446	DCT	*Abbott Labs. v. Sandoz, Inc.*	Product-by-process claims are limited to the claimed process
2009-05-19	2008-1358	ITC	*Erbe Elektromedizin GmbH v. Int'l Trade Comm'n*	Federal Circuit affirms the ITC's finding of noninfringement after construing claim term in light of specification's figures and dictionary definitions
2009-09-03	2008-1459	DCT	*Martek Biosciences Corp. v. Nutrinova, Inc.*	Where there is no clear disavowal of claim scope, a patentee's express definition of a claim term controls

Date	Case No.	Origin	Case Name	Brief Description
2010-01-05	2009-1241	DCT	*Koninklijke Philips Elecs. N.V. v. Cardiac Science Operating Co.*	Claim terms should be construed in view of the originating disclosure when challenged for written description support in interference proceeding
2010-03-31	2008-1602	DCT	*Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd.*	Trial courts cannot look to the prior art merely listed in a patent specification to provide corresponding structure for a means-plus-function limitation
2010-06-02	2009-1557	DCT	*Haemonetics, Corp. v. Baxter Healthcare Corp*	Claim term can have different meanings in different claims when used inconsistently in respective embodiments in specification
2010-07-29	2009-1053	DCT	*Becton, Dickinson & Co v. Tyco Healthcare Grp., LP*	Listing claim elements separately clearly implies those elements are distinct components of the patented invention
2010-08-05	2010-1246	DCT	*Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*	Pharmacokinetic claim terms need not refer to complete FDA regulation
2010-09-13	2009-1323	DCT	*Am. Med. Sys., Inc. v. Biolitec, Inc.*	Preamble term that is not an essential component of the invention should not be construed as a claim limitation
2010-09-21	2010-1028	DCT	*Laryngeal Mask Co. v. Ambu*	Summary judgment vacated after erroneous construction of claim term "backplate"
2011-02-24	2010-1235	DCT	*Hologic, Inc. v. Senorx, Inc.*	Specification limits the invention even in the absence of explicit claim language

O. Double Patenting

Date	Case No.	Origin	Case Name	Brief Description
2007-07-23	2006-1254	DCT	*In re Metoprolol Succiante Patent Litig.*	A patent is invalid for obviousness-type double patenting when an earlier claim to a combination sets forth a laterclaimed element
2008-11-13	2007-1450	PTO	*In re Basell Poliolefine Italia, S.P.A.*	Patent properly considered during reexamination results in obviousness-type double patenting rejection
2009-04-10	2008-1131	DCT	*Takeda Pharm. v. Doll*	Later developments in the art may inform the "patentably distinct" determination for double patenting but only to the extent that the subsequent developments predate the secondary application that triggers a doublepatenting rejection

Date	Case No.	Origin	Case Name	Brief Description
2009-05-06	2008-1545	PTO	*In re Fallaux*	Applicant is not entitled to the narrow exception of the two-way test for assessing obviousnesstype double patenting when the PTO is not at fault for the delay that causes the improvement patent to issue before the basic patent
2010-07-28	2010-1105	DCT	*Sun Pharm. Indus., Ltd., v. Eli Lilly & Co.*	Obviousness-type double patenting analysis for patents claiming a compound should include an examination of any utility disclosed in the specification of the earlier-issued patent
2012-05-07	2011-1126	DCT	*Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*	Obviousness-type double patenting

P. Hatch-Waxman

Date	Case No.	Origin	Case Name	Brief Description
2008-10-15	2008-1097	DCT	*In re Ciprofloxacin Hydrochloride Antitrust Litig.*	Hatch-Waxman reverse payment settlement is lawful under antitrust laws since anticompetitive effects were within the exclusionary zone of the patent
2008-12-08	2007-1269	DCT	*Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*	Baseless Paragraph IV certification compounded with bad-faith litigation makes an abbreviated new drug application case exceptional under 35 U.S.C. § 285
2009-02-24	2009-1071	DCT	*Eli Lilly & Co. v. Teva Pharm., USA*	Statutory thirty-month stay may be extended based on a party's uncooperative discovery practices
2010-07-29	2010-1001	DCT	*Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*	Hatch-Waxman counterclaim provision does not permit generic manufacturer to challenge use code applied to pioneering manufacturer's Orange Book listed patent

Q. Interference

Date	Case No.	Origin	Case Name	Brief Description
2011-10-20	2011-1045	DCT	*Streck, Inc. v. Research & Diagnostic Sys., Inc.*	Section 146 establishes de novo review

Date	Case No.	Origin	Case Name	Brief Description
2012-02-07	2011-1212	PTO	*Adair v. Carter*	To overcome § 135(b)(1) precritical date, claims need to be compared to postcritical date claims, not copied patent claims
2012-02-28	2011-1285	PTO	*Pioneer Hi-Bred Int'l, Inc. v. Monsanto Tech. LLC*	A party to an interference proceeding may rely on multiple precritical date claims to support a postcritical date challenge to a patent

R. Other

Date	Case No.	Origin	Case Name	Brief Description
2007-01-05	2006-1101	DCT	*Abbott Labs. v. An Pharm., Inc.*	Preliminary injunction holdings of unenforceability and invalidity do not collaterally estop patentee from asserting the same claims against another
2007-05-11	2006-1542	PTO	*Henkel Corp. v. Procter & Gamble Co.*	Inventor's awareness of detergent tablet possessing the discernible property required by the interference count enough to show appreciation of the invention
2007-05-24	2005-1570	DCT	*Monsanto Co. v. McFarling*	Reasonable royalty is not limited to license fee regularly charged at time of sale
2007-08-01	2006-1593	DCT	*Biotechnology Indus. Org. v. Dist. of Columbia*	Federal patent laws preempt District of Columbia statute that imposes limits on "excessive" prices for patented drugs
2007-11-16	2006-1405	DCT	*Apotex Corp. v. Merck & Co.*	Attorney argument regarding what inferences to draw and not disclosing details of a process for a defense under 35 U.S.C. § 102(g) when the patent covered a process broadly did not amount to fraud
2008-01-17	2007-1145	DCT	*Innogenetics, N.V. v. Abbott Labs.*	Permanent injunction not appropriate where damages award included market entry fee and ongoing royalty, since such an award negates assertion of irreparable harm due to future sales
2008-04-01	2007-1404	DCT	*Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*	An Article III controversy exists where a patent holder unilaterally grants a covenant not to sue to a subsequent abbreviated new drug application filer and the covenant potentially delays that filer's market entry
2008-07-15	2007-1385	DCT	*Jang v. Boston Scientific Corp.*	Ambiguous consent judgment unreviewable and remanded for clarification because the basis for the judgment could not be ascertained
2008-08-18	2007-1297	DCT	*Voda v. Cordis Corp.*	Showing harm to exclusive licensee is insufficient for grant of permanent injunction

Date	Case No.	Origin	Case Name	Brief Description
2008-10-21	2007-1300	DCT	*Abbott Labs. v. Sandoz, Inc.*	The grant of a preliminary injunction is reviewed for clear error
2009-05-14	2008-1039	DCT	*Altana Pharma AG v. Teva Pharm. USA, Inc.*	A successful invalidity defense to a preliminary injunction need only raise a substantial question of invalidity, a lower standard of proof than the "clear and convincing" standard required at trial
2009-06-10	2008-1600	DCT	*Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*	Award of costs attributed to joint discovery remanded for apportionment to prevent double recovery
2009-07-23	2008-1468	DCT	*Univ. of Pittsburgh of the Commonwealth Sys. of Higher Educ. v. Hedrick*	Proof to a scientific certainty not always required for conception
2009-08-19	2007-1296, -1347	DCT	*Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*	En banc court holds that § 271(f) does not apply to method patents
2010-01-25	2009-1008	DCT	*Therasense, Inc. v. Becton, Dickinson & Co.*	Erroneous jury instructions not grounds for overturning a verdict where jury is not prejudiced
2010-03-31	2006-1522	DCT	*HIF Bio, Inc. v. Yung Shin Pharm. Indus. Co., Ltd.*	District court lacks discretion to remand claims arising under federal patent law to state court
2010-04-12	2008-1288	DCT	*MBO Labs. v. Becton, Dickinson & Co.*	The rule against reissue recapture applies to subject matter surrendered during prosecution of related patent applications
2010-08-30	2007-1386	ITC	*Princo Corp. v. Int'l Trade Comm'n*	En banc court finds no patent misuse where a third party agress not to separately license competitive technology
2010-11-01	2009-1381	DCT	*Astrazeneca LP v. Apotex, Inc.*	Federal Circuit affirms preliminary injunction barring defendant from launching FDA-approved generic drug
2010-11-08	2007-1066	DCT	*Hyatt v. Kappos*	En banc court refuses to limit new evidence in § 145 actions apart from the federal rules of evidence and civil procedure
2011-05-24	2010-1394	DCT	*Allergan, Inc. v. Athena Cosmetics, Inc.*	Standing under California's unfair competition laws only requires an allegation of an injury in fact that was caused by defendants' unfair competition
2011-09-19	2011-1030	PTO	*In re Leithem*	An applicant is entitled to reopen prosecution or request rehearing when the board relies on new facts changing the thrust of an examiner's rejection
2011-10-05	2010-1261	PTO	*In re Stepan Co.*	Board erred by relying on new factual findings without designating a new ground of rejection

Date	Case No.	Origin	Case Name	Brief Description
2011-10-18	2011-1048	DCT	*Sanofi-Aventis v. Apotex Inc.*	Agreement with a formula calculating "actual damages" precludes prejudgment interest
2012-03-15	2010-1548	DCT	*Marine Polymer Techs., Inc. v. HemCon, Inc.*	En banc court holds that intervening rights are invoked for new or amended claims only
2012-03-28	2011-1263	DCT	*Promega Corp. v. Life Techs. Corp.*	Decision compelling arbitration affirmed where valid agreement exists
2012-05-31	2011-1471	DCT	*Merial Ltd. v. Cipla Ltd.*	Nonparty acting in concert with enjoined party may be held in contempt of injunction
2012-07-02	2012-1228	DCT	*Sciele Pharma Inc. v. Lupin Ltd.*	Presumption of validity of an issued patent Is unchanged by mistaken issuance of a claim or previous consideration of prior art by the PTO
2012-08-07	2011-1219	DCT	*Highmark, Inc. v. Allcare Health Mgmt. Sys., Inc.*	Withdrawal of Rule 11 sanctions against an attorney does not preclude an exceptional case finding under 35 U.S.C. § 285
2012-09-01	2010-1005, -1033	DCT	*Eli Lilly & Co. v. Teva Pharm., USA, Inc.*	The Federal Circuit upholds Eli Lilly and Company's Evista® franchise to 2014
2012-11-13	2011-1215	DCT	*Edwards Lifesciences AG v. CoreValve, Inc.*	Equitable aspects must always be considered in determining the availability of injunctive relief regarding valid and infringed patents

S. Year-by-Year Review of Federal Circuit Cases from 2006 to 2012 in Intellectual Property

Year	Number of Precedential Cases in Intellectual Property	Number of Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts (% of total)	En Banc Decisions (% of total)	En Banc Decisions
2010	137	43 (31%)	3 (2%)	*Hyatt v. Kappos*, 625 F.3d 1320 (Fed. Cir. 2010); *Princo Corp. v. ITC*, 616 F.3d 1318 (Fed. Cir. 2010); and *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010).
2009	112	33 (29%)	2 (1.8%)	*Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348 (Fed. Cir. 2009); and *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009)
2008	142	38 (27%)	3 (2%)	*In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008); *Egyptian Goddess v. Swisa Inc.*, 543 F.3d 665 (Fed. Cir. 2008); and *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d 1304 (Fed. Cir. 2008)
2007	139	35 (25%)	1 (0.7%)	*In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007)
2006	131	17 (13%)	1 (0.8%)	*DSU Med. Corp., v. Gametech Int'l, Inc.*, 471 F.3d 1293 (Fed. Cir. 2006)

T. Year-by-Year Summary of the Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts from the Federal Circuit

		Origin			PTO		
Year	Number of Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts	Supreme Court/ District Court	International Trade Commission	PTO	Prosecution	Interference	Reexamination
2012	34	0/28	0	6	4	2	0
2011	26	0/19	0	6	4	0	2
2010	43	1/36	2	4	3	1	0
2009	33	0/29	1	4	3	1	0
2008	38	0/33	0	5	4	0	1
2007	35	1/27	1	6	4	2	0
2006	17	0/17	0	0	0	0	0

VII. Overview of 2006 at the Federal Circuit

A. Summary of the Federal Circuit 2006 Decisions in Intellectual Property

Year	Number of Precedential Cases in Intellectual Property	Number of Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts (% of total)	En Banc Decisions (% of total)	En Banc Decisions
2006	131	17 (13%)	1 (0.8%)	*DSU Medical Corp., v. Gametech Int'l, Inc.*, 471 F.3d 1293 (Fed. Cir. 2006)

B. Summary of the Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts for 2006 from the Federal Circuit

		Origin			PTO		
Year	Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts	Supreme Court/ District Court	International Trade Commission	PTO	Prosecution	Interference	Reexamination
2006	17	0/17	0	0	0	0	0

VIII. Summaries of Cases Decided En Banc and Other Key Decisions from the Federal Circuit in 2006

A. *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312 (Fed. Cir. 2006)

Product-by-Process Claims Not Limited by Claimed Process Steps for Purposes of Anticipation

In *SmithKline Beecham Corp. v. Apotex Corp.*, the Federal Circuit affirmed a district court's summary judgement ("SJ") holding that product-by-process claims were anticipated by a previously disclosed product.

In 1992, SmithKline Beecham Corporation and SmithKline Beecham, P.L.C. (collectively "SmithKline") obtained approval from the U.S. Food and Drug Administration ("FDA") to market a pharmaceutical composition ("paroxetine") sold under the trade name Paxil®. SmithKline applied for and was granted U.S. Patent No. 6,113,944 ("the '944 patent"). Claims 1 and 2 of the '944 patent are product-by-process claims reciting paroxetine tablets made by certain processes.

In March 1998, generic drug manufacturer Apotex Corporation, Apotex Inc., and Torpharm, Inc. (collectively "Apotex") filed an Abbreviated New Drug Application ("ANDA") to the FDA, seeking to market a generic version of Paxil®. Apotex also filed a "paragraph IV certification" in connection with its ANDA, stating, among other things, that the '944 patent was invalid. Pursuant to 35 U.S.C. § 271(e)(2), which makes submitting an ANDA an act of infringement, SmithKline sued Apotex for infringement of the '944 patent in the Eastern District of Pennsylvania. Apotex counterclaimed that the '944 patent was invalid and moved for SJ of invalidity. Apotex argued that an earlier SmithKline patent, U.S. Patent No. 4,721,723 ("the '723 patent"), anticipated the '944 patent. The '723 patent disclosed tablets containing a crystalline form of paroxetine, paroxetine hydrochloride hemihydrate.

The district court held that it was bound to follow the Federal Circuit's decision in *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991), which required the district court to evaluate the validity of the '944 patent claims without reference to any process limitations in the product-by-process claims. Because the '723 patent disclosed tablets containing paroxetine, the district court held that the product disclosed in the '723 patent anticipated the product-by-process claims of the '944 patent. In so holding, the district court did not consider any differences in the products because any such differences were caused by the process limitations, which the court held it could not consider.

On appeal, SmithKline argued that if the district court had treated the process steps recited in claims of the '944

patent as claim limitations, the district court would have held that the '723 patent did not anticipate the '944 patent, or that there was a genuine issue of fact over whether the '723 patent disclosed those process limitations. The Federal Circuit rejected SmithKline's arguments, holding that "once a product is fully disclosed in the art, future claims to the same product are precluded, even if that product is claimed as made by a new process."

The Federal Circuit noted a potential conflict between *Scripps*, where the court construed product-by-process claims without reference to process steps, and *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), where the court read process steps in a product-by-process claim as claim limitations. Although the Federal Circuit declined to directly address the conflict between the two cases, it nevertheless stated that a product-by-process claim is "always to a product, not a process." The Court stated that while the process set forth in a product-by-process claim may be new, that novelty can only be captured by obtaining a process claim. Accordingly, the Federal Circuit affirmed the district court's finding of anticipation.

The Federal Circuit also held that SmithKline waived any argument regarding the differences between the products claimed in the '723 patent and the '944 patent by not including the argument in its opening brief.

Judge Newman dissented, arguing that Federal Circuit precedent requires that all claim limitations limit a claim, and therefore, process limitations cannot be ignored. In Judge Newman's view, process limitations may distinguish an invention as a whole from prior art. Accordingly, a mere product disclosure could not anticipate the product-by-process claims at issue. Additionally, Judge Newman argued that the issues not briefed in SmithKline's appeal should not be deemed waived, because the appeal related solely to the question mentioned in the SJ, i.e., whether the process limitations in the product-by-process claims should be read as limiting the claim. She added that "when the appellant sticks to the issues on appeal he risks a waiver of the non-issues; and when he argues non-issues he risks a scolding."

B. *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349 (Fed. Cir. 2006)

Numerical Ranges of a Preferred Embodiment Do Not Limit Claim Language

In *Conoco, Inc. v. Energy & Environmental International, L.C.*, the Federal Circuit affirmed the district court's findings of infringement.

Conoco, Inc.'s ("Conoco") U.S. Patent No. 5,244,937 ("the '937 patent") claims a process for making suspension-based drag reducing agents ("DRAs"), which are high molecular weight polymers suspended within a carrier system, such as a gel. When injected into, for example, an oil pipeline, a DRA is capable of reducing friction caused by the

pumping operation and, thus, is capable of improving overall efficiency. The '937 patent discloses a process of coating the polymers with a stearate partitioning agent to prevent agglomeration of the polymers, as well as replacing the gel as a carrier system with water or a water-alcohol liquid medium. Conoco's U.S. Patent No. 6,172,151 ("the '151 patent") improves the process by disclosing the use of a fatty acid wax as the partitioning agent, instead of a stearate, in a nonaqueous suspension.

Conoco sued Energy & Environmental International, L.C. ("EEI"), alleging that EEI had infringed the '937 and '151 patents. EEI stipulated to the validity and enforceability of the patents. The district court held that EEI literally infringed claim 1 of the '937 patent. The court further held that EEI infringed claims 1-3 of the '151 patent under the doctrine of equivalents ("DOE") and enjoined EEI from further activities that would infringe the patent. Subsequently, after a contempt hearing, the district court clarified its order and expanded the injunction, prohibiting EEI from manufacturing its reformulated product using polyethylene wax ("PE wax").

On appeal, the Federal Circuit held that the district court correctly construed the claim term "water-alcohol mixture" to mean "more than negligible amounts of water and alcohol." The Court noted that a disclosure of a preferred embodiment by itself is not enough to demonstrate a clear disclaimer of an ordinary meaning of a claim term. In particular, the Court concluded that the statements in the specification that the amount of alcohol in the suspending material "may vary widely" and that it "usually forms between about 0 and 70 weight percent of the suspending material" demonstrated that there was no clear intention to limit the ordinary meaning of the claim language.

Regarding the construction of the terms "consisting of" and "stable nonagglomerating suspension," the Federal Circuit held that, although EEI did not raise the construction of these terms at the district-court level, the doctrine of waiver on appeal did not apply. Specifically, the Court held that "consisting of" is a term of art in patent law with its own construction. And, although EEI did waive its rights regarding the construction of the term "stable nonagglomerating suspension," because the district court explicitly construed the term sua sponte in its Findings of Facts and Conclusions of Law, the construction must also be reviewed.

The Federal Circuit explained that, while the term "consisting of" excludes nonrecited components and steps, it does not exclude components and steps that are unrelated to the invention or impurities that are normally found in any of the listed components. Therefore, the Court agreed with the district court's finding that any nonalcohol and nonwater components in EEI's product were impurities and the district court did not err in finding that the product met the limitations of the claim.

Further, relying on the intrinsic and extrinsic evidence, the Federal Circuit held that the district court properly construed the term "stable nonagglomerating suspension" to mean stable "at the time the DRA is introduced into the pipeline." The Court explained that the district court's construction recognized that the suspension could be assessed at the time of introduction and did not have to be transported over long distances. Moreover, the Court held that the district court did not err in its application of the facts to the construction, as there was sufficient evidence to support

the finding that EEI's product was stable when injected.

The Federal Circuit also agreed with the district court's finding of infringement under the DOE, rejecting EEI's argument that Conoco was estopped from claiming a fatty acid wax equivalent in view of the prosecution history of the '151 patent. During prosecution of the application, an examiner's amendment was made to add the term "fatty acid wax" to the one claim that lacked the limitation, but the record did not contain an explicit explanation for the amendment. The Court explained, however, that the absence of an explanation for the amendment is not an absolute bar and can be rebutted. The Court went on to note that throughout the prosecution history, the examiner and applicants focused their arguments around this limitation as if it were present in the claims. Therefore, the Court concluded the amendment was not made for reasons related to patentability, but instead made to correct an obvious omission.

Moreover, the Court noted that a clear and unmistakable surrender of subject matter must be evident for argument-based estoppel to be applied. In the prosecution of the '151 patent, applicants argued that "fatty acid wax," a stearamide derivative, was not equivalent to another stearamide derivative, "metal stearates," as disclosed in cited prior art. The Court explained that this argument demonstrates a clear surrender of "metal stearates" as an equivalent, but does preclude applicants from other possible fatty acid wax equivalents.

The Court also affirmed the district court's extension of the injunction to encompass PE wax, stating that the district court heard sufficient evidence to conclude that PE wax and "fatty acid wax" are functionality equivalent and, therefore, the extension of the injunction was proper.

C. *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006)

Motivation to Combine Prior-Art Teachings Need Not Be Found in the Art

In Alza Corp. v. Mylan Laboratories, Inc., the Federal Circuit affirmed the district court's holding that the asserted claims of the U.S. Patent No. 6,124,355 ("the '355 patent") were invalid under 35 U.S.C. § 103(a) and not infringed.

Alza Corporation ("Alza") owns the '355 patent, which discloses an oral once-a-day extended-release oxybutynin formulation for the treatment of urinary incontinence. In describing the technology, the Court noted that an oral drug dissolves in the gastrointestinal ("GI") tract and is absorbed into the bloodstream. A drug formulation may be released in the stomach, or may be extended release such that it is released slowly as it passes through the GI tract, resulting in the release of some of the drug in the colon. The Court explained that if the colon cannot absorb a particular drug, then there would be no reason to develop such an extended-release formulation. Claim 2, which is representative of the '355 patent, is directed to "a sustained-release oxybutynin formulation," which delivers specified amounts of the drug over specified periods of time for up to twenty-four hours. Alza markets the patented formulation as Ditropan

XL®. Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan") filed two Abbreviated New Drug Applications ("ANDA") for a generic version of Ditropan XL®, and Alza sued.

In its *Markman* Order, the district court construed the term "deliver" to refer to the rate of in vivo release of oxybutynin in the GI tract. To prove that Mylan's ANDA formulation infringed the '355 patent, Alza presented evidence showing (1) the rate at which Mylan's formulation released oxybutynin in an in vitro dissolution apparatus, and (2) the rate at which Mylan's formulation resulted in the accumulation of oxybutynin in the bloodstream. Alza, however, did not provide any direct evidence that Mylan's formulation released oxybutynin in the GI tract at the claimed rates. Thus, the district court found that Alza failed to meet the burden of proof for infringement. Additionally, the district court found that the asserted claims of the '355 patent were both obvious over and anticipated by the prior art. Alza appealed.

The Federal Circuit first addressed obviousness, noting that obviousness is a question of law based on underlying factual questions. These underlying factual inquiries, as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), include the scope and content of the prior art, the level of ordinary skill in the prior art, and the difference between the claimed invention and the prior art.

The Court reiterated that hindsight reasoning, based on the teachings of the invention at issue, may not enter an obviousness analysis. The secondary indicia of nonobviousness discussed in *Graham* serve to prevent such improper hindsight reasoning. Similarly, the "motivation to combine" analysis prevents improper hindsight reasoning by requiring that a court consider "whether a person of ordinary skill in the art, possessed with the problem facing the inventor, would have been led to make the combination recited in the claims." Thus, the "motivation-suggestion-teaching" test incorporates both the "scope and content of the prior art" and the "level of ordinary skill in the pertinent art," as required by *Graham*. Nevertheless, the Court emphasized that its "motivation-suggestion-teaching" test does not require an actual teaching in the prior art in order to establish that one of ordinary skill in the art would have known to combine references. Rather, "[t]here is flexibility in our obviousness jurisprudence because a motivation may be found implicitly in the prior art."

On appeal, the Federal Circuit affirmed the district court's holding of invalidity on obviousness grounds, and did not reach the issue of anticipation. The Court rejected Alza's argument that one of ordinary skill in the art would not have been motivated to adapt the prior-art teachings to oxybutynin because no one would expect that an extended-release formulation of oxybutynin would have any therapeutic value, in particular because nothing in the prior-art references supported the idea that lipophilicity of a drug correlated to its colonic absorptivity. Instead, the Court emphasized that the motivation to combine references for a finding of obviousness can be found in the knowledge of one of ordinary skill in the art, and relied on the testimony of Mylan's expert, Dr. Amidon, that at the time of the invention, he would have expected oxybutynin to be rapidly absorbed in the colon based on its lipophilicity. The Court explained that expert testimony may establish the knowledge of one of ordinary skill in the art at the time of the invention.

The Federal Circuit further rejected Alza's contention that two additional prior-art references negated Dr. Amidon's

testimony regarding knowledge in the art. The Court explained that, at best, the references Alza presented suggested that other factors, in addition to lipophilicity, affect a drug's absorption behavior in the colon. Thus, the Court found no clear error in the district court's findings. Additionally, the Court agreed with the district court's conclusion that one of ordinary skill in the art would have had a reasonable expectation of success in combining the prior-art teachings. Finally, the Federal Circuit found no clear error in the district court's finding that Alza failed to establish secondary indicia of nonobviousness.

Despite its invalidity holding, the Federal Circuit analyzed Alza's infringement. The Court noted that Alza provided no direct evidence at trial on the rate of release of the accused product in vivo. The Federal Circuit explained that Alza had "failed to credibly link [the indirect evidence it offered] with the relevant pharmacokinetic parameter – the rate of in vivo dissolution in the GI tract." At trial, Alza attempted to equate the oxybutynin blood plasma concentrations with the claimed in vivo dissolution rates, but the only evidence in support of this contention was a statement by Dr. Amidon, which he had promptly recanted. Thus, the Federal Circuit agreed with the district court that the plasma concentration data failed to establish the in vivo release rate of the ANDA formulation. Alza's in vitro dissolution rate data were similarly inadequate. The district court had relied on Dr. Amidon's testimony that the in vitro experiments did not reflect the in vivo behavior of the drug. Thus, the Federal Circuit concluded that the in vitro dissolution rates were not relevant to infringement.

Finally, the Federal Circuit "explicitly reject[ed]" Alza's argument that the district court erred because it did not expressly state that not only was the in vitro and blood-plasma data insufficient on its own, but the combination of data were also insufficient to establish infringement. The Court noted that in this case, each piece of evidence was "severely inadequate" and, therefore, the combination of the two pieces of evidence was likewise insufficient to establish infringement. Thus, Alza had failed to establish infringement.

D. *Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312 (Fed. Cir. 2006)

Whether Subject Matter Was Surrendered Is Determined by an Objective Observer

In *Kim v. ConAgra Foods, Inc.*, the Federal Circuit affirmed the district court's judgment of noninfringement of U.S. Patent No. Re. 36,355 ("the '355 patent") and that the '355 patent is not invalid.

Yoon Ja Kim ("Kim") is the holder of the '355 patent, which relates to breadmaking. The '355 patent claims a combination of ascorbic acid and food acid that serves as an alternative to potassium bromate, which was widely used to improve the quality of bread but now is believed to be a carcinogen. Kim originally obtained U.S. Patent No. 5,510,129 for a potassium bromate replacer composition, but Kim surrendered the patent to the U.S. Patent and

Trademark Office and filed a reissue application, alleging that an error had arisen during prosecution. After prosecuting the reissue application, Kim obtained the '355 patent in 1999.

In 2001, Kim filed suit against ConAgra alleging that ConAgra induced infringement of independent claims 5 and 10 of the '355 patent. Both claims were directed to "a potassium bromate replacer composition *consisting essentially of*" specific amounts of ascorbic acid and food acid and flour. Claim 10 differs from claim 5 in that it contains the additional limitation of yeast. Kim alleged that ConAgra required licensees of its Healthy Choice® brand name to use its recipes, and that the products infringed claims 5 and 10 of the '355 patent. ConAgra stipulated that the recipes for the accused products used ascorbic acid and food acid in the claimed ranges. ConAgra filed a counterclaim for declatory judgement of invalidity and noninfringement of the '355 patent. ConAgra also moved for summary judgement of invalidity based on the recapture rule. The district court denied ConAgra's motion, and the case went to trial.

During trial, after each party's case-in-chief, the opposing party moved for judgement as matter of law ("JMOL"), and the district court reserved ruling on both motions. The jury found that the asserted claims of the '355 patent were not invalid; that ConAgra had induced infringement of claim 10 with the licensing of its Healthy Choice® 7-Grain and Whole Grain products, but that the inducement was not willful; and that claim 5 and the dependent claims were not infringed. ConAgra renewed its motion for JMOL, and the district court partially granted the motion, holding that claim 10 was not infringed. The district court entered final judgment, finding the '355 patent not infringed and not invalid.

On appeal, the Federal Circuit first considered the district court's claim construction and jury charge regarding the phrase "[a] potassium bromate replacer composition" in both claims 5 and 10 of the '355 patent. The Court concluded that while the specification does not explicitly define the term "potassium bromate replacer," it does make clear that the claimed potassium bromate replacer is an oxidizing agent. Accordingly, the Federal Circuit found no error in the district court's construction of "potassium bromate replacer" as a composition that performs essentially the same function in the breadmaking process as potassium bromate, which is to strengthen dough, increase loaf volume, and contribute to fine crumb grain.

The Federal Circuit affirmed the district court's finding that the accused products did not infringe. Because it was undisputed that the accused products included ascorbic acid, food acid, and yeast in the proportions claimed, the key question shifted to whether the claimed ingredients in the accused product satisfied the functionality limitations. The Court noted that Kim did not prove infringement, as the testimony she presented was conclusory, unsupported by examinations or tests of the actual accused products, and based upon analogy; whereas, ConAgra presented evidence that different ingredients in its recipe affected functionality. Consequently, the Federal Circuit agreed with the district court's decision to grant JMOL to ConAgra on claim 10 and the jury's verdict of noninfringement of claim 5 for the same reasons.

The Federal Circuit also affirmed the district court's denial of ConAgra's motion for JMOL of invalidity based on the recapture doctrine. In reaching its decision, the Court focused on whether the broader aspects of the reissued claims

relate to "surrendered" subject matter. The Court explained that "in determining whether 'surrender' of subject matter has occurred, the proper inquiry is whether an objective observer viewing the prosecution history would conclude that the purpose of the patentee's amendment or argument was to overcome prior art and secure the patent." This ensures that the public can rely on a patentee's admission during prosecution of the original patent.

With respect to ConAgra's allegation that Kim surrendered a nonphosphate potassium bromate replacer composition, the Federal Circuit found that the prosecution history refutes ConAgra's argument that phosphate was added by Kim to overcome a rejection. Rather, Kim overcame the obviousness rejection with other amendments, and there was no indication why Kim added the phosphate limitation at the same time. With respect to ConAgra's allegation that Kim surrendered a potassium bromate replacer composition with a food-acid range of 0.015-0.2 parts per 100 parts flour, the court found that Kim's reason for changing the range was not based on obviousness considerations and that the examiner had not indicated that the original range was obvious in light of the prior art.

Finally, addressing claims of anticipation and obviousness, the Federal Circuit concluded that the jury verdict finding the claims not invalid was supported by substantial evidence. In accepting the verdict, the Court noted that the burden was on ConAgra to establish invalidity by clear and convincing evidence, and they had failed to do so. The Court explained that ConAgra made virtually no effort to show that the asserted prior art disclosed the functions of potassium bromate. Moreover, there was substantial evidence that the prior art did not contain the claimed proportions of ascorbic and food acids. Thus, the prior art was not anticipatory nor did it render the '355 patent obvious.

Judge Schall concurred-in-part and dissented-in-part. While he agreed with the majority's opinion regarding recapture and invalidity issues, he disagreed with the majority's construction of the term "potassium bromate replacer" in the '355 patent. He believed that Kim acted as her own lexicographer in defining the term "potassium bromate replacer" as "a slow acting oxidant that is functional throughout the entire manufacturing process." Accordingly, Judge Schall would have vacated the decision of the district court and remanded for an infringement analysis under this claim construction.

E. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006)

The Test for Obviousness Does Not Require an Explicit Suggestion in a Particular Reference to Combine References

In *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, the Federal Circuit reversed the district court's denial of appellants' motion for judgement as a matter of law ("JMOL") of invalidity of claims 1-4 of U.S. Patent No.

5,586,992 ("the '992 patent") for obviousness.

The '992 patent discloses a process for dyeing textile materials with catalytically hydrogenated leuco indigo. Traditionally, the process for dyeing textile materials with catalytically hydrogenated leuco indigo involves six steps: "(1) reducing indigo to its leuco form in solution; (2) stabilizing the leuco indigo solution, usually in paste or powder form; (3) creating a preparation tank in which the dried leuco indigo is re-converted to solution form; (4) adding the solution to the dyebath; (5) dipping; and (6) skying." The '992 patent improved this process by eliminating the second and third steps. In other words, it permitted a dyer to pour prereduced indigo solution directly into a dyebath and commence dyeing immediately.

DyStar Textilfarben GmbH & Co. Deutschland KG ("DyStar") sued C.H. Patrick Co. and Bann Quimica Ltda (collectively "Bann"), alleging direct, contributory, and induced infringement of the '992 patent. The jury found that Bann infringed the '992 patent and declined to hold the patent invalid for lack of enablement, anticipation, or obviousness. Bann moved for JMOL, or alternatively a new trial, on the issue of invalidity of the '992 patent. The district court denied Bann's motion without opinion, stating that the jury's verdict was reasonable and supported by evidence in the record.

On appeal, the Federal Circuit noted that the law of the regional circuit applies when reviewing motions for JMOL and motions for a new trial, and applied Fourth Circuit law to those issues. The Court, however, reviewed the jury's obviousness ruling under its own law, applying the four *Graham* factors. The Court stated that it must consider whether "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and whether there would have been a reasonable expectation of success in doing so." The Federal Circuit specifically noted that it is important to distinguish between the references sought to be combined and "the prior art" when considering what the prior art teaches. According to the Court, the "prior art" is broader, encompassing textbooks, treatises, and basic principles unlikely to be restated in cited references, and the motivation to combine the cited reference may be found in the prior art as a whole.

Because the parties' dispute centered around the relevance of the cited prior art, and therefore the level of ordinary skill in the art, the Federal Circuit began with the third *Graham* factor. The Court agreed with DyStar that the jury accepted its view that a person of ordinary skill in the art had no knowledge of chemistry and must have found the cited prior art either not in the relevant art or not analogous art. Nevertheless, the Court concluded that substantial evidence did not support the jury's findings. The Court explained that the technical problem the '992 patent sought to solve was precisely the same problem the cited references sought to solve, i.e., an improved process for dyeing textiles with indigo. Moreover, the Court concluded that practicing the '992 patent required a "higher-level perspective," not merely "flipping the switch." Thus, one of ordinary skill would have knowledge of chemistry and systems engineering. Accordingly, the Court concluded that the jury's decision to disregard the cited prior art was not supported by substantial evidence.

Turning to the first *Graham* factor, scope and content of the prior art, the Federal Circuit considered "what the prior

art teaches, whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references." The Court focused on art relating to the indigo dyeing process as a whole and rejected DyStar's argument that the cited references were nonanalogous art because they reduced indigo by different methods. Because reduced indigo by any reduction method had been used in the indigo dyeing process, prior art involving indigo reduction by other methods constituted analogous art. Thus, the Court concluded, the cited art recited all the limitations of claim 1 of the '992 patent.

The Federal Circuit next considered whether there was motivation to combine the cited prior art. The Court rejected DyStar's argument that Federal Circuit precedent required the cited references themselves to explicitly contain a suggestion, teaching, or motivation to combine the art. The Federal Circuit explained that DyStar, as well as various commentators, had misread the Court's opinions and mischaracterized its suggestion test. As the Court expounded, the suggestion test is not a rigid and categorical test that requires an explicit teaching to combine references be found in a particular reference. Rather, it "not only permits, but *requires*, consideration of common knowledge and common sense." The Court further explained that when "no prior art reference contains an express suggestion to combine references, then the level of ordinary skill will often predetermine whether an implicit suggestion exists." The inquiry in such a situation would be "whether the ordinary artisan possesses knowledge and skills rendering him capable of combining the prior art references."

Having determined that one of ordinary skill in this case is a dye-process engineer who would possess knowledge of chemistry and systems engineering, and that the asserted innovation of the '992 patent is merely exploitation of the well-known principle of vacuum packaging, the Court concluded that the invention is the work of a skilled chemist, not an inventor. The Court also held that certain secondary considerations of nonobviousness were insufficient to overcome the Court's conclusion that claim 1 was obvious. The Court also held claims 2-4 invalid for obviousness as they do not recite a nonobvious invention beyond claim 1.

F. *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 471 F.3d 1363 (Fed. Cir. 2006)

Inherent Feature in Prior Art Was Anticipating Even Though Not Previously Appreciated

In *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.*, the Federal Circuit reversed the district court's judgment that the claims of U.S. Patent No. 5,990,176 ("the '176 patent") were valid.

Abbott Laboratories and Central Glass Company, Ltd. (collectively "Abbott") are the owners of the '176 patent, which involves a degradation-prevention combination of water or other "Lewis acid inhibitors" with sevoflurane.

Abbott discovered that water mixed in with sevoflurane will deactivate and bind to Lewis acids, therefore protecting sevoflurane against degradation reaction. Baxter Pharmaceutical Products, Inc. and Baxter Healthcare Corporation (collectively "Baxter") also had its own sevoflurane product and filed a certification of invalidation and noninfringement of the '176 patent with the U.S. Food and Drug Administration. Abbott then sued Baxter for infringement of the '176 patent. After a bench trial, the district court held that the asserted claims were valid and enforceable but not infringed.

On appeal, the Federal Circuit considered Baxter's argument that prior art U.S. Patent No. 5,684,211 ("the '211 patent") disclosed a composition of water-saturated sevoflurane and, therefore, anticipated the '176 patent. According to the Court, at the time of the '176 patent, knowledge of the beneficial nature of a water-sevoflurane mix was not known. The '211 patent discloses a composition and the claims are directed to a process for making that composition. The '211 patent, however, does not teach the advantageous feature of that composition.

The Federal Circuit explained that "[o]ur cases have consistently held that a reference may anticipate even when the relevant properties of the thing disclosed were not appreciated at the time." The general principle that a newly discovered property of the prior art cannot support a patent on the same art is not avoided if the patentee explicitly claims that property. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. Abbott argued that at the time of the '211 patent, nobody knew that the water-saturated sevoflurane that the patent disclosed had the property of resisting the Lewis acid degradation. But in the Court's view, the "lack of knowledge is wholly irrelevant to the question of whether the '176 patent claims something 'new' over the disclosure of the '211 patent," because the claimed property of resistance to degradation is found "inherently" in the disclosure.

The Federal Circuit rejected the district court's reliance on *Bristol-Myers Squibb v. Ben Venue Labs*, 246 F.3d 1368 (Fed. Cir. 2001), which held that new uses of known processes may be patentable. As a threshold matter, the Court noted that the proposition only applied to process claims and thus should not have been applied to those claims of the '176 patent directed to a composition. As to the process claims, the Court found that the claimed process in the '176 patent was not directed to a new use – it was the same use. Specifically, both the '176 and '211 patents disclosed methods to guarantee sevoflurane will be of high purity at the time it is dispensed to patients. The Court found that each step in the '176 patent is disclosed in the '211 patent, and for the same purpose, namely, to delivery of safe, effective sevoflurane anesthetic. Thus, the Court reversed the district court's judgment that the asserted claims were valid.

G. *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370 (Fed. Cir. 2006)

Listing of Salts in Specification Limits the Term "Derivatives" to Salts

In *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, the Federal Circuit reversed the district court's finding of literal infringement but affirmed the district court's finding of infringement under the doctrine of equivalents ("DOE").

Mayne Pharma (USA) Inc. ("Mayne") attempted to design around a patent for a pharmaceutical composition used to induce and maintain general anesthesia and sedation in patients, which was owned by Abraxis Bioscience, Inc. ("Abraxis"). During the design-around, Mayne attempted to match the characteristics and stability function of disodium edentate, ethylenediaminetetracetic acid ("EDTA"), a preservative in the patented formulation. They eventually chose the calcium trisodium salt of diethylenetriaminepentaacetic acid (pentatate) ("DTPA") as a replacement because it was "structurally similar to edetate, [and, therefore,] product stability is predicted to be unaffected."

Mayne filed an ANDA on its generic formulation and included a paragraph IV certification that Abraxis's patents were invalid, unenforceable, and would not be infringed by its generic formulation. Abraxis filed suit. The district court issued a *Markman* ruling, construing three contested claim terms, including the term "edentate," which was at issue on appeal. The district court adopted an interpretation of "edetate" that included "EDTA as well as compounds structurally related to EDTA regardless of how they are synthesized." Based on this construction, the district court found that Mayne's product infringed, both directly and under the DOE, after a bench trial.

On appeal, the Federal Circuit agreed with the district court's finding that "edetate" includes "EDTA and derivatives of EDTA," as the term is defined in the specification, but rejected the district court's definition of "derivatives." Under the district court's construction, the term "edetate" encompassed not only salts of EDTA but also structural analogs (a relatively voluminous category of structurally similar chemical compounds, some of which are only tangentially related to EDTA). The Federal Circuit, following the principles set forth in *Phillips*, however, relied on evidence from the claim language itself and the specification to reject the inclusion of the structural analogs. The Court noted that the specification lists only EDTA and specific salts of EDTA, none of which are structural analogs. Additionally, the specification discloses that considerable effort was spent experimenting with preservatives and eventually narrowing down to one specific agent, edetate. Thus, the Federal Circuit concluded that the term "edetate" includes EDTA and derivatives of EDTA, such as salts, but not structural analogs.

Because Abraxis conceded during oral argument that DTPA is not a derivative of EDTA because it cannot be synthesized from EDTA in a laboratory and it is not a salt of EDTA, the Federal Circuit reversed the district court's finding of literal infringement.

The Federal Circuit then went on to analyze infringement under the DOE and agreed with the district court's conclusion

that calcium trisodium DTPA and edetate were equivalent because their differences were insubstantial. In reaching its conclusion, the district court performed the function-way-result test. In reviewing the district court's analysis, the Federal Circuit first held that the district court "properly assessed the 'way' edetate works by referring to the patent and the evidence at trial," which supported the conclusion that DTPA and EDTA both perform as an antimicrobial agent by metal ion chelation.

Second, the Federal Circuit held that it was permissible for equivalents to extend beyond ETPA because "the inventors did not clearly disavow other polyaminocarboxylates, including DTPA, by claiming edetate. There is no evidence that the patentees made a clear and unmistakable surrender of other polyaminocarboxylates, or calcium trisodium DTPA in particular, during prosecution."

Finally, the Federal Circuit noted that "known interchangeability is only one factor to consider in a doctrine of equivalents analysis," and rejected Mayne's argument that the lack of known interchangeability between edetate and DTPA as an antimicrobial agent necessitated the conclusion that the accused product does not infringe under the DOE. The district court made factual findings that insubstantial differences exist between calcium trisodium DTPA and edetate, notwithstanding Mayne's own patent covering the DTPA compound.

Thus, while reversing the district court's claim construction and finding of literal infringement, the Federal Circuit affirmed the district court's analysis of infringement under the DOE.

H. *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366 (Fed. Cir. 2006)

The Enablement Requirement of § 102, Unlike § 112, Does Not Require Proof of Efficacy or Utility

In *Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc.*, the Federal Circuit affirmed a district court's finding of failure to prove inequitable conduct based on omission of alleged material information during prosecution, holding U.S. Patent No. 5,527,814 ("the '814 patent") enforceable. On the issue of invalidity, the Federal Circuit vacated the district court's decision that one prior art reference did not anticipate the claims because it was not enabled, and remanded for further proceedings using the proper legal standard enunciated by the Court. In discussing the proper legal standard, the Court reiterated that the enablement requirement of 35 U.S.C. § 102 differs from the enablement requirement of § 112. The Court explained that enablement under § 102 does not require utility, or proof of efficacy, unlike enablement under § 112.

Aventis Pharmaceuticals Inc. ("Aventis") is the owner of the '814 patent, directed to methods of treating a mammal with amyotrophic lateral sclerosis ("ALS"), commonly known as Lou Gehrig's disease, with 2-amino-6-

(trifluoromethoxy) benzothiazole (international nonproprietary name: riluzole). Impax Laboratories, Inc. ("Impax"), a generic drug manufacturer, filed suit for a declatory judgement in district court that it did not infringe the '814 patent under 35 U.S.C. § 217(e)(2) by filing an Abbreviated New Drug Application ("ANDA"). In its ANDA, Impax sought approval from the U.S. Food and Drug Administration for the sale and/or manufacture of riluzole tablets for the treatment of ALS. Impax alleged in its suit that the '814 patent was unenforceable and invalid. Impax has since conceded that its ANDA product infringes claims 1, 4, and 5 of the '814 patent.

Claims 1-5 of the '814 patent were at issue in the case. Claim 1 is the only independent claim and recites, "[a] method for treating a mammal with amyotrophic lateral sclerosis, comprising the step of administering to said mammal in recognized need of said treatment an effective amount of 2-amino-6-(trifluoromethoxy)benzothiazole or a pharmaceutically acceptable salt thereof." Claims 2-5 add limitations to the forms of ALS treated or dosages of riluzole administered.

In the district court, Impax's allegations concerning inequitable conduct centered on the fact that Aventis had conducted comparative tests of eight different compounds, including riluzole ("tested compounds"), in animal models to evaluate the effectiveness of each compound for treating ALS. Three different criteria were used for the evaluation. Only riluzole was demonstrated to be effective by all three criteria.

During prosecution, Aventis addressed an obviousness rejection based on U.S. Patent No. 5,236,940 ("the '940 patent") by providing the examiner with the comparative test data for riluzole and two of the tested compounds, which were disclosed in the '940 patent. Aventis asserted that those test results showed unexpected results for riluzole, which were not predictable from the prior art. Aventis did not provide the test results for the other tested compounds, which were not disclosed in the '940 patent.

Impax alleged that Aventis's withholding of comparative test data for certain of the tested compounds was material because the withheld test results were inconsistent with an argument advanced by Aventis in support of patentability during prosecution. Impax asserted that the results for the other tested compounds were superior to those provided to the examiner, and thus did not support Aventis's claim of unexpected results for riluzole. The district court disagreed, finding the withheld test results not material and also finding no intent to deceive. Thus, the district court determined that there was no inequitable conduct.

In affirming the district court's determination of no inequitable conduct, the Federal Circuit, along the lines of the district court, found that the withheld test data were not material because (1) the withheld test data did not produce results that indicated effectiveness in treating ALS; (2) the withheld test data were not inconsistent with the representations to the examiner concerning riluzole; and (3) there was no evidence that a reasonable examiner would have considered the withheld test data important in deciding whether to allow the patent application. And, in affirming the district court's finding of lack of intent to deceive, the Federal Circuit decided that failure to disclose test results for compounds that were irrelevant to distinguishing over the cited patent was not enough, on its own, to establish an

intent to deceive. Thus, the Federal Circuit affirmed the district court's determination of no inequitable conduct.

The Court next addressed the district court's decision that the '814 patent was not anticipated by the '940 patent or by its priority application, French Application No. 2,640,624 ("the '624 application"). The '940 patent is directed to a class of compounds of formula I, which encompasses hundreds of compounds. The '940 patent specifies that riluzole is a compound of formula I, but is not part of the invention because it is not new. The '940 patent also provides that "[t]he compounds of formula (I) and their salts…are useful in the treatment of medical conditions associated with the effects of glutamate in which it is desirable to inhibit such effects at least partially.… They are…useful in the treatment and prevention of…neurological conditions in which glutamate may be implicated, such as…amyotrophic lateral sclerosis…." The disclosure of the '624 application is similar to that of the '940 patent, except that it does not exempt riluzole as a claimed compound; in fact, it does not mention riluzole at all.

In the district court, Impax alleged that the '940 patent and '624 application anticipated the claims of the '814 patent because every limitation of the claims was disclosed in the prior art. The district court found that the '940 patent formula included riluzole, but determined that the disclosure did not enable the use of riluzole for treating ALS. According to the district court, "formula I entails such a large number of compounds . . . [that] one of ordinary skill in the art would not have recognized that riluzole was effective in treating ALS without additional detail or guidance that is not found in the disclosure of the '940 patent." The district court concluded that the '940 patent, and for similar reasons, the '624 application, were not enabled, and, therefore, neither reference anticipated the claims of the '814 patent.

Focusing on the district court's pronouncement that the '940 patent was not enabled because it did not disclose "that riluzole was effective in treating ALS," the Federal Circuit reiterated the proper legal standard by which to evaluate the enablement requirement of § 102. The Court explained that "[i]n order to be anticipating, a prior art reference must be enabling so that the claimed subject matter may be made or used by one skilled in the art. . . . The enablement requirement for prior art to anticipate under section 102 does not require utility, unlike the enablement requirement for patents under section 112. . . . Anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art." The Court further noted that "[a] reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. Thus, the question of whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis."

After setting forth the proper legal standard for evaluating whether an anticipatory reference is enabled, the Court vacated the district court's decision regarding the '940 patent, holding that the wrong standard for enablement had been applied. "While the '940 patent includes riluzole as a formula I compound, suggests that formula I compounds may be used to treat ALS, and provides some dosage information, the district court found that the '940 patent did not anticipate the '814 patent because the disclosure of the '940 patent was not enabling at least in part because there was no evidence that it would be 'effective.'" Since the "effectiveness" of the prior art is not relevant, the Federal Circuit remanded the case to the district court to determine whether the '940 patent is enabled under the proper

legal standard.

The Federal Circuit also addressed the district court's finding that the '624 application was not enabled. Unlike the '940 patent, the '624 application does not mention riluzole by name. Accordingly, the Federal Circuit affirmed the district court's finding, stating that "riluzole is just one of hundreds of compounds included in formula I…. Here, with the large number of compounds included in formula I and no specific identification of riluzole by the '624 application, the '624 application does not disclose riluzole, and therefore, cannot enable treatment of ALS with riluzole. The '624 application cannot anticipate any of claims 1-5 of the '814 patent." Accordingly, the Federal Circuit remanded the case for further proceedings.

I. *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369 (Fed. Cir. 2006)

Structurally Similar Chemical Compounds Alone Do Not Render a Compound Obvious

In *Eli Lilly and Co. v. Zenith Goldline Pharmaceuticals, Inc.*, the Federal Circuit affirmed the district court's holding that the asserted claims of U.S. Patent No. 5,229,382 ("the '382 patent") were valid, enforceable, and infringed.

Eli Lilly & Co. ("Lilly") owns the '382 patent, which discloses olanzapine and its use to treat schizophrenia. Lilly had previously discovered other drugs in the same family of thienobenzodiazepines, including clozapine, flumezapine, ethyl flumezapine, and ethyl olanzapine ("Compound '222"). In fact, Lilly marketed clozapine as the first "atypical" antipsychotic drug in the late 1960s; however, it was withdrawn in 1975 following the discovery that it caused a potentially fatal blood disorder in one percent of patients. Fourteen years later, no better drug had been developed, and the U.S. Food and Drug Administration reapproved the use of clozapine in combination with careful blood monitoring.

In 1996, Lilly began marketing olanzapine as Zyprexa®. Olanzapine differs from other members of the thienobenzodiazepine family in two critical respects. First, olanzapine has a hydrogen atom substituted on the benzene ring rather than a chlorine atom (as found in clozapine) or a fluorine atom (as found in flumezapine). This halogen substitution, sometimes referred to as the "neuroleptic substituent," was an electron-withdrawing group widely believed to be responsible for the antipsychotic activity of clozapine, flumezapine, and other antipsychotics, before the discovery of olanzapine. Second, the thiophene ring of olanzapine is substituted with a methyl group rather than an ethyl group, as found on ethyl flumezapine and ethyl olanzapine (both of which did not reach the market because they cause significant side effects).

Zenith Goldline Pharmaceuticals, Inc. (now IVAX Pharmaceuticals, Inc., "IVAX"), Dr. Reddy's Laboratories, Ltd. ("DRL"), and Teva Pharmaceuticals USA, Inc. ("Teva") each filed an Abbreviated New Drug Application for a generic version of

Zyprexa®, thereby conceding infringement. Lilly sued. The district court held that the defendants did not prove by clear and convincing evidence that the claims of the '382 patent were invalid as anticipated or obvious.

On appeal, the Federal Circuit first agreed with the district court that the claims of the '382 patent were not anticipated by a cited reference ("*Chakrabarti*") disclosing millions of compounds in the same general family of thienobenzodiazepines. The Court rejected IVAX's argument that Chakrabarti's disclosure of compounds in the thienobenzodiazepine family anticipated claim 1, to olanzapine, because it did not spell out "a definite and limited class of compounds" that enabled one of ordinary skill in the art to "at once envisage" each member of the limited class. In distinguishing the present case from the cited case law, the Court noted that Chakrabarti disclosed millions of compounds, with sixty compounds specifically examined. None of the preferred compounds resembled olanzapine, and the preferred compounds all had a fluorine or chlorine substituent on the benzene ring rather than a hydrogen, as found in olanzapine. After describing other differences between olanzapine and the prior-art compounds, the Court concluded that there was no anticipation because (1) the cited reference preferred complete compounds, not individual substituents; (2) there was no generic disclosure encompassing olanzapine; and (3) there was no suggestion to modify the closest described compound into a preferred compound.

Turning to obviousness, the Federal Circuit first agreed with the district court that claims to olanzapine are not obvious because the prior art taught away from antipsychotics that lack a halogen substituent on the benzene ring. The Court explained that, for a chemical compound, a prima facie case of obviousness requires the prior art to have "structural similarity" to the claimed compound, and provide a reason or motivation to make the inventive compound. Lilly's own prior-art patent, U.S. Patent No. 4,115,574 ("the '574 patent") disclosed Compound '222, which, like olanzapine, has a hydrogen atom rather than a halogen substituent. However, the Federal Circuit noted that the '574 patent expressed a preference for a halogen-containing compound, and that the "prior art references at the time of this invention taught away from using a non-halogenated compound as a substituent in the benzene ring, exactly where olanzapine has a hydrogen atom."

The Federal Circuit also agreed with the district court's determination that a person of ordinary skill in the art would not have chosen Compound '222 as a starting compound to further modify, because it did not contain the neuroleptic halogen substituent. In addition, Compound '222 has an ethyl group substitution where olanzapine has a methyl group; the Court found no motivation to modify this substituent in the prior art. Going further, the Court found that the art taught away from selection of Compound '222 as a lead compound. The '574 patent did not provide any biological data for Compound '222, but instead indicated that halogen-substituted compounds were preferred, and described the fluorine-substituted ethyl flumezapine as "particularly active." Other art taught that substitution with a fluorine or chlorine increased antipsychotic activity, and reported that Compound '222 was less active than clozapine, the benchmark for this class of compounds.

The Federal Circuit also rejected IVAX's argument that olanzapine is rendered obvious by Compound '222, because structurally, olanzapine is the adjacent homolog of Compound '222. The Court emphasized that the "patentability of a

compound does not depend only on structural similarity." If a "relevant property" of a compound is "unexpected and significant," that property cannot be overlooked, regardless of how structurally similar the compounds may be, but can render the inventive compound nonobvious. Here, although there is some structural similarity of olanzapine to the prior art, olanzapine exhibits "unexpected beneficial properties" which must be accounted for in the analysis, and lead to nonobviousness.

The Federal Circuit also explained that the prior art did not provide motivation to make the modifications required to reach olanzapine. The Federal Circuit dismissed the argument that olanzapine was "bracketed" by two compounds in the prior art with similar structures: combining Compound '222's hydrogen-substituted benzene ring and flumezapine's methyl substitution on the thiophene ring generates the structure of olanzapine, thereby making olanzapine prima facie obvious. Structural similarity is not controlling in this case, and the prior art did not contain any suggestion to make these modifications. Mere identification in the prior art of each component of a composition does not render the combination obvious; the law requires some motivation to select and combine the references to reach the claimed invention.

Even if a prima facie case of obviousness could be established, the Federal Circuit held it would be overcome by Lilly's extensive secondary considerations. "The record shows a long-felt need for a safer, less toxic, and more effective clozapine-like drug; a decade (or more) of failure to find a replacement for clozapine; a reasonable amount of commercial success for olanzapine; and a number of awards for olanzapine as indicators of industry acclaim."

The Federal Circuit next upheld the district court's finding that Lilly's clinical trials of olanzapine were an experimental rather than a public use, and therefore negated any statutory bar under § 102(b). The Court emphasized that a use which occurs in the open will not trigger a statutory bar when undertaken to experiment on or with the claimed invention. Here, phase I clinical trials were performed to test the safety and efficacy of olanzapine. The trials were conducted in the Lilly clinic, with restricted access, security, and confining the volunteers' movements. The Court concluded that because Lilly had "tailored its tests to their experimental drug safety and efficacy purpose, adequately monitored for results, and maintained confidentiality," the trial court did not err in finding no public use.

Finally, the Federal Circuit considered and rejected DRL's assertion that the '382 patent should be declared unenforceable due to inequitable conduct. First, when the U.S. Patent and Trademark Office ("PTO") questioned Lilly about blood-cholesterol levels in dog studies, Lilly did not disclose to the PTO its statements to the Swedish Board about the hematotoxic effects of olanzapine in these studies. Because the hematotoxicity findings were "believed not to have clinical relevance to humans," the Court concluded that Lilly did not fail to disclose information to the PTO. Second, the Federal Circuit did not find that the declaration of a Lilly physician was false, or that certain information was withheld from the PTO with an intent to deceive. On a third inequitable conduct charge, the Court concluded that Lilly's nondisclosure of the Chakrabarti article and the '574 patent was neither a material omission nor done with the intent to deceive, where another Lilly patent with an identical specification was disclosed and the Chakrabarti article was cited by the examiner during prosecution.

IX. Listing of Other Pharmaceutical, Biotech, and Chemical Cases Decided in 2006 from the Federal Circuit

A. Novelty - 35 U.S.C. § 102

Date	Case No.	Origin	Case Name	Brief Description
2006-12-08	2006-1613	DCT	*Sanofi-Synthelabo v. Apotex*	Patent covering Plavix® drug not anticipated and grant of preliminary injunction upheld

B. Obviousness - 35 U.S.C. § 103

Date	Case No.	Origin	Case Name	Brief Description
2006-06-22	2005-1433	DCT	*Abbott Labs v. Andrx Pharm., Inc.*	Preliminary injunction should not issue where substantial questions of validity exist

C. Inventorship

Date	Case No.	Origin	Case Name	Brief Description
2006-01-17	2005-1291	DCT	*Stern v. Trs of Columbia Univ.*	Medical student presented insufficient evidence to corroborate his claim of co-inventorship

D. Inequitable Conduct

Date	Case No.	Origin	Case Name	Brief Description
2006-02-01	2004-1189	DCT	*Purdue Pharma L.P. v. Endo Pharm. Inc.*	There is little basis to infer intent to deceive when materiality is low
2006-02-15	2005-1284	DCT	*Ferring B.V. v. Barr Labs., Inc.*	Failure to disclose relationship between declarants and applicant affirmed to be inequitable conduct
2006-09-25	2005-1479	DCT	*Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*	District court did not abuse its discretion in finding low materiality of a prior-art reference and no intent to deceive

E. Priority

Date	Case No.	Origin	Case Name	Brief Description
2006-02-03	2005-1179	DCT	*Medichem, S.A. v. Rolabo, S.L.*	Inventors' priority testimony must be independently corroborated

F. Other

Date	Case No.	Origin	Case Name	Brief Description
2006-12-29	2006-1074	DCT	*Ventana Med. Sys., Systems, Inc. v. BioGenex Labs., Inc.*	General statements in specification describing improvement over prior art did not act as disclaimer

X. Overview of 2007 at the Federal Circuit

A. Summary of the Federal Circuit 2007 Decisions in Intellectual Property

Year	Number of Precedential Cases in Intellectual Property	Number of Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts (% of total)	En Banc Decisions (% of total)	En Banc Decisions
2007	139	35 (25%)	1 (0.7%)	*In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007)

B. Summary of the Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts for 2007 from the Federal Circuit

		Origin			PTO		
Year	Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts	Supreme Court/ District Court	International Trade Commission	PTO	Prosecution	Interference	Reexamination
2007	35	1/27	1	6	4	2	0

XI. Summaries of Cases Decided En Banc and Other Key Decisions from the Federal Circuit in 2007

A. *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 76 F.3d 1321 (Fed. Cir. 2007)

A Claim Reciting a Single Weight Ratio of "About 1:5" Is Limited to Encompass a "Range of Ratios No Greater Than 1:36 to 1:71"

In *Ortho-McNeil Pharmaceuticals, Inc. v. Caraco Pharmaceutical Laboratories, Ltd.*, the Federal Circuit affirmed the district court's grant of SJ of noninfringement of claim 6 of U.S. Patent No. 5,336,691 ("the '691 patent").

Ortho-McNeil Pharmaceuticals, Inc. ("Ortho") owns the '691 patent directed to pharmaceutical compositions comprising certain weight ratios of two known drugs, tramadol and acetaminophen. Both of these drugs act as pain relievers. The '691 patent discloses that at certain weight ratios, the pharmacological effects of the compositions are superadditive or synergistic. Claim 6 of the '691 patent is directed to a pharmaceutical composition comprising a tramadol material and acetaminophen in a weight ratio of "about 1:5."

The defendant, Caraco Pharmaceutical Laboratories, Limited ("Caraco"), filed an Abbreviated New Drug Application ("ANDA") indicating its intent to make and sell a composition containing tramadol and acetaminophen with an average weight ratio of 1:8.67. The ANDA expressly requires that Caraco's formulation have a weight ratio of no less than 1:7.5. In response to Caraco's ANDA, Ortho filed suit for infringement of claim 6 of the '691 patent. The sole issue before the district court was infringement because both parties agreed to be bound by the outcome of other pending litigations on all issues relating to the validity and enforcement of the '691 patent. Caraco moved for SJ of noninfringement.

The district court granted Caraco's motion. At issue was the claim construction of the term "about 1:5," and whether under a proper claim construction Caraco's ANDA infringed either literally or under the doctrine of equivalents ("DOE") . The district court relied upon intrinsic and extrinsic evidence to construe the term "about 1:5" to mean "approximately 1:5, encompassing a range of ratios no greater than 1:3.6 to 1:7.1." Under this claim construction, the district court concluded that Caraco's ANDA-defined product did not literally infringe the '691 patent. In addition, the district court found that there was no infringement under the DOE because such a finding would render meaningless the "about 1:5" limitation under the doctrine of claim vitiation.

On appeal, the Federal Circuit reviewed the district's construction of the term "about 1:5," particularly the meaning of

"about." The Court explained that "about" does not have a universal meaning in patent claims; rather, its meaning depends on the technological facts of a particular case. To determine the meaning of the term "about 1:5," the Court focused on the criticality of the 1:5 ratio to the invention in claim 6 of the '691 patent. They looked first to the intrinsic evidence in the '691 patent and then to extrinsic evidence, and found that the term "about 1:5" has a narrow meaning and that the limitation is critical to the invention.

The intrinsic evidence that the Federal Circuit considered in its claim construction included the language of the claims and specification. First, the Court noted that the '691 patent included fifteen claims, all of which use the term "about" to modify the claimed weight ratio or weight ratio ranges of tramadol to acetaminophen. Of these fifteen claims, only two of the claims claim *a single* weight ratio, while the other thirteen claims distinctly point out *ranges* of weight ratios. From this language, the Court concluded that one of ordinary skill in the art would understand that the inventors intended a range when they claimed one, and something more precise when they did not.

Next, the Federal Circuit looked to the specification, where the inventors disclosed a broad range of weight ratios, and then the most preferred range of weight ratios. In addition to ranges of weight ratios, the inventors specifically disclosed two single weight ratios of "about 1:1" and "about 1:5." Again, the Court found that the qualifier "about" is narrow because to find otherwise would allow the scope of the specifically identified ratio, i.e., 1:5, to encompass a range of ratios that could potentially render meaningless the other specifically identified ratio of 1:1.

The Federal Circuit then looked to the data points from experiments described in the specification to support their conclusion that the term "about 1:5" was meant to be narrow. The Court noted that the specification showed data points for several ratios of tramadol to acetaminophen, yet the patentees chose to specifically claim ratios of 1:1 and 1:5. The Court thus concluded that the inventors intended to claim compositions very close to these ratios.

The Federal Circuit also credited the extrinsic evidence provided by Ortho's expert regarding the confidence bounds of the data. The expert used statistical analyses to determine that the ratio of "about 1:5" would not be statistically different from ratios from 1:3.6 to 1:7.1. Considering both intrinsic and extrinsic evidence, the Court concluded that the district court made no error in construing the term "about 1:5" to mean "approximately 1:5, encompassing a range of ratios no greater than 1:3.6 to 1:7.1."

The Federal Circuit agreed with the district court that there could be no literal infringement because Caraco's formulation must have a weight ratio of no less than 1:7.5, which is not encompassed by Ortho's claim. Additionally, the Court agreed with the district court's holding that a finding of infringement under the DOE would impermissibly vitiate the "about 1:5" limitation of the claim. Having distinctly identified the 1:5 ratio versus all other ratios or ratio ranges, the Court concluded that Ortho could not now argue through the DOE that the parameter is broad enough to encompass ratios outside of the confidence intervals expressed in the '691 patent. Next the Federal Circuit looked to the specification, where the inventors disclosed a broad range of weight ratios, and then the most preferred range of weight ratios. In addition to ranges of weight ratios, the inventors specifically disclosed two single weight ratios of

"about 1:1" and "about 1:5." Again, the Court found that the qualifier "about" is narrow because to find otherwise would allow the scope of the specifically identified ratio, i.e., 1:5, to encompass a range of ratios that could potentially render meaningless the other specifically identified ratio of 1:1.

B. *Andersen Corp. v. Fiber Composites, LLC,* 474 F.3d 1361 (Fed. Cir. 2007)

Product Claim Limited by Process Steps Because Process Steps Are Essential for Practicing Invention

In *Andersen Corp. v. Fiber Composites, LLC*, the Federal Circuit affirmed the judgment of the district court in all respects except with regards to the district court's grant of SJ that Fiber Composites, LLC ("Fiber") infringed U.S. Patent Nos. 5,486,533 and 5,539,027 to Andersen Corporation ("Andersen"). On that issue, the Federal Circuit reversed and remanded for any necessary proceedings.

Andersen owns various patents relating to composite materials made from a mixture of polymer and wood fiber, including structural parts made from those composite materials. Fiber manufactures and sells deck railing and spindle products made from polymer/wood fiber composites. Andersen sued Fiber for infringement of six of its patents, which were grouped as follows for purposes of the litigation: U.S. Patent Nos. 5,827,607; 5,932,334; 6,015,611; and 6,015,612 (collectively "the Group I patents") directed to a patented "composite composition," and U.S. Patent Nos. 5,486,533 and 5,539,027 (collectively "the Group II patents") directed to a patented "composite structural member." The parties agreed that the terms "composite composition" and "composite structural member" have the same meaning throughout the patents in each respective group.

The district court granted SJ that Fiber's repro did not infringe the Group I patents, but held that a subset of Fiber's products infringed the Group II patents. Following a trial, a jury found that the Group II patents were not invalid and awarded Andersen $46,020 in damages. In post-trial motions, the district court denied Andersen's request for a permanent injunction and denied Fiber's request for judgement as a matter of law ("JMOL") regarding the validity of the Group II patents.

On appeal, both Andersen and Fiber challenged the district court's construction of the claim terms "composite composition" and "composite structural member." In particular, both parties disputed whether the claim terms "composite composition" and "composite structural member" should be limited to pellet and linear extrudate forms. Andersen further appealed the district court's summary judgement ("SJ") grant of noninfringement of the Group I patents; Fiber appealed the district court's denial of its JMOL motion.

First, the Federal Circuit addressed the term "composite composition" as claimed in the Group I patents. After

analyzing the specifications and prosecution histories of the Group I patents, the Court determined that the steps of linear extrusion or pelletization were not merely embodiments disclosed in the Group I patents, but instead were essential features of the claimed composite composition. Specifically, the Court noted that the Group I patents share a common specification, which makes clear that the formation of pellets or linear extrudates is required for realizing the claimed physical properties of the "composite composition." The Court further noted that the patentee repeatedly distinguished the invention over the prior art by referring to the pellet form or the pelletization process as an essential part of the invention. Having determined that the formation of pellets or linear extrudate was essential, the Federal Circuit concluded that the district court properly limited its construction of the term "composite composition."

The Federal Circuit was not persuaded by Andersen's argument that the specification occasionally refers to a "composite material" without reference to linear extrudate or pellets. The Court reasoned that the disclosed "composite material" is synonymous with the claimed "composite composition" and thus similarly restricted in its meaning. Andersen also argued that the doctrine of claim differentiation supports a broader construction of "composite composition." The Court dismissed this argument on the basis that "the written description and prosecution history overcome any presumption arising from the doctrine of claim differentiation." Finally, Andersen argued that a restriction requirement during prosecution of one of the Group I patents identified certain "pellet and composite" claims to be patentably distinct from the "composition" claims. However, the Federal Circuit disagreed with the restriction, finding that Andersen did not adequately support this argument.

Next, the Federal Circuit addressed the term "composite structural member" as claimed in the Group II patents. Andersen urged that the claimed structural member should not be limited by any particular process of manufacture, such as forming the member from pellets or linear extrudates. In response, the Court reasoned that "[t]he specification [of the Group II patents], however, uses language of requirement, not preference, when it states that the manufacture of the composition and pellet of the invention 'requires two important steps,' one of which is the pelletizing step." Moreover, the Court held that "[non-recited] process steps can be treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention."

The Federal Circuit pointed to several portions of the Group II patents as evidence that formation of pellets or linear extrudate was required for forming the claimed structural member and, thus, a necessary limitation of the asserted claims. In addition, the Court pointed out that the patentees clearly disavowed broader claim coverage during prosecution of the Group II patents by arguing that the claimed "composite structural member" distinguishes the prior art by "forming pelletized material." The Court explained that "[b]y distinguishing [the prior art] in that manner, applicants clearly disclaimed structural members made through a direct extrusion process." The Court also observed that the Group I and II patents trace their origins to closely related applications, filed the same day and sharing common descriptions for manufacturing composite structural members, further supporting the Court's conclusion that the pelletization process was an essential process in the Group II patents. The Court further held that while it is generally true that product claims are not limited to the methods of manufacture disclosed in the specification, "process steps can be treated as part of a product claim if the patentee has made clear that the process steps are an

essential part of the claimed invention."

Turning to the issue of the district court's SJ grant of noninfringement of the Group I patents, the Federal Circuit affirmed the lower court's holding. Specifically, the Court determined that Fiber's repro is neither a pellet nor a linear extrudate. Indeed, Andersen conceded that repro does not consist of pellets. However, Andersen suggested that repro is a linear extrudate because it "has a length to it." The Court dismissed this argument as overbroad, since every object has a length.

Finally, the Court addressed the issue of whether Fiber's JMOL was properly denied regarding the validity of the Group II patents. Fiber argued that although the asserted claims recite a lower limit for a claimed Young's modulus value, they do not comply with the written-description or enablement requirements because they fail to recite a corresponding upper limit value. Fiber asserted a similar argument concerning a claimed coefficient of thermal expansion. The Court dismissed Fiber's arguments since an unbounded claim value is proper, as in the instant case, where the specification enables one skilled in the art to approach the useful limits of the claimed value.

C. *In re Omeprazole Patent Litig.*, 483 F.3d 1364 (Fed. Cir. 2007)

Prior Art Disclosing Only Product Ingredients Can Inherently Anticipate a Process Claim

In *In re Omeprazole Patent Litigation*, the Federal Circuit affirmed the district court's judgment that the asserted claims of U.S. Patent No. 6,013,281 ("the '281 patent") were literally infringed but inherently anticipated, thereby permitting a generic alternative to Prilosec®, the "purple pill" for relieving heartburn.

AstraZeneca L.P. and related companies (collectively "Astra") asserted the claims in the '281 patent relating to a process for making a formulation of omeprazole (found in Prilosec®) against generic drug manufacturer Andrx Pharmaceuticals, Inc. ("Andrx"). Omeprazole inhibits gastric-acid production in cells lining the stomach (parietal cells). Astra's formulation of omeprazole contains two components allowing the drug to survive gastric acids until it reaches parietal cells: a protective coat and an alkaline-reaction component to stabilize the active ingredient in the core. The '281 patent claimed a process for making that formulation by "forming *in situ* a separating layer as a water-soluble salt product," separating the coating from the core. Andrx asserted counterclaims of invalidity and unenforceability. The district court held that the claims of the '281 patent were literally infringed but invalid as anticipated or obvious over a Korean patent application. The court also ruled that certain counterclaims relating to unenforceability were moot in light of invalidity.

On appeal, the Federal Circuit first affirmed that Andrx's process of formulating omeprazole literally infringed the '281 patent. Andrx contended that its process did not form a layer of "a water-soluble salt" because its separating

layer included talc, which is insoluble in water. Focusing on the specification, the Court determined that the claimed separating layer could include an insoluble material. The "Summary of the Invention" stated that "the separating layer comprises a water soluble salt," noted the Court, and one example in the '281 patent included talc. Because Andrx's separating layer included talc in an otherwise water-soluble separating layer, the Court held that Andrx's formulation process literally infringed the asserted claims.

Addressing the invalidity counterclaims, the Court held that all but one of the asserted claims in the '281 patent were anticipated by a Korean patent application assigned to a company that was earlier accused by Astra of infringing Astra's related Korean patent in a litigation in Korea. That patent claimed a process of manufacturing omeprazole. The Korean application expressly disclosed all limitations but the "forming *in situ* a separating layer." In the earlier Korean proceedings, Astra relied on expert testimony and argued that the accused process inherently involved in situ formation of the separating layer.

The Federal Circuit affirmed the district court's finding that the Korean application inherently anticipated Astra's patent, emphasizing the expert testimony in the Korean proceeding. The Federal Circuit echoed the district court's characterization of the testimony as "prior admissions of inherency" and "evidence that *in situ* formation does result from the [accused] process." The Court also cited its precedent that artisans of ordinary skill need not recognize the inherent characteristics or functioning of the prior art in order to anticipate. Here, the Court reasoned, "[t]he record shows formation of the *in situ* separating layer in the prior art even though that process was not recognized at the time." The Court referred to the earlier testimony by Astra's experts supporting their realization that "the formation of a separating layer [in the accused process] was a natural result flowing from the combination of certain ingredients listed in the [method]." According to the Court, "[t]he new realization alone does not render that necessary prior art patentable."

Regarding the one dependent claim that was not anticipated, the Court held that it was obvious. The claim was drawn to the alkaline reaction component of the core as an alkaline salt. In affirming the district court's determination of obviousness, the Court noted that the prior art (the same Korean patent application) identified the core ingredient arginine as "basic" and "alkali." Further, the Court perceived certain statements made by Astra in the prior Korean proceeding as general admissions of obviousness; for instance, that the claimed alkaline reaction compound and arginine listed in Astra's Korean patent could act as substitutes. The Court rejected Astra's argument that its statements in the Korean proceeding should apply only to Astra's Korean patent, not to the '281 patent at issue. Nonetheless, the Court found no error in the district court's finding of obviousness with respect to that claim.

Regarding Andrx's claims of unclean hands, fraud, and inequitable conduct, the Court held that the district court did not err in declining to find the '281 patent unenforceable. The district court had refused to fully address Andrx's fraud and inequitable conduct claims, calling them moot after finding all the asserted claims invalid. The Court disagreed, stating that such claims were technically not moot, since they could render the entire patent unenforceable rather than just the asserted claims held invalid. But the Court found that the ruling on mootness did not prejudice Andrx

here, as the record failed to show any misrepresentation by the inventors. Indeed, the Court noted, the inventors had disclosed the Korean proceeding to the U.S. Patent Trademark Office, and the accused company in that case insisted that its product did *not* have a separating layer. The inventors, then, had every reason to believe they had invented the process in the '281 patent. Thus, the Court found nothing inequitable in their conduct.

The Court also affirmed the denial of attorneys' fees to Andrx, agreeing with the district court that Andrx was not the prevailing party and thus could not assert a claim under 35 U.S.C. § 285. The judgment in this patent case represented but one phase in this four-phase litigation involving multiple patents. In other phases, Astra had prevailed on many of its infringement claims based on related patents. Overall, Astra was the prevailing party, and Andrx therefore could not recover attorneys' fees.

Judge Newman concurred that the claims of the '281 patent were literally infringed but disagreed that they were anticipated or obvious. In her dissent, Judge Newman questioned the Court's "novel theory of 'inherent anticipation.'" In her view, the Court confused the law governing the patentability of a newly discovered use of a known composition (here achieved by a process claim) with the unpatentability of the known composition itself. Judge Newman also discredited the Korean application as an anticipatory reference, since it neither made public the trade-secret process nor did it enable those skilled in the art to carry out that process.

D. *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897 (Fed. Cir. 2007)

Nondisclosure of Prior-Art Rejection from Copending Application Results in Finding of Inequitable Conduct

In *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, the Federal Circuit upheld the district court's finding that U.S. Patent No. 4,857,716 ("the '716 patent") was unenforceable due to inequitable conduct.

In 2002, McKesson Information Solutions, Inc. ("McKesson") filed a patent-infringement suit against Bridge Medical, Inc. ("Bridge Medical"). The district court bifurcated the trial, the first phase being a bench trial on the issue of inequitable conduct, followed, if necessary, by a jury trial on the remaining claims, counterclaims, and affirmative defenses.

The '716 patent claims "a patient identification and verification system" that relates items with patients and ensures that an identified item corresponds to an identified patient. The only independent claim of the '716 patent recites "three node communication" and "programmable unique identifier" limitations.

Following a bench trial, the district court held the '716 patent to be unenforceable. Specifically, the district court found

that in the course of prosecuting the '716 patent, the prosecuting attorney, Schumann, failed to disclose to Examiner Trafton (1) the existence of U.S. Patent No. 4,456,793 to Baker ("the Baker patent"), which was cited in a rejection in another very similar application, U.S. Application No. 06/862,149 ("the '149 application"), that was being prosecuted by Schumann before a different examiner, Lev; (2) Examiner Lev's rejection of the initially broad claims in the '149 application; and (3) the allowance of the claims in another application prosecuted by Schumann before Examiner Trafton that recited a three-node communication feature, which issued as U.S. Patent No. 4,835,372 ("the '372 patent"). The district court found these to be material omissions made with an intent to deceive.

On appeal, the Federal Circuit first addressed Schumann's failure to disclose the Baker patent to Examiner Trafton during prosecution of the applications leading to the '716 patent. The Court rejected McKesson's argument that the Baker patent was cumulative and less relevant than another reference, the Hawkins patent, that was before Examiner Trafton. In rejecting this argument, the Court noted that one of Schumann's primary arguments for the patentability of the claims of the '716 patent was the use of three-node communication. The Court found no error in the district court's conclusion that "Baker discloses three-node communication more clearly than Hawkins," and that Baker therefore would have been important to a reasonable examiner.

Nor was the Federal Circuit persuaded by McKesson's argument that Baker was cumulative of other prior art before Examiner Trafton that disclosed three-node systems. The Court noted that "the description of the preferred embodiment in Baker spans over eleven columns and provides a highly technical discussion of the implementation of the three-node communication system with unique addressing, whereas the same description in [the prior art patent before Examiner Trafton] is just under two columns and provides only cursory implementation details." The Court also found that the district court did not clearly err in concluding that the Baker patent undermined Schumann's argument to Examiner Trafton that "none of the references [either singularly or in combination] teach the three node approach to communications as provided in the claimed invention."

Regarding the intent-to-deceive prong, McKesson argued that there was no such deceptive intent because the features disclosed in Baker were already present in the art of record. The Court found this argument to be nothing more than an attempt to rehash the same argument made with respect to the materiality prong.

The Federal Circuit was also unconvinced by McKesson's argument that Schumann did not know and should not have known of Baker's materiality because Examiner Lev cited it for a "unique addressing" feature that was already before Examiner Trafton in the Hawkins patent. The Court explained that simply because Examiner Lev cited Baker for its unique addressing feature "did not release Schumann from the relevance of Baker's other teachings," especially considering the small size of the Baker patent, which put Schumann on notice of the content of the whole document.

McKesson further argued that the seventeen-day gap between Schumann's assertion to Examiner Trafton that none of the prior art teaches three-node communication and Schumann's interview with Examiner Lev regarding Baker could not be evidence of intent, given that the assertion to Examiner Trafton was *before* the interview with Baker. The

Federal Circuit rejected this argument, noting that Schumann's duty to disclose material information to the U.S. Patent and Trademark Office ("PTO") extended well beyond the interview with Examiner Lev. Moreover, the Court explained, "[t]he mere seventeen-day gap is important…because it bolsters the district court's inferences that Schumann knew or should have known of Baker's materiality to the [application leading to the '716 patent], and that he intentionally withheld Baker from Examiner Trafton with deceptive intent."

With regard to the prosecuting attorney's failure to disclose Examiner Lev's rejections in the '149 application, the Federal Circuit explained that it addressed the failure to disclose rejections in copending applications in *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003). In that case, the Court held that a contrary decision of another examiner reviewing a "substantially similar" claim meets the "reasonable examiner" threshold materiality test. McKesson argued on appeal that the district court misapplied Dayco because it used a lesser "in some respects identical" test that failed to account for differences between the compared sets of claims.

The Federal Circuit rejected McKesson's argument, explaining that a "showing of substantial similarity is *sufficient* to prove materiality. It does not necessarily follow, however, that a showing of substantial similarity is *necessary* to prove materiality." Here, the district court correctly found under the accepted "reasonable examiner" standard that Examiner Lev's rejection of certain '149 application claims was in fact material to the prosecution of the application that led to the '716 patent before Examiner Trafton.

The Federal Circuit also noted that the district court did compare the differences between the claims and explained the rationale for rejecting those differences as insufficient to undermine a finding of materiality. Moreover, the Court noted that Schumann's response to Examiner Lev's office action in the '149 application was nearly identical to a response made to Examiner Trafton one month later about similar claims in the '716 patent. In addition, Schumann's cancellation of claims in response to Examiner Lev's rejection was evidence that the rejections could not be easily overcome—further evidence of materiality.

As to intent, McKesson argued, as evidence of good faith, that Schumann made two separate disclosures of the existence of the '149 application to Examiner Trafton during prosecution of the '716 patent. According to McKesson, given the state of the law in the mid-1980s, "there was no awareness" that the further disclosure of rejections in copending applications was necessary. The Federal Circuit, however, concluded that "the [Manual of Patent Examining Procedure ('MPEP') to which Schumann would have referred . . . leaves no doubt that material rejections in co-pending applications fall squarely within the duty of candor," and, thus, the district court did not err in finding deceptive intent.

Finally, with regard to Schumann's failure to notify Examiner Trafton of the allowance of the '372 patent claims, the Federal Circuit found that "the district court's stated basis for finding materiality—the conceivability of a double patenting rejection—is not incorrect because allowance of the three-node system of the '372 patent claims plainly gives rise to a conceivable double patenting rejection". Further, the Federal Circuit dismissed McKesson's argument

that the district court allegedly failed to consider that Examiner Trafton was the examiner who allowed the '372 patent claims, and that he did so within a few months of allowing the '716 patent claims. The Court noted that the MPEP at the time explained that a prosecuting attorney should not assume that a PTO examiner retains details of every pending file in his mind when he is reviewing a particular application, and PTO regulations required all disclosures to be in writing. The Court thus held that Schumann was not entitled to assume that Examiner Trafton would recall his decision to grant the claims of the '372 patent when he was examining the application that led to the '716 patent in the absence of a written disclosure to that effect. The Court thus affirmed the district court's finding that the '716 patent was unenforceable due to inequitable conduct before the PTO.

Writing in dissent, Judge Newman stated that there was not clear and convincing evidence of deceptive intent. "To avoid the inequity resulting from litigation-driven distortion of the complex procedures of patent prosecution," she wrote, "precedent firmly requires that the intent element of inequitable conduct must be established by clear and convincing evidence of deceptive intent -- not of mistake, if there were such, but of culpable intent." She further warned that "[t]his court returns to the 'plague' of encouraging unwarranted charges of inequitable conduct, spawning the opportunistic litigation that here succeeded despite consistently contrary precedent."

E. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007)

A New Compound Is Not Prima Facie Obvious over an Old Compound Absent a Suggestion in the Prior Art to Make Specific Molecular Modifications

In *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, the Federal Circuit affirmed the district court's judgment that the asserted claims of U.S. Patent No. 4,687,777 ("the '777 patent") were not obvious.

Takeda Chemical Industries, Ltd. and Takeda Pharmaceuticals North America, Inc. (collectively "Takeda") manufacture the Type 2 diabetes drug pioglitazone, sold in the United States under the trade name ACTOS® and the subject of Takeda's '777 patent. ACTOS® is a member of a class of drugs known as thiazolidinediones ("TZD"). ACTOS® acts by ameliorating the insulin resistance experienced by patients with Type 2 diabetes.

The generic drug manufacturer Alphapharm Pty., Ltd. and three other generic manufacturers (collectively "Alphapharm") filed Abbreviated New Drug Applications ("ANDAs") pursuant to the Hatch-Waxman Act seeking approval by the U.S. Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j) et seq. to manufacture and sell generic versions of pioglitazone. Because Takeda had listed the '777 patent in the FDA's Orange Book as covering ACTOS®, Alphapharm filed pursuant to 21 U.S.C. § 505(j)(2)(B)(ii) a certification with its ANDA, asserting that the

relevant claims of Takeda's '777 patent were invalid as obvious. In response, Takeda sued Alphapharm, alleging that Alphapharm had infringed or would infringe claims 1, 2, and 5 of the '777 patent.

Claim 2 of the '777 patent is directed to the compound pioglitazone. In pioglitazone, an ethyl group is attached to the 5-position of a pyridyl ring. Alphapharm argued in the district court that the asserted claims of the '777 patent were obvious over the prior art "compound b" that was referenced in the '777 patent. Compound b includes a pyridyl ring with a methyl group attached at the 6-position of the ring. Thus, pioglitazone differs from compound b in that the methyl group of compound b is replaced by an ethyl group in pioglitazone and that group is attached at the 5-position in pioglitazone rather than the 6-position. Following a bench trial, the district court held that the asserted claims of the '777 patent were not obvious over compound b.

On appeal, the Federal Circuit began by rejecting Alphapharm's argument that the district court misapplied the law relating to obviousness of chemical compounds. The Federal Circuit acknowledged that a known compound may suggest compounds with similar structure because such compounds often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties. The Court explained, however, that in order to make a prima facie case of unpatentability in such instances, a showing that the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention is also required.

That test for prima facie obviousness for chemical compounds, the Court held, is consistent with the legal principles enunciated in *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007). The Federal Circuit explained that while the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness inquiry, "it acknowledged the importance of identifying a 'reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination." Moreover, the Federal Circuit noted that the *KSR* Court held that the TSM test can provide helpful insight to an obviousness inquiry as long as the test is not applied as a rigid and mandatory formula. Thus, the Federal Circuit held, "in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound."

The Federal Circuit agreed with the district court that Alphapharm failed to make that showing. Alphapharm argued that the prior art would have led one of ordinary skill in the art to select compound b as a lead compound for further investigation. The person of ordinary skill would then have made two obvious chemical changes: replacing a methyl group with an ethyl group, and moving the ethyl group to the 5-position rather than the 6-position. The Federal Circuit rejected Alphapharm's arguments, noting that the district court found that one of ordinary skill in the art would not have selected compound b as the lead compound. Although compound b was disclosed in Takeda's prior-art U.S. Patent No. 4,287,200 ("the '200 patent"), that patent also disclosed hundreds of millions of other TZD compounds. Furthermore, although the '200 patent specifically identified fifty-four TZD compounds and during

prosecution Takeda submitted evidence to the U.S. Patent Trademark Office ("PTO") to demonstrate the superiority of nine of them, including compound b, the basis for that superiority was not related to antidiabetic effect.

The Court also pointed to the district court's findings regarding an article by Sodha et al. ("the Sodha article"). Although the article disclosed compound b as one of 101 TZD compounds relating to hypolgycemic activity and plasma triglyceride lowering activity, compound b was not identified as one of the three most favorable compounds and was singled out as having the undesirable side effects of causing considerable increases in body weight and brown fat weight.

Next, the Court pointed approvingly to the district court's findings relating to Takeda's related U.S. Patent No. 4,444,779 ("the '779 patent"). Compound b is specifically claimed in claim 4 of the '779 patent and a preliminary amendment in the prosecution history of that patent contained a statement that "the compounds in which these heterocyclic rings are substituted have become important, especially [compound b]." The district court discounted that evidence, however, focusing instead on testimony from experts for both Takeda and Alphapharm, emphasizing that in view of the Sodha II article, a person of ordinary skill in the art would not have selected compound b as a lead compound.

The Federal Circuit then rejected Alphapharm's contention that, under *KSR,* the claimed compounds would have been obvious because the prior- art compound fell within "the objective reach of the claim," and the evidence demonstrated that using the techniques of homologation and ring-walking would have been "obvious to try." According to the Court, this was not a situation, as identified in *KSR*, with a problem having a finite number of identified and predictable solutions. Instead, compound b, the closest prior art, "exhibited negative properties that would have directed one of ordinary skill in the art away from that compound." Thus, the Court concluded, "this case fails to present the type of situation contemplated by the [*KSR*] Court when it stated that an invention may be deemed obvious if it was 'obvious to try.'"

The Federal Circuit also found that Alphapharm's reliance on *Pfizer, Inc. v. Apotex, Inc*., 480 F.3d 1348 (Fed. Cir. 2007), fared no better. In contrast to *Pfizer*, in this case, the district court found nothing in the prior art to narrow the possibilities of a lead compound to compound b. Instead, the district court found that one of ordinary skill in the art would have chosen one of the many compounds disclosed in the Sodha article without toxicity or side effects rather than to choose compound b as a starting point.

The Federal Circuit went on to state that even if Alphapharm had established that the prior art would have led to the selection of compound b as the lead compound, Alphapharm's obviousness argument failed on a second ground. Specifically, the district court found nothing in the prior art to suggest making the specific molecular modifications to compound b that would be necessary to achieve the claimed compounds. First, the district court found that the process of modifying lead compounds was not routine at the time of the invention. Second, the district court found that nothing in the prior art provided a reasonable expectation that adding a methyl group to compound b would

reduce or eliminate its toxicity. There was also no reasonable expectation in the art that changing the positions of a substituent on a pyridyl ring would result in beneficial changes.

Alphapharm also argued that under *In re Wilder*, 563 F.2d 457 (CCPA 1977), differences in a chemical compound's properties resulting from a small change made to the molecule are reasonably expected to vary by degree and thus are insufficient to rebut a prima facie case of obviousness. The Federal Circuit rejected the applicability of *Wilder*, however, noting that in *Wilder* the claimed compound and its analog shared similar properties, whereas pioglitazone was shown to exhibit unexpectedly superior properties over the prior-art compound b. Moreover, the district court did not clearly err in finding that there was no reasonable expectation that pioglitazone would posses the desirable property of nontoxicity, particularly in light of the toxicity of compound b. The Court reasoned that Takeda had rebutted any presumed expectation that compound b and pioglitazone would share similar properties.

Finally, the Federal Circuit rejected Alphapharm's contention that the district court erred in its consideration of the scope of the prior art. The Court observed that even if, as Alphapharm asserted, the district court may have incorrectly implied that prosecution histories are not accessible to the public, the court nonetheless considered the prosecution history of the '779 patent in its obviousness analysis and accorded proper weight to the statements contained therein. Accordingly, any error committed by the district court was harmless.

In a concurring opinion, Judge Dyk joined the opinion of the Court in upholding the district court's judgment that claim 2, limited to pioglitazone, would have been nonobvious over the prior art. Judge Dyk noted, however, that claims 1 and 5 are broader, and in his view likely invalid. In fact, at oral argument, Takeda admitted that the prior art '200 patent also generically covers a 6-ethyl compound within the scope of claims 1 and 5 of the '777 patent, and admitted that there is no evidence of unexpected results for the 6-ethyl compound. Nonetheless, this would not have changed the outcome that claim 2 is valid and infringed by Alphapharm's filing of the ANDA for pioglitazone.

F. *In re Metoprolol Succinate Patent Litig.*, 494 F.3d 1011 (Fed. Cir. 2007)

A Patent Is Invalid for Obviousness-Type Double Patenting When an Earlier Claim to a Combination Sets Forth a Later Claimed Element

In *In re Metoprolol Succinate Patent Litigation*, the Federal Circuit affirmed the district court's holding of invalidity based on double patenting, but vacated its holding of inequitable conduct and remanded.

AstraZeneca AB, Aktiebolaget Hässle, and AstraZeneca LP (collectively "Astra") manufacture and market metoprolol succinate in "extended release" forms under the brand name Toprol-XL®. Metoprolol is used in the treatment of

angina, hypertension, and congestive heart failure.

In 1971, an Astra employee, Toivo Nitenberg, synthesized metoprolol succinate at Astra's facilities in Sweden. In 1983, two Astra employees, Curt Appelgren and Christina Eskilsson, left Astra to join another company, Lejus Medical AB ("Lejus"), which filed a patent application with the Swedish Patent Office, describing "delayed and extended release dosage forms of pharmaceutical compositions, including metoprolol succinate, " and naming Appelgren and Eskilsson as inventors. Lejus subsequently filed U.S. Application Serial No. 690,197 ("the '197 application"), claiming priority from the Swedish application. When Astra noticed the publication of the Swedish application, Astra commenced a transfer of ownership action with the Swedish Patent Office asserting that Nitenberg, not Appelgren and Eskilsson, invented metoprolol succinate. Astra and Lejus subsequently settled this ownership dispute. Lejus agreed to divide claims to "metoprolol succinate" and to a "pharmaceutical composition, characterized in that the active substance is metoprolol succinate" from the '197 application and to assign the divided claims to Astra. Astra agreed that Lejus retained the rights to the '197 application that did not include the divided claims. The '197 application subsequently issued as U.S. Patent No. 4,780,318 ("the '318 patent").

In accordance with the settlement agreement, Lejus filed U.S. Application Serial No. 172,897 ("the '897 application"), which is a continuation-in-part of the '197 application. Lejus named Appelgren and Eskilsson as inventors. Both before and after the filing of the '897 application, Astra's in-house counsel asserted to Lejus that Nitenberg, not Appelgren and Eskilsson, was the inventor of metoprolol succinate. Similarly, after Lejus transferred the prosecution of the '897 application to Astra, Astra's in-house counsel asserted that "there remains an open question who is the proper inventor." In March 1991, the '897 application issued as U.S. Patent No. 5,001,161 ("the '161 patent"). The only claim of the '161 patent reads: "A pharmaceutical composition comprising metoprolol succinate together with a sustained release pharmaceutically acceptable carrier." In January 1992, a continuation of the '897 application issued as U.S. Patent No. 5,081,154 ("the '154 patent"), the only claim of which simply reads "Metoprolol succinate." The '161 and '154 patents both list Appelgren and Eskilsson as the inventors, and Astra as the assignee. Astra never revealed the inventorship issue to the U.S. Patent and Trademark Office ("PTO").

Astra filed multiple suits in various district courts asserting that the Abbreviated New Drug Applications filed by KV Pharmaceutical Company, Andrx Pharmaceuticals, LLC and Andrx Corporation, and Eon Labs, Inc., which were seeking approval to market generic versions of Toprol-XL®, infringed Astra's '161 and '154 patents. The Judicial Panel on Multidistrict Litigation consolidated the suits in the U.S. District Court for the Eastern District of Missouri. All three defendants moved for summary judgement ("SJ") of invalidity of the '161 and '154 patents based on double patenting in view of Lejus's '318 patent and of unenforceability of the '161 and '154 patents based on Astra's failure to notify the PTO of the inventorship dispute. The district court granted both motions. Astra appealed the grant of SJ of invalidity based on double patenting with respect to only the '154 patent and the grant of SJ for unenforceability of both patents based on inequitable conduct.

On appeal, the Federal Circuit affirmed the district court's holding of invalidity based on double patenting. The Court

observed that the purpose of the nonstatutory or obviousness-type double-patenting doctrine is "to prevent claims in separate applications or patents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection." The Court stated that an obviousness-type double-patenting analysis entails two steps: "First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences. Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct."

Applying this two-part test, the Federal Circuit noted that the parties agreed with the district court's claim constructions and that it did not perceive any error in the district court's claim constructions. Therefore, the Court noted that the only issue on appeal regarding the invalidity of the '154 patent is whether the district court correctly found the claims to be not patentably distinct. The Federal Circuit observed that the district court found that claim 8 of the '318 patent "is directed to certain pharmaceutical compositions containing metoprolol succinate" and that the '154 patent "broadly claims any pharmaceutical compositions containing metoprolol succinate." As a result, the district court concluded that the '154 patent is a genus of the species claimed by the '318 patent and that since the species claimed by the '318 patent issued prior to the genus claimed by the '154 patent, the '154 patent was invalid for double patenting because it is not patentably distinct from claim 8 of the '318 patent.

Astra argued that the district court erred in concluding that claim 8 of the '318 patent and claim 1 of the '154 patent recited a species/genus relationship and that the claims instead define an element/combination relationship. The Federal Circuit rejected this argument, however, stating that such disputes about the characterization of the relation between the two claims in a double-patenting context are irrelevant. The Court observed that "Claim 1 of the '154 Patent claiming a compound (A1) is an obvious variation of Claim 8 of the '318 Patent claiming a composition compris[ing] of one compound of an enumerated list (A1, A2, A3, etc.), an inner layer (B), and an outer layer (C)." It stated that "it would have been an obvious variation of Claim 8 of the '318 Patent to omit the inner layer (B) and the outer layer (C)."

The Court also rejected Astra's argument that certain decisions of the Court of Customs and Patent Appeals, one of its predecessors, stand for the proposition that there is no double patenting because an earlier claim to a combination sets forth a later-claimed element. The Court explained that while the cases cited by Astra do appear to support this proposition, a later-issued decision by that same court refutes Astra's argument and that this later-issued decision controls because "the Court of Customs and Patent Appeals always sat in banc and therefore later decisions overcome earlier inconsistent ones." In addition, the Court reasoned that "adopting Astra's argument that there can never be 'double patenting simply because a later claimed element is set forth in an earlier claim to the combination,'. . . would require that this court eviscerate obviousness-type double patenting, thereby reducing invalidity based on double patenting to the § 101 statutory prohibition against claims of the same invention." Accordingly, it affirmed the district court's SJ holding that the '154 patent is invalid over the '308 patent for obviousness-type double patenting.
On the issue of inequitable conduct, the Federal Circuit found that the district court erred in holding on SJ that the '161 and '154 patents were unenforceable based on inequitable conduct. The Court focused its analysis on the district

court's finding of intent to deceive. It noted that the district court inferred intent to deceive based on an analysis of what could have happened if Astra had disclosed the inventorship dispute to the PTO. Relying on this "but for" analysis, the district court found by clear and convincing evidence that Astra's motivation to not reveal the dispute was great based on the risk of losing its metoprolol inventions as anticipated by prior art and that the intent to deceive was clearly present. The Federal Circuit held that, "[e]ven assuming arguendo that the patents at issue would have been invalid based on anticipation if Astra had disclosed the inventorship dispute to the U.S. Patent & Trademark Office, the district court erred in equating the presence of an incentive with an intent to deceive on summary judgment." The Court observed that because the deposition of Astra's in-house patent counsel indicated that he did not know of and was not concerned about the incentives identified by the district court in its "but for" analysis, the record revealed a genuine factual dispute of whether Astra had an intent to deceive the PTO. The Court concluded that the district court incorrectly resolved this factual dispute on SJ and thus vacated the district court's inequitable-conduct finding and remanded.

Judge Schall agreed with the majority's decision regarding inequitable conduct, but disagreed with its decision finding the '154 patent invalid based on double patenting. In his view, claim 1 of the '154 patent is patentably distinct from claim 8 of the '318 patent. He stated that "[f]ar from claiming an obvious variation on the three-element composition claimed in the '318 patent, the '154 . . . patent lacks any semblance to the second two elements in the three-element composition of claim 8." He disagreed with the majority's reading of the case law and opined that "the law is that there is no double patenting simply because a later claimed element is set forth in an earlier claim to a combination." He added that allowance of claim 1 of the '154 patent to metoprolol succinate will not result in the improper extension of the patent for the invention claimed in the '318 patent because in this case, "each patent is capable of being practiced by itself, without infringing the other."

G. *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007)

Isolation of the Most Therapeutically Active Ingredient Was Obvious Where the Ingredient Was Present in a Mixture in the Prior Art

In *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, the Federal Circuit reversed the district court and held that the subject matter of the asserted claims of U.S. Patent No. 5,061,722 ("the '722 patent") was invalid as obvious over various prior-art references.

Aventis Pharma Deutschland GmbH ("Aventis") was issued the '722 patent directed to the pharmaceutical compound ramipril in a formulation "substantially free of other isomers." Ramipril, like many complex organic molecules, is one

of a family of stereoisomers. An isomer of a compound is a separate compound in which each molecule contains the same constituent atoms as the first compound, but with those atoms arranged differently. A stereoisomer is an isomer in which the same atoms are bonded to the same other atoms, but where the configuration of those atoms in three dimensions differs.

In the structural formula that represents ramipril, there are five carbon atoms that may take either of two orientations – or five "stereocenters," as such atoms are known. To differentiate among members of the family of stereoisomers, each member's stereocenters are labeled either "R" or "S," depending upon its configuration. The five stereocenters in ramipril are expressly oriented in the "S" configuration and, as a result, it is known as an "SSSSS" or a "5(S)" stereoisomer.

Ramipril is in the family of drugs known as "Angiotensin-Converting Enzyme inhibitors," or "ACE inhibitors." ACE inhibitors are useful for treating high blood pressure because they inhibit a biochemical pathway that constricts blood vessels. Enalapril is the ACE inhibitor that immediately preceded ramipril. Enalapril has three stereocenters.

Ramipril is marketed as a blood-pressure medication under the name Altace® by King Pharmaceuticals, Inc. ("King"), the exclusive licensee of the '722 patent. After Lupin, Ltd. and Lupin Pharmaceuticals, Inc. (collectively "Lupin") filed an Abbreviated New Drug Application seeking approval for a generic version of ramipril, Aventis and King sued Lupin for infringement of the '722 patent. After a bench trial on validity, the district court concluded that the '722 patent was neither anticipated nor obvious.

On appeal, the Federal Circuit first rejected an Aventis challenge to the prior-art status of U.S. Patent No. 5,348,944 ("the '944 patent") because Aventis had not raised the issue below. The Federal Circuit also found that Dr. Elizabeth Smith's synthesis of a mixture called SCH 31925 qualified as prior art under 35 U.S.C. § 102(g), which affords prior-art status to an invention made in the United States by another inventor who has not abandoned, suppressed, or concealed it. The Federal Circuit rejected Aventis's argument that Dr. Smith abandoned, suppressed, or concealed SCH 31925, noting that a method similar to Dr. Smith's method for synthesizing SCH 31925 was disclosed in a patent application filed by Dr. Smith's employer, Schering. That application was based on the work of Dr. Smith. The Court further noted that the exact method used by Dr. Smith to synthesize SCH 31925 was disclosed in a related Schering patent, and that SCH 31925 was developed in the course of extensive ongoing research and development and concurrent ongoing patent prosecution.

Turning to the question of obviousness, the Court noted that the key question is whether the 5(S) stereoisomer of ramipril, in a form substantially free of other isomers, would have been obvious over the prior art at the time of the '722 patent's priority date. The Court further noted that the district court found that it was a close case, but held that Lupin failed to meet its burden of proof by clear and convincing evidence that a person of ordinary skill in the art would have been motivated to purify 5(S) ramipril into a composition substantially free of other isomers.

The Federal Circuit pointed out that after the date of the district court's decision, the Supreme Court decided

KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007), which counsels against applying the teaching, suggestion, or motivation ("TSM") test as a rigid and mandatory formula. The Federal Circuit explained that it remains necessary, however, to show "'some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness,' but such reasoning 'need not seek out precise teachings directed to specific subject matter of the challenged claim.'" The Federal Circuit concluded that "[r]equiring an explicit teaching to purify the 5(S) stereoisomer from a mixture in which it is the active ingredient is precisely the sort of rigid application of the TSM test that was criticized in *KSR*."

In the chemical arts, the Court noted that it has long been held that "structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness." The Federal Circuit explained that the necessary "reason or motivation" may be established by showing that "the claimed and prior art compounds possess a 'sufficiently close relationship . . . to create an expectation,' in light of the totality of the prior art, that the new compound will have 'similar properties' to the old." Once a prima facie case of obvious has been established, it is the burden of the applicant or patentee to rebut it by showing, for example, that the claimed compound has unexpected properties.

The Court explained that the analysis is similar where, as here, a claimed composition is a purified form of a mixture that existed in the prior art. Such a purified compound is not always prima facie obvious over the mixture; for example, it may not be known that the purified compound is present in or an active ingredient of the mixture, or the state of the art may be such that discovering how to perform the purification is an invention of patentable weight in itself. However, the Court elaborated, "if it is known that some desirable property of a mixture derives in whole or in part from a particular one of its components, or if the prior art would provide a person of ordinary skill in the art with reason to believe that this is so, the purified compound is prima facie obvious over the mixture even without an explicit teaching that the ingredient should be concentrated or purified." If it is known how to perform the isolation of the compound of interest, the Court explained, doing so "is likely the product not of innovation but of ordinary skill and common sense."

Having laid out the legal framework, the Court turned to analysis of the prior art in the case. The Court concluded that the record suggested that when Dr. Smith synthesized SCH 31925—a prior-art mixture of 5(S)-configuration ramipril and its SSSSR stereoisomer—she understood that the 5(S) form of ramipril was the mixture's therapeutically active ingredient. Even if she did not, the Court said, other prior art provides a sufficient reason to look to the 5(S) configuration. Several pieces of prior-art suggested that the S configuration is more potent than the R configuration. For example, a prior-art article taught that the SSS configuration of enalapril is 700 times as potent as the SSR form. Moreover, the Court noted, prior art U.S. Patent No. 5,348,944 ("the '944 patent") specifically taught that stereoisomers of ramipril can be separated by conventional methods. The Court concluded that, Aventis's protestations notwithstanding, there was no evidence that separating 5(S) and SSSSR ramipril was outside the capability of an ordinarily skilled artisan.

Aventis attempted to rebut the prima facie case of obviousness by asserting that 5(S) ramipril exhibited unexpected results in the form of increased potency over the next most potent isomer, the RRSSS form. The Federal Circuit rejected this comparison, noting that Aventis had to show unexpected results not over all of the stereoisomers, but over the SCH 31925 mixture disclosed in the prior art. The Court found that all of the evidence suggested that potency varies with the absolute amount of 5(S) isomer in a mixture, and the potency of pure 5(S) ramipril was precisely what one would expect. Thus, the Court concluded that the asserted claims of the '722 patent were invalid as obvious over the SCH 31925 mixture, the '944 patent, and the enalapril references in the prior art.

Finally, the Court addressed asserted claims 4 and 5 of the '722 patent, noting that it must evaluate obviousness on a claim-by-claim basis. The additional limitations of claim 4, concerning a hypotensively effective amount, and claim 5, concerning a method for reducing blood pressure by administering the compound of claim 1, appeared almost verbatim in virtually all of the prior-art patents. The Federal Circuit found claims 4 and 5 identified a manner of using ACE inhibitors that was well understood by ordinarily skilled artisans and held both claims also to be invalid as obvious.

XII. Listing of Other Pharmaceutical, Biotech, and Chemical Cases Decided in 2007 from the Federal Circuit

A. Obviousness - 35 U.S.C. § 103

Date	Case No.	Origin	Case Name	Brief Description
2007-03-22	2006-1261	DCT	*Pfizer, Inc. v. Apotex, Inc.*	A prima facie case of obviousness was found over the same prior art references considered by the examiner during the prosecution
2007-08-29	2006-1507	PTO	*In re Sullivan*	PTO must consider rebuttal evidence of nonobviousness
2007-09-12	2006-1564	DCT	*Daiichi Sankyo Co. v. Apotex, Inc.*	Appropriate level of ordinary skill in the art pertaining to a patent for a method for treating ear infections is that of a person with experience in pharmaceutical formulations, not just a pediatrician or general practitioner
2007-09-27	2006-1489	PTO	*In re Buszard*	Board's finding of obviousness reversed because prior art rigid foam that is crushed could not reasonably be construed to be a flexible foam reaction mixture

B. Infringement

Date	Case No.	Origin	Case Name	Brief Description
2007-07-20	2006-1122	DCT	*Benitec Austl., Ltd. v. Nucleonics, Inc.*	A patentee's dismissal of its infringement claims may destroy the "immediacy and reality" required under the declaratory judgment act for jurisdiction over counterclaims of invalidity or unenforceability
2007-09-05	2007-1059	DCT	*Forest Labs., Inc. v. IVAX Pharm., Inc.*	Party supplying abbreviated new drug application ("ANDA") filer with data may be enjoined along with the filer if they will be joint participants in commercialization, but an injunction may not extend beyond the product described in the ANDA

Date	Case No.	Origin	Case Name	Brief Description
2007-09-21	2006-1572	DCT	*In re Gabapentin Patent Litig.*	Comparative quantitative testing not necessary when testing provides sufficient evidence of infringement
2007-10-04	2006-1472	DCT	*Monsanto Co. v. Syngenta Seeds, Inc.*	Multistep process not infringed when the patentee performed some of the claimed steps, and claims were not enabled when a patent was filed before transformation of cells covered by the claims was possible

C. Inequitable Conduct

Date	Case No.	Origin	Case Name	Brief Description
2007-02-14	2006-1265	DCT	*Cargill, Inc. v. Canbra Foods, Ltd.*	Omission of test data related to the issue which bedeviled the examiner is evidence of an intent to deceive the PTO

D. Patent Term

Date	Case No.	Origin	Case Name	Brief Description
2007-03-29	2006-1401	DCT	*Merck & Co. v. Hi-Tech Pharmacal Co.,*	Hatch-Waxman patent-term extension may be applied to a patent subject to a terminal disclaimer
2007-10-04	2007-1447	DCT	*Somerset Pharm., Inc. v. Dudas*	The PTO can only extend a patent term in the interim under 35 U.S.C. § 156(e)(2) when the patent would expire before a denial of an extension under § 156(d)(1)

E. Jurisdiction

Date	Case No.	Origin	Case Name	Brief Description
2007-10-11	2007-1019	DCT	*Abbott Labs., v. TorPharm, Inc.*	A district court has subject-matter jurisdiction to conduct contempt proceedings in an abbreviated new drug application ("ANDA") litigation, but filing of a second ANDA does not violate an injunction where the injunction does not prohibit such a filing
2007-11-13	2006-1522	DCT	*HIF Bio, Inc. v. Yung Shin Pharm. Indus. Co.*	Federal Circuit lacked jurisdiction to review a district court remand declining supplemental jurisdiction over state-law claims

F. Priority

Date	Case No.	Origin	Case Name	Brief Description
2007-08-08	2006-1434	PTO	*Boston Scientific v. Medtronic Vascular*	Foreign priority requires nexus between inventor and foreign applicant at the time the foreign application was filed
2007-08-20	2006-1154	PTO	*Frazer v. Schlegel*	Australian application provided priority date despite later discovery and unpredictable technology
2007-12-05	2007-1221	PTO	*In re Garner*	A patent specification is not "new evidence" when submitted as evidence of priority

G. Prosecution History Estoppel/Doctrine of Equivalents

Date	Case No.	Origin	Case Name	Brief Description
2007-10-12	2007-1074	DCT	*Schwarz Pharma, Inc. v. Paddock Laboratories, Inc.*	An exclusive licensee has standing to appeal on its own if the patentee was a party in the district court, and prosecution history estoppel bars application of doctrine of equivalents when a narrowing amendment is directly related to the range of equivalents sought to be recaptured

H. Safe Harbor

Date	Case No.	Origin	Case Name	Brief Description
2007-07-27	2002-1052	SC	*Integra Lifesciences I, Ltd. v. Merck KGaA*	FDA "safe harbor" provision applied to experiments not ultimately submitted to the FDA

I. Double Patenting

Date	Case No.	Origin	Case Name	Brief Description
2007-07-23	2006-1254	DCT	*In re Metoprolol Succiante Patent Litig.*	A patent is invalid for obviousness-type double patenting when an earlier claim to a combination sets forth a laterclaimed element

J. Other

Date	Case No.	Origin	Case Name	Brief Description
2007-01-05	2006-1101	DCT	*Abbott Labs. v. Anrdx Pharm,, Inc.*	Preliminary injunction holdings of unenforceability and invalidity do not collaterally estop patentee from asserting the same claims against another
2007-05-11	2006-1542	PTO	*Henkel Corp. v. Procter & Gamble Co.*	Inventor's awareness of detergent tablet possessing the discernible property required by the interference count enough to show appreciation of the invention
2007-05-24	2005-1570	DCT	*Monsanto Co. v. McFarling*	Reasonable royalty is not limited to license fee regularly charged at time of sale
2007-08-01	2006-1593	DCT	*Biotechnology Indus. Org v. Dist. of Columbia*	Federal patent laws preempt district of columbia statute that imposes limits on "excessive" prices for patented drugs
2007-11-16	2006-1405	DCT	*Apotex Corp. v. Merck & Co.*	Attorney argument regarding what inferences to draw and not disclosing details of a process for a defense under 35 U.S.C. § 102(g) when the patent covered a process broadly did not amount to fraud

XIII. Overview of 2008 at the Federal Circuit

A. Summary of the Federal Circuit 2008 Decisions in Intellectual Property

Year	Number of Precedential Cases in Intellectual Property	Number of Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts (% of total)	En Banc Decisions (% of total)	En Banc Decisions
2008	142	38 (27%)	3 (2%)	*In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008); *Egyptian Goddess v. Swisa Inc.*, 543 F.3d 665 (Fed. Cir. 2008); and *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d 1304 (Fed. Cir. 2008).

B. Summary of the Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts for 2008 from the Federal Circuit

		Origin			PTO		
Year	Number of Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts	Supreme Court/ District Court	International Trade Commission	PTO	Prosecution	Interference	Reexamination
2008	38	0/33	0	5	4	0	1

XIV. Summaries of Cases Decided En Banc and Other Key Decisions from the Federal Circuit in 2008

A. *Regents of the Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364 (Fed. Cir. 2008)

Tangential Exception Applied to Prevent Prosecution History Estoppel

In *Regents of the University of California v. Dakocytomation California, Inc.*, the Federal Circuit affirmed the district court's denial of a preliminary injunction, affirmed-in-part the grant of summary judgement ("SJ") of noninfringement as to one patent, and reversed-in-part the district court's grant of SJ of noninfringement as to a second patent. The Court remanded for further proceedings in light of its revised claim construction and its holding that the patentee is not precluded from asserting infringement of the claim limitation "blocking nucleic acid" under the doctrine of equivalents ("DOE").

The Regents of the University of California, Abbott Molecular, Inc., and Abbott Laboratories, Inc. (collectively "the Regents") are the owners and exclusive licensees of two patents, U.S. Patent Nos. 5,447,841 ("the '841 patent") and 6,596,479 ("the '479 patent"). The '841 and the '479 patents are directed towards improved methods for identifying and classifying chromosomes in order to detect chromosomal abnormalities. Dako A/S and Dako North America, Inc. (collectively "Dako") manufacture and sell HER2 FISH pharm DX kits ("HER2 kits"), which the Regents allege infringe the '841 and the '479 patents. The district court denied the Regents' motion for a preliminary injunction to enjoin manufacture and sale of the HER2 kits, concluding they failed to show a likelihood of success on the merits in light of its claim-construction determinations. The Regents appealed from this denial. Additionally, the district court later granted partial SJ of noninfringement based, inter alia, on its claim-construction determinations and the conclusion that the Regents were barred from asserting infringement of a claim limitation under the DOE. The Regents filed an interlocutory appeal after the district court certified its order granting partial SJ of noninfringement.

On appeal, the Federal Circuit considered the preliminary injunction and SJ appeals together in view of the overlapping issues affecting both appeals. First, the Court affirmed the district court's construction of a "heterogeneous mixture of labeled unique sequence nucleic acid fragments," a limitation that is required by every claim of the '479 patent. The Court stated that the district court initially erred in reasoning that the heterogeneous mixture excludes repetitive sequences in light of the '841 patent, which the district court characterized as prior art to the '479 patent. After realizing its error, however, the district court issued an amended preliminary injunction order that instead rejected the

Regents' proposed claim construction because it would likely render the '479 patent invalid for obviousness-type double patenting in view of the '841 patent. The Court agreed that the patentee disclaimed embodiments that included repetitive sequences during prosecution of the '479 patent and that the accused products, which employ a mixture that includes repetitive sequences, did not infringe the '479 patent.

In fact, the Court found that the prosecution history "sheds decisive light" on the scope of the claim term. During prosecution of the '479 patent, the original claim was cancelled and replaced with a new independent claim after the examiner issued rejections for lack of enablement, anticipation, and indefiniteness. The Court concluded that the patentees added the "unique sequence" limitation to this claim to overcome the enablement rejection and that statements made during prosecution with respect to this limitation evidenced a clear and unmistakable intent to limit the claims to embodiments that excluded repetitive sequences from the DNA mixture to disable the hybridization capacity of those repetitive sequences. Though the patentees did not expressly state that this limitation was added in response to the examiner's enablement rejection, the Court noted that the examiner recognized that the original claim failed to include a limitation directed towards a problem that existed in the prior art—reducing the nonspecific binding of repetitive sequences—and that this problem would not arise with the new claim that restricted the heterogeneous mixture to labeled probes of "unique sequences." The Court also stated that this conclusion was supported by the patentees' decision to limit the '841 patent to the blocking method claims and to pursue certain claims in the '479 patent.

The Court rejected the Regents' argument that the "unique sequences" limitation was added to overcome the anticipation rejection and had nothing to do with the issue of nonspecific binding of repetitive sequences. The Court noted that one of the anticipation references disclosed the unique sequence probes and that the patentees' statements accompanying the amendment pointed to other amended claim language to overcome the anticipation rejection. Thus, the Court found "no basis for reversing the [district] court's claim construction." Having found that the patentee limited the scope of the heterogeneous mixture to one that contains only unique sequences of nucleic acid fragments, the Court affirmed the district court's grant of SJ of noninfringement as to the '479 patent.

The Court then turned to the district court's determination on SJ that the '841 patent was not infringed by two accused products—the HER2 kit and the TOP2A kit. The Court concluded that the district court erred in applying prosecution history estoppel to the claim limitation "blocking nucleic acid," which is present in all claims of the '841 patent. The Court stated that because the prosecution history suggests that the patentees limited the claim to the blocking method at least in part to overcome the examiner's rejections, the patentees presumptively surrendered all equivalents of the "blocking nucleic acid" limitation. However, the Court determined that the prosecution history reveals that in narrowing the claim to overcome the prior-art rejections, the focus of the patentees' arguments centered on the method of blocking, not on the particular type of nucleic acid that could be used for blocking. Indeed, the "nucleic acid" limitation was never narrowed during prosecution and was not at issue in the office action rejecting the claims, the Examiner Interview Summary Record, or the patentees' remarks accompanying the amendment. Thus, the Court concluded that the Regents met their burden of showing that the amendment did not surrender the equivalent

in question because the narrowing amendment was only tangential to the accused PNA equivalent found in Dako's accused kits—the peptide nucleic acid. Accordingly, the Court remanded this issue for the district court to consider whether Dako's products infringe the '841 patent under the DOE.

In considering the preliminary-injunction denial, the Federal Circuit noted that it already considered the "heterogeneous mixture" claim-construction issue and agreed with the district court's construction of this claim limitation. Thus, it also affirmed the district court's denial of the preliminary injunction based on the failure to show a likelihood of success that Dako's HER2 kit met this limitation of the '479 patent. The Federal Circuit then turned to the remaining issue presented in the preliminary-injunction appeal—the construction of a "morphologically identifiable cell nucleus." The Court noted that this issue need not be reached in order to consider the merits of the preliminary-injunction denial, but decided to consider it in the interest of judicial efficiency, as the issue had been fully briefed and that term would likely be at issue on remand.

The Court determined that the district court erred in its construction of this term. First, the plain language of the claim term "morphologically identifiable cell nucleus" suggests that the nucleus must be identifiable by form or structure, and does not indicate that a full set of chromosomal DNA must be present in the cell nucleus in contrast to the district court's construction of this term as "a single cell nucleus that contains the full complement of chromosomal DNA." Dako did not dispute that the word "morphological" generally refers to form or structure, not to identity of chromosomal DNA content. Also, the prosecution history of the '841 patent revealed that the term "morphologically identifiable cell nucleus" was added to the claim to clarify that the target chromosomal DNA remained in a natural biological structure during in situ hybridization. The Court stated that nowhere in the prosecution history, or the specification for that matter, did it find any indication that the "morphologically identifiable" language was added to impose a requirement that the cell nucleus must retain its full complement of chromosomal DNA. Thus, the Court held that the proper construction of "morphologically identifiable cell nucleus" is one that is capable of being identified by its form or structure.

Judge Prost dissented from the Court's holding that prosecution history estoppel did not apply to the term "blocking nucleic acid." Judge Prost stated that this conclusion was contrary to the Court's precedent and to the proper application of prosecution history estoppel, as set forth by the Supreme Court. In her view, the fact that narrowing the claim to a method of blocking with a "blocking nucleic acid" may not have been necessary to distinguish over the prior art did not change the analysis. Here, the amendment narrowed the scope of the invention to a method of disabling repetitive sequences using "blocking nucleic acids" and the parties stipulated that "blocking nucleic acid" means "fragments of repetitive-sequence-enriched DNA or RNA." Therefore, in Judge Prost's view, the patentee surrendered methods of blocking other than with DNA or RNA. Judge Prost stated that it is irrelevant to the determination of the scope of the surrendered territory that to overcome the prior-art references, the patentee did not need to amend the claims to the scope it used but instead could have amended the claims to a method of disabling repetitive sequences by blocking.

Judge Prost further concluded that the tangential exception of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739-40 (2002), the only one raised before the district court and on appeal, did not save the patentees from a prosecution history estoppel bar. Focusing on the question of whether the amendment was peripheral or not directly relevant to the alleged equivalent, Judge Prost concluded that the amendment limited the claims to a method of disabling repetitive sequences by blocking with DNA or RNA, which are nucleic-acid sequences. The accused Dako kit equivalent (PNA), however, functions to do exactly that, i.e., to disable repetitive sequences. Thus, the purpose for the amendment was directly related to the equivalent—they both related to means for disabling repetitive sequences. Based on this analysis, Judge Prost concluded that the Regents should be estopped from asserting that PNA is an equivalent to "blocking nucleic acid" in the context of the '841 patent.

B. *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358 (Fed. Cir. 2008)

Claim Term "and" Meant "or," and Invention Was Not Obvious Because Infringer Was Relying on Hindsight to Show Obviousness

In Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc., the Federal Circuit held that the district court correctly construed the claim term "and" in U.S. Patent No. 4,513,006 ("the '006 patent") owned by Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil"); affirmed its dismissal of Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc.'s (collectively "Mylan") invalidity defenses based on obviousness, inequitable conduct, and nonenablement; and found that the district court had not erred in resetting the effective date of Mylan's Abreviated New Drug Application ("ANDA").

The '006 patent claims the anticonvulsive drug topiramate, an epilepsy drug with annual sales exceeding $1 billion. Mylan filed an ANDA with the U.S. Food and Drug Administration ("FDA") with a paragraph IV certification, asserting that the '006 patent was invalid and not infringed. As a result, Ortho-McNeil filed this lawsuit against Mylan. After a *Markman* hearing, the district court rejected Mylan's position that claim 1 of the '006 patent did not cover topiramate. In light of this construction, Mylan stipulated that its generic topiramate infringed claim 1 and other claims of the '006 patent. On summary judgement, the district court also ruled against Mylan's affirmative defenses of unenforceability due to inequitable conduct and invalidity based on obviousness and nonenablement. In addition, the district court reset the effective date of Mylan's ANDA. Mylan appealed.

On appeal, Mylan argued that the district court erred in construing the word "and" to mean "or" in claim 1 of the '006 patent and that, under the proper construction, the claim did not cover topiramate. The Federal Circuit disagreed. The Court explained that as used in the claim, "and" conjoined mutually exclusive possibilities and that the claim did not use "and" in isolation but in a larger context that clarified its meaning. The Court noted that construing claim 1 to

require a conjunctive meaning of "and" would render several dependent claims meaningless and that the specification also supported the district court's reading of "and." It added that dictionary definitions also supported the district court's reading of the term. Accordingly, the Court held that the district court properly construed the claim.

The Court next considered Mylan's inequitable-conduct defense. Mylan accused Ortho-McNeil of committing inequitable conduct because it disclosed certain references ("Kochetkov") to the U.S. Patent and Trademark Office ("PTO"), but failed to disclose the results of nonpublic tests it conducted on Kochetkov compounds. Mylan argued that Ortho-McNeil's statements about the Kochetkov references during prosecution were inconsistent with Ortho-McNeil's own information about the compounds. The Federal Circuit disagreed. The Court reviewed the statements in the prosecution history and noted that Ortho-McNeil did not make any misrepresentations to the PTO. Accordingly, it held that the district court was correct in dismissing Mylan's inequitable-conduct defense.

Regarding the obviousness defense, Mylan, relying on *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007), argued that a person of ordinary skill in the art faced with finding a diabetes drug (as the inventor was) would necessarily design an FBPase inhibitor. Disagreeing with Mylan, the Federal Circuit noted that the record showed that even if an ordinarily skilled artisan sought an FBPase inhibitor, that person would not have chosen topiramate. The Court determined that this invention, contrary to Mylan's characterization, did not present a finite (and small in the context of the art) number of options easily traversed to show obviousness. It observed that Mylan's expert simply retraced the path of the inventor with hindsight, discounted the number and complexity of the alternatives, and concluded that the invention of topiramate was obvious.

The Court explained that after *KSR*, a flexible teaching, suggestion, or motivation ("TSM") test remains the primary guarantor against a nonstatutory hindsight analysis, which is what occurred in this case. It reasoned that "[t]he TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence — teachings, suggestions (a tellingly broad term), or motivations (an equally broad term) — that arise before the time of invention as the statute requires." The Court reiterated that those teachings, suggestions, or motivation need not always be written references, but may be found within the knowledge and creativity of ordinary skilled artisans. The Court determined that here, the record amply supported the district court's finding of nonobviousness, which included consideration of objective criteria showing nonobviousness. Accordingly, the Court affirmed the district court's dismissal of Mylan's obviousness defense. The Court also rejected Mylan's argument that claims 6-8 were not enabled because the drug's effective amount was unclear and its determination would require undue experimentation. In so doing, the Court noted that the disclosure adequately enabled the claims and that even if clinical trials informed the effective amount, the record did not show that extensive or undue tests would be required to practice the invention. It thus concluded that the district court was correct in summarily dismissing Mylan's nonenablement defense.

Finally, the Federal Circuit turned to and affirmed the district court's decision to reset the effective date of Mylan's ANDA. The Court explained that when a generic manufacturer files an ANDA with a paragraph IV certification, the Hatch-Waxman Act grants the brand name pharmaceutical manufacturer a thirty-month stay of the approval of that

ANDA within which to litigate the case. At the expiration of the thirty months, the ANDA is automatically approved unless the court grants a preliminary injunction or finds infringement. Because neither of those two events occurred before expiration of thirty months, the U.S. Food and Drug Administration approved Mylan's ANDA by operation of law. Therefore, after determining infringement, the district court reset the effective date of approval pursuant to 35 U.S.C. § 271(e)(4)(A), which provides that "[f]or an act of infringement…, the court shall order the effective date of any approval of the drug…involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed." The Federal Circuit explained that although the statute does not expressly reset the effective date when the thirty-month stay expires before the patent is found to be infringed or a preliminary injunction granted, the statute, as informed by its legislative history, supported the district court's action of resetting the effective date. The Court noted further that 21 U.S.C. § 355(j)(5)(B)(iii), which lays out two measures for delaying an ANDA's approval, did not limit a court's authority to reset the approval date. Accordingly, the Federal Circuit concluded that the district court was correct in resetting the effective date of Mylan's ANDA.

C. *Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d 1304 (Fed. Cir. 2008)

Rewriting Dependent Claims into Independent Form Resulted in a Narrowing Amendment Leading to Prosecution History Estoppel and a Bar to DOE

In *Honeywell International, Inc. v. Hamilton Sundstrand Corp.*, the Federal Circuit affirmed the district court's judgment that the patentee was barred from asserting the doctrine of equivalents ("DOE"). The Court held that the patentee could not show that the alleged equivalent was unforeseeable at the time of the narrowing amendment or that the narrowing amendment bore no more than a tangential relation to the alleged equivalent.

Honeywell International, Inc. and Honeywell Intellectual Properties, Inc. (collectively "Honeywell") brought suit against Hamilton Sundstrand Corporation ("Sundstrand") for infringement of certain claims of U.S. Patent Nos. 4,380,893 and 4,428,194. These patents claim technology to control airflow surge in auxiliary power units ("APUs"). An APU is a gas turbine engine that generates electricity for an aircraft and includes a load compressor to supply compressed air for starting the aircraft's main engines and for controlling the cabin's environment during flight. APUs must be able to control against surges in flight. Honeywell's patents claim a more efficient APU surge-control system utilizing adjustable inlet guide vanes ("IGVs"). During prosecution, the independent claims had no reference to IGVs for use in surge-control systems. The independent claims were cancelled in light of prior art and the dependent claims that recited IGVs were rewritten into independent claims. Sundstrand manufactures an APU device with a surge-control system that overcomes a phenomenon at high flow levels known as the double-solution problem by using, in part, IGVs.

A jury found that Sundstrand infringed the Honeywell patents under the DOE and awarded damages to Honeywell. The district court denied Sundstrand's motions for judgement as matter of law and a new trial. Both parties appealed. The Federal Circuit held that Honeywell's act of rewriting dependent claims into independent form coupled with the cancellation of the original independent claims created a presumption of prosecution history estoppel. The Court vacated and remanded for a determination of whether Honeywell could rebut the presumption. On remand, the district court held a two-day bench trial to determine whether prosecution history estoppel barred Honeywell from asserting the DOE. The district court held that Honeywell could not rebut the presumption of surrender by demonstrating that the alleged equivalent was not foreseeable at the time of the narrowing amendment or that the rationale underlying the narrowing amendment bore more than a tangential relation to the equivalent in question. Honeywell appealed from these two determinations and from the district court's rulings with respect to whether damages should be limited and whether the evidence was sufficient to support the jury's infringement verdict.

On appeal, the Federal Circuit agreed with the district court's interpretation that the narrow equivalent proposed by Honeywell was foreseeable and, thus, precluded by estoppel principles. The Court reiterated that the goal of the principle of foreseeability is to "ensure that the claims continue to define patent scope in all foreseeable circumstances, while protecting patent owners against insubstantial variations from [the] claimed element in unforeseeable circumstances." In evaluating whether Honeywell could overcome the presumption of surrender, the Court assumed that Honeywell's proposed articulation of the equivalent element was correct. The Court examined whether the use of IGV position to detect flow was later-developed technology and, thus, unforeseeable at the time of the amendments. The Court noted that foreseeability only requires that one of ordinary skill in the art would have reasonably foreseen the proposed equivalent at the pertinent time.

The Court found that Sundstrand developed its equivalent well after Honeywell's amendments, but stated that the mere temporal relationship of the equivalent to the patent acquisition and amendment process did not make the equivalent unforeseeable. The Court commented that the evidence suggested that the IGV solution may have been foreseeable. The Court acknowledged Honeywell's contention that during the relevant time frame, surge-control systems did not use IGV position to ascertain the existence of flows for surge control. However, the Court found that it was known that the control of surge was important, that systems had been developed for that purpose, and that IGVs were routinely used in surge-control systems and affected the air-flow rate. The Court observed that the record supported the district court's finding that a person of ordinary skill in the art would have known of the use of IGV position to distinguish between flows to resolve the double-solution problem. It concluded that Honeywell could have foreseen and included the alleged equivalent in the claims when they were amended. Accordingly, it agreed with the district court that Honeywell did not rebut the presumption of surrender with evidence of unforeseeability.

The Court also rejected Honeywell's procedural challenges to the district court's foreseeability conclusion, finding no fatal error in the district court's refusal to estop Sundstrand from reversing its prior position that its accused product and its particular use of IGV position was unique (and perhaps unforeseeable). The Court stated that judicial estoppel only applies when the party had been successful and had prevailed based on the former position. Here, noted the

Court, the record did not link Sundstrand's success on any issues based on its former position. In sum, the Court found no error in the district court's foreseeability conclusion.

On the tangential-relation prong, the Court found that Honeywell was not able to rebut the presumption that the patentee's objectively apparent reason for the narrowing amendment bore more than a tangential relation to the equivalent in question. In so finding, the Court noted that the tangential-relation criterion for overcoming the *Festo* presumption is very narrow and focuses on the "patentee's objectively apparent reason for the narrowing amendment." It explained that to rebut the estoppel presumption with tangentiality, a patentee must show that the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent. The Court looked to the context around the examiner's statement that the dependent claims would be allowed if rewritten into independent form. It noted that the original independent claims were rejected as obvious in light of the prior art and that the dependent claims were then rewritten into independent form and incorporated the limitations of the rejected independent claims. Thus, the Court found the key to the tangential-relation inquiry was the content of the original dependent claims, which included the IGV limitation. Accordingly, the Court found that the IGV limitation was added to the claimed invention and that because the alleged equivalent focused on the IGV limitation, the amendment "bore a direct, not merely tangential, relation to the equivalent."

Therefore, the Court concluded that tangentiality did not help Honeywell to overcome the presumption of surrender.

Finally, because Honeywell was not able to rebut the prosecution history estoppel presumption, the Court dismissed as moot Honeywell's challenges to the district court's ruling with respect to whether damages should be limited and whether the evidence was sufficient to support the jury's infringement verdict.

Judge Newman dissented. She disagreed with the application of the "new presumption of surrender to all equivalents of the claim elements and limitations that originated in dependent claims that were never amended and that were not the subject of prosecution history estoppel." On the issue of foreseeability, she stated that while the prior art showed that the problem was not new, recognition of the problem did not render the solution foreseeable if the solution was discovered a decade later. According to her, presenting claims of varying scope is not a narrowing amendment or argument and that the U.S. Patent and Trademark Office encourages use of dependent claims through lower fees because it facilitates examination. This protocol, she noted, has no relevance to whether a claim element is amended or narrowed or argued during prosecution, and should not be deemed to raise the *Festo* presumption.

Regarding the tangential-relation factor, Judge Newman stated that there was no indication in the prosecution history of any relationship between Honeywell's cancellation of the independent claim and the alleged equivalent of Sundstrand's apparatus or method. She explained that the tangential criterion related to why an accused amendment was made, and it did not become irrebuttable simply when the accused equivalent concerned the same element that was added by amendment. She stated that the question was "whether the subject matter of the accused equivalent was relinquished by the patentee during prosecution" and felt that it should be answered on its facts, not by converting it into a complete bar.

D. *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334 (Fed. Cir. 2008)

Intent to Deceive Was Sufficient to Establish Inequitable Conduct

In *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, the Federal Circuit affirmed the district court's finding of inequitable conduct before the U.S. Patent and Trademark Office ("PTO") and unenforceability of U.S. Patent Nos. 5,389,618 ("the '618 patent") and RE 38,743 ("the '743 patent").

Aventis Pharma S.A. ("Aventis") is the owner of both patents at issue; the '618 patent was surrendered upon the issuance of the '743 patent. The patents are directed to a composition comprising low molecular weight heparins ("LMWHs"). According to the '618 patent specification, there are several advantages of the claimed LMWHs as compared to heparin, including that they exhibit a longer half-life.

During prosecution of the '618 patent, the examiner rejected the claims under 35 U.S.C. §§ 102(b) and 103 over several references, including European Patent No. 40,144 ("EP '144"). The rejection was based on the prior-art teachings of sulfated heparinic admixtures within the molecular weight ("MW") range of the claims that were considered by the examiner to be inherently the same as the claimed admixtures. The examiner stated that because the prior art teaches a product that is "*identical or nearly identical*" to the claimed invention, it is "incumbent upon the Applicant to convincingly demonstrate that the claimed product provides some *unexpected or unobvious property* not demonstrated by the prior art products."

In response, Aventis, through its outside counsel, independently addressed the §§ 102 and 103 rejections. With respect to § 102, Aventis argued that EP '144 did not expressly state that the mixture contains two types of polysaccharides with the claimed MWs or MW ratio. Additionally, Aventis pointed to Example 6 of the '618 patent, which was prepared with the help of Dr. Uzan, a noninventor, in which the claimed invention was compared to EP '144. Based on the Example, Aventis argued that the claimed LMWHs exhibited a significantly longer half-life than formulations prepared in accordance with EP '144, and that evidence of a difference in a property (i.e., half-life) serves as evidence of a difference in structure. With respect to § 103, Aventis argued that EP '144 did not suggest, to a person of ordinary skill in the art, the specific modifications to the EP '144 product required to attain the particular combination of claimed structural elements. The examiner maintained the §§ 102 and 103 rejections.

Aventis subsequently amended its claim and submitted a declaration from Dr. Uzan ("first Uzan declaration") in which he (1) noted that the half-life of the claimed formulation was greater than 4½ hours 45% of the time, as compared to EP '144, which achieved such a half-life only 17% of the time; (2) remarked "[t]his represents an increase in 250% in the half life and is very significant because it enables the same effect to be achieved with lower dosages"; and (3) analyzed the MW of the oligosaccharide chains of the EP '144 formulations, concluding that they were clearly outside of the scope of the claimed invention. With respect to § 102, Aventis argued that the EP '144 compounds were

not inherently the same as the claimed compounds because of the difference in half-life and because compounds prepared in accordance with EP '144 fall outside of the scope of the claims. With respect to § 103, Aventis argued that the prior art did not exhibit the unexpected properties of the claimed combination of MW chains.

In a third office action, the examiner affirmatively withdrew several rejections, but maintained the § 103 rejection based on EP '144. The examiner continued to require that the applicant demonstrate some "unexpected or unobvious property," but now referred to the prior art as teaching a product "which is nearly identical to that claimed." Finding a lack of evidence on unexpected results and statistically significant differences in half-lives, the examiner maintained the rejection.

In response, Aventis submitted another declaration from Dr. Uzan ("second Uzan declaration"), which included five tables comprising the raw data from the half-life comparisons and results showing a statistically significant difference in half-life. The table indicated that the dosage of the claimed compound was 40 mg, but did not indicate the dosage of the EP '144 compound. Aventis asserted that the second Uzan declaration demonstrated statistically significant differences in half-life and, therefore, that the claimed compounds and prior art were unexpectedly different in properties. The application was subsequently allowed.

Amphastar Pharmaceuticals, Inc. ("Amphastar") and Teva Pharmaceuticals USA, Inc. ("Teva") each filed an ANDA to obtain approval to market a generic version of Lovenox®, the Abbreviated New Drug Applications containing a paragraph IV certification challenging the listed patents. Aventis sued both Amphastar and Teva in the district court. Amphastar filed a motion for summary judgement ("SJ") on its affirmative defense and counterclaim that the '618 patent was unenforceable due to inequitable conduct because Dr. Uzan failed to disclose that the half-life comparisons were made using different doses. The district court found Aventis's representation regarding improved half-life to be material to patentability because Aventis referred to it at least four times during prosecution and the examiner ultimately allowed the application after Aventis's representation regarding the statistical significance of the data. The district court found a strong inference of intent to deceive because of its conclusion that there was no credible explanation for using different doses and because a comparison at the same dose showed little difference in half-life. After weighing the evidence of materiality and intent, the district court granted SJ against Aventis and held the '618 patent unenforceable.

One day prior to issuance of the district court's order, Aventis surrendered the '618 patent to the PTO pursuant to reissue proceedings in the '743 patent application. The district court subsequently granted Aventis's motion to substitute the '743 patent for the '618 patent and amended its earlier holding to apply to the '743 patent, based on the well-settled principle that a reissue proceeding cannot rehabilitate a patent held to be unenforceable due to inequitable conduct.

On appeal for the first time, the Federal Circuit held that there was no genuine issue of material fact that Dr. Uzan failed to disclose that the comparison was made using different doses and that such failure prevented the examiner from considering information important to patentability and constituted a failure to disclose material information.

The Federal Circuit, however, found that the district court erred in finding intent to deceive on SJ, because the different-dose comparison may have been reasonable and the failure to disclose may have been due purely to inadvertence. The Court thus remanded on that issue.

Following remand, the district court held a bench trial on the issue of intent and ultimately rejected each rationale for the nondisclosure. Based on the totality of the facts and circumstances, the district court concluded that but for Dr. Uzan's intentional omissions, the probability was high that the '618 patent would not have issued, even though the PTO issued the '743 reissue patent without any reliance on the half-life comparison. Thus, the district court held the '743 patent unenforceable.

On appeal for a second time, Aventis alleged that the district court clearly erred by (1) finding that the central question relating to patentability was compositional differences (i.e., anticipation rather than obviousness) and by concluding that the issue of obviousness "necessarily folds into, and is subsumed, by inherency"; and (2) that the purpose of Dr. Uzan's comparisons was to show differences in composition rather than properties.

Addressing Aventis's first point, the majority of the Federal Circuit panel noted that Aventis appeared to ask the Court to revisit its materiality findings, but because materiality and intent to deceive are necessarily intertwined, the panel majority addressed the merits of the argument with respect to deceptive intent. Although the district court erroneously suggested that obviousness is subsumed by inherency, the panel majority concluded that the inherency statement was merely a recognition that the properties of a compound are inherent in its composition and, therefore, a difference in property could demonstrate a difference in composition. Thus, the panel majority did not find clear error in the district court's ultimate conclusion.

Second, the panel majority addressed Aventis's argument that the MW analysis in the first Uzan declaration was directed to anticipation, whereas the half-life comparisons were directed to obviousness. The panel majority found no clear error in the district court's determination that the half-life comparisons were, "at least in part, intended to show compositional differences" and, thus, were directed to both rejections: (1) nothing in Example 6 of the specification indicated that it was designed to show only nonobviousness and not lack of identity, and (2) the first Uzan declaration did not clearly delineate between evidence intended to address § 102 and evidence intended to address § 103. Thus, because the panel majority concluded that the comparisons were intended to address both rejections, to the extent they were directed to anticipation, the failure to disclose the dosage information evidenced intent to deceive.

Additionally, even though the panel majority conceded that the district court may have erred in concluding that the anticipation rejection was still pending in the third office action, as Aventis asserted, the panel majority did not agree that such error was critical to the court's ultimate finding of intent to deceive because the panel majority held that the evidence submitted prior to the third office action, namely, Example 6 and the first Uzan declaration, evidenced intent to deceive.

The panel majority then addressed a further argument it attributed to Aventis: that the district court erred by excluding

evidence that comparisons of half-lives at different doses were the standard practice in the LMWH field; specifically, that those in the field used the "clinically relevant dose" for comparisons, and that is why Dr. Uzan selected the 40 mg dose for the patented compound and the 60 mg dose for the EP '144 compound. The panel majority found no abuse of discretion in the district court's exclusion of the evidence.

First, evidence of industry practice in that regard would only be relevant if the half-life comparisons were only directed to obviousness (which the panel majority found they were not), because Aventis conceded that half-life comparisons must be at the same dose to show compositional differences.

Second, the district court did not accept that Dr. Uzan selected the clinically relevant dose for the comparisons. While the 40 mg dose was clinically relevant for prevention of deep venous thrombosis ("DVT") during high-risk orthopedic surgery, neither the claims nor the specification were limited to such use and there was no dispute that the claimed invention could be used at different doses for different indications.

Additionally, there was significantly less of a difference in half-lives when any other dose (20 mg, 60 mg, or 80 mg) of the patented compound was compared to the 60 mg dose of EP '144, and, according to the panel majority, there was no evidence corroborating Dr. Uzan's testimony that he selected the 40 mg dose for its efficacy in preventing DVT. Thus, the panel majority concluded that evidence of industry practice would not have impacted the district court's credibility determination with respect to whether Dr. Uzan intended to use the clinically relevant doses and, therefore, the court did not abuse its discretion in excluding that evidence.

The panel majority then addressed several additional arguments by Aventis focused on whether Dr. Uzan actually had deceptive intent. First, the panel majority rejected an argument that Dr. Uzan believed he informed the examiner that he was comparing half-lives at different doses in the following statement in his first declaration: "[T]his represents an increase in 250% in the half life and is very significant because it enables the same effect to be achieved with lower dosages." The panel majority reiterated that during the first appeal, the Court had concluded that there was no genuine issue of material fact that Dr. Uzan's statement had not disclosed that the comparison was made between different doses, but it had left open the possibility that Dr. Uzan *intended* his statement to disclose that fact. The panel majority asserted that on remand, the district court heard Dr. Uzan's testimony and determined that it did not outweigh the cumulative evidence evincing an intent to deceive. Thus, the panel majority ruled that the district court did not commit clear error.

Second, the panel majority rejected Aventis's assertion that Dr. Uzan disclosed the dosage information for the patented compound to the examiner in Example 6, and in the second Uzan declaration by including the raw half-life data. Even if the data at other doses were disclosed, the panel majority noted, the disclosure was made in a very misleading way, and the district court did not clearly err in finding that the prior-art dosage was not disclosed.

Finally, the panel majority rejected Aventis's contention that the failure to disclose the dosage information was due purely to inadvertence. The panel majority noted that even if other errors during prosecution were made, there is

sufficient evidence of concealment to warrant a determination that the dose information was intentionally withheld. Thus, the district court did not clearly err by concluding that the failure to disclose was not due to mere inadvertence.

In dissent, Judge Rader stated that he did not view the record as showing clear and convincing evidence of intent to deceive the PTO, and that the Federal Circuit's case law restricts a finding of inequitable conduct only to the most extreme cases of fraud and deception. Judge Rader reiterated the view that pleading inequitable conduct as a litigation strategy had become a "plague" and noted that the Federal Court's *Kingsdown* decision was intended to reduce abuse of inequitable conduct. After discussing the facts of *Kingsdown*, in which the evidence reflected a material mistake, but not intent to deceive, Judge Rader noted that, more recently, the judicial process has emphasized materiality to the near exclusion of the required level of intent, which has revived the litigation tactic of pleading inequitable conduct.

Specifically, Judge Rader noted that one of the study charts used by Dr. Uzan showing the clinical studies comparing the half-lives of the claimed LMWH invention compared to the prior-art LMWHs did not show the dosage information for the prior-art LMWHs. Judge Rader accepted that Dr. Uzan should have disclosed the dosage information in Example 6, but did not. However, Judge Rader also pointed out that Dr. Uzan did not attempt to conceal data that were otherwise present; rather, he submitted the study chart in unaltered form without adding to the disclosure. Thus, even if negligent, Judge Rader did not believe this omission to reach Kingsdown's level of culpable intent to deceive. Additionally, Judge Rader thought that Dr. Uzan's explanation for why he did not submit the different dose information in the first Uzan declaration "has merit," because it was appropriate to compare drug properties at their clinically relevant dosages. Again, even if negligent, such conduct did not rise to the level of intent to deceive.

Finally, Judge Rader pointed to other factors that he believed distinguished the level of intent from *Kingsdown*: (1) the absence of dosage information in a part of Example 6, as compared to other parts of that Example, made the absence so blatantly obvious, and if Dr. Uzan really intended to deceive the PTO, he would not have made the omission so conspicuous; (2) Dr. Uzan has had a magnificent fifty-year career with Aventis, has published over 350 scientific articles, and has received numerous prestigious awards, including France's highest award for drug discovery, and would be unlikely to risk his reputation and tarnish his career for a single example in the prosecution of a patent in which he was not an inventor; (3) the errors were made by collective action (i.e., two individuals, Dr. Uzan and Aventis's prosecuting attorney), which are less likely to show intent to deceive because the attorney did not know that the dosages were different and Dr. Uzan admitted that he inadvertently neglected to add the dosage data; (4) Dr. Uzan himself revealed the error when he submitted all of the raw data to the PTO in his second declaration, thus correcting the mistake before issuance of the patent (which the examiner still issued); (5) Aventis filed a reissue application for the '618 patent, which reissued with all of the original independent claims, but without Example 6, thus indicating that the half-life data were not even necessary for patentability; and (6) Aventis did not have the opportunity to make the last point to the district court because the PTO granted the reissue a day before the district court granted SJ on the unenforceability of the '618 patent. Thus, because "materiality and intent seem suspect on this record," Judge Rader would reverse.

E. *Eisai Co. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008)

In the Chemical Arts, *KSR*'s Focus on "Identified, Predictable Solutions" May Present a Difficult Hurdle

In *Eisai Co. v. Dr. Reddy's Laboratories, Ltd.*, the Federal Circuit affirmed the district court's findings that Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "Dr. Reddy's") and Teva Pharmaceuticals USA, Inc. ("Teva") infringed Eisai Co., Ltd. and Eisai, Inc.'s (collectively "Eisai") U.S. Patent No. 5,045,552 ("the '552 patent"). The Court also affirmed the district court's finding that the '552 patent is not obvious over the prior art and that Eisai's alleged acts during prosecution did not rise to the level of inequitable conduct.

The '552 patent claims rabeprazole and its salts. Rabeprazole is a proton-pump inhibitor, which suppresses gastric-acid production. Rabeprazole's sodium salt is the active ingredient in Aciphex, a pharmaceutical approved for the treatment of duodenal ulcers, heartburn, and associated disorders.

Dr. Reddy's and Teva each filed Abbreviated New Drug Applications seeking to manufacture a generic version of Aciphex before the expiration of the '552 patent. Eisai sued Dr. Reddy's and Teva. Dr. Reddy's and Teva conceded infringement, but asserted that the '552 patent was unenforceable for inequitable conduct. Moreover, Teva argued that the claims were invalid for obviousness.

On summary judgement, the district court ruled in favor of Eisai on validity and enforceability, and after a bench trial found that Dr. Reddy's and Teva had failed to prove inequitable conduct. Teva appealed the district court's judgment on validity, and Dr. Reddy's and Teva appealed the district court's judgments of enforceability.

Teva asserted obviousness over a combination of three references: a European patent claiming the antiulcerative compound lansoprazole; a U.S. patent claiming the proton-pump inhibitor omeprazole; and an article by Brändström describing a class of antiulcerative compounds having a particular core structure, which is shared by rabeprazole, lansoprazole, and omeprazole.

The Federal Circuit agreed with the district court that the European patent teaches that the fluorinated substituent of lansoprazole provides "a special path to achieving lipophilicity." The Federal Circuit then explained that, under *KSR*, in cases involving new chemical compounds, it was necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound. Thus, the Court stated that "post-*KSR*, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound." Accordingly, the Federal Circuit concluded that the record contained no reasons a skilled artisan would have considered modifying lansoprazole by removing the lipophilicity-conferring fluorinated substituent as an identifiable, predictable solution. The Federal Circuit therefore agreed with the district court that the record did not support a case of obviousness of the '552 patent as a matter of law.

The Federal Circuit then considered the district court's rulings on inequitable conduct. Specifically, Teva and Dr. Reddy's alleged on appeal that Eisai misled the U.S. Patent and Trademark Office ("PTO") in five ways: (1) failing to disclose Eisai's own copending '013 application, which claimed the "ethyl homolog" of rabeprazole; (2) withholding rejections from the '013 application's prosecution that also would have been applicable to the '552 patent's prosecution; (3) failing to disclose the prior-art "Byk Gulden patent" (WO 8602646); (4) submitting a misleading declaration (the "Fujisaki Declaration"); and (5) concealing lansoprazole from the examiner. The district court rejected the last assertion on SJ and the other four after a bench trial.

In considering the failure to disclose the copending '013 application, the Federal Circuit held that while disclosure would have been prudent, it agreed with the district court's finding that the level of materiality of the '013 application was low and that the record is devoid of any real suggestion of intent to deceive the PTO, much less the clear and convincing evidence required to support a finding of inequitable conduct.

In considering the failure to disclose the rejections made in the '013 application prosecution while prosecuting the '552 patent, the district court did not reach materiality because it found insufficient proof of intent to deceive based on the credibility of Eisai's fact witnesses. The Federal Circuit agreed that the facts did not rise to the level of culpability required to establish intent to deceive, or even a level suggesting gross negligence.

Further, the district court rejected Teva's theory that Eisai deliberately "hid the ball" from the PTO by filing separate applications because it would have been "implausibly risky," given that similar applications are usually assigned to the same examiner in the same art unit. Thus, the Federal Circuit held that the district court had ample bases from which to conclude that Eisai's failure to disclose its copending '013 application along with the rejections issued in its prosecution, while not completely forthcoming, did not rise to the level of inequitable conduct.

With respect to the Byk Gulden patent, the Federal Circuit agreed with the district court that the reference was not material as it was cumulative to references already disclosed to the PTO. Further, even if it had been material, the Federal Circuit concluded that the lack of clear and convincing evidence of intent to deceive "would nonetheless have imposed an insurmountable bar to finding inequitable conduct."

The Federal Circuit also rejected the argument that the data presented by Eisai in the Fujisaki Declaration were misleading because the declaration did not discuss the ethyl homolog of rabeprazole. The Court held that Eisai had no obligation to include additional, unnecessary data. Thus, even though the submission to the PTO was highly material to prosecution, "the lack of deceptive intent rendered stillborn yet another allegation of inequitable conduct."

Finally, the Federal Circuit rejected the assertion that Eisai deceptively declined to inform the examiner of a patent application for lansoprazole. The strongest evidence was a vague, subjective statement that was not sufficient to establish materiality, let alone intent. Thus, the Federal Circuit affirmed the district court's determination of enforceability.

F. *In re Swanson*, 540 F.3d 1368 (Fed. Cir. 2008)

Neither Consideration During Prior Litigation Nor Consideration During Initial Examination by the PTO Precluded the Use of a Reference During Reexamination Where It Raised a Substantial New Question of Patentability

In *In re Swanson*, the Federal Circuit affirmed the Board's rejection of claims 22-25 of U.S. Patent No. 5,073,484 ("the '484 patent") in a reexamination hearing. The Court previously affirmed a district court's judgment that some of the claims of the '484 patent were not invalid. Although the prior-art reference had been considered during initial examination and by the Court, the Federal Circuit held that, under the reexamination statute, there was a substantial new question of patentability ("SNQ") regarding whether the prior-art reference anticipated and made obvious the claims that warranted reexamination.

The '484 patent discloses a method of quantitatively analyzing small amounts of biological fluids to detect the presence of a particular substance. During prosecution of the '484 patent, the examiner originally issued a § 103 rejection based on various combinations of prior art, including U.S. Patent No. 4,094,647 ("Deutsch"). The applicant amended the claims, and the '484 patent issued and was assigned to Surmodics, Inc. ("Surmodics"), who exclusively licensed the patent to Abbott Laboratories ("Abbott").

Abbott sued Syntron Bioresearch, Inc. ("Syntron") for infringement of two patents, including the '484 patent. Syntron counterclaimed that the '484 patent was invalid in light of Deutsch. The jury found that the patents were not infringed, and that Syntron had failed to prove by clear and convincing evidence that the claims were invalid. Abbott appealed, and Syntron cross-appealed to the Federal Circuit, which affirmed the judgment of validity on all the asserted claims of the '484 patent.

Syntron then filed a request for an ex parte reexamination of the '484 patent, alleging that there was an SNQ. The examiner granted the request and, on reexamination, rejected several claims of the '484 patent as anticipated or rendered obvious by Deutsch. The Board affirmed the examiner's rejections, and additionally rejected Surmodics's claim that the reexamination was improper as to Deutsch because Deutsch did not raise "a substantial new question of patentability," as required by 35 U.S.C. § 303. Surmodics appealed.

On appeal, the Federal Circuit first looked to the statute and to congressional intent to determine the meaning of "a substantial new question of patentability" as described in § 303. The Court noted that Congress intended reexaminations to provide an important "quality check" on patents that would allow the government to remove defective and erroneously granted patents. To prevent potential harassment of patentees, the U.S. Patent and Trademark Office ("PTO") may only grant a reexamination request if it determines that a "substantial new question of patentability" has been raised. In *In re Portola Packaging Inc.*, 110 F.3d 786 (Fed. Cir. 1997), the Court interpreted the "substantial new question of patentability" requirement to preclude reexamination based on prior art previously

considered by the PTO in relation to the same or broader claims. Congress, however, disagreed with the Federal Circuit's interpretation of § 303 and amended the statute to expressly state that the existence of an SNQ is not precluded by the fact that a patent or printed publication was previously cited by or to the PTO or considered by the PTO.

The Federal Circuit disagreed with Surmodics's argument that the district court's consideration of Deutsch in determination of the validity of the '484 patent precluded the reference from raising an SNQ in subsequent reexamination proceedings. The Court noted that the language of the § 303 amendment discusses references previously cited by or to the PTO or considered by the PTO, and does not discuss or address consideration by courts. The Court also indicated that the legislative history for both the original statute and the amendment suggest that Congress was concerned only with the consideration of issues in prior PTO examinations, not prior civil litigations.

The Court then noted that PTO examination procedures have distinctly different standards and purposes compared to civil litigation. The Court noted that in civil litigation, the presumption of validity must be overcome with clear and convincing evidence that the patent is invalid. Thus, the Court held, a prior holding of validity is not necessarily inconsistent with a subsequent holding of invalidity and is not binding on subsequent litigation or PTO reexaminations.

In PTO examinations and reexaminations, the standard of proof—a preponderance of evidence—is substantially lower than in a civil case, there is no presumption of validity, and claims are construed more broadly. In light of these differences, the Court noted that considering an issue at the district-court level is not equivalent to the PTO having had the opportunity to consider it. The Court held that Congress did not intend a prior court judgment upholding the validity of a claim to prevent the PTO from finding a substantial new question of validity regarding an issue that has never been considered by the PTO. The Court further stated that to hold otherwise would allow a civil litigant's failure to overcome the statutory presumption of validity to thwart Congress's purpose of allowing for a reexamination procedure to correct an examiner's errors, without which the presumption of validity never would have arisen. The Court also held that there was no constitutional violation of the separation of powers when reexamination considers the same issue of validity as a prior district court proceeding. The Court's final judgment and the examiner's rejection are not duplicative—they are differing proceedings with differing evidentiary standards for validity.

The Court also addressed Surmodics's claim that Deutsch did not raise a "substantial new question of patentability" because Deutsch was considered by the PTO during the initial examination as a secondary reference for rejecting various dependent claims as obvious. The Court relied on the amendment to § 303(a), which explicitly mandates that the existence of an SNQ is not precluded by the fact that a patent or printed publication was previously cited by or to the PTO or considered by the PTO. The Court noted that the "amendment removes the focus of the new question inquiry from whether the reference was previously considered, and returns it to whether the particular question of patentability presented by the reference in reexamination was previously evaluated by the PTO." The Court further stated that, as was true before the amendment, an argument already decided by the PTO cannot raise a new question

of patentability.

The Court agreed with the Board of Patent Appeals and Interferences ("BPAI") that the use of Deutsch in the reexamination did create an SNQ. The Court found that in the original examination, Deutsch was relied upon solely as a secondary reference rather than a primary reference that taught or made obvious the specific analytical method claimed. The Court noted that in the original examination, the independent claims were found obvious without any reliance on Deutsch, and nowhere in its decision did the examiner consider the particular analytical method disclosed by Deutsch. Accordingly, the Court held that in light of this extremely limited purpose for which the examiner considered Deutsch in the initial examination, the issue of whether Deutsch anticipated the methods disclosed in the claims of the '484 patent raised an SNQ at reexamination.

Because Surmodics did not argue the merits of the BPAI's rejections on appeal, the Court held those arguments had been waived and affirmed the BPAI's rejection of the claims.

G. *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 545 F.3d 1312 (Fed. Cir. 2008)

Prior-Art Patent's Dosage Guidelines Failed to Provide Sufficient Guidance to Prescribe a Treatment Regimen and Did Not Enable Claimed Invention so as to Anticipate Patent-in-Suit

In *Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc.*, No. 07-1513 (Fed. Cir. Oct. 3, 2008), the Federal Circuit held that the district court correctly determined that U.S. Patent No. 5,236,940 ("the '940 patent") was not an enabling prior-art reference and therefore did not anticipate U.S. Patent No. 5,527,814 ("the '814 patent") owned by Aventis Pharmaceuticals Inc. ("Aventis").

The '814 patent relates to the use of riluzole to treat Lou Gehrig's disease or amyotrophic lateral sclerosis ("ALS"). Impax Laboratories, Inc. ("Impax") filed an Abbreviated New Drug Application seeking approval by the U.S. Food and Drug Administration to market generic riluzole. Impax then sued Aventis seeking a declaratory judgement of noninfringement, invalidity, and unenforceability. With respect to invalidity, Impax alleged that the '940 patent, which disclosed pharmaceutical compositions useful for the treatment of medical conditions associated with the effects of glutamate, enabled the use of riluzole to treat ALS and therefore qualified as enabling prior art.

The district court found that the disclosure of the '940 patent did not put one of ordinary skill in possession of the invention. As such, the district court determined that Impax did not prove that the '814 patent was anticipated by the '940 patent. *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 333 F. Supp. 2d 265 (D. Del. 2004).

On appeal by Impax, the Federal Circuit remanded for a specific determination on whether the '940 patent enabled

a person of ordinary skill in the art to treat ALS with riluzole without regard to the efficacy of such treatment. *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1384 (Fed. Cir. 2006). On remand, the district court concluded that nothing in the '940 patent would direct a skilled artisan to recognize that riluzole could be used to treat ALS, rejecting that "the mere mention of riluzole [was] sufficient to put one skilled in the art in the possession of the claimed invention." *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 496 F. Supp. 2d 428, 432 (D. Del. 2007). In addition, the trial court noted that the dosage guidelines in the disclosure were broad and not specific to any of the hundreds of formulas of the claimed invention or to any of the listed diseases. Finally, the district court also noted the absence of working examples. In view of these findings, the district court found that a skilled artisan would have needed extensive experimentation to link riluzole with the treatment of ALS such that the '940 patent did not enable the claims and thus did not anticipate the '814 patent.

On appeal, the Federal Circuit noted that the '940 patent's dosage guidelines were broad and general without sufficient direction or guidance to prescribe a treatment regimen. The Court also noted the absence of working examples or anything in the '940 patent that would have led a skilled artisan to identify riluzole as a treatment for ALS. Thus, the Court stated that "each component of the claimed invention—identifying riluzole as a treatment for ALS and devising dosage parameters—would require undue experimentation based on the teachings of the '940 patent."

In addition, the Court addressed Impax's argument that the district court's silence on remand regarding the initial presumption of enablement to both claimed and unclaimed material in the '940 patent was reversible legal error. The Court stated that the district court correctly placed the burden of proving nonenablement of the '940 patent on the patentee. The Court stated that the district court did not need to specifically articulate its correct burden-shifting framework. As such, the Court affirmed the district court's holding that the '940 patent was not an enabling prior art reference and did not anticipate the claims of the '814 patent.

H. *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc)

To Be Patentable Under § 101, a Process Must Be Tied to a Machine or Transform an Article into a Different State or Thing

In *In re Bilski*, the Federal Circuit affirmed the decision of the Board of Patent Appeals and Interferences, finding that the method claims in Bernard L. Bilski and Rand A. Warsaw's (collectively "Bilski") patent application were not directed to statutory subject matter under 35 U.S.C. § 101. In doing so, the Court noted that the machine-or-transformation test is the test that should be used to determine whether a process claim is drawn to statutory subject matter. The Court explained that under this test, a claimed process is patentable under § 101 if (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.

Bilski filed a patent application with claims directed to a method for hedging risk in the field of commodities trading. Claim 1 recites "[a] method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of . . . initiating a series of transactions between said commodity provider and consumers of said commodity"; "identifying market participants for said commodity having a counter-risk position to said consumers"; and "initiating a series of transactions between said commodity provider and said market participants."

The examiner rejected Bilski's claims under § 101, reasoning that they were not directed to the "technological arts" and that they were not limited by any specific apparatus. On appeal, the Board held that the examiner erred to the extent he relied on a "technological arts" test because the case law did not support such a test. It noted that the examiner's requirement of a specific apparatus was also erroneous. Nonetheless, the Board sustained the examiner's rejection, finding that the claims were directed to an abstract idea ineligible for patent protection. Bilski appealed.

On appeal, a panel heard oral argument on October 1, 2007. Prior to disposition by the panel, however, the Federal Circuit sua sponte ordered an en banc review. In its order, the Federal Circuit posed five questions for supplemental briefing by the parties and amici:

(1) Whether claim 1 of Bilski's application claims patent-eligible subject matter under 35 U.S.C. § 101?

(2) What standard should govern in determining whether a process is patent-eligible subject matter under § 101?

(3) Whether the claimed subject matter is not patent eligible because it constitutes an abstract idea or mental process; when does a claim that contains both mental and physical steps create patent-eligible subject matter?

(4) Whether a method or process must result in a physical transformation of an article or be tied to a machine to be patent-eligible subject matter under § 101?

(5) Whether it is appropriate to reconsider *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), and *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999), in this case and, if so, whether those cases should be overruled in any respect?

The Federal Circuit began its analysis with the language of the statute, noting that § 101 recites four categories of patent-eligible subject matter: processes, machines, manufactures, and compositions of matter. The Court observed that the issue here involved what the term "process" in § 101 meant, and how to determine whether a given method claim recites a process that complies with § 101. The Court rejected the dictionary definition of the term "process," noting that the Supreme Court has held that the meaning of "process" as used in § 101 is narrower than its ordinary meaning. Specifically, the Court noted that a claim is not a patent-eligible "process" if it claims laws of nature, natural phenomena, or abstract ideas, which the Court characterized as "fundamental principles." The Court explained that a process claim that incorporates a "fundamental principle" may be patented only if it recites a particular application

of the fundamental principle. It added that the "machine-or-transformation test" is the "definitive test" for determining when a process claim encompasses only a particular application of a fundamental principle. According to this test, "[a] claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."

The Court acknowledged arguments by Bilski and several amici that the Supreme Court did not intend the machine-or-transformation test to be the sole test for patentable processes. The Court, however, noted that its reliance on this test as the applicable test for § 101 analysis was "sound." It added that the Supreme Court or the Federal Circuit may need to change the test because "future developments in technology and the sciences may present difficult challenges to the machine-or-transformation test, just as the widespread use of computers and the advent of the Internet has begun to challenge it in the past decade." But, for now, it declined to depart from this test.

The Federal Circuit also reiterated two other important aspects of the Supreme Court's § 101 jurisprudence. First, the Court noted whether a claimed process is novel or nonobvious is irrelevant to the § 101 analysis. And, second, it is inappropriate to determine the patent eligibility of a claim as a whole based on whether selected limitations constitute patent-eligible subject matter.

The Federal Circuit next addressed the issue of whether several other purported articulations of § 101 tests were valid and useful, and rejected all of them. It started with the *Freeman-Walter-Abele* test, which requires determining whether the claim recites an "algorithm" and then determining whether the algorithm is "applied" in any manner to physical elements or process steps. The Court found that this test was inadequate in light of its opinion here and that it had previously recognized that a claim failing that test may nonetheless be patent eligible. Similarly, the Court concluded that the "useful, concrete and tangible result" test associated with *State Street* was inadequate. It explained that "while looking for 'a useful, concrete and tangible result' may in many instances provide useful indications of whether a claim is drawn to a fundamental principle or a practical application of such a principle, that inquiry is insufficient to determine whether a claim is patent-eligible under § 101."

The Court also declined to adopt the "technological arts test" urged by some amici. It reasoned that the contours of such a test would be unclear because the meanings of the terms "technological arts" and "technology" were both ambiguous and ever-changing. The Court likewise rejected calls for categorical exclusions. In so doing, the Court reaffirmed its conclusion in *State Street* that the so-called "business method exception" is unlawful and that "business method claims . . . are 'subject to the same legal requirements for patentability as applied to any other process or method.'" The Court also declined to adopt a test that would allow claims that recite "physical steps" without any connection to a particular machine or apparatus.

Having rejected these other tests, the Federal Circuit provided additional guidance on how to perform the § 101 analysis using the machine-or-transformation test. In so doing, the Court drew heavily from *Parker v. Flook*, 437 U.S. 584 (1978), and *Gottschalk v. Benson*, 409 U.S. 63 (1972). The Court explained that the machine-or-transformation

test is a two-branched inquiry; an applicant may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article. The Court noted that "the use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility," and that "the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity."

As to machine implementation, the Court explained that because Bilski admitted that the language of claim 1 did not limit any process step to any specific machine or apparatus, issues specific to the machine-implementation part of the test were not before it. Thus, the Court left for another day whether and when the recitation of a computer alone would suffice to tie a process claim to a particular machine. With respect to the transformation part of the test, the Court noted that a claimed process is patent eligible if it transforms an article into a different state or thing. It explained that the transformation must be central to the purpose of the claimed process and that the main aspect of the transformation test that required clarification was what sorts of things constitute "articles" such that their transformation is sufficient to impart eligibility under § 101.

The Court observed that it was virtually self-evident that a process for chemical or physical transformation of physical objects or substances is statutory. It noted, however, that "the raw materials of many information-age processes . . . are electronic signals and electronically-manipulated data" and "so-called business methods" that involve the "manipulation of even more abstract constructs such as legal obligations, organizational relationships, and business risks." It questioned which, if any, of these processes qualified as a transformation or reduction of any article into a different state or thing constituting patent-eligible subject matter. It noted that its case law has taken a measured approach to this question and that it saw no reason to expand the boundaries of what constitutes patent-eligible transformations of articles. It explained that "[s]o long as the claimed process is limited to a practical application of a fundamental principle to transform specific data, and the claim is limited to a visual depiction that represents specific physical objects or substances, there is no danger that the scope of the claim would wholly pre-empt all uses of the principle."

Finally, the Court applied the principles mentioned above to Bilski's claims to determine whether those claims satisfied the machine-or-transformation test. The Court held that the claimed process did not transform any article to a different state or thing. It explained that mere manipulations of legal obligations or relationships, business risks, or "other such abstractions" could not meet the transformation prong of the test because they were not and did not represent physical objects or substances. In addition, the Court noted that because Bilski admitted that the claims did not involve a machine or an apparatus, that prong was also not satisfied. Accordingly, the Court concluded that Bilski's claims were not drawn to patent-eligible subject matter under § 101 and affirmed the decision of the Board.

Judge Dyk, joined by Judge Linn, filed a concurring opinion to document statutory support for the majority's opinion, analyzing the history of the patent statute beginning with the Patent Act of 1793 and its English underpinnings. He disagreed with the dissenters that the majority "usurp[ed] the legislative role." Following a review of patents issued

under the English Statute of Monopolies and the legislative histories of the 1793 and 1952 Patent Acts, Judge Dyk noted that "the uniform assumption was that the only processes that were patentable were processes for using or creating manufactures, machines, and compositions of matter." He concluded that the history of § 101 fully supported the majority's holding that Bilski's claims do not recite patentable subject matter.

Judge Newman dissented. She observed that the exclusion of certain process inventions was contrary to the statute and precedent, and ignored the constitutional mandate. She explained that by limiting patent eligibility to those processes that satisfy the machine-or-transformation test, the majority contravened the Supreme Court's refusal to so hold in *Benson* and *Flook*. She also examined the English origins and legislative history of the 1793 Patent Act, concluding that nothing in the statute supported demoting processes to "second class status" behind the other categories of patentable subject matter. To avoid a sure disincentive to innovation-based commerce, Judge Newman concluded that the law permitted patenting any process invention "that is not clearly a 'fundamental truth, law of nature, or abstract idea.'"

Judge Mayer also dissented, arguing that the majority did not go far enough. He explained that the Court should have overruled *State Street* and *AT&T*. According to him, affording patent protection to business methods lacks constitutional and statutory support, and retards innovation. Judge Mayer also listed patents granted since *State Street* ranging "from the somewhat ridiculous to the truly absurd" and noted the "thundering chorus of criticism" that ensued. He urged adopting a "technological arts" test that would exclude from patent eligibility any process that draws its inventive concept from disciplines such as business, law, sociology, or psychology.

Finally, Judge Rader also dissented, arguing that the majority created a new circuitous judge-made test in contravention of Supreme Court precedent. He explained that § 101 broadly grants patent eligibility to "any" process, subject to the other conditions for patentability. According to him, the majority should have merely noted that Bilski is attempting to patent an abstract idea and that nothing more was needed.

I. *In re DBC*, 545 F.3d 1373 (Fed. Cir. 2008)

During Ex Parte Reexamination, Evidence That Sales Were a Direct Result of the Unique Characteristics of the Claimed Invention Was Necessary to Demonstrate Nonobviousness Based on Commercial Success

In *In re DBC*, the Federal Circuit affirmed the rejection by the Board of Patent Appeals and Interferences ("BPAI") of all claims of U.S. Patent No. 6,730,333 ("the '333 patent") as obvious and further held that DBC, LLC ("DBC") waived challenging the appointment of the Administrative Patent Judges ("APJs") who presided over its appeal.

The '333 patent is directed to a nutraceutical composition comprising a mixture of the pulp and pericarp of the mangosteen fruit. The '333 patent defines a nutraceutical as "any compound[] or chemical[] that can provide dietary

or health benefits when consumed by humans or animals." The '333 patent further states that studies have isolated in the mangosteen tree and its fruit chemical constituents known as xanthones, which are biologically active compounds potentially able to provide a variety of health benefits.

The U.S. Patent and Trademark Office ("PTO") granted a third party's request for ex parte reexamination of the '333 patent. During reexamination, the examiner rejected all claims of the '333 patent as obvious over a combination of seven prior-art references, including Japanese Patent No. 11043442 ("JP '442") and Japanese Patent No. 08208501 ("JP '501"). Of the seven references, JP '442 was the only reference not before the original examiner. To provide objective evidence of nonobviousness, DBC submitted three declarations that attempted to demonstrate the success of the commercial embodiment of the patented invention, known commercially as XanGo™ juice. The examiner was not persuaded by DBC's evidence and made the rejection final. DBC appealed the examiner's final rejection to the BPAI, which affirmed the examiner's obviousness rejection of the pending claims.

DBC appealed, contending that the BPAI erred in finding a prima facie case of obviousness based on a substantial new question of patentability ("SNQ"), and that even if the BPAI properly found a prima facie case of obviousness, it erred by concluding that DBC's evidence of commercial success was insufficient to rebut the prima facie case. DBC also argued that even if the BPAI correctly affirmed the examiner's rejection of the claims as obvious, its decision must be vacated because two members of the panel that heard the appeal were unconstitutionally appointed.

On appeal, the Federal Circuit rejected DBC's first argument that the BPAI's decision must be reversed because two members of the panel that heard the appeal were unconstitutionally appointed. Under the theory advanced by DBC, legislation enacted in 2000 delegating the power to appoint APJs to the Director of the PTO instead of the Secretary of Commerce was constitutionally infirm under the Appointments Clause of the U.S. Constitution.

The Court found that DBC waived the issue by failing to raise it before the BPAI, noting that it is well established that a party generally may not challenge an agency decision on a basis that was not presented to the agency. The Court explained that the requirement that a party object to an agency before attacking that agency's action in court serves two primary purposes. First, it gives the agency an opportunity to correct its own mistakes before it is haled into federal court, and thus discourages disregard of the agency's procedures. Second, it promotes judicial efficiency, as claims generally can be resolved much more quickly and economically in proceedings before the agency than in litigation in federal court.

The Federal Circuit, noting that it retains discretion to reach issues raised for the first time on appeal, further determined that this was not an exceptional case that warranted consideration of the Appointments Clause issue despite its tardy presentation. The Court reemphasized that while the issue could have been raised before the BPAI, it was not. The Court also noted that legislation in August 2008 redelegated the power of appointment to the Secretary of Commerce, thereby eliminating the issue of unconstitutional appointments going forward. The Court stated that because Congress's action meant that its decision would not affect cases decided by future panels of the

BPAI, this further argued against exercising discretion to address the issue. Additionally, DBC made no allegation of incompetence or other impropriety regarding the APJs who heard its appeal, and those same APJs were reappointed by the Secretary of Commerce, acting under the new statute. The Court concluded that such circumstances did not warrant the exercise of its discretion to hear DBC's Appointments Clause challenge.

The Federal Circuit next rejected DBC's argument that the Board failed to establish a prima facie case of obviousness based upon an SNQ and that JP '442 was cumulative and nonanalogous art. The Court stated that JP '442 was plainly material to patentability because it teaches a nutraceutical beverage combining fruits and fruit juices and mangosteen rind in the same composition. The Court also noted that JP '442 was not cumulative over JP '501 because, unlike JP '442, JP '501 does not teach that mangosteen rind (or extract) can be made into a composition with fruits or fruit juices to make a nutraceutical composition, only that it can be made into a syrup, solution, or suspension with a carrier. The Court therefore rejected DBC's argument that JP '442 did not raise an SNQ and found that JP '442, together with the other references cited, provided substantial evidence fully supporting the BPAI's finding of a prima facie case of obviousness.

Finally, the Court found that substantial evidence supported the Board's determination that DBC's evidence of commercial success was insufficient to upset the prima facie case of obviousness. Declarations made by officers and employees of XanGo, LLC ("XanGo"), the exclusive licensee of DBC and marketer of XanGo™ juice, were offered in an attempt to show that the juice was made according to the claims of the '333 patent and to demonstrate the commercial success of XanGo™ juice.

The Federal Circuit first agreed with DBC that the BPAI erred by concluding that the evidence failed to show that XanGo™ juice was commensurate with the claims. The Court stated that the Bean declaration submitted by DBC was sufficient to demonstrate that XanGo™ juice fell within the scope of the claims. The Court found that the BPAI also erred in suggesting that the commercial embodiment of the claim must contain both a fruit juice and a vegetable juice, where the claim recites "at least one second juice selected from the group consisting of fruit juice and vegetable juice." The Court stated that DBC need not sell every conceivable embodiment of the claims to rely upon evidence of commercial success, so long as what was sold was within the scope of the claims.

The Court, however, found that evidence of commercial success alone is not sufficient to demonstrate nonobviousness of a claimed invention. Rather, the proponent must offer proof "that the sales were a direct result of the unique characteristics of the claimed invention—as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter." The sales evidence submitted by DBC did not reveal in any way that the driving force behind those sales was the claimed combination. Nor was there any evidence that sales of XanGo™ juice were not merely attributable to the increasing popularity of mangosteen fruit or the effectiveness of the marketing efforts employed. The Court therefore affirmed the BPAI's decision.

J. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075 (Fed. Cir. 2008)

Prior Disclosure of a Racemic Mixture of a Compound Does Not Anticipate or Render Obvious a Claim to an Isolated Enantiomer Having Unpredictable Properties

In *Sanofi-Synthelabo v. Apotex, Inc.*, No. 07-1438 (Fed. Cir. Dec. 12, 2008), the Federal Circuit affirmed the district court's ruling sustaining the validity of U.S. Patent No. 4,847,265 ("the '265 patent") owned by plaintiffs Sanofi-Synthelabo, Sanofi-Synthelabo, Inc., and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership (collectively "Sanofi").

The suit relates to Sanofi's commercial product Plavix®, which is a platelet aggregation inhibiting agent used to reduce thrombotic events such as heart attacks and strokes. The active ingredient in Plavix®, clopidogrel bisulfate, is claimed in the '265 patent. Clopidogrel is the common name for the dextrorotatory enantiomer of methyl alpha-5(4,5,6,7-tetrahydro(3,2-c)thienopyridyl)(2-chlorophenyl)-acetate ("MATTPCA"). Generally, enantiomers are chemical compounds that have the same chemical structure, but differ in their orientation in three-dimensional space. An equal mixture of enantiomers produces what is called a racemate. The dextrorotatory enantiomer of clopidogrel is unique as it possesses all of the desirable biological properties without any of the negative side effects found in the racemic mixture.

Defendants Apotex, Inc. and Apotex Corp. (collectively "Apotex") filed an Abbreviated New Drug Application ("ANDA") seeking approval by the U.S. Food and Drug Administration to sell clopidogrel bisulfate. The ANDA included a paragraph IV certification asserting invalidity of the '265 patent. In response, Sanofi filed suit for infringement and Apotex counterclaimed, alleging the '265 patent was invalid. The district court granted a preliminary injunction, enjoining Apotex's sale of generic clopidogrel bisulfate. The district court later held that the asserted claims of the '265 patent were not invalid, as the prior disclosure of the racemate of clopidogrel did not anticipate or render claim 3 of the '265 patent obvious.

On appeal, the Federal Circuit first addressed Apotex's assertion that claim 3 of the '265 patent was anticipated by U.S. Patent No. 4,529,596 ("the '596 patent") and Canadian Patent No. 1,194,875 ("the '875 patent"). Claim 3 of the '265 patent requires (1) the bisulfate salt of (2) the dextrorotatory enantiomer of (3) MATTPCA (4) to be substantially separated from the levorotatory enantiomer. Apotex conceded that the references did not show any separated enantiomers or describe how to separate them, but argued that such detail is not required because persons of ordinary skill would know the existing techniques for separating enantiomers. Relying on *In re Ruschig*, 343 F.2d 965 (C.C.P.A. 1965), the Court affirmed the district court's determination that the general statements in the '596 and '875 patents were not an anticipatory disclosure of the separated dextrorotatory enantiomer. Specifically, the Court noted that the "knowledge that enantiomers may be separated is not 'anticipation' of a specific enantiomer that has not been separated, identified, and characterized."

Additionally, the Federal Circuit affirmed the district court's finding that the prior-art references did not enable the separation of enantiomers, as they contained no guidance as to how to separate the enantiomers. Apotex argued that the issued patents are entitled to a presumption of enablement, as they carry a presumption of validity. The Court, however, noted that any presumption does not exclude consideration of whether undue experimentation is required, as discussed in *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Noting the known difficulty of separating enantiomers and the unpredictability of their properties, the Court affirmed the holding that the reference patents would not have enabled a person of ordinary skill to obtain clopidogrel substantially separated from the levorotatory enantiomer.

Turning to Apotex's obviousness argument, the Federal Circuit considered whether claim 3 of the '265 patent was rendered obvious by the disclosures in the '596 and '875 patents. The Court found no clear error in the district court's finding that one of skill in the art would not have reasonably predicted that the dextrorotatory enantiomer would provide all of the antiplatelet activity but none of the adverse neurotoxicity. The Court also found no clear error in the district court's extensive findings concerning the difficulty and unpredictability of separating the enantiomers. The Federal Circuit held that these findings undermined Apotex's hindsight argument that the separation of the enantiomers would have been obvious. Finally, the Court found no clear error in the district court's conclusion that whether or not separating the enantiomers would have been obvious to try, the wide range of possible outcomes, relative unlikelihood that the resulting compound would exhibit the maximal increase in antiplatelet aggregation activity, and the absence of neurotoxicity makes the compound nonobvious.

The Federal Circuit also rejected Apotex's argument that the separations would have been obvious based on a regulatory requirement that would have alerted a person to the need to separate enantiomers. The evidence of record indicated that Sanofi began separating the enantiomers in an attempt to address certain side effects of the racemic mixture, and not because of a possible future regulatory requirement. The Court therefore found no clear error in the district court's findings.

Finally, the Court rejected Apotex's assertion that, as in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), claim 3 was obvious as it recited a combination of familiar elements according to known methods, therefore yielding predictable results. Given the extensive evidence of the unpredictable nature of the separation of enantiomers, the Court affirmed that the principles of *KSR* did not control.

XV. Listing of Other Pharmaceutical, Biotech, and Chemical Cases Decided in 2008

A. Novelty - 35 U.S.C. § 102

Date	Case No.	Origin	Case Name	Brief Description
2008-10-07	2008-1029	DCT	*Cohesive Techs., Inc. v. Waters Corp.*	Novelty analysis is separate and distinct from nonobviousness analysis

B. Infringement

Date	Case No.	Origin	Case Name	Brief Description
2008-02-05	2007-1104	DCT	*Monsanto Co. v. David*	Planting seed containing a gene sequence infringes a patent covering that sequence
2008-08-20	2007-1414	DCT	*In re Omeprazole Patent Litig.*	Court upholds findings of infringement and validity for Prilosec® patents
2008-10-02	2007-1530	DCT	*Johns Hopkins Univ. v. Datascope Corp.*	Infringement judgment reversed where expert's testimony did not address claim limitation
2008-12-18	2007-1560	DCT	*Rentrop v. Spectranetics Corp.*	Failure to notify the district court of a change in law constituted a waiver on appeal

C. Written Description, Enablement, Definiteness, and Best Mode - 35 U.S.C. § 112

Date	Case No.	Origin	Case Name	Brief Description
2008-09-08	2007-1267, -1266	DCT	*Carnegie Mellon University v. Hoffman-La Roche Inc.*	A claim to a genus described in functional terms was not supported by the specification's disclosure of species that were not representative of the entire genus

Date	Case No.	Origin	Case Name	Brief Description
2008-10-30	2008-1079	PTO	*In re Alonso*	Insufficient written description under representative number of species test where only one species was identified

D. Inventorship

Date	Case No.	Origin	Case Name	Brief Description
2008-07-16	2008-1075	DCT	*Serdarevic v. Advanced Med. Optics, Inc.*	Inventorship claim was barred by laches, and related unjust-enrichment and fraud claims were barred by statute of limitations

E. Inequitable Conduct

Date	Case No.	Origin	Case Name	Brief Description
2008-01-25	2007-1109	DCT	*Monsanto Co. v. Bayer Bioscience N.V.*	Nondisclosure of notes describing a poster at a conference rendered patent-in-suit and related patents unenforceable
2008-08-25	2007-1448	DCT	*Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*	The elevated standard of proof in the inequitable-conduct context remains paramount

F. Jurisdiction

Date	Case No.	Origin	Case Name	Brief Description
2008-08-15	2007-1524	DCT	*Prasco, LLC v. Medicis Pharm. Corp.*	"Reasonable apprehension of suit" test revived as one of several ways to establish declaratory judgment jurisdiction
2008-09-09	2007-1163	DCT	*Med. Solutions, Inc. v. C Change Surgical LLC*	No personal jurisdiction because display of accused infringing device at a trade show held not to be an infringing "use" in the forum state

G. Prosecution History Estoppel/Doctrine of Equivalents

Date	Case No.	Origin	Case Name	Brief Description
2008-05-06	2007-1512	DCT	*PSN Ill., LLC v. Ivoclar Vivadent, Inc.*	Unasserted or cancelled claims may provide "probative evidence" that an embodiment is not within the scope of an asserted claim
2008-07-09	2008-1021	DCT	*Roche Palo Alto LLC v. Apotex, Inc.*	The equitable scope of a claim under reverse doctrine of equivalents is determined by the specification, prosecution history, and the prior art

H. Reexamination

Date	Case No.	Origin	Case Name	Brief Description
2008-08-19	2008-1130	DCT	*Cooper Techs. Co. v. Dudas*	PTO's interpretation that "original application" as used in the inter partes reexamination statute includes continuation applications filed after November 29, 1999, is reasonable

I. Safe Harbor

Date	Case No.	Origin	Case Name	Brief Description
2008-03-07	2007-1271	DCT	*Pfizer, Inc. v. Teva Pharm. USA, Inc.*	Safe harbor of section 121 applies to divisionals only, not continuations-in-part
2008-08-05	2007-1428	DCT	*Proveris Scientific Corp. v. Innovasystems, Inc.*	Safe harbor provision of 35 U.S.C. § 271(e)(1) does not apply to patented inventions that are not themselves subject to FDA regulation

J. Hatch-Waxman

Date	Case No.	Origin	Case Name	Brief Description
2008-10-15	2008-1097	DCT	*In re Ciprofloxacin Hydrochloride Antitrust Litig.*	Hatch-Waxman reverse-payment settlement is lawful under antitrust laws since anticompetitive effects were within the exclusionary zone of the patent
2008-12-08	2007-1269	DCT	*Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*	Baseless Paragraph IV certification compounded with bad-faith litigation makes an abbreviated new drug application case exceptional under 35 U.S.C. § 285

K. Double Patenting

Date	Case No.	Origin	Case Name	Brief Description
2008-11-13	2007-1450	PTO	*In re Basell Poliolefine Italia, S.P.A.*	Patent properly considered during reexamination results in obviousness-type double-patenting rejection

L. Other

Date	Case No.	Origin	Case Name	Brief Description
2008-01-17	2007-1145	DCT	*Innogenetics, N.V. v. Abbott Laboratories*	Permanent injunction not appropriate where damages award included market entry fee and ongoing royalty, since such an award negates assertion of irreparable harm due to future sales
2008-04-01	2007-1404	DCT	*Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*	An Article III controversy exists where a patent holder unilaterally grants a covenant not to sue to a subsequent abbreviated new drug application filer and the covenant potentially delays that filer's market entry
2008-07-15	2007-1385	DCT	*Jang v. Boston Scientific Corp.*	Ambiguous consent judgment unreviewable and remanded for clarification because the basis for the judgment could not be ascertained
2008-08-18	2007-1297	DCT	*Voda v. Cordis Corp.*	Showing harm to exclusive licensee is insufficient for grant of permanent injunction

Date	Case No.	Origin	Case Name	Brief Description
2008-10-21	2007-1300	DCT	*Abbott Labs. v. Sandoz, Inc.*	The grant of a preliminary injunction is reviewed for clear error

XVI. Overview of 2009 at the Federal Circuit

A. Summary of the Federal Circuit 2009 Decisions in Intellectual Property

Year	Number of Precedential Cases in Intellectual Property	Number of Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts (% of total)	En Banc Decisions (% of total)	En Banc Decisions
2009	112	33 (29%)	2 (1.8%)	*Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348 (Fed. Cir. 2009); and *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009)

B. Summary of the Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts for 2009 from the Federal Circuit

		Origin			PTO		
Year	Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts	Supreme Court/ District Court	International Trade Commission	PTO	Prosecution	Interference	Reexamination
2009	33	0/29	1	4	3	1	0

XVII. Summaries of Cases Decided En Banc and Other Key Decisions from the Federal Circuit in 2009

A. *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348, 91 U.S.P.Q.2d 1898 (Fed. Cir. 2009) (en banc)

En Banc Court Holds That § 271(f) Does Not Apply to Method Patents

In *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, the Federal Circuit held en banc that 35 U.S.C. § 271(f) cannot apply to method or process patents. Additionally, a panel of the Federal Circuit reversed the district court's summary judgement ("SJ") of invalidity, reinstating the jury's verdict of validity, held that inequitable-conduct arguments could not be asserted on remand, affirmed the district court's limit on damages to only those products that actually performed the patented method, and declined to reassign the case to a different judge on remand.

Cardiac Pacemakers, Inc. ("Cardiac") is the exclusive licensee of U.S. Patent No. 4,407,288 ("the '288 patent"), which claims a method of heart stimulation using an implantable heart stimulator capable of detecting heart arrhythmias. Cardiac sued St. Jude Medical, Inc. ("St. Jude") for infringement of the '288 patent, among others. After a jury trial, the jury found the '288 patent valid and enforceable but not infringed, rejecting St. Jude's arguments that it was obvious and unenforceable for inequitable conduct. But the district court granted St. Jude's judgement as a matter of law ("JMOL") on invalidity and also granted a conditional new trial on obviousness and inequitable conduct should the JMOL decision be reversed. The district court also denied Cardiac's JMOL for infringement.

Cardiac appealed, and a panel of the Federal Circuit reversed the district court, holding that the court had exceeded its discretionary authority by granting St. Jude's JMOL and reversing the district court's claim construction of one claim term. The panel remanded the case to the district court for a new trial on infringement and reassessment of damages. During the remanded trial, the district court allowed St. Jude to argue new invalidity and unenforceability defenses. At the conclusion of the remanded trial, the district court granted Cardiac's SJ motion for infringement and held that Cardiac's potential damages included the sale of infringing devices exported from the United States to other countries under 35 U.S.C. § 271(f). But the district court also granted St. Jude's SJ motion for anticipation and limited damages to products that actually performed the method steps. Cardiac and St. Jude both appealed these rulings.

On appeal, a panel of the Federal Circuit found that the district court improperly allowed St. Jude to present invalidity arguments during the remanded trial. Prior Federal Circuit panels had expressly limited the remanded trial to an

assessment of infringement, calculation of any damages, and any directly related new issues. The Court stated that while a changed claim construction may permit new anticipation arguments, the changed term must have been an element missing from the prior art. The Court found that the term at issue was uncontested at trial and never served as a basis for distinguishing the prior art. Thus, the Court reinstated the jury's verdict of nonobviousness because the jury's verdict of validity could not have depended on the erroneous construction of the claim.

The Federal Circuit also found that the district court improperly allowed St. Jude to make inequitable conduct arguments on remand. The Court concluded that St. Jude had either failed to pursue their arguments at trial or failed to appeal the arguments, and had therefore waived them. In addition, the Court found that St. Jude had entered into a stipulation with Cardiac that precluded it from pursuing its remaining viable inequitable-conduct argument. With all of St. Jude's inequitable-conduct arguments either waived or covered by the stipulation, the Court reinstated the jury's verdict of enforceability.

The Court then turned to the district court's rulings on damages. First, the Court affirmed the district court's ruling that damages could only apply to products that actually performed the claimed method, and not to products with the mere capability to practice the method. Cardiac argued that *Stryker Corp. v. Intermedics Orthopedics, Inc.*, 96 F.3d 1409 (Fed. Cir. 1996), indicated that a plaintiff could receive damages on sales of an infringing product that lacked a required element, so long as the element was capable of being supplied. The Federal Circuit disagreed, distinguishing *Stryker* on its facts. The Court stated that in *Stryker*, the plaintiff sought lost profits on a patented apparatus and the entire apparatus was supplied during surgery. In the present case, Cardiac sought royalties on a patented method, and all the elements of the method could not be supplied until a device actually performs all of the steps. Therefore, the Court reasoned, Cardiac could only receive infringement damages on those devices that actually performed the patented method.

Finally, the Court turned to the district court's ruling that § 271(f) applied to method claims, the only issue heard en banc. Although the district court based its decision on *Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co.*, 425 F.3d 1366 (Fed. Cir. 2005), which held that § 271(f) applied to method claims, the Court noted that *Union Carbide* and its predecessors were decided before the Supreme Court examined and gave direction on § 271(f) in *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007). The Court stated that the Supreme Court's decision in *Microsoft* sent a clear message that the territorial limits of patents should not be lightly breached.

First, the Federal Circuit looked to the definition of the word "component," as used in § 271(f). Court stated that "a component of a tangible product, device, or apparatus is a tangible part of the product, device, or apparatus, whereas a component of a method or process is a step in that method or process," and "not the physical components used in performance of the method." The Federal Circuit rejected Cardiac's argument that a component of a process may encompass the apparatus that performs the process. In doing so, the Court pointed to the language of § 271(c), where Congress contrasts a component of a patented machine with a material or apparatus for use in practicing a patented process, to show that Congress clearly believed that a component was separate and distinct from a material

or apparatus for use in practicing a patented process.

Having found that the components of a method are the steps of the method, the Federal Circuit concluded that § 271(f)'s requirement that components be supplied from the United States eliminates method patents from its reach. The Court stated that the word "supply" implies the transfer of a physical object and "[s]upplying an intangible step is thus a physical impossibility." The Court reasoned that the legislative history of § 271(f) supports this conclusion because Congress was focused on closing the loophole, presented by the Supreme Court's decision in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972), that shipping an unassembled patented product abroad for later assembly avoids patent infringement. "The legislative history of Section 271(f) is almost completely devoid of any reference to the protection of method patents and the Supreme Court has advised us that it is Congress's right, not the courts', to extend the statute beyond the *Deepsouth* problem it was designed to fix."

The Federal Circuit also rejected Cardiac's argument that a statement in the legislative history indicated that Congress understood "components" to apply also to method patents. The Court reasoned that a statement by one private proponent of a pending bill in Congress cannot override the clear language of the statute and the context in which it was enacted. In addition, to support its holding that § 271(f) does not apply to method patents, the Court pointed to the presumption against extraterritoriality and the narrow view of § 271(f) taken by the Supreme Court in *Microsoft*. The Court stated that the presumption compelled them not to extend the reach of § 271(f) to method patents.

Finally, the Federal Circuit expressly overruled the decision in *Union Carbide*, as well as any other decisions, that § 271(f) applies to method patents. Because the patent at issue in the present case was a method patent, the Federal Circuit reversed the district court and held that Cardiac could not receive any damages for sales of devices outside the United States.

In her dissent, Judge Newman disagreed with the Court's holding that all process patents fall outside the scope of § 271(f). Judge Newman stated that the text of the statute is not ambiguous, the term "patented invention" applies to all patent-eligible subject matter, and Congress explicitly states a specific statutory class when it intends to single one out. The dissent concluded that because Congress did not single out process patents but used the term "patented invention" in § 271(f), the statute must cover process patents as well as the other statutory classes. The dissent further noted that the original language of § 271(f) expressly listed "a patented machine, manufacture, or composition of matter," but this was changed to "patented invention" in the final version. Citing the statutory construction rule that "[w]here Congress includes limiting language in an earlier version of a bill but deletes it prior to enactment, it may be presumed that the limitation was not intended," Judge Newman concluded that Congress intended § 271(f) to apply to process patents.

Judge Newman then examined how § 271(f) applies to process components. First, she stated that a process may involve both product and process aspects. "It appears that the heart stimulator is supplied from the United States and combined with process steps that are taught from the United States and performed abroad." The dissent noted this

issue was not brought out in the appeal. Next, Judge Newman made an analogy between coinfringement and § 271(f). Judge Newman reasoned that the holding in *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007), that in some cases the practice of steps of a patented method by two parties can be combined, whereby the party that performs earlier steps "supplies" this component to the party that performs the later steps, was "commensurate with the application of § 271(f) to processes that are partly performed in the United States." This precedent, she asserted, does not support a conclusion that it is a physical impossibility to read § 271(f) as applying to processes.

Finally, Judge Newman addressed the sovereignty issue of extraterritoriality. Using the example of a patented process that is practiced so that some steps are performed in the United States and others offshore, she opined that the "purloiner of the patented process may escape liability everywhere," and that the legislators could not have intended to enable avoidance of process patents by this ploy. Judge Newman concluded that for process patents, the majority opinion reopened the loophole exposed by *Deepsouth* and overreached by dumping the statute entirely in an overreaction to the facts of one case.

B. *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009) (en banc)

Product-by-Process Claims Are Limited to the Claimed Process

In *Abbott Laboratories v. Sandoz, Inc.*, and *Lupin Ltd. v. Abbott Laboratories*, the Federal Circuit decided two appeals involving U.S. Patent No. 4,935,507 ("the '507 patent"), owned by Astellas Pharma, Inc. and exclusively licensed to Abbott Laboratories (collectively "Abbott"). One appeal was from the U.S. District Court for the Eastern District of Virginia and the other was from the U.S. District Court for the Northern District of Illinois. The Federal Circuit held that the Eastern District of Virginia correctly construed the claims of the '507 patent and affirmed its partial summary judgement ("SJ") of noninfringement. The Court also affirmed the Northern District of Illinois's denial of a motion for a preliminary injunction, which was based on the Eastern District of Virginia's claim construction.

In the Eastern District of Virginia, Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively "Lupin") sought a declaratory judgement of noninfringement of the '507 patent against Abbott. Lupin had approval from the U.S. Food and Drug Administration ("FDA") to market a generic version of Abbott's Omnicef. Abbott's branded product contains the Crystal A form of crystalline cefdinir as claimed by the '507 patent, whereas Lupin's generic product contains almost exclusively the Crystal B form. The Virginia court construed the claims and granted-in-part Lupin's motion for SJ of noninfringement of claims 1-5. The Virginia court also concluded that claims 2-5 were product-by-process claims and, based on the Federal Circuit's opinion in *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), limited the process terms indicated by the phrase "obtainable by" to the processes and process steps.

In the Northern District of Illinois, Abbott sued several entities, including Sandoz, Inc., Sandoz GmbH, Teva

Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries, Limited (collectively "Sandoz and Teva") for infringement of the '507 patent. Abbott sought a preliminary injunction, and the parties agreed to adopt the Eastern District of Virginia's claim construction for purposes of the motion. The Illinois court denied Abbott's motion based on the Virginia court's claim constructions.

Abbott asserted all five claims of the '507 patent against Lupin, Sandoz, and Teva. Claim 1 of the patent claims "crystalline" cefdinir, defining it by a powder X-ray diffraction ("PXRD") pattern of seven angles that are specified in the claim. In contrast, claims 2-5 claim crystalline cefdinir, without any peak limitations, but with descriptions of processes used to obtain the crystalline cefdinir.

On appeal from the Eastern District of Virginia's decision, Abbott challenged only the district court's construction of the terms "crystalline" and "obtainable by." The Federal Circuit affirmed the Virginia court's construction of"crystalline" as meaning "Crystal A" "as outlined in the specification." Crystal A was the only embodiment described in the specification. The Court stated that the specification's recitation of Crystal A as the sole embodiment does not alone justify the district court's construction limiting the claim to the single embodiment. But the Court explained that the rest of the intrinsic evidence, including the prosecution history, evinces a clear intention to limit the '507 patent to Crystal A as defined by the specification. While the parties agreed that "crystalline" ordinarily means that the compound/substance exhibits "uniformly arranged molecules or atoms," the intrinsic evidence supported a more specific construction. Given the exclusive focus on Crystal A in the specification and the prosecution history, the Federal Circuit agreed that the term "crystalline" in claims 1-5 of the '507 patent should be limited to "Crystal A."

The Federal Circuit next sua sponte considered en banc the proper interpretation of product-by-process claims in determining infringement. Initially, the Court determined that the Eastern District of Virginia correctly categorized the claims as product-by-process claims. Next, the Court resolved a conflict in two of its prior decisions: *Atlantic Thermoplastics*, 970 F.2d at 846-47 (holding "process terms in product-by-process claims serve as limitations in determining infringement"), and *Scripps Clinic & Research Foundation v. Genentech, Inc*., 927 F.2d 1565, 1583 (Fed. Cir. 1991) ("[T]he correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims."). In a split decision, the Federal Circuit clarified en banc the scope of product-by-process claims by adopting the rule in *Atlantic Thermoplastics*. Thus, a product-by-process claim is not infringed by products manufactured by processes other than the one claimed. The Court found support for this interpretation of product-by-process claims in the decisions of the Supreme Court, the U.S. Court of Customs and Patent Appeals, and its sister circuits. In addition, the Court relied on the doctrine of equivalents ("DOE") principle that each element contained in a patent claim is deemed material to defining the scope of the patented invention. The Federal Circuit expressly overruled its decision in *Scripps Clinic* to the extent it is inconsistent with the Court's current decision. Thus, the Federal Circuit concluded that the Eastern District of Virginia correctly limited product-by-process claims 2-5 to the claimed process steps in its infringement analysis.

With respect to the construction of the term "obtainable by," the Federal Circuit disagreed with Abbott's plain-language

argument that the term introduces an optional process, even if "obtained by" would introduce limiting process steps. The Court noted that claims 2-5 do not furnish any test by which to identify the cefdinir crystals except that they are the result of their respectively claimed processes. Relying on the specification and the prosecution history, the Court concluded that a patentee's use of the word "obtainable" rather than "obtained by" does not give it the opportunity to escape the limitations of the product-by-process claiming doctrine. The Court stated that claims that include such ambiguous language should be viewed extremely narrowly. Thus, the Court held that the Eastern District of Virginia correctly construed the process limitations beginning with "obtainable by" in claims 2-5 as limiting the asserted claims to products made by those process steps.

The Court then reviewed the Eastern District of Virginia's grant of SJ of noninfringement of claims 2-5, both literally and under the DOE, and of claim 1 under the DOE. The "bulk" of Lupin's generic product is Crystal B, not Crystal A. The Federal Circuit affirmed the district court's grant of SJ as to claims 2-5 because the parties agreed that literal infringement of these claims could not be shown if the product-by-process analysis was performed pursuant to *Atlantic Thermoplastics* because Abbott did not present any evidence that Lupin practiced the claimed process steps. As for equivalency, the Federal Circuit concluded that because "crystalline" in claims 1-5 is limited to the Crystal A form, the bounds of Crystal A equivalents cannot ignore the patentee's choice to distinguish Crystal B from the claimed invention. Thus, the Federal Circuit concluded that Crystal B compounds fall outside the scope, both literally and by equivalents, of claims 1-5 of the '507 patent. In the alternative, the Court noted that because the patentee chose not to claim the Crystal B form even though it was disclosed as an embodiment in the Japanese priority document, the patentee dedicated that embodiment to the public, foreclosing any recapture under the DOE.

The Court dismissed Abbott's argument that Lupin effectively admitted infringement under the DOE when it claimed to the FDA that its generic product was bioequivalent to Abbott's Omnicef product because, while bioequivalence may be relevant to the function prong of the function-way-result equivalency test, bioequivalence and equivalents under the DOE are different inquiries. The Court concluded that because Crystal B is not an equivalent of Crystal A, the Eastern District of Virginia did not err in granting SJ of noninfringement of claims 1-5.

The Court next turned to the Northern District of Illinois's denial of Abbott's preliminary injunction. Sandoz and Teva's generic Omnicef product, like Lupin, also contained primarily the Crystal B form of cefdinir. Based on the Eastern District of Virginia's construction, the Federal Circuit determined that the Illinois court did not abuse its discretion in denying the request for a preliminary injunction because, as properly construed, the '507 patent excludes Crystal B forms of cefdinir. With respect to the alleged presence of small amounts of Crystal A in Sandoz's and Teva's generic products, the Court found that the Illinois court did not abuse its discretion in not being persuaded by this evidence. The Court noted that a district court has broad leeway to discern a "likelihood of success" in a preliminary-injunction analysis. While the Illinois court may have made some misstatements about the law with respect to the alleged presence of small amounts of Crystal A, the Court found that they were harmless because they merely formed an alternative basis for the Illinois court's reasonable assessment of the evidence offered in support of the preliminary-injunction motion.

Judge Newman, with whom Judges Mayer and Lourie joined, dissented from the en banc portion of the majority's decision. Specifically, Judge Newman dissented from the majority's sua sponte procedure for addressing this issue en banc because there was no notice, briefing, or oral argument. In addition, Judge Newman concluded that the majority's en banc ruling does not comport with product claims for new and unobvious products whose structure is not fully known, and for which process parameters are used to aid in defining the product. Judge Newman then discussed prior case law that she believed contradicted the majority's en banc ruling, some of which was not mentioned by the majority. Judge Newman also asserted that the majority misinterpreted precedent that contravened the majority's holding. Judge Newman also disagreed with the panel's construction of "obtainable by."

Judge Lourie also wrote a separate dissent from the en banc decision. While Judge Lourie agreed that there is substantial Supreme Court precedent that holds that product-by-process claims require use of the recited process for there to be infringement, he found that many of those cases applied overly broad language to fact situations involving old products or used vague language that made it difficult to determine whether the products were old or new. According to Judge Lourie, when a product is old, a product-by-process claim should not be interpreted as a claim to the product made by any process because the product is already known in the art and unpatentable per se. Judge Lourie stated, however, that a different situation should apply to today's chemical-biological products than to mechanical products of more than a century ago. In his view, when a product is new and the inventor claims it by a process of preparation, the product-by-process claim should be interpreted as a product claim that can be infringed even when the product is made by means other than the one recited in the claim. In addition, according to Judge Lourie, the results should depend on the exact wording of the claim. For example, the claim language "when made by" might require use of the process in order to infringe, but a claim reading "obtainable by" refers to capability so that it might not require use of the process to infringe. Judge Lourie found that "obtained by," however, is ambiguous. While speculating that today's analytical techniques may obviate the need for product-by-process claims, Judge Lourie noted that product-by-process issues still come before the Court. Accordingly, Judge Lourie stated that he would make a distinction between old products and new products in interpreting product-by-process claims.

C. *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989 (Fed. Cir. 2009)

Positional Isomer Not Obvious Where Compounds Are Unpredictable and General Teaching Would Not Have Provided a Reasonable Expectation of Success

In *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, the Federal Circuit affirmed the district court's decision that The Procter & Gamble Company's ("P&G") claims to a bone resorption inhibitor and related compositions and methods were not invalid for either obviousness or obviousness-type double patenting.

P&G is the owner by assignment of U.S. Patent Nos. 5,583,122 ("the '122 patent") and 4,761,406 ("the '406 patent"). The '122 patent claims a composition and methods relating to a bisphosphonate compound known as risedronate. The '406 patent, which had previously expired, relates to intermittent dosing regiments for treating osteoporosis and lists thirty-six polyphosphonate molecules as treatment candidates. The '406 patent further identifies eight preferred compounds for intermittent dosing, including 2-pyr EHDP, but does not disclose or claim risedronate. Risedronate and 2-pyr EHDP are position isomers, meaning that they have similar structures, except that the functional group is positioned at a different location along the pyridinyl ring.

In August 2004, P&G sued Teva Pharmaceuticals USA, Inc. ("Teva") for infringing various claims of the '122 patent by marketing a generic version of risedronate under the name Actonel®. Following a bench trial, the district court held that the asserted claims of the '122 patent were not invalid as obvious in light of the structural similarities between risedronate and the 2-pyr EHDP identified in the '406 patent. The district court further held that the claims of the '122 patent directed to risedronate were not invalid due to obviousness-type double patenting over the claims of the '406 patent, which covered the structurally similar 2-pyr EHDP.

On appeal, the Federal Circuit addressed whether it would have been obvious to modify 2-pyr EHDP to create risedronate. The Court first considered whether a person of ordinary skill in the art would have had "reason to attempt to make the composition" (i.e., risedronate) and "a reasonable expectation of success in doing so." Noting that such questions often turn on the structural similarities and differences between the claimed compound and the prior-art compound, the Court considered the structure of 2-pyr EHDP and risedronate. As 2-pyr EHDP and risedronate are positional isomers, the Court noted that they differed in three-dimensional shape, charge distribution, and hydrogen-bonding properties. Thus, the Court questioned whether the prior art would have suggested modifying 2-pyr EHDP to create risedronate. Ultimately, the Court noted that the bisphosphonate compounds, such as 2-pyr EHDP and risedronate, were unpredictable. Accordingly, the Court held that there was insufficient motivation for a person of ordinary skill to synthesize and test risedronate.

Addressing various cases that have applied *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Court next observed that, when a person of ordinary skill is faced with a finite number of identified, predictable solutions to a problem and pursues the known options within his or her technical grasp, the resulting discovery is likely the product not of innovation but of ordinary skill and common sense. On the other hand, the Court recognized that in other cases, researchers can only vary all parameters or try each of numerous possible choices until one possibly arrives at a successful result, where the prior art gives either no indication of which parameters are critical or no direction as to which of many possible choices is likely to be successful. In such cases, the Court warned against applying hindsight to render a patent invalid. With respect to risedronate, the Federal Circuit concluded that Teva had presented no credible evidence that a structural modification of 2-pyr EHDP to create risedronate would have been routine. Accordingly, the Federal Circuit concluded that the district court did not clearly err in finding that Teva had not established a prima facie case of obviousness for the '122 patent.

Despite holding that Teva had not presented a prima facie case of obviousness, the Court nevertheless considered P&G's nonobviousness arguments. First, the Court concluded that, even had Teva established a prima facie case of obviousness, P&G had "introduced sufficient evidence of unexpected results to rebut any finding of obviousness." As for secondary considerations, the Court clarified that it was required to "look to the filing date of the challenged invention to assess the presence of a long-felt and unmet need." Thus, because competing products were not available until ten years after the date of invention, those products could not have satisfied the long-felt, unmet need. Accordingly, the Court held that "it was not clear error for the district court to conclude that risedronate met [a long-felt and unmet] need and that secondary considerations supported a finding of non-obviousness."

The Federal Circuit next rejected P&G's argument that the '122 patent could not be held obvious in light of the '406 patent because risedronate was first synthesized before the '406 patent was filed, and the '406 patent was therefore not prior art. The Court concluded that "P&G did not provide adequate corroborating evidence of an earlier invention date for risedronate." Rather, P&G had only provided an unwitnessed laboratory notebook entry detailing the structure of risedronate and how to make it. P&G did not provide any other corroborating evidence. As a result, the Federal Circuit agreed with the district court's conclusion that P&G's evidence was insufficient to establish inventorship. The Court reasoned that a putative inventor "must provide independent corroborating evidence in addition to his own statements and documents." Thus, the '406 patent was available as prior art for the obviousness analysis.

Finally, the Federal Circuit affirmed the district court's holding that P&G's claims at issue were not invalid for obviousness-type double patenting. The Court concluded that Teva "failed to present clear and convincing evidence of overlap between the claims of the two patents." Rather, the Court observed that "while claims 4 and 16 of the '122 patent explicitly claim the risedronate compound, the '406 patent claims an intermittent dosing regimen for the treatment of osteoporosis and claims no new compounds." Thus, the Federal Circuit agreed with the district court that "the claims of the '122 patent are distinct from the claims of the '406 patent."

D. *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009)

The "Obvious to Try" Rationale May Provide the Basis for an Obviousness Rejection After *KSR*

In *In re Kubin*, the Federal Circuit affirmed the rejection by the Board of Patent Appeals and Inerferences ("BPAI") of the claims of U.S. Patent Application Serial No. 09/667,859 ("the '859 application") to Marek Kubin and Raymond Goodwin (collectively "appellants") as obvious under 35 U.S.C. § 103(a).

The '859 application related to the isolation and sequencing of a human gene that encodes a particular domain of a protein. Specifically, the '859 application claimed DNA molecules that encode the protein known as the Natural Killer

Cell Activation Inducing Ligand ("NAIL"). Natural Killer ("NK") cells are a class of cytotoxic lymphocytes that play a major role in fighting tumors and viruses. NAIL is a specific receptor protein that plays a role in activating NK cells.

The specification recited an amino-acid sequence and a polynucleotide sequence of a NAIL polypeptide. The appellants also contended that they had discovered a binding relationship between NAIL and a CD48 protein. The NAIL-CD48 interaction has important biological consequences for NK cells, including an increase in cell cytotoxicity and in production of interferon. Representative claim 73 recited a genus of isolated polynucleotides encoding a protein that binds CD48 and is at least 80% identical to the disclosed amino-acid sequence for the CD48-binding region of NAIL.

The BPAI rejected the claims under 35 U.S.C. § 112 for inadequate written description. The BPAI also rejected the claims as obvious over the combined teachings of U.S. Patent No. 5,688,690 ("Valiante") in view of 2 Joseph Sambrook et al., *Molecular Cloning: A Laboratory Manual* 43-84 (2d ed. 1989) ("Sambrook"). The Board also considered another reference ("Mathew") that it found to be cumulative to Valiante and Sambrook. The appellants appealed the BPAIs decision.

On appeal, the appellants argued that the record did not contain substantial evidence to support the BPAI's conclusion that the appellants' methodology of isolating NAIL DNA was essentially the same as the methodologies and teachings of Valiante and Sambrook. The Federal Circuit noted that any putative difference in the prior art's and appellants' processes does not directly address the obviousness of representative claim 73, which claims a genus of polynucleotides. Nevertheless, the Federal Circuit held that the BPAI had substantial evidence to conclude that the appellants used conventional methods, as taught by Valiante and Sambrook, to isolate a gene sequence for NAIL. The Court also found substantial evidence supports the BPAI's finding that the Mathew reference reinforces the relative ease of deriving the claimed sequence following the teachings of the prior art. The Court further noted that Mathew did not "teach away" from combining its teachings with Valiante.

The Federal Circuit then addressed the BPAI's application of an "obvious to try" rationale in its obviousness rejection. The Court held that such an inquiry was now proper in view of *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). The Federal Circuit then revisited its findings regarding the "obvious to try" doctrine set forth in *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995). In *Deuel*, the Court indicated that "obvious to try" was not an appropriate test for obviousness. The Federal Circuit stated that the Supreme Court in *KSR* had "unambiguously discredited" the holding in *Deuel* with respect to the "obvious to try" doctrine. Given the Supreme Court's admonition against a "formalistic approach to obviousness in this context," the Federal Circuit resurrected its holding in *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

To differentiate between proper and improper applications of "obvious to try," *O'Farrell* set out two classes of situations where "obvious to try" would be erroneously equated with obviousness. In *Kubin*, the Court stated that the first situation where a finding of obviousness would not be established is where an inventor merely throws "metaphorical darts at a board filled with combinatorial prior art possibilities" without providing any guidance or direction as to which

of many possible choices is likely to be successful. According to the *Kubin* decision, the Supreme Court encapsulated the inverse of this proposition, stating that "where a skilled artisan merely pursues 'known options' from a 'finite number of identified, predictable solutions,' obviousness under § 103 arises." The second situation occurs where what was "obvious to try" was to explore a promising new technology, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. The Federal Circuit reasoned that the Supreme Court affirmed the logical inverse of this statement as well, stating that § 103 bars patentability unless "the improvement is more than the predictable use of prior art elements according to their established functions."

The Federal Circuit then found that the prior art disclosed the protein of interest, a motivation to isolate the gene coding for that protein, and illustrative instructions to use a monoclonal antibody specific to the protein for cloning the gene. The Court held that the record showed that a skilled artisan would have had reasonable expectation of success in deriving the claimed invention in light of the teachings of the prior art.

The Court then noted that it declined to limit *KSR* to the "predictable arts" (as opposed to the "unpredictable art" of biotechnology). It held that, at any rate, the record showed that one of skill in that advanced art would find the claimed results predictable. Therefore, the Court held that it cannot, "in the face of *KSR*, cling to formalistic rules for obviousness, customize its legal tests for specific scientific fields in ways that deem entire classes of prior art teachings irrelevant, or discount the significant abilities of artisans of ordinary skill in an advanced area of art."

Here, the Court noted that because the prior art did not explicitly disclose the amino-acid sequence for the NAIL protein or a DNA sequence for the NAIL gene, the invention represented some minor advance in the art. But the Federal Circuit stated that allowing such minor advances to be patentable might stifle further innovation in this field. Thus, the Federal Circuit concluded that the claimed invention was reasonably expected in light of the prior art and was obvious to try.

Having reached its decision on these grounds, the Court did not address the issue of invalidity under 35 U.S.C. § 112, ¶ 1, for lack of written description.

XVIII. Listing of Other Pharmaceutical, Biotech, and Chemical Cases Decided in 2009 from the Federal Circuit

A. Subject Matter - 35 U.S.C. § 101

Date	Case No.	Origin	Case Name	Brief Description
2009-09-17	2008-1403	DCT	*Prometheus Labs., Inc. v. Mayo Collaborative Servs.*	Claims to methods of optimizing therapeutic efficacy are patent-eligible subject matter under 35 U.S.C. § 101

B. Novelty - 35 U.S.C. § 102

Date	Case No.	Origin	Case Name	Brief Description
2009-03-26	2008-1453	PTO	*In re Gleave*	A reference that lists every fifteen-base sense oligodeoxynucleotide in a known nucleic acid sequence anticipates claims to specific antisense sequences having particular properties
2009-03-31	2008-1003	DCT	*Cordis v. Boston Scientific*	The mere fact that a document is distributed without a legal obligation of confidentiality is not in and of itself sufficient to render the document a "printed publication" under 35 U.S.C. § 102(b)
2009-09-14	2008-1306	DCT	*Fresenius USA, Inc. v. Baxter Int'l, Inc.*	Structural and functional analysis of disclosed and prior-art elements are required when means-plus-function limitations are at issue
2009-11-19	2009-1018	DCT	*Iovate Health Scis., Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*	Claims are invalid because an advertisement disclosed the invention in a printed publication before the critical date

C. Obviousness - 35 U.S.C. § 103

Date	Case No.	Origin	Case Name	Brief Description
2009-01-15	2008-1073	DCT	*Boston Scientific Scimed, Inc. v. Cordis Corp.*	Court finds obviousness based on adjacent figures in a single prior art reference
2009-01-30	2008-1247		*Sud-Chemie, Inc. v. Multisorb Techs., Inc.*	The district court erred in granting summary judgment of obviousness and by not taking into account evidence of secondary considerations
2009-04-24	2008-1528	DCT	*Ritchie v. Vast Res., Inc.*	Patent for a device containing an "appreciable amount of an oxide of boron to render it lubricious and resistant to heat, chemicals, electricity and bacterial absorptions" is invalid for obviousness, since patent's reference to "appreciable amounts" of oxide of boron simply claims use of glass that has amount of boron oxide usually found in borosilicate glass
2009-08-05	2008-1282	DCT	*Bayer Schering Pharma AG v. Barr Labs. Inc.*	A drug formulation is obvious if there are a finite number of options for making the formulation

D. Infringement

Date	Case No.	Origin	Case Name	Brief Description
2009-06-01	2008-1240		*Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*	Evidence of copying in a case of direct infringement is relevant only to *Seagate*'s second prong, as it may show what the accused infringer knew or should have known about the likelihood of its infringement
2009-06-09	2008-1228	DCT	*Ecolab, Inc. v. FMC Corp.*	Federal Circuit upholds high standards for prosecution history disclaimer and induced infringement

E. Written Description, Enablement, Definiteness, and Best Mode - 35 U.S.C. § 112

Date	Case No.	Origin	Case Name	Brief Description
2009-03-13	2008-1077	DCT	*ICU Med., Inc. v. Alaris Med. Sys., Inc.*	Federal Circuit affirms award of attorneys' fees for litigation misconduct

Date	Case No.	Origin	Case Name	Brief Description
2009-06-04	2008-1466	DCT	*Agilent Tech., Inc. v. Affymetrix, Inc.*	When a party challenges written-description support for a copied claim in an interference, the claims are construed in light of the originating disclosure
2009-09-25	2008-1594	DCT	*In re '318 Patent Infringement Litig.*	Patent claiming a method of treatment was not enabled where it failed to establish utility

F. Inequitable Conduct

Date	Case No.	Origin	Case Name	Brief Description
2009-03-24	2007-1487	DCT	*ClearValue, Inc. v. Pearl River Polymers, Inc.*	Withholding relevant test results of an accused product is sanctionable misconduct
2009-08-04	2006-1491	DCT	*Exergen Corp. v. Wal-Mart Stores, Inc.*	Allegations of inequitable conduct must set forth particular factual bases to satisfy Rule 9(b)
2009-09-25	2008-1480	DCT	*Astrazeneca Pharm. LP v Teva Pharm. USA, Inc.*	Failure to provide unpublished information about less similar compounds is not inequitable conduct

G. Priority

Date	Case No.	Origin	Case Name	Brief Description
2009-03-18	2008-1447	PTO	*Henkel Corp. v. Proctor & Gamble Co.*	Factual findings supporting award of priority reviewed for substantial evidence

H. Safe Harbor

Date	Case No.	Origin	Case Name	Brief Description
2009-09-15	2009-10260	DCT	*Amgen, Inc. v. F. Hoffman-La Roche, Ltd.*	35 U.S.C. § 121 safe harbor from double patenting rejections does not apply to continuation applications

I. Claim Construction

Date	Case No.	Origin	Case Name	Brief Description
2009-02-02	2007-1340	DCT	*Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*	District court's failure to construe a disputed claim term considered harmless error
2009-05-19	2008-1358	ITC	*Erbe Elektromedizin GmbH v. Int'l Trade Comm'n*	Federal Circuit affirms the ITC's finding of noninfringement after construing claim term in light of specification's figures and dictionary definitions
2009-09-03	2008-1459	DCT	*Martek Biosciences Corp. v. Nutrinova, Inc.*	Where there is no clear disavowal of claim scope, a patentee's express definition of a claim term controls
2009-09-22	2009-1006	DCT	*Edwards Lifesciences LLC. v. Cook, Inc.*	Written description and prosecution history may trump the plain language of the claims and the doctrine of claim differentiation during claim construction

J. Double Patenting

Date	Case No.	Origin	Case Name	Brief Description
2009-04-10	2008-1131	DCT	*Takeda Pharm. v. Doll*	Later developments in the art may inform the "patentably distinct" determination for double patenting but only to the extent that the subsequent developments predate the secondary application that triggers a doublepatenting rejection
2009-05-06	2008-1545	PTO	*In re Fallaux*	Applicant is not entitled to the narrow exception of the two-way test for assessing obviousnesstype double patenting when the PTO is not at fault for the delay that causes the improvement patent to issue before the basic patent

K. Hatch-Waxman

Date	Case No.	Origin	Case Name	Brief Description
2009-02-24	2009-1071	DCT	*Eli Lilly & Co. v. Teva Pharm., USA*	Statutory thirty-month stay may be extended based on a party's uncooperative discovery practices

L. Other

Date	Case No.	Origin	Case Name	Brief Description
2009-05-14	2008-1039	DCT	*Altana Pharma AG v. Teva Pharm. USA, Inc.*	A successful invalidity defense to a preliminary injunction need only raise a substantial question of invalidity, a lower standard of proof than the clear and convincing standard required at trial
2009-06-10	2008-1600	DCT	*Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*	Award of costs attributed to joint discovery remanded for apportionment to prevent double recovery
2009-07-23	2008-1468	DCT	*Univ. of Pittsburgh of the Commonwealth Sys. of Higher Educ. v. Hedrick*	Proof to a scientific certainty not always required for conception

XIX. Overview of 2010 at the Federal Circuit

A. Summary of the Federal Circuit 2010 Decisions in Intellectual Property

Year	Number of Precedential Cases in Intellectual Property	Number of Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts (% of total)	En Banc Decisions (% of total)	En Banc Decisions
2010	137	43 (31%)	3 (2%)	*Hyatt v. Kappos*, 625 F.3d 1320 (Fed. Cir. 2010); *Princo Corp. v. ITC*, 616 F.3d 1318 (Fed. Cir. 2010); and *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010).

B. Summary of the Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts for 2010 from the Federal Circuit

		Origin			PTO		
Year	Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts	Supreme Court/ District Court	International Trade Commission	PTO	Prosecution	Interference	Reexamination
2010	43	1/36	2	4	3	1	0

XX. Summaries of Cases Decided En Banc and Other Key Decisions from the Federal Circuit in 2010

A. *Hyatt v. Kappos*, 625 F.3d 1320 (Fed. Cir. 2010) (en banc)

1. En Banc Court Refuses to Limit New Evidence in § 145 Actions Apart from the Federal Rules of Evidence and Civil Procedure

In *Hyatt v. Kappos*, the Federal Circuit vacated the district court's grant of summary judgement ("SJ") relating to claim unpatentability. The Court remanded for further proceedings that allow the patent applicant, Gilbert P. Hyatt ("Hyatt"), to present new evidence in a 35 U.S.C. § 145 action that he could have submitted during the earlier administrative proceedings. In doing so, the en banc Court reversed the stance of its panel and held that § 145 "imposes no limitation on an applicant's right to introduce new evidence before the district court, apart from the evidentiary limitations applicable to all civil actions contained in the Federal Rules of Evidence and Federal Rules of Civil Procedure."

Hyatt is the sole named inventor of U.S. Patent Application No. 08/471,702, which relates to a computerized display system for processing image information. The patent examiner issued a final office action rejecting all claims on various grounds, including failure to comply with the written-description requirement. Hyatt appealed to the Board of Patent Appeals and Interferences ("BPAI"), which affirmed numerous of the examiner's rejections. The BPAI later dismissed Hyatt's Request for Rehearing. In the proceedings before both the examiner and the BPAI, Hyatt presented evidence in an effort to satisfy the written-description requirement.

Hyatt then filed a civil action in the U.S. District Court for the District of Columbia against the Director of the Patent Office ("Director") pursuant to 35 U.S.C. § 145. The Director moved for SJ that the pending claims were invalid for failure to comply with the written-description requirement. Hyatt opposed the motion and submitted a new written declaration in which he identified portions of the specification that one of skill in the art would understand to describe the limitations challenged by the Director. The district court determined that it could not consider Hyatt's new declaration and granted SJ in favor of the Director. Hyatt appealed.

The Federal Circuit agreed to hear the appeal en banc to determine, among other things: (1) whether there are any limitations on the admissibility of evidence in § 145 proceedings; and (2) what standard of review is applicable in § 145 cases.

The Court first considered the text of § 145, which provides a dissatisfied patent applicant "remedy by civil action" unless appeal has been taken to the Federal Circuit. 35 U.S.C. § 145. According to the Court, this statute provides no indication that a § 145 civil action is somehow different from a customary civil action, nor does it provide any unique rules of evidence. The Court also noted that § 145 makes clear that the civil action is distinct from an appeal, in which the applicant would be limited to the record before the U.S. Patent and Trademark Office ("PTO"). Rather, the Court reasoned, the statute directs that the district court may "adjudge that such applicant is entitled to receive a patent for his invention…as the facts in the case appear."

Next, the Federal Circuit turned to the lengthy legislative history of the statute. In particular, the Court considered § 4915 of the Revised Statutes, a predecessor to 35 U.S.C. § 145. The Court stated that proponents and opponents of § 4915 alike recognized, and conveyed to Congress, that the remedy by bill in equity allowed an applicant to introduce new evidence in the district court, regardless of whether that evidence had been provided to the PTO in earlier proceedings. Based on the legislative history, the Court reasoned that Congress intended that applicants would be free to introduce new evidence in § 145 proceedings subject only to the rules applicable in all civil actions, the Federal Rules of Evidence, and the Federal Rules of Civil Procedure. Specifically, the Court rejected the argument that Congress intended that only evidence that could not have reasonably been presented to the PTO in the first instance should be admissible in § 145 proceedings.

The Federal Circuit further noted that no Supreme Court case had ever placed any limitations on the admissibility of evidence in a § 145 proceeding apart from the ordinary rules applicable to all civil actions. The Court found no support in Supreme Court precedent for allowing new evidence only if the evidence could not reasonably have been provided to the PTO.

Although the Court held that new evidence is generally admissible in a § 145 case, it also recognized that the proceedings before the PTO remain relevant in a § 145 action. First, the Federal Circuit explained that in adjudicating entitlement to a patent, the district court must consider the record before the PTO, as well as any new evidence admitted by the applicant. Second, although the Court noted that Hyatt did raise the written-description issue before the PTO, it stated that "issues (and evidence relating to new issues) that were not raised in the Patent Office proceedings generally may not be raised in a § 145 proceeding." Thus, the Court recast its holding and concluded that "consonant with the language of the statute, legislative history, and Supreme Court precedent, the only limitations on the admissibility of evidence in § 145 proceedings (for issues raised before the Patent Office) are the Federal Rules of Evidence and Civil Procedure."

Even though district courts may be required to admit new evidence in § 145 cases, the Federal Circuit explained that district courts may consider the proceedings before, and findings of, the PTO in deciding what weight to afford an applicant's newly admitted evidence. The Court noted that, should the facts of a particular case cast suspicion on new evidence that an applicant failed to introduce before the PTO, the district court in a § 145 action would be within its discretion to give that evidence less weight.

Next, the Federal Circuit addressed the applicable standard of review in § 145 proceedings. The Court explained that, if the parties to a § 145 action do not introduce any new evidence before the district court, the court reviews the case on the same record presented to the agency and the reviewing court must apply the Administrative Procedure Act's (APA) substantial-evidence standard to PTO findings of fact. But when new evidence is introduced, the Federal Circuit instructed that the district court is to act as a fact-finder with respect to that new evidence and make de novo factual findings if the evidence conflicts with any related PTO finding. The Court recognized, however, that the district court must still consider the administrative record in making its de novo factual findings.

In a separate opinion concurring-in-part and dissenting-in-part, Judge Newman agreed that new evidence may be provided in a civil action brought under 35 U.S.C. § 145. Judge Newman, however, stated that issues in a § 145 proceeding should receive a de novo determination, whether or not new evidence is adduced in the district court. It is contrary to statute, Judge Newman noted, when the same deferential review is applied to both civil actions under § 145 and APA direct appeals to the Federal Circuit. "The statutory plan is designed to differ from such a duplicative procedure, not to create it." Judge Newman further explained that "[t]he purpose of the section 145 proceeding is to achieve fresh judicial determination of patentability issues that had been decided by the Patent Office, and to conduct this determination de novo on the evidence before the court, whether or not the same evidence or all of it was before the examiner."

In a separate dissenting opinion, which Judge Gajarsa joined, Judge Dyk stated that district court proceedings in § 145 actions should follow the established administrative-law standard embodied in § 706 of the APA. Judge Dyk explained that the APA requires judicial review on the agency record and submission of all relevant evidence to the agency. While Judge Dyk agreed that § 145 contemplates the introduction of new evidence, he noted that this should only be allowed when agency procedures are inadequate. With regard to the PTO, Judge Dyk found that the agency procedures are inadequate only insofar as they do not provide for live testimony when it is deemed necessary. Judge Dyk noted that allowing a trial de novo in the district court denigrates the important expertise of the PTO. In addition, Judge Dyk wrote that the majority opinion invites applicants to deliberately withhold evidence from the PTO in favor of a more hospitable district court forum. Judge Dyk also warned that the majority's decision "reflects yet another misguided effort to craft special rules for patent cases that the Supreme Court in other cases has held to be impermissible."

B. *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318 (Fed. Cir. 2010) (en banc)

En Banc Court Finds No Patent Misuse Where a Third Party Agrees Not to Separately License Competitive Technology

In *Princo Corp. v. International Trade Commission*, the Federal Circuit affirmed the International Trade Commission's ("ITC")

determination that the doctrine of patent misuse did not bar the patentee, U.S. Philips Corporation ("Philips"), from enforcing its patent rights against Princo Corporation and Princo America Corporation (collectively "Princo").

This case began when Philips commenced a proceeding before the ITC, alleging that Princo was importing recordable compact discs ("CDs") that infringed two of Philips's patents, referred to as the "Raaymakers patents." The Raaymakers patents are directed to the encoding of position information on a disc so that a consumer's CD reader/writer could maintain proper positioning while writing data to the disc. In its defense, Princo asserted that Philips's Raaymakers patents were unenforceable based on the doctrine of patent misuse. Among other arguments, Princo contended that Philips had improperly forced Princo and other licensees, as a condition of licensing patents that were necessary to manufacture CDs, to take licenses to other patents not necessary to manufacture those products. In particular, Princo alleged that Philips forced its licensees to license Sony Corporation's ("Sony") "Lagadec patent," which is directed to a method of encoding location codes on the disc grooves—an alternative method of encoding to the approach taken in the Raaymakers patents. The approach taken in the Raaymakers patents was selected for incorporation in the standard for manufacturing CDs.

The ITC agreed with Princo that Philips's patents were unenforceable because Philips's package-licensing practice constituted patent misuse for unlawfully tying patents that were essential for the manufacturing standard to licenses for other patents that were not essential. After the Federal Circuit reversed and remanded, the ITC ultimately rejected Princo's misuse defense. Princo appealed.

The Federal Circuit agreed to hear the appeal en banc to determine whether an agreement between Philips and Sony to suppress potentially competing technology embodied in Sony's Lagadec patent would constitute patent misuse and would therefore be a defense to Philips's infringement claim against Princo. Specifically, the Court considered whether Philips had misused the asserted Raaymakers patents (1) by agreeing with Sony to jointly license the Raaymakers patents together with the Lagadec patent and providing, as part of that agreement, that the alternative technology embodied in the Lagadec patent would not be licensed in competition with the Raaymakers technology; and (2) by securing an agreement from the licensees of the Raaymakers and Lagadec patents barring them from using the Lagadec patent to develop an alternative technology that would compete with the Raaymakers technology. The en banc Court ultimately affirmed the ITC's finding that the agreements did not constitute misuse.

The Court explained that Philips's alleged misuse did not involve the Raaymakers patents that were the subject of Princo's infringing activities. Instead, the alleged misuse concerned an anticompetitive agreement to suppress technology covered by Sony's Lagadec patent. While an improper anticompetitive agreement to suppress competing technology might have increased the licensing value of the Raaymakers patents, and while such an agreement might itself be vulnerable to challenge under antitrust laws, the Court refused to characterize the agreement as misuse of the Raaymakers patents. According to the Court, a misuse allegation must relate directly to the alleged misused patent and not merely to a collateral agreement that might impact the value of an otherwise enforceable patent.

Thus, because the alleged agreement between Philips and Sony did not specifically leverage the Raaymakers patents, it did not impermissibly enlarge the physical or temporal scope of those patents, and the majority was therefore unwilling to immunize Princo against the legal effects of its infringing conduct.

The Court went on to articulate a second reason why Princo could not find protection from infringement prosecution in its misuse allegation—Princo had failed to show either that the alleged agreement to suppress the Lagadec technology was per se anticompetitive, or that, as a factual matter, the agreement's overall effect was to restrain competition unlawfully in the relevant market. As for Princo's allegation that the agreement between Philips and Sony was per se anticompetitive, the Court stated that "[a]lthough joint ventures can be used to facilitate collusion among competitors and are therefore subject to antitrust scrutiny, research joint ventures such as the one between Philips and Sony can have significant procompetitive features, and it is now well settled that an agreement among joint venturers to pool their research efforts is analyzed under the rule of reason."

While the Court recognized that the Lagadec technology provided a potential alternative to the Raaymakers technology, it ultimately viewed the agreement between Philips and Sony as a legitimate exchange of assurances that the resources invested by one party to a joint venture would not be undermined or competitively exploited to the sole benefit of the other.

Absent a finding of a per se anticompetitive agreement, the Court next considered whether Princo had shown that the challenged agreement had a significant anticompetitive effect under a rule-of-reason analysis, and concluded that it had not. To support its conclusion, the Court noted that the Lagadec technology was not a commercially viable technological alternative to the Raaymakers patents, nor was it likely to become so. Thus, the majority affirmed the ITC's orders granting relief against Princo.

In a separate concurring opinion, which Judge Mayer joined, Judge Prost agreed that the patent-misuse defense was unwarranted in this case because Princo failed to show that the alleged agreement between Sony and Philips had anticompetitive effects. However, Judge Prost took issue with the majority's view that antitrust considerations are an entirely different issue, separate from the question of whether there has been patent misuse. Instead, Judge Prost explained that whether use of a patent runs afoul of antitrust law seemed probative of whether the patent owner had also misused the patent, and she would not foreclose a finding of patent misuse based, at least in part, on finding an antitrust violation. Unlike the majority, Judge Prost would be willing to consider whether the combined effect of an agreement to license the Raaymakers patents, but not the Lagadec patent, might amount to misuse. However, because Princo's failure to show that the alleged agreement between Sony and Philips had anticompetitive effects was sufficient to affirm the ITC's judgment, Judge Prost opted to refrain from articulating the precise metes and bounds of the patent-misuse doctrine.

In a separate dissenting opinion, which Judge Gajarsa joined, Judge Dyk viewed Sony and Philips's noncompete agreement as part and parcel of the agreements governing the asserted Raaymakers patents because the

noncompete agreement was designed to protect the Raaymakers patents from competition from the alternative Lagadec technology. The agreement to suppress the Lagadec technology, according to the dissent, was therefore enough to constitute misuse of the Raaymakers patents. As to the anticompetitive-effect analysis, Judge Dyk reasoned that an agreement between competitors not to compete was a classic antitrust violation and that, given the inherently suspect nature of Philips's agreement to suppress the Lagadec technology, the burden should have been on Philips to offer a plausible competitive justification for the restraint.

C. *Daiichi Sankyo Co., v. Matrix Labs., Ltd.*, 619 F.3d 1346 (Fed. Cir. 2010)

Selection of and Motivation to Modify a Lead Compound Follows from the Possession of Useful Properties, Not Mere Structural Similarity

In *Daiichi Sankyo Co. v. Matrix Laboratories, Ltd.*, the Federal Circuit affirmed the district court's ruling that the patent at issue was not invalid as obvious under 35 U.S.C. § 103. Defendants Matrix Laboratories, Ltd., Mylan Inc., Mylan Laboratories, Inc., and Mylan Pharmaceuticals, Inc. (collectively "Mylan") failed to establish a prima facie case for the selection of a lead compound and, even if selected, failed to establish a motivation to modify the lead compound to obtain the claimed compound.

Daiichi Sankyo Company, Ltd. and Daiichi Sankyo, Inc. (collectively "Daiichi") own U.S. Patent No. 5,616,599 ("the '599 patent"), which claims compounds and their use as angiotensin receptor blockers ("ARBs") for treating high blood pressure. Claim 13 covers the compound olmesartan medoxomil, a drug approved by the U.S. Food and Drug Administration and the active ingredient in Benicar®, Benicar HCT®, and Azor®.

The invention of olmesartan medoxomil follows from the development of small-molecule ARBs beginning in the late 1970s. Years later, scientists at E.I. du Pont de Nemours and Company ("DuPont") invented the first orally active ARB, losartan. Like the earlier compounds, losartan contained an imidazole ring core, but DuPont modified the 1- and 5-position substituents found in a lead compound. In its patent covering losartan, DuPont disclosed more than 400 related compounds as well as binding affinity data for more than half of the compounds. The data were used by chemists to correlate chemical structure with activity ("structural-activity relationships," or SARs), which could be used to develop improved compounds.

More than twenty pharmaceutical companies launched research programs for ARBs; Daiichi's program resulted in the synthesis of olmesartan medoxomil. Olmesartan shares the imidazole ring, 1-position biphenyltetrazole substituent, and 2-position alkyl group of losartan. Olmesartan differs from losartan, however, at both the 4- and 5-positions.

At the 4-position, olmesartan replaces losartan's lipophilic chlorine atom with a hydrophilic hydroxyisopropyl group. The vast majority of compounds disclosed in DuPont's patent contained lipophilic groups at the 4-position. One compound disclosed in the DuPont patent with a hydrophilic group at the 4-position is a regioisomer of losartan, in which the 4- and 5-position substituents were exchanged.

At the 5-position, olmesartan replaced losartan's hydroxymethyl group with a masked carboxy group, carboxy medoxomil. In the body, the medoxomil group is removed to yield the carboxylic acid group. Losartan's hydroxymethyl group is also metabolized to a carboxylic acid in the body.

Some second-generation ARBs, which are prior art to olmesartan, replaced losartan's 4-position chlorine atom with other lipophilic groups, such as alkyl or perfluoroalkyl groups. The court determined that ARBs disclosed in another patent to DuPont, U.S. Patent No. 5,137,902 ("the '902 patent"), are the closest structurally to olmesartan. Example 6 of the '902 patent differs only by the replacement of a hydroxy group with hydrogen. Other second-generation ARBs vary more significantly by using, for example, a different core ring than imidazole.

Mylan filed several Abbreviated New Drug Applications and served paragraph IV certifications challenging the validity of the '599 patent. Daiichi filed suit for patent infringement. The parties stipulated to infringement of claim 13, but the case proceeded on Mylan's counterclaim of invalidity for obviousness. The district court ruled after a bench trial that the '599 patent was not invalid as obvious, and Mylan appealed.

Mylan first challenged the lower court's finding that one of skill in the art would not have chosen the ARBs in DuPont's '902 patent as lead compounds. The Federal Circuit, however, affirmed the ruling that Mylan failed to show that one of ordinary skill in the art would have selected the '902 patent's ARBs as lead compounds. The Court accepted as true that the '902 compounds represented a continuation of the disclosure and the data found in the earlier DuPont patent, and recognized that the compounds exhibited about 2- to 4-fold higher activity than the most active compounds in DuPont's previous disclosure. However, other second-generation ARBs exhibited even greater activity and had been more thoroughly studied than the DuPont ARBs. Thus, the Court found that a skilled artisan would have selected the other secondary ARBs, which exhibited 7-, 100-, and 180-fold higher activity to be a lead compound, not the '902 compounds.

The Court did not accept Mylan's argument that because the '902 compounds have the closest structure in the prior art, that should be dispositive for finding them to be lead compounds. Instead, the Court emphasized that "it is the possession of promising useful properties in a lead compound that motivates a chemist to make structurally similar compounds." To choose the '902 compounds as lead compounds would suffer from hindsight bias. The state of the art at the time of the invention must be the basis for finding motivation to select and then modify a lead compound. The Court stated that "[p]otent and promising activity in the prior art trumps mere structural relationships." The oral activity, binding activity, and selectivity data, for example, among the other second-generation compounds would motivate their selection as lead compounds over the '902 compounds. A court is not required to find a single, best

lead compound. Here, several compounds were selected as leads, and the '902 compounds were not included in that set. The lower court did not commit clear error in reaching this finding.

Mylan next challenged the finding that one would not be motivated to modify the '902 patent's compounds at the 4- and 5-positions where the first DuPont patent specifically taught a hydroxyalkyl group at the 4-position, and the art taught medoxomil as a prodrug providing improved oral activity. The Federal Circuit, however, again affirmed the lower court's finding that even if the '902 compounds were selected as lead compounds, one of skill in the art would not be motivated to modify them to obtain olmesartan medoxomil.

The Federal Circuit first explained that the prior art as a whole taught away from the use of a hydrophilic substituent at the 4-position of the imidazole ring. The SAR data and the use of lipophilic groups at this position in the other second-generation compounds would teach away from modifying the '902 compounds' lipophilic alkyl groups to the hydrophilic hydroxyisopropyl group of olmesartan. The DuPont data revealed a clear preference for lipophilic groups at the 4-position. Three subseries analyzing the binding affinity as a function of the 4-position substituent confirmed the preference for having a lipophilic group. "Thus, the compounds in the prior art, including [Mylan's] proposed lead compounds, favor lipophilic 4-substituents rather than the 4-hydrophilic group of olmesartan medoxomil."

Regioisomers that transpose the 4- and 5-position substituents and DuPont's second-generation ARBs all demonstrated the preference for lipophilicity at the 4-position. No other second-generation ARB besides olmesartan had a hydrophilic group at this position. Mylan argued that the motivation to modify was nonetheless found in one of the DuPont example compounds having a hydrophilic group at the 4-position. The Court found, however, that the SAR data contradicted this, and that Mylan's argument relied on selecting the '902 compounds, which improved on losartan by using even more lipophilic groups at the 4-position, only to reject that very feature to obtain olmesartan medoxomil.

Finally, Mylan challenged the finding that one of skill in the art would not have had a reasonable expectation of success in modifying the '902 patent's ARBs to arrive at olmesartan as a similarly effective ARB. The Court declined to address this alternative ground for the ruling because it had affirmed the district court's findings that Mylan failed to establish the selection of prior art ARBs as a lead compound, or the motivation to modify the prior-art compounds to obtain olmesartan medoxomil.

D. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc)

En Banc Court Confirms Existence of Written-Description Requirement Separate from Enablement

In *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, the Federal Circuit held en banc that 35 U.S.C. § 112 contains a

written-description requirement separate from enablement.

Ariad Pharmaceuticals, Inc., the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College (collectively "Ariad") sued Eli Lilly & Company ("Lilly"), alleging infringement of U.S. Patent No. 6,410,516 ("the '516 patent"). The '516 patent relates to the regulation of gene expression by the transcription factor NF-κB. The claims in the '516 patent are genus claims, encompassing the use of all substances that achieve the desired result of reducing the binding of NF-κB to NF-κB recognition sites.

At trial, a jury found infringement, and found none of the asserted claims invalid. A Federal Circuit panel reversed the district court's denial of Lilly's motion for judgement as a matter of law and held the asserted claims invalid for lack of written description, but upheld the district court's finding of no inequitable conduct. Ariad petitioned for rehearing en banc, challenging the existence of a written-description requirement separate from the enablement requirement.

A case involving statutory interpretation, the Court began with the language of the statute itself. The Court agreed with Lilly and read the statute to give effect to its language that the specification "shall contain a written description of the invention," and held that § 112, first paragraph, contains two separate description requirements: a "written description [i] of the invention, and [ii] of the manner and process of making and using [the invention]." The Court held that if Congress had intended enablement to be the sole description requirement of § 112, first paragraph, the statute would have been written differently.

The Court held that a separate requirement to describe one's invention is basic to patent law. The specification must then, the Court explained, describe how to make and use the invention (i.e., enable it), but that is a different task.

The Court also read Supreme Court precedent as recognizing a written-description requirement separate from an enablement requirement. The Court held that a separate written-description requirement also does not conflict with the function of the claims. The Court noted that claims define and circumscribe, while the written description discloses and teaches.

In addition to the statutory language and Supreme Court precedent supporting the existence of a written-description requirement separate from enablement, stare decisis impelled the Court to uphold it. To change course now, according to the Court, would disrupt the settled expectations of the inventing community, which has relied on it in drafting and prosecuting patents, concluding licensing agreements, and rendering validity and infringement opinions. The Court explained that if the law of written description is to be changed, such a decision would rest with Congress.

The Court rejected Ariad's argument that original claims, as part of the original disclosure, constitute their own written description of the invention. Although many original claims will satisfy the written-description requirement, certain claims may not. For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including the original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus. The problem is especially acute with

genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally defined genus.

In fact, the Court held, this case illustrates the problem of generic claims. The claims in this case recite methods encompassing a genus of materials achieving a stated useful result, i.e., reducing NF-κB binding to NF-κB recognition sites in response to external influences. But the specification does not disclose a variety of species that accomplish the result.

The Court recognized that there may be little difference in some fields between describing an invention and enabling one to make and use it, but that is not always true of certain inventions, including chemical and chemical-like inventions. Thus, although written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described. For example, a propyl or butyl compound may be made by a process analogous to a disclosed methyl compound, but, in the absence of a statement that the inventor invented propyl and butyl compounds, such compounds have not been described and are not entitled to a patent. The written-description requirement also ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function—a problem that is particularly acute in the biological arts.

Adopting the analysis of the original panel, the Court concluded that the asserted claims of the '516 patent are not supported by a written description because the specification of the '516 patent fails to adequately disclose how the claimed reduction of NF-κB activity is achieved. The Court held that the '516 patent discloses no working or even prophetic examples of methods that reduce NF-κB activity and no completed syntheses of any of the molecules prophesized to be capable of reducing NF-κB activity. The state of the art at the time of filing was primitive and uncertain, leaving Ariad with an insufficient supply of prior-art knowledge with which to fill the holes in its disclosure. The specification, the Court held, at best describes decoy molecule structures and hypothesizes with no accompanying description that they could be used to reduce NF-κB activity. Yet, the asserted claims are far broader. The Court therefore concluded that the jury lacked substantial evidence for its verdict that the asserted claims were supported by adequate written description and thus held the asserted claims invalid. The Court also reinstated Part II of the panel decision, affirming the district court's finding of no inequitable conduct.

Judge Newman joined the majority but wrote separately to add that the subject matter of this case was basic research, which was taken to the patent system before its practical application was demonstrated. In Judge Newman's view, the threshold in all cases requires a transition from theory to practice.

Judge Gajarsa concurred, writing that in his view, the text of § 112, ¶ 1, is a model of legislative ambiguity. He found the majority's interpretation of the statute reasonable but disagreed that an independent written-description requirement is a necessity of patent law. Judge Gajarsa explained that empirical evidence demonstrates that written description serves little practical purpose as an independent invalidity device, and better serves the goals of the Patent Act when confined to the priority context. He concluded that confining written description to the priority context would provide greater clarity to district courts and practitioners, "both of whom are currently left to trudge through a thicket of written description jurisprudence that provides no conclusive answers and encourages a shotgun approach to litigation.... [O]nly Congress wields the machete to clear it."

Judge Rader, with whom Judge Linn joined, dissented-in-part and concurred-in-part. Judge Rader concluded that the statute is unambiguous and has no separate written-description requirement. Judge Rader stated that a proper reading of the statutory description requirement recognizes that the enablement requirement identifies the invention and tells a person of ordinary skill what to make and use. Further, he concluded that the written-description doctrine only has meaning if the Court ignores its own claim-construction rules. That is, according to Judge Rader, the Court gets power to err twice – both in construing the claims so broadly as to exceed the scope of the rest of the specification and then to invalidate those claims because it reads the specification as failing to support the Court's own broad conception of the claimed subject matter.

Judge Linn, with whom Judge Rader joined, also wrote separately to dissent-in-part and concur-in-part. Judge Linn wrote that the statutory arguments fail to justify establishing a separate written-description requirement apart from enablement and beyond the priority context, and fail to tether that written-description requirement to a workable legal standard. He believed the appeal should have been returned to the panel for resolution of the enablement question, but concurred in the affirmance of no inequitable conduct.

E. *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010)

PTO Incorrectly Calculated Patent-Term Adjustments in Situations of Overlapping PTO Delays

In *Wyeth v. Kappos*, the Federal Circuit affirmed the district court's determination that Wyeth and Elan Pharma International Limited (collectively "Wyeth") were entitled to extended patent-term adjustments ("PTAs") under 35 U.S.C. § 154(b) due to the U.S. Patent and Trademark Office's ("PTO") delay in prosecuting their patent applications.

Congress passed the American Inventors Protection Act ("AIPA") in 1999, promising patent applicants a full PTA for any delay during prosecution caused by the PTO. The promise included two guarantees to patentees. Paragraph A of 35 U.S.C. § 154(b)(1) (the "A guarantee" or the "A clause") promises prompt PTO responses by extending the term

of the patent one day for each day the PTO does not meet certain examination deadlines, including a fourteen-month deadline to issue a first response to a filed application. Paragraph B of § 154(b)(1) (the "B guarantee" or "B clause") extends the term of the patent one day for each day issuance is delayed due to the PTO's failure to issue a patent within three years after the actual filing date of the application. The A and B clauses are expressly subject to the general limitation that restrict the period of adjustment when any of the "periods of delay" overlap. 35 U.S.C. § 154(b)(2)(A). Under the PTO's definition, the "period of delay" caused the B guarantee to start with the filing of the application and not three years later. Under that interpretation, "overlap" between A adjustments and B adjustments could arise and begin during the pendency of the patent application. Thus, the PTO used either the greater of the A delay or the B delay to determine the appropriate adjustment but never combined the two.

Wyeth owns U.S. Patent Nos. 7,179,892 ("the '892 patent") and 7,189,819 ("the '819 patent") for inventions that treat Alzheimer's disease. During prosecution of these patents, the PTO undisputedly caused delays in issuing the patents that entitled Wyeth to both A and B guarantees.

The PTO calculated 462 days of PTA for the '892 patent and 492 days of PTA for the '819 patent, using the greater-of-A-or-B rubric. Wyeth contended that § 154(b) entitled it to PTAs of 756 days and 722 days, respectively, because the "period of delay" for purposes of the B clause could not have started until three years after the application's filing date. Wyeth first sought reconsideration of the PTA determination with the PTO. Upon denial of reconsideration, Wyeth challenged the PTA determination by filing suit in the U.S. District Court for the District of Columbia under 35 U.S.C. § 154(b)(4)(A). Both parties filed motions for summary judgement. The district court granted Wyeth's motion, finding that, even if *Chevron* deference was applicable, the PTO's interpretation is contrary to the plain language of the statute.

On appeal, the Federal Circuit began with statutory construction. The Court detected no ambiguity in the terms "periods of delay" and "overlap" in the context of § 154(b). The Court found that the "period of delay" for the A clause runs from the date the PTO misses the specified deadline to the date of response to the underlying action. The Court also found that the "period of delay" under the express language of the B clause runs from the three-year mark after filing until the application issues. The Court therefore held that no "overlap" can transpire between the A delay and the B delay before the three-year mark because the B delay has yet to begin or take effect.

The PTO argued that the B delay could occur anytime after the application is filed. The Court rejected this interpretation as contrary to the language of the statute. In response, the PTO argued that it would be double counting if A and B delays were both used for PTA because A delays "cause" B delays. The Court, however, noted that the statute requires as much.

The Court also examined the legislative history of the AIPA but found nothing to support the PTO's arguments. The Court noted that, from the legislative history, it was apparent that the statutory language should provide a minimum seventeen-year term for most patents. The PTO also argued that because the B guarantee was added to the draft sections of § 154(b) after the A delay, Congress did not intend to give patentees already eligible for A adjustments

additional compensation during the first three years of prosecution. The Court rejected this argument, finding it did not amount to an extraordinary showing of contrary intentions, as required when the language of the statute is clear.

Finally, the Court rejected the PTO's claim to deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). The Court held that because the language of the statute was unambiguous, there was no reason to afford special deference to the PTO's interpretation. Accordingly, the Court affirmed the judgment of the district court.

XXI. Listing of Other Pharmaceutical, Biotech, and Chemical Cases Decided in 2010 from the Federal Circuit

A. Subject Matter - 35 U.S.C. § 101

Date	Case No.	Origin	Case Name	Brief Description
2010-12-17	2008-1403	SC	*Prometheus Labs., Inc. v. Mayo Collaborative Servs.*	Eligibility of claims previously held valid under machine-or-transformation test reaffirmed

B. Novelty - 35 U.S.C. § 102

Date	Case No.	Origin	Case Name	Brief Description
2010-08-02	2009-1437	DCT	*King Pharm., Inc. v. Eon Labs, Inc,*	The Federal Circuit invalidated the "advising" and "informing" claims for lack of novelty under the printed-matter doctrine. The act of administering metaxalone to patients was known, and the "advising" or "informing" steps, while new as a factual matter, could not render the claims novel as a legal matter

C. Obviousness - 35 U.S.C. § 103

Date	Case No.	Origin	Case Name	Brief Description
2010-02-24	2009-1270	PTO	*In re Chapman*	Board's misunderstanding of prior art calls into question conclusions on obviousness and constitutes harmful error
2010-06-09	2009-1423	DCT	*Trimed, Inc. v. Stryker Corp.*	Court reverses summary judgment of invalidity and orders assignment to new judge to preserve appearance of justice; a federal district court invoking common sense or any other basis for extrapolating from prior art to conclusion of obviousness must articulate its reasoning with sufficient clarity for appellate review

Date	Case No.	Origin	Case Name	Brief Description
2010-09-09	2009-1538	DCT	*Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*	Lost profits not awarded where the patentee corporation did not sell any patented products and patentee's parent and sister companies were not owners or exclusive licensees of the patent

D. Infringement

Date	Case No.	Origin	Case Name	Brief Description
2010-08-12	2010-1058	DCT	*Baran v. Med. Device Techs.*	Means-plus-function element having two functions must be construed to include both functions, regardless of placement of modifier

E. Written Description, Enablement, Definiteness, and Best Mode - 35 U.S.C. § 112

Date	Case No.	Origin	Case Name	Brief Description
2010-03-08	2009-1081	ITC	*Ajinomoto Co., v. Int'l Trade Comm'n*	Patents invalidated for failing to disclose best mode
2010-03-26	2009-1281	DCT	*Enzo Biochem, Inc. v. Applera Corp.*	Language of magnitude can be definite without reference to a precise numerical range if the intrinsic evidence provides sufficient comparative information
2010-04-07	2008-1577	PTO	*Yorkey v. Diab*	Court affirms board's interference ruling after finding claims satisfied writtendescription requirement
2010-04-07	2008-1578	PTO	*Yorkey v. Diab*	Court affirms board's finding of adequate written description and reverses board's finding of failure to establish actual reduction to practice in an interference
2010-04-26	2009-1058	DCT	*Medtronic Navigation, Inc. v. Brainlab Medizinische Computersysteme GmbH*	Absent misrepresentation, a party may rely on a favorable judgment as a matter of law determination and jury verdict as objective evidence that its infringement claims are not frivolous
2010-04-26	2009-1350	DCT	*Alza Corp. v. Andrax Pharm., LLC.*	Ordinary skill cannot substitute for disclosure of an invention's novel aspects to satisfy the enablement requirement

Date	Case No.	Origin	Case Name	Brief Description
2010-09-01	2010-1005	DCT	*Eli Lilly & Co. v. Teva Pharm. USA, Inc.*	The Federal Circuit upholds Eli Lilly and Company's Evista® franchise to 2014
2010-09-07	2009-1156	PTO	*Goeddel v. Sugano*	Claimed subject matter that can be "envisioned" from the specification fails to meet the written-description requirement
2010-09-07	2009-1455	DCT	*Green Edge Enters., LLC v. Rubber Mulch Etc., LLC*	Misidentifying best mode did not warrant summary judgment and trademark counterclaims met case or controversy standard

F. Inventorship

Date	Case No.	Origin	Case Name	Brief Description
2010-04-09	2009-1258	DCT	*Vanderbilt Univ. v. ICOS Corp.*	Plaintiff university fails to provide clear and convincing evidence of joint inventorship where the parties' respective stories are "equally plausible"
2010-10-13	2009-1161	DCT	*Solvay S.A. v. Honeywell Int'l, Inc.*	Reproducing an invention in the United States does not constitute inventorship under 35 U.S.C. § 102(G)(2)

G. Inequitable Conduct

Date	Case No.	Origin	Case Name	Brief Description
2010-01-25	2008-1511	DCT	*Therasense, Inc. v. Becton, Dickinson & Co.*	Federal Circuit finds inequitable conduct based on applicant's conflicting statements made to the European Patent Office
2010-11-09	2010-1204	DCT	*Cancer Research Tech. & Schering v. Barr Labs.*	Court clarifies the prejudice requirement for prosecution laches and the intent requirement for inequitable conduct

H. Patent Term

Date	Case No.	Origin	Case Name	Brief Description
2010-05-10	2009-1362	DCT	*Ortho-McNeil Pharm., Inc. v. Lupin Pharm., Inc.*	Distinct enantiomers are different "drug products" and properly subject to statutory term extensions
2010-05-10	2009-1557	DCT	*Photocure ASA v. Kappos*	New and improved drug product eligible for patent term extension pursuant to 35 U.S.C. § 156

I. Prosecution History Estoppel/Doctrine of Equivalents

Date	Case No.	Origin	Case Name	Brief Description
2010-08-04	2009-1568	DCT	*Intervet Inc. v. Merial Ltd.*	Prosecution history estoppel does not bar application of DOE for patent directed to DNA encoding
2010-12-09	2008-1425	DCT	*Erbe Elektromedizin GmbH v. Canady Tech. LLC.*	Prosecution history estoppel from distinguishing argument overcomes claim differentiation based on facially narrower dependent claim

J. Safe Harbor

Date	Case No.	Origin	Case Name	Brief Description
2010-01-25	2009-1032	DCT	*Boehringer Ingelheim International GmbH v. Barr Labs., Inc.*	Safe-harbor provision of 35 U.S.C. § 121 applies to a divisional of a divisional—even one filed voluntarily, claiming several nonelected inventions

K. Claim Construction

Date	Case No.	Origin	Case Name	Brief Description
2010-01-05	2009-1241	DCT	*Koninklijke Philips Elecs. N.V. v. Cardiac Sci. Operating Co.*	Claim terms should be construed in view of the originating disclosure when challenged for written-description support in interference proceeding
2010-03-31	2008-1602	DCT	*Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd.*	Trial courts cannot look to the prior art merely listed in a patent specification to provide corresponding structure for a means-plus-function limitation
2010-06-02	2009-1557	DCT	*Haemonetics, Corp. v. Baxter Healthcare Corp.*	Claim term can have different meanings in different claims when used inconsistently in respective embodiments in specification
2010-07-29	2009-1053	DCT	*Becton, Dickinson & Co v. Tyco Healthcare Grp., LP*	Listing claim elements separately clearly implies those elements are distinct components of the patented invention
2010-08-05	2010-1246	DCT	*Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*	Pharmacokinetic claim terms need not refer to complete FDA regulation
2010-09-13	2009-1323	DCT	*Am. Med. Sys., Inc. v. Biolitec, Inc.*	Preamble term that is not an essential component of the invention should not be construed as a claim limitation
2010-09-21	2010-1028	DCT	*Laryngeal Mask Co. v. Ambu*	Summary judgment vacated after erroneous construction of claim term “backplate”

L. Double Patenting

Date	Case No.	Origin	Case Name	Brief Description
2010-07-28	2010-1105	DCT	*Sun Pharm. Indus., Ltd., v. Eli Lilly & Co.*	Obviousness-type double patenting analysis for patents claiming a compound should include an examination of any utility disclosed in the specification of the earlier-issued patent

M. Hatch-Waxman

Date	Case No.	Origin	Case Name	Brief Description
2010-07-29	2010-1001	DCT	*Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*	Hatch-Waxman counterclaim provision does not permit generic manufacturer to challenge use code applied to pioneering manufacturer's Orange Book listed patent

N. Other

Date	Case No.	Origin	Case Name	Brief Description
2010-01-25	2009-1008	DCT	*Therasense, Inc. v. Becton, Dickinson & Co.*	Erroneous jury instructions not grounds for overturning a verdict where jury is not prejudiced
2010-03-31	2006-1522	DCT	*Hif Bio, Inc. v. Yung Shin Pharm. Indus. Co.*	District court lacks discretion to remand claims arising under federal patent law to state court
2010-04-12	2008-1288	DCT	*MBO Labs. v. Becton, Dickinson & Co.*	The rule against reissue recapture applies to subject matter surrendered during prosecution of related patent applications
2010-11-01	2009-1381	DCT	*Astrazeneca LP v. Apotex, Inc.*	Federal Circuit affirms preliminary injunction barring defendant from launching FDA approved generic drug

XXII. Overview of 2011 at the Federal Circuit

A. Summary of the Federal Circuit 2011 Decisions in Intellectual Property

Year	Number of Precedential Cases in Intellectual Property	Number of Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts (% of total)	En Banc Decisions (% of total)	En Banc Decisions
2011	99	26 (26%)	2 (2%)	*TiVo Inc. v. EchoStar Corp.*, 646 F.3d 869 (Fed. Cir. 2011); and *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011)

B. Summary of the Precedential Cases in the Pharmaceutical, Biotech and Chemical Arts for 2011 from the Federal Circuit

		Origin			PTO		
Year	Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts	Supreme Court/ District Court	International Trade Commission	PTO	Prosecution	Interference	Reexamination
2011	26	0/19	0	6	4	0	2

XXIII. Summaries of Cases Decided En Banc and Other Key Decisions from the Federal Circuit in 2011

A. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc)

Federal Circuit En Banc Tightens the Standards for Inequitable Conduct for Both Intent and Materiality

In *Therasense, Inc. v. Becton, Dickinson & Co.*, the Federal Circuit vacated the district court's finding of unenforceability due to inequitable conduct and remanded for further proceedings consistent with its tightened standards for inequitable conduct.

In 1984, Therasense, Inc. (now Abbott Diabetes Care, Inc.) and Abbott Laboratories (collectively "Abbott") filed a patent application which led to U.S. Patent No. 5,820,551 ("the '551 patent") regarding disposable blood-glucose test strips for testing whole blood without a membrane. During prosecution, the examiner rejected the claims over another Abbott patent, U.S. Patent No. 4,545,382 ("the '382 patent"), which noted that the membrane was optional. To overcome these rejections, Abbott's patent attorney and director of research and development submitted a declaration stating that one skilled in the art would have read the '382 patent specification to require a membrane when used with whole blood. Then, while prosecuting the European counterpart to the '382 patent several years later, Abbott represented that their invention did not require a membrane.

In 2004, Becton, Dickinson and Co. ("Becton") sued Abbott in the District of Massachusetts seeking a declaratory judgement of noninfringement of U.S. Patent Nos. 6,143,164 ("the '164 patent") and 6,592,745 ("the '745 patent") involving its blood-glucose test strip. Abbott countersued in the Northern District of California alleging infringement of the '164, '745, and '551 patents. The District of Massachusetts transferred its case to the Northern District of California. Abbott also sued Nova Biomedical Corp. ("Nova"), Becton's supplier, and Bayer Healthcare LLC ("Bayer"). The Northern District of California consolidated all of these cases.

The district court granted summary judgement of noninfringement of all asserted claims in the '164 and '745 patents. The district court also found nearly all of the asserted claims of the '745 patent anticipated as well as several of the asserted claims of the '551 patent obvious in light of the '382 patent. Further, the district court held the '551 patent unenforceable for inequitable conduct because Abbott did not disclose to the U.S. Patent and Trademark Office ("PTO") its briefs filed with the European Patent Office ("EPO"). Abbott appealed and a panel of the Federal Circuit

upheld the judgments of invalidity, unenforceability, and noninfringement, but the Federal Circuit granted Abbott's petition for rehearing en banc.

Writing for the majority, Chief Judge Rader stated that inequitable conduct is an equitable defense that evolved from a trio of Supreme Court cases applying the doctrine of unclean hands to patent cases involving egregious misconduct. In addition, the Court explained the divergence of inequitable conduct from the doctrine of unclean hands and the fluctuations of the standards for intent and materiality over time. Due to these fluctuations, the Court noted that the inequitable-conduct doctrine has plagued not only the courts but also the entire patent system. Therefore, citing numerous issues of unintended consequences, the majority chose to "now tighten…the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public."

First, as to the intent element, the Court held that an accused infringer must prove by clear and convincing evidence that the patentee acted with the specific intent to deceive the PTO. In reaching this standard, the Court noted that the gross negligence and "should have known" standards are insufficient to satisfy the specific-intent requirement. In addition, the majority specifically noted that in cases involving nondisclosure of information, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.

Moreover, the Court explained that intent and materiality are separate requirements. Therefore, a district court should not use a "sliding scale" to infer intent from materiality, but instead should weigh the evidence of intent to deceive independent of its analysis of materiality. Still, the majority clarified that since direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence. Nonetheless, to meet the "clear and convincing evidence" standard, the Court explained that the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence. Further, because the party alleging inequitable conduct bears the burden of proof, the majority explained that the patentee need not offer any good-faith explanation unless the accused infringer first proves a threshold level of intent to deceive by clear and convincing evidence.

Second, addressing the materiality element, the Court held that, as a general matter, the materiality required to establish inequitable conduct is but-for materiality, dismissing the definition of materiality in PTO Rule 56. Therefore, in assessing the materiality of a withheld reference, the district court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the district court should apply the "preponderance of the evidence" standard and give claims their broadest reasonable construction. Recognizing the early unclean hands from which inequitable conduct evolved, the majority carved out an exception to the but-for materiality test for affirmative egregious misconduct. The Court explained that in cases where the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material as a patentee is unlikely to go to great lengths to deceive the PTO unless it believes it will affect the issuance of the patent.

Since the district court applied the PTO's Rule 56 materiality standard, the Court vacated the district court's finding of materiality and remanded for determination under the but-for materiality standard. Further, since the district court found intent to deceive based on the absence of a good-faith explanation for failing to disclose the European Patent Office briefs, the Court vacated the district court's finding of intent and remanded for determination under the Court's specific-intent analysis. Ultimately, the Court affirmed-in-part the district court's judgment of obviousness, noninfringement, and anticipation while it vacated-in-part its finding of inequitable conduct and remanded-in-part for further proceedings consistent with its opinion.

In a separate opinion, Judge O'Malley dissented-in-part to the majority's opinion regarding materiality and concurred-in-part to the remainder of the majority's decision and judgment. Judge O'Malley joined the majority's findings regarding the standard for the specific intent to deceive. But, Judge O'Malley's views diverged from the dissent regarding materiality, as she believed that both the majority and the dissent strain too hard to impose hard and fast rules. Instead of the majority's but-for materiality approach, Judge O'Malley would adopt a more flexible test, including discretion as to the remedy, such as rendering fewer than all claims unenforceable, dismissing the action before it, or another remedy as long as it was commensurate with the violation. Specifically, Judge O'Malley would deem conduct material where (1) but for the conduct, the patent would not have issued; (2) the conduct constitutes a false or misleading misrepresentation of fact; or (3) the district court finds that the behavior is so offensive that the court is left with a firm conviction that the integrity of the PTO process as to the application-at-issue was wholly undermined. Finally, Judge O'Malley noted that she would have affirmed the district court's finding of materiality under her flexible and discretionary approach.

In a dissenting opinion, Judge Bryson, joined by Judges Gajarsa, Dyk, and Prost, proposed adhering to the materiality standard set forth in PTO Rule 56 instead of the majority's fundamental change to the inequitable-conduct doctrine through adoption of a but-for materiality test. The dissent raised two reasons for its preference of the PTO's Rule 56 materiality test. First, the PTO is in the best position to know what information examiners need to conduct effective and efficient examinations, i.e., what information is material to the examination process. Second, the higher but-for materiality standard adopted by the majority will not provide appropriate incentive for patent applicants to comply with the disclosure obligations the PTO places upon them. Ultimately, the dissent would affirm the district court's finding that the '551 patent is unenforceable because the court's factual findings were not clearly erroneous and because its legal analysis comports with the proper role of the doctrine of inequitable conduct in patent law.

B. *TiVo Inc. v. EchoStar Corp.*, 646 F.3d 869 (Fed. Cir. 2011) (en banc)

En Banc Court Establishes New Test for Contempt Proceedings in Infringement Cases

In *TiVo Inc. v. EchoStar Corp.*, the Federal Circuit vacated the district court's finding that defendants EchoStar

Corporation and several other entities (collectively "EchoStar") were in contempt of the first provision of a permanent injunction and remanded for further factual determinations. The Court affirmed the district court's finding of contempt of the second provision of the injunction and upheld the award of sanctions against EchoStar.

TiVo Inc. ("TiVo") owns U.S. Patent No. 6,233,389 ("the '389 patent"), which relates to technology permitting a viewer to "time-shift" a television broadcast, simultaneously recording and viewing it, using a digital video recorder ("DVR"). TiVo brought suit against EchoStar in 2004, alleging that its satellite television receivers infringed various "hardware" and "software" claims of the '389 patent.

The district court issued a two-part permanent injunction after a finding of willful infringement by a jury. That injunction ordered EchoStar to cease making, using, offering for sale, or selling the infringing satellite television receivers (the "infringement provision"), and to disable the DVR functionality in existing receivers that had been, or would be, placed with its customers (the "disablement provision"). EchoStar appealed, challenging the claim construction and finding of infringement, but did not appeal the grant of the permanent injunction. The Federal Circuit upheld the claim construction and infringement finding as to the software claims relevant to this appeal, reversing and remanding as to the hardware claims. Following the appeal, TiVo moved the district court to find EchoStar in contempt of the permanent injunction, which had been stayed during the appeal and became effective afterwards. The district court found EchoStar in contempt of both the infringement and disablement provisions, and imposed almost $90 million in sanctions. EchoStar again appealed.

The Federal Circuit first addressed the test for determining contempt in cases of alleged continued infringement. As an initial matter, it rejected EchoStar's contention that good faith, as evidenced by a costly redesign and subsequent noninfringement opinion from outside patent counsel, was a defense to civil contempt. The Court explained that good faith is not a defense because civil contempt is remedial in nature, although it may be considered in assessing penalties.

The Federal Circuit also rejected the two-part test established in *KSM Fastening Systems, Inc. v. H.A. Jones Co.*, 776 F.2d 1522, 1530-32 (Fed. Cir. 1985), which had required an initial inquiry into the propriety of initiating contempt proceedings, conducted by comparing the accused and adjudged infringing products to determine whether there was "more than a colorable difference" between them, in which case infringement would be determined by a new trial. In the absence of more than a colorable difference, the Court would evaluate the redesigned product for infringement. The Court concluded that the two-step inquiry was unworkable, confused the merits of the contempt with the propriety of initiating contempt proceedings, and was not observed in practice. Instead, the Federal Circuit concluded that a district court should combine the inquiries, leaving the question of the propriety of initiating contempt proceedings to the discretion of the trial court. A contempt proceeding is merited where the injured party provides a "detailed accusation. . . setting forth the alleged facts constituting the contempt." The Federal Circuit explained that, on appeal, it would not consider allegations that contempt proceedings were improper, but would only review the enforceability and violation of injunctions, as well as the propriety of imposed sanctions. It noted, however, that there may be circumstances under which the initiation of contempt proceedings could constitute abuse of a district

court's discretion.

The Federal Circuit explained that a patentee seeking enforcement of an injunction must prove, by clear and convincing evidence, first, that a newly accused product is not more than colorably different from the adjudged infringing product and, second, that the newly accused product actually infringes. A district court's comparison of the newly accused and adjudged infringing products should focus on any differences between the features relied upon to establish infringement and the modified features of the newly accused products. If the modification or removal of a relied-upon feature is significant, as determined by reference to the relevant prior art, optionally with the assistance of expert testimony, then the newly accused product is more than colorably different, in which case contempt is inappropriate and a new trial should be held. The court's evaluation should also account for the policy favoring legitimate design-arounds.

In the event that a district court finds only a colorable difference between the modified and adjudged infringing products, the Federal Circuit instructed that the district court should proceed to determine whether the modified product also infringes. In doing so, the district court should apply the same claim construction that was initially used in determining infringement, and should compare the redesigned product to the asserted claim on a limitation-by-limitation basis. The Federal Circuit indicated that it would review the court's factual determinations as to colorable differences and infringement for clear error, and would review any award of sanctions for continued infringement for abuse of discretion.

Applying its test to the infringement provision of the permanent injunction, the Federal Circuit began by noting that TiVo had relied upon the start-code-detection feature of EchoStar's original receivers to satisfy a "parsing" limitation of the software claims and prove infringement, and that EchoStar had replaced that feature with a statistical-estimation feature. The Court also noted that the district court's analysis relied upon an alternative feature of EchoStar's modified devices to satisfy the parsing limitation of the software claims. Consequently, the Federal Circuit vacated the contempt finding as to the infringement provision, remanding to the district court to determine whether the statistical-estimation feature of the modified receivers was significantly different from the start-code-detection feature and, if not, whether the replaced feature continued to meet the parsing limitation of the software claims.

The Federal Circuit then turned to the disablement provision of the permanent injunction, rejecting EchoStar's arguments that that provision was unenforceable. First, the Court rejected EchoStar's argument that the injunction was unenforceable as vague because of ambiguity in the term "Infringing Products." Although the Federal Circuit agreed that vagueness can serve as a defense to contempt in appropriate circumstances, it was not persuaded that the injunction was vague. The Court held, however, that, if the injunction were facially vague, then EchoStar had the burden of seeking clarification or modification of the injunction from the district court.

Next, the Court rejected EchoStar's argument that the disablement provision unlawfully prohibited noninfringing activity and was therefore unenforceable for overbreadth. The Court concluded that EchoStar should have appealed the injunction at the time it was issued, and, hence, its arguments regarding overbreadth were waived for failure

to raise them earlier. The Federal Circuit indicated that it therefore would not address the legitimacy of EchoStar's arguments, but nevertheless explained in a footnote that injunctive restraint of noninfringing activities, although strongly discouraged, was within the discretion of a district court. Thus, the Federal Circuit affirmed the finding of contempt with regard to the disablement provision. Consequently, it affirmed the sanctions award, explaining that the sanctions had been expressly awarded on alternative grounds for violation of either of the two provisions of the injunction.

Judge Dyk, with whom Chief Judge Rader and Judges Gajarsa, Linn, and Prost joined, joined the majority in its general description of the applicable law but dissented as to its application in this case. Judge Dyk would have overturned the finding of contempt with regard to the disablement provision on the grounds that the injunction did not bar the installation of modified software rendering the devices noninfringing or, alternatively, could not provide the basis for a finding of contempt due to lack of clarity. Judge Dyk further contended that the majority decision undermined the policy encouraging accused infringers to design around patent claims and the well-established principle that contempt sanctions could not be imposed for violation of an unclear injunction. Judge Dyk also concluded that the infringement provision plainly was not violated because the statistical-estimation feature was substantially different from the start-code-detection feature and was not known in the prior art, necessitating a finding that the two products were more than colorably different and thus rendering remand unnecessary. Finally, Judge Dyk disagreed with the majority's decision to affirm the sanctions award, explaining that the award, as calculated by the district court, was clearly based in large part on EchoStar's alleged violation of the infringement provision, which was reversed by the majority.

C. *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341 (Fed. Cir. 2011)

1. Claims to Antibodies with Specific Properties Are Not Always Fully Described by Disclosing the Protein

In *Centocor Ortho Biotech, Inc. v. Abbott Laboratories*, the Federal Circuit reversed the district court's denial of Abbott Laboratories' ("Abbott") motion for judgement as a matter of law ("JMOL") on invalidity and held that the asserted claims of Centocor Ortho Biotech, Inc.'s ("Centocor") U.S. Patent No. 7,070,775 ("the '775 patent") failed to comply with the written-description requirement of 35 U.S.C. § 112.

The '775 patent, issued in 2006, is directed to antibodies to human tumor necrosis factor α ("TNF-α"). For purposes of the appeal, the Federal Circuit explained that antibodies basically consist of two regions: a constant region and a variable region. Changing the variable region can result in an antibody that does not bind to TNF-α or that does not have neutralizing activity. Centocor identified a mouse antibody to human TNF-α, which had high affinity and neutralizing activity ("the A2 mouse antibody"), and produced a "chimeric" antibody containing a mouse variable

region and a human constant region. In 1991, Centocor filed a patent application claiming its A2 mouse antibody and chimeric antibody. Subsequently, in 1994, Centocor filed three continuation-in-part ("CIP") applications adding new matter, but did not present claims to human variable regions.

Abbott also sought to engineer a fully-human antibody, taking a different path than Centocor. Rather than start from the A2 mouse antibody, Abbott worked directly with human variable regions. By 1995, Abbott had created the therapeutic antibody Humira® and filed a patent application disclosing this fully-human antibody to human TNF-α in 1996. Following the grant of its patent in 2000, Abbott obtained regulatory approval to market Humira® in 2002.

After Abbott received regulatory approval, Centocor filed the '775 patent application claiming, for the first time, fully-human anti-TNF-α antibodies (i.e., antibodies possessing human variable and constant regions). The '775 patent application contained a priority claim to Centocor's earlier-filed patent applications.

Shortly after the issuance of the '775 patent, Centocor sued Abbott, alleging that Abbott's therapeutic antibody Humira® infringed several claims of the '775 patent. After a jury verdict finding all of the asserted claims valid and willfully infringed, and awarding Centocor $1.67 billion in damages, the district court granted Abbott's motion for JMOL of no willful infringement but denied its motions for JMOL on noninfringement and invalidity.

On appeal, the Federal Circuit noted that the pivotal issue was whether the '775 patent provides adequate written description for the claimed human variable regions. The Court explained that Centocor must rely on a priority date from an earlier-filed application because it first sought claims to human variable regions and fully-human antibodies in the '775 patent application filed in 2002. At that time, Abbott had already discovered and patented a fully-human antibody to TNF-α that had high affinity and neutralizing activity. Since Centocor had relied on the 1994 CIP applications, the Court examined them to determine whether the written description supported an antibody to human TNF-α with (1) a human constant region, (2) a human variable region, (3) high affinity for human TNF-α, (4) neutralizing activity, and (5) the ability to bind to TNF-α in the same place as Centocor's A2 mouse antibody ("A2 specificity").

The Federal Circuit found that the CIP specifications did not describe a single antibody that satisfies the claim limitations or disclose any relevant identifying characteristics for fully-human antibodies or even a single human variable region. In addition, the Court determined that the specifications failed to disclose any relationship between the human TNF-α protein, the known mouse variable region that satisfies the critical claim limitations, and potential human variable regions that would satisfy the claim limitations. "At bottom, the asserted claims constitute a wish list of properties that a fully-human, therapeutic TNF-α antibody should have: high affinity, neutralizing activity, and the ability to bind in the same place as the mouse A2 antibody." The Court thus found that the specifications, at best, describe a plan for making fully-human antibodies, but that a mere wish or plan for obtaining the claimed invention was not sufficient for written-description purposes. Accordingly, the Court held that because Centocor had not invented a fully-human, high-affinity, neutralizing A2 specific antibody in 1994, a reasonable jury could not conclude

that Centocor possessed one.

The Court also rejected Centocor's argument that *Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004), and the U.S. Patent and Trademark Office ("PTO") written-description guidelines support the view that fully disclosing the human TNF-α protein provides adequate written description for any antibody that binds to it. As explained by the Federal Circuit, the PTO guidelines example permits an applicant to "claim an antibody to novel protein X without describing the antibody when (1) the applicant fully discloses the novel protein and (2) generating the claimed antibody is so routine that possessing the protein places the applicant in possession of an antibody." The Court also explained that while *Noelle* suggests that written description for certain antibody claims can be satisfied by disclosing a well-characterized antigen, that reasoning applies to the disclosure of newly characterized antigens where creation of the antibodies is routine.

The Federal Circuit noted that, unlike the example in the PTO guidelines and the invention claimed in *Noelle*, the human TNF-α protein and antibodies to that protein were not novel; rather, they were known in the literature. The claimed invention is a class of antibodies containing a human variable region that has particularly desirable therapeutic properties. The Court explained that "[c]laiming antibodies with specific properties, e.g., an antibody that binds to human TNF-α with A2 specificity, can result in a claim that does not meet written description even if the human TNF-α protein is disclosed because antibodies with those properties have not been adequately described." Importantly, the Court found that obtaining a high-affinity, neutralizing, A2 specific antibody with a human variable region was not possible in 1994 using "conventional," "routine," "well developed and mature" technology. Thus, unlike the antibody example in the PTO guidelines, the Federal Circuit concluded that the simple possession of the known TNF-α protein did not place Centocor in possession of the claimed antibodies.

Accordingly, the Federal Circuit found the asserted claims of the '775 patent invalid for lack of written description and reversed the judgment of the district court.

D. *Monsanto Co. v. David*, 516 F.3d 1009 (Fed. Cir.), *cert. denied*, 129 S. Ct. 309 (2008)

Planting Seed Containing a Gene Sequence Infringes a Patent Covering That Sequence

In *Monsanto Co. v. David*, the Federal Circuit affirmed the district court's finding of infringement in favor of Monsanto Company and Monsanto Technology LLC (collectively "Monsanto"), but vacated-in-part the district court's damages award and remanded.

Monsanto sells Roundup® brand herbicide, a glyphosate-based herbicide that kills all types of plants, whether the

plant is a weed or a crop. Monsanto has also developed Roundup Ready® Technology. Crops grown from seeds with Roundup Ready® Technology are resistant to Roundup and other glyphosate-based herbicides. When Roundup Ready® seeds are planted and used in conjunction with a glyphosate-based herbicide, Roundup Ready® plants will survive, while weeds and other plants lacking the Roundup Ready® Technology will be killed. Monsanto has claimed this technology in U.S. Patent No. 5,352,605 ("the '605 patent").

Roundup Ready® Technology has been introduced into numerous agricultural products, including soybeans. Monsanto licenses seed companies to incorporate the Roundup Ready® Technology into their plants and to sell soybean seeds containing that technology. All purchasers of such seeds are required to enter into a Technology Agreement, which provides that buyers may use the seeds for the planting of only a single commercial crop and that no seeds from that crop may be saved for future harvests. The agreement assures Monsanto that farmers must purchase new Roundup Ready® seeds each harvesting season, rather than simply saving seeds from the prior year's harvest, as they normally would with conventional soybean seeds. The agreement also provides Monsanto legal fees and costs incurred in enforcing the agreement.

In 1999, Loren David ("David"), a commercial soybean farmer, signed a Monsanto Technology Agreement. This case arose from the soybean seed David planted in 2003. Monsanto claims that the seeds that David planted were Roundup Ready® soybeans improperly saved from the previous year's harvest. In April 2004, after David's 2003 crop had already been harvested and sold, Monsanto obtained and tested samples of the soybean plant material remaining from some of David's fields. Based on the testing, Monsanto filed suit for patent infringement, breach of contract, unjust enrichment, and conversion, alleging that David had illicitly saved and planted Roundup Ready® seeds.

After a bench trial, the district court entered judgment against David. It held that David had willfully infringed the '605 patent and breached the Technology Agreement by planting saved seed from a prior year's crop. It awarded Monsanto $226,214.40 in compensatory damages. In addition, the district court awarded Monsanto enhanced damages, attorneys' fees, prejudgment interest, and costs, bringing the total damages award to $786,989.43. David appealed.

With respect to infringement, David argued that because the '605 patent claims a gene sequence, not a plant variety or a seed, it could not be infringed merely by saving seeds from plants containing the patented gene sequence. He contended that under *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124 (2001), plants can only receive patent protection under the Plant Patent Act of 1930, 35 U.S.C. §§ 161-164; the Plant Variety Protection Act of 1970, 7 U.S.C. § 2321 ("PVPA"); or under a utility patent on a plant variety (as opposed to a gene sequence). The Federal Circuit disagreed, reasoning that nothing in *J.E.M.* invalidated or limited the '605 patent or any utility patent on a gene sequence in a seed or a plant. The Court explained that the '605 patent covering the gene sequence was infringed by planting a seed containing the gene sequence because the seed contains the gene. It noted that the gene itself was being used in the planting, an infringing act.

The Federal Circuit noted that David's real complaint was that he should be able to save seed from his harvest,

regardless of the '605 patent. The Federal Circuit again disagreed. The Court noted that it had addressed a similar argument in *Monsanto Co. v. McFarling*, 302 F.3d 1291 (Fed. Cir. 2002), where it held that a farmer who saved seed containing a patented gene was liable for patent infringement and established that the right to save seed of plants registered under the PVPA did not impart the right to save seeds of plants patented under the Patent Act. The Federal Circuit noted that because *McFarling* also dealt with the '605 patent, it could not disregard that case.

David also argued that the district court's finding of infringement was clearly erroneous and that there was no evidence from which to infer that he saved Roundup Ready® soybeans from his 2002 harvest for planting in 2003. The Federal Circuit rejected this argument. The Court reviewed the relevant evidence and concluded that the district court did not clearly err in determining that David planted saved seed. Finally, David argued that the district court erred by allowing Monsanto's expert to testify about the results of tests establishing that David planted his fields with Roundup Ready® soybean seed. David did not challenge the reliability of the testing methods or data, but argued that Monsanto's scientific team had conducted the tests rather than Monsanto's expert. The Federal Circuit also rejected this argument, explaining that experts may base their opinions on scientific test results prepared by others and that Monsanto's expert testimony was therefore properly admitted.

David also appealed the district court's attorneys' fees and cost awards, as well as the reasonable-royalty award. With respect to the attorneys' fees and cost awards, the Federal Circuit affirmed. The Court explained that the district court had not erred in finding the case exceptional and in awarding attorneys' fees, noting that this was "a case of a farmer with apparent disregard for patent rights, license agreements, and the judicial process." The Court also rejected David's challenge to the attorney-fee clause in the Technology Agreement, noting that it had already decided this issue in *McFarling*, which involved a nearly identical Technology Agreement, and held that, absent a showing of fraud, a party who signs an agreement is bound by its terms. The Court noted that David had not claimed that Monsanto used fraud to procure his signature on the Technology Agreement. Finally, the Federal Circuit also disagreed with David's argument that attorneys' fees should be limited to those recoverable under 35 U.S.C. § 285 and costs should be limited to those available under 28 U.S.C. § 1920. The Court reasoned that there was no reason to limit fees or costs because the Technology Agreement explicitly provided for fees and costs with no limit.

Regarding the damages award based on a reasonable royalty, David challenged both the royalty rate and the number of units to which this rate was applied. The Federal Circuit affirmed the district court's royalty rate, but vacated its determination of the seed density that was used to calculate the number of units. The Court explained that, based on the evidence, the district court clearly erred in estimating the seed density. The Court provided specific guidelines that the district court could use to determine the seed density and remanded.

E. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011)

Majority Holds § 101 Does Not Exclude Claims Directed to a Specific, Tangible Application

In *Classen Immunotherapies, Inc. v. Biogen IDEC*, the Federal Circuit, on remand from the Supreme Court, held that two patents contain patentable subject matter under 35 U.S.C. § 101 but that a third patent does not. The Court also affirmed a grant of SJ of noninfringement, but declined to review the denial of a motion for summary judgement ("SJ") of anticipation under 35 U.S.C. § 102. Finally, the Court concluded that the safe-harbor provision of 35 U.S.C. § 271(e)(1) did not protect the accused infringers' activities.

Classen Immunotherapies, Inc. ("Classen") holds three related patents related to its inventor's thesis that the schedule of infant immunization for infectious diseases can affect the later occurrence of chronic immune-mediated disorders, and that immunization should be conducted on the schedule that presents the lowest risk with respect to such disorders. Two of Classen's patents, U.S. Patent Nos. 6,638,739 ("the '739 patent") and 6,420,139 ("the '139 patent"), are directed to a method whereby information on immunization schedules and the occurrence of chronic disease is "screened" and "compared," the lower risk schedule is "identified," and the vaccine is "administered" on that lower risk schedule. The third Classen patent at issue, U.S. Patent No. 5,723,283 ("the '283 patent"), is directed to a method involving immunizing mammals in a treatment group according to one schedule and comparing the outcomes to the outcomes associated with a control group. Of the three patents, only the '283 patent does not include performing immunizations in accordance with the information learned by the claimed method.

In an earlier nonprecedential opinion issued before the Supreme Court's decision in *Bilski v. Kappos*, 561 U.S., 130 S. Ct. 3218 (2010), a panel consisting of Judge Newman, Judge Moore (author), and District Judge Farnan (sitting by designation) found all three Classen patents ineligible under § 101 due to their failure to satisfy the machine-or-transformation test. After the Supreme Court issued its *Bilski* decision, it granted Classen's petition for certiorari, vacated the Federal Circuit's decision, and remanded the case for reconsideration in light of the guidance given in *Bilski*.

The Federal Circuit on remand characterized the Supreme Court's *Bilski* decision as encouraging the "preservation of the legal and practical distinctions between the threshold inquiry of patent-eligibility, and the substantive conditions of patentability." The Federal Circuit explained that the Supreme Court "recognized the separation of the § 101 'categories' of eligible subject matter from the § 102 'conditions' of patentability."

Applying this distinction to the Classen patents, the Federal Circuit first reviewed the district court's finding that none of the three patents meets the § 101 threshold because the method claimed in the three patents includes the mental step of reviewing the relevant literature to determine the lower-risk immunization schedule. The Court noted that "the presence of a mental step is not of itself fatal to § 101 eligibility, and that the 'infinite variety' of mental and physical

activity negates application of a rigid rule of ineligibility." The Court analogized to its recent decision in *Research Corp. Technologies, Inc. v. Microsoft Corp.*, 627 F.3d 859 (Fed. Cir. 2010), a case in which the Court concluded that a method was "functional and palpable," and, therefore, the method claims at issue recited "tangible limitations on performing the specified method of comparing images." Further citing *Research Corp.*, the Court explained that "the preferable procedure, when the claims are within the general classes of § 101 subject matter and not manifestly abstract, is to apply the substantive conditions and requirements of patentability."

Observing that "the commercial application of the technology is relevant to deciding whether an invention is so abstract as to negate § 101 subject matter," the Court found that the '139 and '739 patents "are directed to a method of lowering the risk of chronic immune-mediated disorder, including the physical step of immunization on the determined schedule," and are therefore "directed to a specific, tangible application."

Because the '283 patent lacks the step of immunization on an optimal schedule, a step required in both the '139 and '739 patents, the Federal Circuit found that the '283 patent involved only collecting and comparing known information. Without applying the data in a step of the overall method, the '283 patent failed to qualify for patent eligibility under § 101. The Court found that the '283 patent claims invite a reader to review existing knowledge; they "do not include putting this knowledge to practical use, but are directed to the abstract principle that variation in immunization schedules may have consequences for certain diseases." "In contrast, the claims of the '139 and '739 patents require the further act of immunization on accordance with a lower-risk schedule, thus moving from abstract scientific principle to specific application."

In addition to the Court's determinations regarding § 101, the Court declined to review the district court's denial of SJ of invalidity based on anticipation. Stating that there was no record, no factual findings, and no basis for factual inferences, the Court declined to rule on the anticipation question in view of its general rule that a party may not appeal the denial of an SJ motion.

The Federal Circuit next affirmed the district court's grant of accused infringer Merck & Co., Inc.'s ("Merck") motion for SJ of noninfringement. The Court agreed with the district court that Classen's complaint alleged infringement by Merck based on Merck's participation or facilitation of a particular study, and Classen could not prove its infringement allegations where Merck presented uncontroverted evidence that it had no involvement in that study. The Court also affirmed the district court's rejection of untimely motions filed by other accused infringers for SJ on the same grounds as Merck, finding the district court acted within its discretion.

Finally, addressing arguments regarding the safe-harbor provision of 35 U.S.C. § 271(e)(1), the Federal Circuit found that the statute provided no protection for the activities of accused infringers Biogen IDEC and GlaxoSmithKline. The Court explained that the statute provides safe harbor for the use of a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs…." Interpreting the statute in view of the legislative history, the Court found that the safe-

harbor provision was intended to protect the expedited development of information for regulatory approval of generic counterparts of patented products. Thus, the Court concluded that the safe-harbor provision does not apply to information that is routinely reported to the U.S. Food and Drug Administration ("FDA") after marketing approval has already been obtained, such as the reporting by the accused infringers of vaccine relationships, recommendations in view of relevant literature, adverse vaccine effects, or other regulation-required information to the FDA.

Judge Moore, the author of the first *Classen* opinion finding the three patents subject matter ineligible under the machine-or-transformation test, dissented with the majority opinion here, authored by Judge Newman, who also was a member of the earlier *Classen* panel. In Judge Moore's view, the claims at issue are to a fundamental scientific principle that is too basic and fundamental to be patentable. Comparing the method claimed in the Classen patents to the claimed method in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 628 F.3d 1347, 1350 (Fed. Cir. 2010), *cert. granted*, 566 S. Ct. 566 (June 20, 2011), Judge Moore would have found all three patents subject matter ineligible under 35 U.S.C. § 101. According to Judge Moore, in *Prometheus*, the Federal Circuit concluded that administering drugs transforms the human body, but that the *Prometheus* court did not end its analysis there. Rather, the *Prometheus* court concluded that the transformative steps in the claims were not merely data-gathering steps or insignificant postsolution activity and that the claims recite specific treatment steps with specific drugs. Judge Moore found no such analysis in the majority opinion with regard to the *Classen* patents. Moreover, Judge Moore found no consideration of the extent of preemption by "these staggeringly broad and abstract claims."

Judge Moore would also have affirmed the district court's denial of Merck's motion for SJ of anticipation, interpreted the safe-harbor provision of § 271(e)(1) more broadly to include both preapproval and postapproval uses of patented inventions, and found that accused infringers Biogen IDEC and GlaxoSmithKline were not entirely protected by the safe harbor because some of the activities accused of infringement did not reasonably relate to the development and submission of data to the FDA.

In addition to joining the majority opinion, Chief Judge Rader filed "additional views," joined by Judge Newman, expressing the view that the Federal Circuit should decline to accept invitations to restrict subject-matter eligibility despite a rising number of challenges under 35 U.S.C. § 101. Judge Rader explained two unintended consequences of § 101 restrictions. First, patent-claim drafters devise new ways to write claims to avoid judicially imposed restrictions, such as the Beauregard claim. This "game where lawyers learn ingenious ways to recast technology" makes the doctrine hollow, increases the costs of prosecution, and harms naïve inventors who draft claims poorly. Second, Judge Rader explained that restrictions on subject-matter patentability could drive innovation outside the United States.

F. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352 (Fed. Cir. 2011)

Functional and Pharmaceutical Properties of a Lead Compound Can Be More Relevant Than Chemical Structure When Judging the Obviousness of a Patented Formulation Designed to Mimic an FDA-Approved Formulation

In *Unigene Laboratories, Inc. v. Apotex, Inc.*, the Federal Circuit affirmed the district court's SJ of nonbviousness, denial of summary judgement ("SJ") of obviousness, denial of Apotex, Inc. and Apotex Corp.'s (collectively "Apotex") crime-fraud motion, and dismissal of Apotex's new claims and defenses.

Unigene Laboratories, Inc. ("Unigene") owns U.S. Patent No. RE40,812E ("the '812E patent"), which is a reissue of U.S. Patent No. 6,440,392 ("the '392 patent"). The '812E patent covers Fortical®, a pharmaceutical nasal spray approved by the U.S. Food and Drug Administration ("FDA") with the active ingredient salmon calcitonin that treats, inter alia, postmenopausal osteoporosis. Unigene's New Drug Application for Fortical® under 21 U.S.C. § 355(b)(2) established that it was bioequivalent to Miacalcin®, Fortical®'s reference drug, also a calcitonin nasal spray. While Miacalcin® and Fortical® use the same concentration of salmon calcitonin as active ingredients, they have different formulations. Miacalcin® also contains sodium chloride, nitrogen, hydrochloric acid, purified water, and benzalkonium chloride ("BZK"), which functions as a preservative, absorption enhancer, and surfactant. In contrast, Fortical® contains 20 mM of citric acid, which functions as an absorption enhancer and stabilizer/buffer; polyoxyethylene(2) sorbitan monooleate ("polysorbate 80"), which acts as a surfactant; and phenylethyl alcohol and benzyl alcohol, as preservatives.

Apotex filed an Abbreviated New Drug Application and certified under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that it intended to market a generic version of Fortical® prior to the '812E patent's expiration. Unigene filed suit in response, asserting only claim 19, which claims "[a] liquid pharmaceutical composition for nasal administration comprising . . . about 20 mM citric acid . . . ." Apotex's original and Amended Answers contained numerous affirmative defenses, including invalidity, noninfringement, and inequitable conduct based on, inter alia, failure to disclose prior art and an error in Table 3 of the '392 patent.

Apotex moved to pierce Unigene's attorney-client privilege under the crime-fraud exception based on substantially the same conduct underlying Apotex's inequitable-conduct claims: (1) Unigene's alleged failure to disclose U.S. Patent No. 5,912,014 ("the '014 patent"), even though the '014 patent shared a named inventor with the '812E patent; and (2) errors in Table 3 of the '392 patent. The district court denied Apotex's motion, finding that the '014 patent was either immaterial to the '392 patent because the disclosed formulations were "considerably different," or cumulative to other cited references, and that Apotex's evidence of fraudulent intent was insufficient to establish a prima facie case of fraud.

After the U.S. Patent and Trademark Office reissued the '392 patent, the district court granted Unigene's motion to

amend the Complaint to replace all references to the '392 patent with the '812E patent. Apotex filed an Amended Answer and included additional inequitable-conduct claims.

The parties cross-moved for SJ and the district court found that it would not have been obvious to modify Miacalcin® to reach the claimed formulation because (1) the prior art did not teach using 20 mM citric acid to achieve both shelf stability and enhanced bioavailability in a nasal salmon calcitonin formulation; (2) a skilled artisan would have been motivated to find FDA-approved compounds like benzylkonium chloride ("BZK") that serve as both absorption enhancers and preservatives of calcitonin; and (3) the prior art taught alternative methods for improving bioavailability and absorption of calcitonin. The district court granted Apotex's motion for reconsideration of its inequitable-conduct counterclaims, but held that Apotex's defenses and counterclaims were conceded, waived, barred, abandoned, or improperly raised. Apotex appealed.

The Federal Circuit, addressing Apotex's crime-fraud motion, noted that a party must establish *Walker Process* fraud (common-law fraud) to pierce the attorney-client privilege under the crime-fraud exception. Common-law fraud in the patent context "must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance." The Court found that Apotex failed to present clear evidence of intent. The record only contained Apotex's unsupported allegation regarding the '014 patent, and the errors in Table 3 were typographical in nature, corrected on reissue, and the inventor submitted a declaration in the reissue proceedings to explain the errors, which reflected "an honest mistake, though perhaps a careless one." Thus, the Federal Circuit found no abuse of discretion with the findings on intent, and did not need to reach the issue of materiality.

Additionally, the Federal Circuit held that the district court acted within its discretion in finding that Apotex's added counterclaims were not "colorable grounds for relief." The district court rejected Apotex's counterclaims because Unigene's replacement of the '392 patent with the '812E patent did not materially alter the proceedings. The Federal Court agreed, finding that the record "shows insufficient evidence of fraudulent intent and erects an insurmountable obstacle to Apotex's new counterclaims."

The Federal Circuit also agreed that the '812E patent was nonobvious as a matter of law. In light of *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007), the Court noted that "when design need and market pressure may dictate a commonsensical path using a finite number of identified predictable solutions to one of ordinary skill, deviations from that path are likely products of innovation." Because claim 19 covers a new composition or formulation, it "is not obvious if a person of ordinary skill would not select and combine the prior art references to reach the claimed composition or formulation." "In the context of a composition or formulation patent where the patented formulation was made to mimic a previously FDA-approved formulation, the functional and pharmaceutical properties of the 'lead compound' can be more relevant than the actual chemical structure (though not always mutually exclusive)." Thus, the Court observed that the term "reference composition" is more appropriate than "lead compound" in this context.

As applied here, the Federal Circuit first noted that the BZK in Miacalcin® acts as a preservative, absorption enhancer, and surfactant, whereas the "about 20 mM citric acid" in claim 19 acted as an absorption enhancer and surfactant. Second, a skilled artisan would have had (1) the design need to achieve a bioequivalent composition, and (2) the market demand to achieve a composition that treats the same symptoms as the reference formulation. Third, creating a bioequivalent composition could result in FDA approval. Fourth, the Court noted that "the Hatch-Waxman Act encourages and rewards replication of protected compounds in some circumstances — an activity that rarely, but can, lead to innovative products." Finally, the Court rejected Apotex's assertion, raised for the first time at oral argument, that claim 19 was obvious in light of three pieces of prior art: the '014 patent, Miacalcin®, and the Day reference.

With respect to the '014 patent, the Court found that no reasonable juror could conclude that it would give a skilled artisan sufficient reason or motivation to use about 20 mM citric acid in a liquid nasal salmon calcitonin composition because the '014 patent (1) described a solid oral formation of salmon calcitonin; (2) disclosed citric acid in concentrations much higher than those in claim 19; and (3) examined citric acid for bioavailability in the context of a liquid injection into a rat duodenum, not a human use in a liquid pharmaceutical formulation.

Considering the role of BZK in Miacalcin®, the Federal Circuit held that about 20 mM citric acid would not have been an obvious substitute for BZK's functions as an absorption enhancer and surfactant. The Court noted that citric acid's function, even in the closest prior art, U.S. Patent No. 5,124,315 ("the '315 patent"), was unclear. While an example in the '315 patent disclosed the use of citric acid, it made clear that "citric acid was not used as an absorption enhancing agent." Rather, the Court found that the '315 patent taught away from using "about 20 mM citric acid" as an absorption enhancing agent or stabilizing agent because, as the parties agreed, when the '315 patent discussed another prior-art patent's disclosure of over fifty examples of absorption agents including citric acid, the '315 patent reported that citric acid yielded "discouraging" test results.

Finally, with respect to the Day reference, the Court noted that citric acid appeared to be listed as a pH adjuster or buffer, not as a preservative. The Court thus found that Day provided "no evidence to support the conclusion that a person of ordinary skill would expect a combination of citric acid, benzyl alcohol, phenylethyl alcohol, and polysorbate 80 to contain a buffer, pH adjuster, preservative, and surfactant, but no absorption enhancer or excipient to promote bioavailability." Therefore, even with a design need and market pressure to develop a pharmaceutical bioequivalent to Miacalcin®, there was "no evidence in the record that claim 19 would be an obvious solution to those motivations."

Accordingly, the Federal Circuit affirmed the district court's SJ of nonobviousness, denial of SJ of obviousness, denial of Apotex's crime-fraud motion, and dismissal of Apotex's new claims and defenses.

XXIV. Listing of Other Pharmaceutical, Biotech, and Chemical Cases Decided in 2011 from the Federal Circuit

A. Novelty - 35 U.S.C. § 102

Date	Case No.	Origin	Case Name	Brief Description
2011-03-28	2010-1019	PTO	*In re Jung*	Prima facie case established when examiner sufficiently articulates statutory basis of rejection and identifies references relied upon
2011-12-01	2011-1091	DCT	*Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP*	Proving prior invention does not require that the prior inventor appreciated the subject matter using the same words of the claim

B. Obviousness - 35 U.S.C. § 103

Date	Case No.	Origin	Case Name	Brief Description
2011-01-05	2010-1141	PTO	*In re Glatt Air Techniques, Inc.*	Single embodiment is sufficient evidence to show commercial success
2011-05-13	2010-1307	PTO	*In re Huai-Hung Kao*	Evidence of secondary considerations can be commensurate with the scope of the claims without testing or selling every conceivable embodiment of the claims, but there must be a nexus to the novel aspects of the claimed invention
2011-05-19	2010-1102	DCT	*In re Brimonidine Patent Litig.*	A combination of ingredients from two separate solutions previously used together as part of an overall treatment regimen is not necessarily obvious
2011-06-06	2010-1411	PTO	*In re Klein*	Nonanalogous prior art cannot support an obviousness rejection
2011-06-22	2010-1513	DCT	*Tyco Healthcare Grp. LP v. Mut. Pharm. Co., Inc.*	Prior-art range encompassing the claimed invention creates a rebuttable presumption of obviousness

Date	Case No.	Origin	Case Name	Brief Description
2011-08-25	2010-1006	DCT	*Unigene Labs., Inc. v. Apotex, Inc.*	Functional and pharmaceutical properties of a lead compound can be more relevant than chemical structure when judging the obviousness of a patented formulation designed to mimic an FDA-approved formulation
2011-08-26	2010-1183	DCT	*Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*	Speculative and tentative disclosures in the prior art may not sufficiently direct or instruct a skilled artisan

C. Written Description, Enablement, Definiteness, and Best Mode - 35 U.S.C. § 112

Date	Case No.	Origin	Case Name	Brief Description
2011-04-29	2010-1249	DCT	*Wellman, Inc. v. Eastman Chem. Co.*	Claims invalidated because specification does not set forth the best mode as contemplated by at least one of the inventors
2011-04-29	2010-1401	DCT	*Billups-Rothenberg, Inc. v. Associated Reg'l & Univ. Pathologists, Inc.*	Claims to a method of detecting a genetic disorder not adequately described where the gene sequence or its specific disease-causing mutations were not disclosed
2011-06-07	2010-1230	DCT	*Boston Scientific Corp. v. Johnson & Johnson*	State of the art could not fill the gaps in disclosure for written-description support where the specifications indicated unpredictability and a lack of knowledge in the art

D. Jurisdiction

Date	Case No.	Origin	Case Name	Brief Description
2011-06-24	2010-1445	DCT	*Creative Compounds, LLC .V Starmark Labs.*	"Competing patents" not sufficient to confer declaratory judgment jurisdiction
2011-08-23	2010-1264	DCT	*Genetics Inst., LLC v Novartis Vaccines & Diagnostics, Inc.*	Expiration of patent does not divest a court of jurisdiction in a § 291 interference proceeding

E. Prosecution History Estoppel/Doctrine of Equivalents

Date	Case No.	Origin	Case Name	Brief Description
2011-02-24	2010-1145	DCT	*Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramins & Plastics, Inc.*	Burden of proof for infringement under the doctrine of equivalents is not heightened in cases of separate patentability
2011-07-21	2010-1419	DCT	*Duramed Pharma v. Paddock Labs*	Disclosure of a less-than-ideal use of a prior-art compound is sufficient to render it foreseeable for purposes of prosecution history estoppel

F. Claims Construction

Date	Case No.	Origin	Case Name	Brief Description
2011-02-24	2010-1235	DCT	*Hologic, Inc. v. Senorx, Inc.*	Specification limits the invention even in the absence of explicit claim language

G. Interference

Date	Case No.	Origin	Case Name	Brief Description
2011-10-20	2011-1045	DCT	*Streck, Inc. v. Research & Diagnostic Sys., Inc.*	Section 146 establishes de novo review

H. Other

Date	Case No.	Origin	Case Name	Brief Description
2011-05-24	2010-1394	DCT	*Allergan, Inc. v. Athena Cosmetics, Inc.*	Standing under California's unfair competition laws only requires an allegation of an injury in fact that was caused by defendants' unfair competition

2011-09-19	2011-1030	PTO	*In re Leithem*	An applicant is entitled to reopen prosecution or request rehearing when the Board relies on new facts changing the thrust of an examiner's rejection
2011-10-05	2010-1261	PTO	*In re Stepan Co.*	Board erred by relying on new factual findings without designating a new ground of rejection
2011-10-18	2011-1048	DCT	*Sanofi-Aventis v. Apotex Inc.*	Agreement with a formula calculating "actual damages" precludes prejudgment interest

XXV. Overview of 2012 at the Federal Circuit

A. Summary of the Federal Circuit 2012 Decisions in Intellectual Property

Year	Number of Precedential Cases in Intellectual Property	Number of Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts (% of total)	En Banc Decisions (% of total)	En Banc Decisions
2012	137	34 (25%)	3 (0.7%)	*Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012); *Marine Polymer Techs., Inc. v. HemCon, Inc.*, 672 F.3d 1350 (Fed. Cir. 2012); and *Zoltek Corp. v. United States*, 672 F.3d 1309 (Fed. Cir. 2012)

B. Summary of the Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts for 2012 from the Federal Circuit

		Origin			PTO		
Year	Number of Precedential Cases in the Pharmaceutical, Biotech, and Chemical Arts	Supreme Court/ District Court	International Trade Commission	PTO	Prosecution	Interference	Reexamination
2012	34	0/28	0	6	4	2	0

XXVI. Summaries of Cases Decided En Banc and Other Key Decisions from the Federal Circuit in 2012

A. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012) (en banc)

En Banc Court Holds That a Party Can Show Induced Infringement of Method Claim Where Inducer and Induced Party Each Perform Some of the Steps

In *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, and *McKesson Technologies, Inc. v. Epic Systems Corp.*, the Federal Circuit held that "all the steps of a claimed method must be performed in order to find induced infringement, but that it is not necessary to prove that all the steps were committed by a single entity."

The Federal Circuit stated that it was righting a perceived error in the law that a finding of induced infringement required a showing of direct infringement by a single entity, the so called "single-entity rule." In this respect, the Court reversed *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007), and its progeny of cases. The Court specifically held that "[r]equiring proof that there has been direct infringement as a predicate for induced infringement is not the same as requiring proof that a single party would be liable as a direct infringer." The Court noted the "bizarre result" of the single-entity rule, where a party inducing infringement could avoid all liability by merely performing some of the claimed method steps himself. According to the Court, "[t]he party who actually participates in performing the infringing method is, if anything, more culpable than [the] one who does not perform any steps." In terms of intent, the Court explained that "inducement does not require that the induced party be an agent of the inducer or be acting under the inducer's direction or control to such an extent that the act of the induced party can be attributed to the inducer as a direct infringer." Rather, the Court noted that "[i]t is enough that the inducer 'cause[s], urge[s], encourage[s], or aid[s]' the infringing conduct and that the induced conduct is carried out."

The Court characterized its decision as in line with the text of § 271(b), which provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." According to the Court, "'infringement' in this context appears to refer most naturally to the acts necessary to infringe a patent, not to whether those acts are performed by one entity or several." Likewise, the Court concluded that the legislative history supported the interpretation of induced infringement as not requiring that a single entity must perform all steps to infringe the claimed method. The Court cited comments by Judge Rich, where he made clear that "the revised provisions on infringement were intended to reach cases of divided infringement, even when no single entity would be liable for direct infringement. The Court also

found that principles of criminal and tort laws support the holding that a party may be liable for inducing joint infringement.

The en banc Court thus reversed the previous panels' decisions and remanded the cases, instructing the district courts that liability could be found under induced infringement. For example, the Court stated that "Limelight would be liable for inducing infringement if the patentee could show that (1) Limelight knew of Akamai's patent, (2) it performed all but one of the steps of the method claimed in the patent, (3) it induced the content providers to perform the final step of the claimed method, and (4) the content providers in fact performed that final step."

Writing separately, Judge Newman agreed with the en banc Court's decision that the panels' decisions in both cases should be reversed. Judge Newman, however, dissented from the en banc Court's "inducement-only rule," arguing that instead, the Court should "restore direct infringement to its status as occurring when all of the claimed steps are conducted, whether by a single entity or in interaction or collaboration." According to Judge Newman, remedies would then be "allocated as appropriate to the particular case." Even under the inducement standard, however, Judge Newman disagreed with the majority that the cases required remanding. Rather, Judge Newman would have found infringement liability in both cases under either her proposed standard or the inducement standard.

A separate dissent, authored by Judge Linn and joined by Judges Dyk, Prost, and O'Malley, stated that the Court's decision contravenes the statute and Supreme Court precedent that stands for the proposition that "if there is no direct infringement of a patent there can be no contributory infringement." The dissent also cited to passages from the congressional record, including testimony of Judge Rich, in support of its position. According to the dissent, "[t]he well established doctrine of vicarious liability is the proper test for establishing direct infringement liability in the multi-actor context." The dissent further noted that "[a]bsent direct infringement, the patentee has not suffered a compensable harm," and concluded with a recitation of the standards discussed in *BMC* and *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008).

B. *Marine Polymer Techs., Inc. v. HemCon, Inc.*, 672 F.3d 1350 (Fed. Cir. 2012) (en banc)

En Banc Court Holds that Intervening Rights Are Invoked for New or Amended Claims Only

In *Marine Polymer Technologies, Inc. v. HemCon, Inc.*, the Federal Circuit, sitting en banc, held that intervening rights do not apply to claims that have not been amended and are not new, and affirmed the judgment of the district court that HemCon, Inc. ("HemCon") infringed U.S. Patent 6,864,245 ("the '245 patent") assigned to Marine Polymer Technologies, Inc. ("Marine Polymer").

Marine Polymer accused HemCon of infringing the '245 patent, which claims preparations of "biocompatible" poly-β-1→4-N-acetylglucosamine ("p-GlcNAc") used to treat serious wounds. The district court found the patent valid and infringed, and awarded Marine Polymer $29.4 million in damages. Initially, HemCon appealed to the Federal Circuit ("the panel") and argued that the verdict should be overturned under the doctrine of intervening rights. While the litigation was in progress, HemCon initiated an ex parte reexamination of the patent, where, according to HemCon, Marine Polymer amended the claims, thus giving rise to intervening rights. During the reexamination proceeding, Marine Polymer argued for a narrower construction of the term "biocompatible" and canceled claims that might be inconsistent with this narrower construction. Marine Polymer neither added any new claims nor amended any existing claim. The examiner in the reexamination proceeding subsequently upheld the patentability of the remaining claims.

The panel agreed that HemCon had acquired intervening rights and overturned the district court's decision. Marine Polymer filed a petition for rehearing en banc, which was granted, and a majority of the en banc Court held that HemCon had not acquired intervening rights, because Marine Polymer had not amended claims nor added new claims during the reexamination proceeding. While the Court was split as to whether the district court's claim construction was correct, it nevertheless affirmed the district court's decision of infringement.

With respect to claim construction, HemCon argued that the district court's construction of "biocompatible"—to mean *no* detectable biological reactivity—was erroneous. In supporting this assertion, HemCon relied primarily on the presence of the six dependent claims in the original '245 patent (eventually cancelled in reexamination) that required elution test scores of one or two, as well as passages in the specification characterizing certain biocompatibility tests as being satisfied despite detectable bioreactivity.

The Court ultimately found HemCon's focus on the possibility of nonzero "passing" scores unpersuasive. The Court reasoned that the specification discussed nonzero passing scores only in generalized descriptions of test methods used to assess biocompatibility, but "when read as a whole, the specification makes clear that the p-GlcNAc *of the invention* outperforms baseline standards and shows 'no detectable biological reactivity as determined by biocompatibility tests.'" An equally divided Court thus affirmed the district court's construction of "biocompatible" as meaning p-GlcNAc "with low variability, high purity, and *no* detectable biological reactivity as determined by biocompatibility tests."

In addition, HemCon sought to overturn the jury's award of $29 million in damages as unreasonable and not supported by substantial evidence. Specifically, HemCon argued that Marine Polymer's expert lacked a sufficient basis for his testimony on what would constitute a reasonable royalty rate and that the jury improperly relied on the entire market value for its damages calculation. The Court affirmed the jury's damage award, reasoning that both experts used the same method to calculate total sales of the accused products, and Marine Polymer's use of "the entire market value" as the royalty base was acceptable. The Court further held that the jury was entitled to evaluate the conflicting evidence and credit the testimony of Marine Polymer's expert over that of HemCon. Thus, the Court affirmed the damages award.

As to intervening rights, HemCon argued that it did not infringe the '245 patent because it acquired intervening rights during the reexamination proceeding. HemCon asserted that the district court's interpretation of "biocompatible" incorrectly narrowed the term by requiring "no" detectable biological reactivity, a construction it alleges conflicts not only with statements in the specification, but also with the presence of dependent claims reciting elution test scores of one or two. HemCon contends that prior to reexamination, the term "biocompatible" must have encompassed low, nonzero levels of bioreactivity, so that the proper construction at that time was necessarily broader than the district court's interpretation.

HemCon also argued that by cancelling certain dependent claims that recited nonzero bioreactivity levels, and persuading the examiner to adopt the district court's construction of "biocompatible" during reexamination, Marine Polymer affected a substantive change in the scope of each remaining claim—essentially, from allowing some reactivity in the originally issued claims to permitting "no detectable biological reactivity" after reexamination. Citing the Federal Circuit's decision in *Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1346-47 (Fed. Cir. 1998), HemCon argued that the key to intervening rights lies in determining "whether the *scope* of the reexamined claims differs from the original claims." HemCon concluded that this perceived "substantive change" to the surviving claims of the '245 patent during reexamination triggered intervening rights with respect to those claims. Marine Polymer disagreed and argued that intervening rights cannot apply with respect to claims that have not been amended or newly introduced in the reexamination proceeding.

The Court agreed with Marine Polymer that intervening rights do not apply here, because the claims had not been amended and were not new. The Court opined that with respect to reissued patents, the concept of intervening rights was codified by the Patent Act of 1952, and that intervening rights do not accrue where the accused product or activity infringes a claim that existed in the original patent and remains "without substantive change" after reissue. The Court noted that although intervening rights originated as a defense against patents modified through reissue procedures, the doctrine has since been extended to the context of patent reexamination. Pursuant to 35 U.S.C. §§ 307(b) and 316(b), respectively, both ex parte and inter partes reexaminations can give rise to intervening rights. Thus, after a patent emerges from reexamination, the statute makes available intervening rights to the same extent provided in the reissue statute, but only with respect to "amended or new" claims in the reexamined patent.

A majority of the Court held that even if the district court's claim construction was erroneous, HemCon's intervening rights argument must fail because it disregards the plain and unambiguous language of § 307(b), which governs intervening rights arising from ex parte reexamination and specifies that only "amended or new" claims incorporated into a patent during reexamination "will have the same effect as that specified in section 252," i.e., will be susceptible to intervening rights. The Court found that HemCon ignored this threshold statutory requirement and asked that the Court proceed directly to the subsidiary "substantive change" analysis, which derives from § 252. The Court concluded that "under § 307(b), the first question when assessing whether intervening rights [arise] from a reexamination is whether the asserted claim is 'amended or new'; if the answer is no, that ends the inquiry. Only if the claim at issue is new or has been amended may the court proceed to the second step in the analysis and assess the

substantive effect of any such change pursuant to § 252."

The Court reasoned that here, the patent claims asserted against HemCon were neither "new" nor "amended"– claims 6, 7, 10-12, 17, and 20 contained identical language before *and* after reexamination. Whether or not Marine Polymer's arguments to the examiner and cancellation of claims during reexamination may have affected the remaining claims' effective scope, the Court found that Marine Polymer did not "amend" those claims for intervening-rights purposes or make them "new," which is what the statutory language requires. The Court thus concluded that intervening rights were unavailable under § 307(b) as a matter of law.

HemCon argued that Marine Polymer's actions in reexamination rendered the asserted claims effectively "amended" by disavowal or estoppel, even though the language of the claims was not formally changed. The Court disagreed, reasoning that "amend" means "to alter . . . formally by adding, deleting, or rephrasing." The Court further held that even if the term were ambiguous standing alone, any doubts are resolved by its context within § 307, which identifies three categories of claims in a reexamined patent, one of them being amended or new claims. Finally, the Court reasoned that it is clear that "amended" is a term of art in patent prosecution, including reexamination proceedings, and in that context connotes formal changes to the actual language of a claim. The Court concluded that a claim can not be "amended" for purposes of § 307(b) without changing the claim language itself. The Court thus determined that intervening rights did not apply here, since the actual words of the claims had not changed, and no new claim had been introduced during the reexamination proceeding.

Judge Dyk dissented with the majority's claim-construction analysis, noting that the majority construed the term based upon only two instances or examples in the specification. Judge Dyk commented that the majority's approach to claim construction would enable patentees to eliminate questions of validity by narrowing claims in accordance with a preferred embodiment or single example, while also allowing alleged infringers to narrow claims beyond their valid scope to avoid infringement.

With respect to the intervening-rights issue, in Judge Dyk's view, the majority is incorrect in their statutory interpretation of § 307(b). In particular, Judge Dyk noted that § 307(b) specifically incorporates the intervening-rights provisions of reissued patents found in § 252, and contended that Congress was explicit that § 307(b) should be interpreted to be identical in scope to § 252. Thus, the "amended or new" language in § 307(b) was clearly intended to have the same meaning as "substantially identical" in § 252. According to Judge Dyk, the focus then should be on whether the old and new claims are "substantially identical," not on whether the actual words of the claim had changed.

Here, Judge Dyk commented that the original and new claims were not "substantially identical." He reasoned that during reexamination the patentee agreed, by both argument and by amending the claims to cancel six dependent claims, that the term "biocompatible" should be construed to mean "no detectable biological reactivity." In doing so, Judge Dyk believed that the patentee adopted a construction that was different than the correct construction of the

original claims, namely, that "biocompatible" meant, inter alia, "little or no detectable reactivity." The effect was to narrow the claims and protect them from a finding of invalidity.

Finally, in Judge Dyk's view, not every argument during reexamination should give rise to intervening rights, but intervening rights should be available where an argument during reexamination rises to the level of a clear and unambiguous disclaimer or disavowal of the original, correct claim construction. He would find that Marine Polymer clearly and unambiguously disclaimed the scope of its claim by effectively becoming its own lexicographer and presenting a specific, limiting definition of the term "biocompatible."

C. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir.), *cert. granted*, 133 S. Ct. 694 (2012)

Claims to Isolated DNA and Screening Method Are Patent Eligible, but Claims to Analyzing and Comparing Methods Are Not

In *Association for Molecular Pathology v. U.S. Patent & Trademark Office*, the Federal Circuit affirmed-in-part and reversed-in-part the district court's decision that certain medical organizations, researchers, genetic counselors, and patients (collectively "Plaintiffs") had standing under the Declaratory Judgement ("DJ") Act to challenge patents owned by Myriad Genetics, Inc. and the Directors of the University of Utah Research Foundation (collectively "Myriad"). The Court also affirmed-in-part and reversed-in-part the district court's grant of summary judgement ("SJ") that all of the challenged claims are drawn to nonpatentable subject matter under 35 U.S.C. § 101.

The Plaintiffs filed suit against Myriad, seeking a declaration that fifteen claims from seven patents assigned to Myriad are drawn to patent-ineligible subject matter under § 101. The challenged claims include composition claims directed to two "isolated" human *BRCA* genes and certain mutations associated with a predisposition to breast and ovarian cancers, method claims directed to "analyzing" or "comparing" a patient's *BRCA* sequence with the wild-type sequence to identify the presence of cancer-predisposing mutations, and a method claim directed to a method of screening potential cancer therapeutics.

Regarding standing, Myriad argued that they did not have adverse legal interests with the plaintiffs and that the plaintiffs failed to allege a controversy of sufficient immediacy and reality to warrant the issuance of a DJ. The Court noted that "to establish an injury in fact traceable to the patentee, a [DJ] plaintiff must allege both (1) an affirmative act by the patentee related to the enforcement of his patent rights"; "and (2) meaningful preparation to conduct potentially infringing activity."

The Court found that only three of the plaintiffs alleged an injury traceable to Myriad, and that only one of those,

Dr. Harry Ostrer ("Dr. Ostrer"), clearly alleged a sufficiently real and imminent injury because he alleged an intention to actually and immediately engage in allegedly infringing activities. "Myriad's challenged . . . claims undisputedly provided 'an absolute barrier' to Dr. Ostrer's ability to undertake *BRCA* diagnostic testing activities, and a declaration of those claims' invalidity would remove that barrier." The Court "conclude[d] that it [was] likely, not merely speculative, that Dr. Ostrer's injury [would] be redressed by a favorable decision."

Regarding the other plaintiffs, the Court held that "[s]imply disagreeing with the existence of a patent on isolated DNA sequences or even suffering an attenuated, non-proximate, effect from the existence of a patent does not meet the Supreme Court's requirement for an adverse legal controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." The Court thus reversed the district court's holding that the plaintiffs other than Dr. Ostrer had standing to maintain the DJ suit.

Having found one plaintiff with standing to maintain the action, the Court turned to the merits of Myriad's appeal of the district court's SJ decision that all fifteen challenged claims were invalid under § 101. The Court noted that the issue before them was patent eligibility, not patentability, and held that the composition claims and the screening-method claim were patent eligible, while the analyzing and comparing method claims were not.

In addressing the patent eligibility of the composition claims, the Court noted that the parties and the government appeared to agree that isolated DNAs are compositions of matter, but disagreed on whether and to what degree such molecules fall within the patent-ineligible exception for products of nature. The Court held that the challenged claims to isolated DNAs, whether limited to cDNAs or not, are directed to patent-eligible subject matter under § 101. The Court reasoned that "[o]ne distinction…between products of nature and human-made invention for purposes of § 101 turns on a change in the claimed composition's identity compared with what exists in nature." The Court held that "the claims cover molecules that are markedly different—have a distinctive chemical structure and identity—from those found in nature," and therefore were patent eligible. "Under the statutory rubric of § 101, isolated DNA is a tangible, man-made composition of matter defined and distinguished by its objectively discernible chemical structure."

The Court rejected the government's earlier-proposed "magic microscope" test as misunderstanding the difference between science and invention, and as failing to take into account the existence of molecules as separate chemical entities. "The ability to visualize a DNA molecule through a microscope, or by any other means, when it is bonded to other genetic material, is worlds away from possessing an isolated DNA molecule that is in hand and usable." "Visualization does not cleave and isolate the particular DNA; that is the act of human invention."

The Court disputed the dissent's analogy to snapping a leaf from a tree, stating that "[s]napping a leaf from a tree is a physical separation, easily done by anyone," whereas "[c]reating a new chemical entity is the work of human transformation, requiring skill, knowledge, and effort." The Court also disputed the dissent's analogy to removing a kidney from the human body, stating that "[a] kidney is an organ, not a well defined composition of matter or an article of manufacture specified by § 101," whereas "[a]n isolated DNA is properly characterized as a composition of

matter under § 101…."

The Court then turned to the method claims and held that the claims directed to a method of analyzing or comparing DNA sequences are not patent eligible, while the claim directed to a method of screening is. Regarding the analyzing and comparing claims, the Court found that they were directed to abstract mental processes. "Although the *application* of a formula or abstract idea in a process may describe patent-eligible subject matter, Myriad's claims do not apply the step of comparing two nucleotide sequences in a process." "Rather, the step of comparing two DNA sequences is the entire process that is claimed." The Court found these claims to be indistinguishable from the claims the Supreme Court found invalid under § 101 in *Mayo*.

Regarding the screening claim, the Court held that it "includes more than the abstract mental step of looking at two numbers and 'comparing' two host cells' growth rates," because it "applies certain steps to transformed cells that . . . are a product of man, not of nature." "The fact that the claim also includes the steps of determining the cells' growth rates and comparing growth rates does not change the fact that the claim is based on a man-made, non-naturally occurring transformed cell—patent-eligible subject matter." The Court noted that "the claim does not cover all cells, all compounds, or all methods of determining the therapeutic effect of a compound," but rather "is tied to specific host cells *transformed* with specific genes and grown in the presence or absence of a specific type of therapeutic." The Court thus held that the screening method was directed to patent-eligible subject matter under § 101.

Judge Moore concurred-in-part. Judge Moore joined the majority with respect to standing, the method claims, and the claims directed to isolated DNA sequences, but "wr[o]te separately to explain [her] reasoning." Judge Moore stated that even when an invention does not exist in nature in the claimed state, it may still be directed to subject matter that is not patentable. Judge Moore contended that "courts have long applied the principles articulated in *Funk Brothers* and *Chakrabarty* to different factual scenarios in order to determine whether an invention, as claimed, falls into the laws of nature exception," and that "[she] see[s] no reason to deviate from this longstanding flexible approach in this case."

Judge Bryson concurred with the majority's decision on standing, the cDNA claims, and the method claims, and dissented with regard to claims to *BRCA* genes and gene fragments. In Judge Bryson's view, "the process of isolating genetic material from a human DNA molecule [does not make] the isolated genetic material a patentable invention." Judge Bryson stated that "a contrary ruling is likely to have substantial adverse effects on research and treatment in this important field."

D. *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 619 F.3d 1329 (Fed. Cir. 2010)

The Federal Circuit Upholds Eli Lilly and Company's Evista® Franchise to 2014

In *Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc.*, the Federal Circuit affirmed the district court's findings that the principal patents underlying Eli Lilly and Company's ("Lilly") blockbuster osteoporosis drug, Evista®, were valid and infringed. Specifically, U.S. Patent Nos. 6,906,086; RE39,049; RE38,968 (collectively "the Bone-Loss Patents"); and RE39,050 ("the Low-Dose Patent") were held nonobvious and enabled. The Court therefore affirmed the district court's permanent injunction preventing any manufacture or distribution of a generic version of Evista® until these patents expire in 2014. The Federal Circuit also affirmed the district court's ruling that certain claims of other patents directed to particle size, U.S. Patent Nos. 6,458,811 and 6,894,064 (collectively "the Particle-Size Patents"), were invalid for lack of written description. Teva Pharmaceuticals USA, Inc. ("Teva") filed an Abbreviated New Drug Application with the U.S. Food and Drug Administration ("FDA") for raloxifene hydrochloride for the prevention of postmenopausal osteoporosis and included a paragraph IV certification to Lilly's patents for Evista®. Lilly timely filed its infringement suit on the Bone-Loss Patents, the Low-Dose Patent, and the Particle-Size Patents. After trial, the district court held that Lilly's Bone-Loss Patents and its Low-Dose Patent were not invalid for obviousness under 35 U.S.C. § 103. The district court held that the Bone-Loss Patents and Low-Dose Patent are not invalid for failure to satisfy the enablement requirement of 35 U.S.C. § 112. The district court, however, held that the Particle-Size Patents lacked an adequate written description to satisfy 35 U.S.C. § 112.

The Federal Circuit affirmed the district court on all counts. The Court held that raloxifene's long history of bioavailability problems, specifically, the rapid metabolism and excretion of the compound, foreclosed a reasonable expectation of successfully treating postmenopausal osteoporosis with raloxifene. Because of this widely known deficiency, the Court noted that Teva pointed to no evidence that "would teach, suggest, or motivate or supply any common sense reason for a person of ordinary skill in the art to reject the bioavailability concerns and routinely, simply, or easily arrive" at Lilly's invention in the Bone-Loss Patents and Low-Dose Patent. Moreover, the Court rejected Teva's argument that the Low-Dose Patent claims were invalid for nonstatutory double patenting over the Bone-Loss Patents. Teva acknowledged that it did not raise the issue before the district court, and the Court concluded that the record was insufficiently clear for it to conclude that the proper resolution was beyond any doubt. The Court therefore "decline[d] to excuse Teva for failing to raise the nonstatutory double patenting issue at trial."

Teva further argued that if the Bone-Loss Patents and the Low-Dose Patent were nonobvious due to concerns about raloxifene's bioavailability, then the patents could not be enabled under § 112, first paragraph, because of the prevailing view that raloxifene would not work in humans. But the Federal Circuit affirmed that those skilled in the art could make and use the claimed invention, and that the specification disclosed the results of previously unpublished Lilly experiments. The Court also cited the U.S. Patent and Trademark Office's policy that FDA approval of a clinical

trial, the blueprint of which was described in the Bone-Loss Patents and which was ongoing at the time the application was filed, presumptively establishes "that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility."

Lastly, the Federal Circuit upheld the district court's invalidation of the Particle-Size Patents under written description. The Court noted that the proper test for written description was "whether the disclosure of the application … reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." While the Federal Circuit agreed that the district court may have improperly focused on "whether the patent includes a description of the steps that may be used to prove infringement," the result nevertheless could be affirmed. Because the specification only disclosed measurements of bulk raloxifene, and because the record was conflicting as to whether persons of ordinary skill would determine that the inventor possessed the invention of formulated raloxifene falling within the claimed size range, the Court could not hold that the district court made a clearly erroneous factual finding as to the Particle-Size Patents.

E. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 932 (2013)

Federal Circuit Issues New Standards for Determining Willfulness

In *Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.*, the Federal Circuit vacated portions of its previous decision in *Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.*, 670 F.3d 1171 (Fed. Cir. 2012), relating to willfullness. The Court held that the threshold objective prong of the willfulness standard enunciated in *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (en banc), is a question of law based on underlying mixed questions of law and fact, and is subject to de novo review. The Court remanded the issue of willfulness to the district court to reconsider its denial of judgement as a matter of law ("JMOL") of no willful infringement, with instructions that, if the court grants the JMOL, it should then reconsider its decisions on enhanced damages and attorneys' fees.

The Federal Circuit previously held that the district court was correct in its judgment and affirmed all of the conclusions reached by the district court. W.L. Gore & Associates, Inc. ("Gore") then filed a petition for rehearing and rehearing en banc, in which Gore again faulted the district court's willfulness analysis. Separately, an amicus brief in support of Gore's petition argued that the objective prong of willfulness should be considered a question of law subject to de novo review on appeal. The Federal Circuit granted the petition for rehearing en banc and asked the original panel to revisit the issue of willfulness and the applicable standard of review.

In revisiting the issue of willfulness, the Federal Circuit noted that *Seagate* established a two-pronged test for establishing willful infringement. First, "a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." Once the "threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk . . . was either known or so obvious that it should have been known to the accused infringer." The *Seagate* court left it to future cases to further develop the application of this standard. Following *Seagate*, the Federal Circuit established the rule that, generally, the objective prong of *Seagate* is not met where an accused infringer relies on a reasonable defense to a charge of infringement. Thus, the question on appeal is often whether a defense or noninfringement theory is "reasonable."

The ultimate question of willfulness has long been treated as a question of fact. The Federal Circuit, after reviewing its and the Supreme Court's precedent in similar contexts, concluded that simply stating that willfulness is a question of fact oversimplifies the issue, however. The Court explained that, while the ultimate question of willfulness based on an assessment of the second prong of *Seagate* may be a question of fact, the threshold determination of objective recklessness entails an objective assessment of potential defenses based on the risk presented by the patent. Those defenses may include questions of infringement, but also can be expected to entail questions of validity that are not necessarily dependent on the factual circumstances of the particular party accused of infringement.

The Court explained that when an "issue falls somewhere between a pristine legal standard and a simple historical fact, the fact/law distinction at times has turned on a determination that, as a matter of sound administration of justice, one judicial actor is better positioned than another to decide the issue in question." Applying this principle, the Federal Circuit decided that the Court is in the best position for making the determination of reasonableness. Accordingly, the Court held that the objective determination of recklessness, even though predicated on underlying mixed questions of law and fact, is best decided by the judge as a question of law subject to de novo review. The Federal Circuit instructed that, in considering the objective prong of *Seagate*, a judge may allow the jury to determine the underlying facts relevant to the defense in the first instance, for example, the questions of anticipation or obviousness. But, the ultimate legal question of whether a reasonable person would have considered there to be a high likelihood of infringement of a valid patent should always be decided as a matter of law by the judge.

Having clarified the legal standard for *Seagate*'s objective willfulness prong, the Court concluded that remand was appropriate to permit the district court to apply the correct standard to the question of willfulness in the first instance. Gore asserted several defenses that it says were "reasonable"– inventorship, inadequate written description, obviousness, and anticipation. On remand, the Court directed the district court to determine whether a reasonable litigant could realistically expect those defenses to succeed. If, in view of the facts, the asserted defenses were not reasonable, only then can the jury's subjective willfulness finding be reviewed for substantial evidence. Judge Newman concurred with vacating the previous determination on willfulness, but dissented from the partial remand. Judge Newman concluded that no remand was necessary because the record contained "a host of potentially relevant facts" that Gore could reasonably have believed would invalidate the patent at issue or support Gore's right to continue to

produce the accused products. Judge Newman believed that, if the Court insisted on a retrial of willfulness, the appealed issues of validity and inventorship should also be reviewed, as the question of infringement could evaporate, mooting any question of willfulness.

XXVII. Listing of Other Pharmaceutial, Biotech, and Chemical Cases Decided in 2012 from the Federal Circuit

A. Novelty - 35 U.S.C. § 102

Date	Case No.	Origin	Case Name	Brief Description
2012-02-17	2011-1078	DCT	*ClearValue, Inc. v. Pearl River Polymers, Inc.*	Broad range in prior art anticipates narrow range in claims
2012-05-08	2011-1376	PTO	*In re Montgomery*	Actual reduction to practice is not required for inherent anticipation of a therapeutic method
2012-06-22	2011-1140	DCT	*Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC.*	A reference may anticipate even if it requires a person of ordinary skill to pick items from lists of components to assemble the invention
2012-11-28	2011-1576	DCT	*Fox Grp., Inc. v. Cree, Inc.*	Invalidation under § 102(g) does not require prior conception if there was prior reduction to practice

B. Obviousness - 35 U.S.C. § 103

Date	Case No.	Origin	Case Name	Brief Description
2012-01-09	2010-1547	DCT	*Celsis In Vitro, Inc. v. CellzDirect, Inc.*	Market need properly linked to the invention can be probative of long-felt need and supportive of nonobviousness
2012-04-16	2011-1399	DCT	*In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*	Federal Circuit reaffirms broad and expansive obviousness inquiry, rejecting a formal burden-shifting framework
2012-05-17	2011-1073	PTO	*In re Baxter Int'l, Inc.*	Court affirms Board's decision of unpatentability despite previous affirmance of earlier declaration of validity by district court
2012-08-08	2011-1455	DCT	*Alcon Research, Ltd. v. Apotex Inc.*	The concentration range in an independent claim must include the concentrations in the dependent claims

Date	Case No.	Origin	Case Name	Brief Description
2012-09-21	2011-1600	PTO	*In re Droge*	Obviousness by combination of references is not undermined by inventor's declarations to the contrary
2012-11-30	2011-1638	DCT	*Arcelormittal France v. AK Steel Corp.*	Commercial success of embodiments having features not recited in the claims may be considered when determining obviousness

C. Infringement

Date	Case No.	Origin	Case Name	Brief Description
2012-02-09	2011-1182	DCT	*AstraZeneca Pharm. LP. v. Apotex Corp.*	Abbreviated New Drug Application seeking to market a drug for unpatented uses cannot infringe method-of-use patents under 35 U.S.C. § 271(e)(2)
2012-04-16	2011-1143	DCT	*Bayer Schering Pharma AG v. Lupin, Ltd.*	No liability for induced infringement where drug label does not instruct the patented method of use
2012-08-15	2011-1329	DCT	*Meyer Intellectual Props. Ltd. v. Bodum, Inc.*	Summary judgment of infringement of a patented method is inappropriate where plaintiff offers no evidence of actual use of the method
2012-09-28	2011-1584	DCT	*Pozen Inc. v. Par Pharm., Inc.*	Doctrine of equivalents not foreclosed where qualitative claim limitation is given a quantitative construction

D. Written Description, Enablement, Definiteness, and Best Mode - 35 U.S.C. § 112

Date	Case No.	Origin	Case Name	Brief Description
2012-09-04	2010-1360	DCT	*Santarus, Inc. v. Par Pharm., Inc.*	A negative claim limitation has adequate written description if the specification provides a reason to exclude the limitation

E. Inventorship

Date	Case No.	Origin	Case Name	Brief Description
2012-11-14	2011-1540	DCT	*Hor v. Chu*	For correction of inventorship under 35 U.S.C. § 256, the laches period begins when the patent issues

F. Inequitable Conduct

Date	Case No.	Origin	Case Name	Brief Description
2012-04-09	2011-1018	DCT	*Aventis Pharma S.A. v. Hospira, Inc.*	An inventor's lack of credibility can lead to a conclusion of intent to deceive and a finding of inequitable conduct
2012-12-14	2010-1460	DCT	*AstraZeneca v. Aurobindo*	No inference of deceptive intent where it is "equally plausible" that patent owner believed prosecution requirements had been met

G. Jurisdiction

Date	Case No.	Origin	Case Name	Brief Description
2012-04-16	2011-1507	DCT	*Dey Pharma, LP. v. Sunovion Pharm. Inc.*	Declaratory judgement jurisdiction exists even if the action may later become moot

H. Prosecution History Estoppel/Doctrine of Equivalents

Date	Case No.	Origin	Case Name	Brief Description
2012-09-28	2011-1516	PTO	*In re Abbott Diabetes Care Inc.*	A "clear disavowal" in a patent specification is not required to disclaim claim scope

I. Safe Harbor

Date	Case No.	Origin	Case Name	Brief Description
2012-08-03	2012-1062	DCT	*Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*	The § 271(e)(1) safe harbor covers generic quality control batch testing even after FDA approval

J. Double Patenting

Date	Case No.	Origin	Case Name	Brief Description
2012-05-07	2011-1126	DCT	*Otsuka Pharm. Co., v. Sandoz, Inc.*	Obviousness-type double patenting

K. Interference

Date	Case No.	Origin	Case Name	Brief Description
2012-02-07	2011-1212	PTO	*Adair v. Carter*	To overcome § 135(b)(1) precritical date, claims need to be compared to postcritical-date claims, not copied patent claims
2012-02-28	2011-1285	PTO	*Pioneer Hi-Bred Int'l, Inc. v. Monsanto Tech. LLC*	A party to an interference proceeding may rely on multiple precritical-date claims to support a postcritical-date challenge to a patent

L. Other

Date	Case No.	Origin	Case Name	Brief Description
2012-03-28	2011-1263	DCT	*Promega Corp. v. Life Techs. Corp.*	Decision compelling arbitration affirmed where valid agreement exists
2012-05-31	2011-1471	DCT	*Merial Ltd. v. Cipla Ltd.*	Nonparty acting in concert with enjoined party may be held in contempt of injunction

2012-07-02	2012-1228	DCT	*Sciele Pharma Inc. v. Lupin Ltd.*	Presumption of validity of an issued patent is unchanged by mistaken issuance of a claim or previous consideration of prior art by the PTO
2012-08-07	2011-1219	DCT	*Highmark, Inc. v. Allcare Health Mgmt. Sys., Inc.*	Withdrawal of Rule 11 sanctions against an attorney does not preclude an exceptional case finding under 35 U.S.C. § 285
2012-11-13	2011-1215	DCT	*Edwards Lifesciences AG v. CoreValve, Inc.*	Equitable aspects must always be considered in determining the availability of injunctive relief regarding valid and infringed patents