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Last Month at the Federal Circuit

September 2011

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In re NTP, Inc.

No. 10-1277 (Fed. Cir. Aug. 1, 2011)

In re NTP, Inc.

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[Appealed from Board]

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[Appealed from D. Md., Judge Quarles, Jr.]

Abbreviations

ALJ	Administrative Law Judge
ANDA	Abbreviated New Drug Application
APA	Administrative Procedures Act
APJ	Administrative Patent Judge
Board	Board of Patent Appeals and Interferences
Commissioner	Commissioner of Patents and Trademarks
CIP	Continuation-in-Part
DJ	Declaratory Judgment
DOE	Doctrine of Equivalents
FDA	Food and Drug Administration
IDS	Information Disclosure Statement
ITC	International Trade Commission
JMOL	Judgment as a Matter of Law
MPEP	Manual of Patent Examining Procedure
NDA	New Drug Application
PCT	Patent Cooperation Treaty
PTO	United States Patent and Trademark Office
SJ	Summary Judgment
TTAB	Trademark Trial and Appeal Board

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Spotlight Info

In *Classen Immunotherapies, Inc. v. Biogen IDEC*, Nos. 06-1634, -1649 (Fed. Cir. Aug. 31, 2001), the Federal Circuit, on remand from the Supreme Court following *Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218 (2010), held, inter alia, that two patents contain patentable subject matter under 35 U.S.C. § 101 but that a third patent does not. Classen Immunotherapies, Inc. ("Classen") holds three related patents directed to a schedule of infant immunization designed to reduce risk for later occurrence of chronic immune-mediated disorders. Following the Supreme Court's guidance from *Bilski* on remand, the Federal Circuit found that, although the claimed methods in two of Classen's patents included a mental step, these claims also included a physical step and therefore are directed to a specific, tangible application. In contrast, the Federal Circuit found that the claimed method in the third Classen patent only involved collecting and comparing known information, and thus failed to qualify for patent eligibility under § 101. Judge Moore dissented from the Court's holding, because in her view, the claims-at-issue are to a fundamental principle that is too basic to be patentable. Thus, Judge Moore would have found the subject matter of all three patents ineligible under § 101. 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, because patent drafters devise new ways to circumvent judicially imposed restrictions and these restrictions could drive innovation outside the United States. See this month's edition of *Last Month at the Federal Circuit* for a full summary of the decision.

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Looking Ahead

On September 1, 2011, in *Harari v. Lee*, Nos. 10-1075, -1076 (Fed. Cir. Sept. 1, 2011), the Federal Circuit, in deciding two patent interferences, provided guidance on at least two important issues. First, the Court reiterated that the standard for determining whether and to what extent a patent application incorporates material by reference is “whether one reasonably skilled in the art would understand the application as describing with sufficient particularity the material to be incorporated.” Slip op. at 6 (citing *Zenon Envtl., Inc. v. U.S. Filter Corp.*, 506 F.3d 1370, 1378-79 (Fed. Cir. 2007)). As applied here, the Court found that the language “[t]he disclosures of the two applications are hereby incorporate[d] by reference” incorporates the entire disclosures of the two applications rather than just specific portions of the referenced applications.

Second, the Federal Circuit held that the indefinite article “a” in the claim term “a bit line,” within an open-ended (i.e., “comprising”) claim, means “a single bit line” based on the claim language and the contextual usage in the specification. The Court distinguished its decision in *Baldwin Graphic Systems, Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008), in which it held that a claim reciting a system comprising “a pre-soaked fabric roll” and a “means for locating said fabric roll” encompassed systems with more than one fabric roll. Slip op. at 19. The Court noted that “*Baldwin* . . . does not set a hard and fast rule that ‘a’ always means one or more than one.” *Id.* Rather, as discussed in *Insituform Technologies, Inc. v. Cat Contracting, Inc.*, 99 F.3d 1098, 1105-06 (Fed. Cir. 1996), the term “a” must be construed in light of the claim and specification. In this case, the Court found that the term was limited to one. Read the full summary in next month’s edition of *Last Month at the Federal Circuit*.

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PTO May Consider § 112 Issues During Reexamination When Determining Entitlement to a Priority Claim

Daniel A. Lev

Judges: Gajarsa (author of *NTP One*), Clevenger, Moore (author of *NTP Seven*)
[Appealed from Board]

On August 1, 2011, the same Federal Circuit panel issued two decisions related to the reexaminations of eight of NTP, Inc.'s ("NTP") patents, all of which the Board found invalid. In *In re NTP, Inc.*, No. 10-1277 (Fed. Cir. Aug. 1, 2011) ("*NTP One*"), the Federal Circuit affirmed the rejection of all 764 claims of U.S. Patent No. 6,317,592 ("the '592 patent"), affirmed the Board's holding that the PTO may consider priority in the context of a reexamination, and affirmed the Board's construction of the claim term "destination processor." In the other decision, *In re NTP, Inc.*, Nos. 10-1243, -1254, -1263, -1274, -1275, -1276, -1278 (Fed. Cir. Aug. 1, 2011) ("*NTP Seven*"), the Federal Circuit vacated-in-part, reversed-in-part, and remanded the case to the Board, holding that the Board's constructions of the claim term "electronic mail message" and similar terms were overly broad. The Court also found that a certain prior art reference was a printed publication under 35 U.S.C. § 102(b).

Both *In re NTP* decisions relate to a family of eight patents directed to an electronic mail system that transmits an electronic mail message from an originating processor to a destination processor through a radio frequency ("RF") data transmission network. The NTP patent family pertains to technology for transmitting e-mail messages over RF networks, e.g., cellular phone networks. The Federal Circuit previously considered this patent family when NTP sued Research In Motion, Ltd. ("RIM") for patent infringement. See *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 2005). During the course of that infringement litigation, which the parties eventually settled, RIM filed the eight reexaminations that are the subject of the two *In re NTP* decisions. *NTP One* relates to the '592 patent. *NTP Seven* relates to the following seven U.S. Patent Nos.: 5,436,960 ("the '960 patent"); 5,438,611 ("the '611 patent"); 5,479,472 ("the '472 patent"); 5,625,670 ("the '670 patent"); 5,631,946 ("the '946 patent"); 5,819,172 ("the '172 patent"); and 6,067,451 ("the '451 patent").

NTP One

In some embodiments of the '592 patent-at-issue in *NTP One*, the electronic mail message is transmitted through the data transmission network using a gateway switch and/or an interface switch. A gateway switch stores information that it receives from an originating processor before that information is transmitted to a destination processor. An interface switch connects the gateway switch to the RF transmission network to transmit the stored information.

During reexamination of the '592 patent, the examiner rejected all 764 claims as anticipated, obvious, lacking written description, and/or lacking enablement. The examiner found that eight prior art references anticipated or rendered obvious some or all of the claims. One of those references, U.S.

Patent No. 6,219,694 (“Lazaridis”), was prior art under 35 U.S.C. § 102(e) only because the examiner concluded that the pending claims were not entitled to the earlier priority date of the parent application of the '592 patent. Specifically, the examiner found that the written description of the parent application did not support a “destination processor” that could retransmit the contents of an electronic mail message, as claimed in the '592 patent. NTP appealed to the Board, which rejected NTP’s argument that a destination processor could be an intermediate node device, i.e., that it could both receive and retransmit e-mail messages in the e-mail messaging system of the invention. The Board agreed with the examiner that the written description of the parent application described only a destination processor that can receive an electronic mail message. Thus, the Board held that Lazaridis anticipated all the claims of the '592 patent. NTP appealed to the Federal Circuit, which addressed three issues related to the '592 patent: (1) whether the Board properly construed the term “destination processor”; (2) whether priority is properly considered during reexamination; and (3) if it is, whether determining priority is appropriate in this case.

On appeal, NTP did not dispute that Lazaridis anticipates all the claims of the '592 patent if the '592 patent is not entitled to claim the priority date of its parent application. Instead, NTP argued that the Board erred in construing the term “destination processor.” Under NTP’s proposed construction, the written description of the parent application would support the claimed functions of the destination processor and thus entitle the '592 patent to claim an earlier priority date. NTP also argued that the PTO generally erred by considering the '592 patent’s priority claim during reexamination proceedings.

“There is no statutory limitation during a reexamination proceeding prohibiting the examiner from conducting a priority analysis. Otherwise, the examiner would be stripped of a critical legal tool needed in performing a proper reexamination.” *NTP One* slip op. at 15.

The Federal Circuit first gave the term “destination processor” its broadest reasonable interpretation consistent with the specification, reviewing the PTO’s claim construction *de novo*. The Court affirmed the Board’s construction of “destination processor” because it “is legally correct and is reasonable in view of the written description and how the written description would be interpreted by one of ordinary skill in the art.” *NTP One* slip op. at 9.

The Federal Circuit also affirmed the PTO’s consideration of the '592 patent’s priority claim during reexamination. The Court explained that, in the reexamination context, nothing in 35 U.S.C. §§ 301 *et seq.* entitles a patentee to a claim of right to its earliest priority date. Thus, the Court held that, during reexamination as in initial examination, a patentee must prove entitlement to an earlier priority date. Finding “no statutory limitation during a reexamination proceeding prohibiting the examiner from conducting a priority analysis” and declining to strip the examiner “of a critical legal tool needed in performing a proper reexamination,” the Court affirmed the PTO’s decision to analyze priority during reexamination. *Id.* at 15.

The Federal Circuit also concluded that the Board properly determined priority in this case. In so doing, the Court reminded that Congress amended 35 U.S.C. § 303(a) in 2002 to explain that “[t]he existence of a substantial new question of patentability 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].” *Id.* at 16 (first alteration in original) (citation omitted). Thus, the Court reminded that there is no presumption that the examiner considered whether the written description of the parent application supports the claims of the '592 patent simply because the MPEP requires it. Whether the examiner actually considered this issue can only be determined by reviewing the prosecution history, which the Court found did not support NTP’s position. Accordingly, the Federal Circuit affirmed the Board’s determination of priority.

NTP Seven

The seven patents-at-issue in *NTP Seven* share substantially identical specifications. The patents are directed to a system for sending information from an originating processor to a destination processor using an RF receiver as an intermediary. The Federal Circuit addressed four issues that NTP raised in

seven related appeals: (1) whether the Board properly construed the terms “electronic mail message” and “electronic mail system”; (2) whether the Board erred when it found that NTP could not antedate several references under 37 C.F.R. § 1.131; (3) whether a particular reference cited by the reexamination requester, called “Telenor,” qualifies as a printed publication under 35 U.S.C. § 102(b); and (4) whether the Board properly rejected NTP’s patent claims based on various prior art references.

First, the Federal Circuit reviewed de novo the Board’s construction of “electronic mail” or “electronic mail message” and “electronic mail system,” giving the terms their broadest reasonable construction consistent with the specification. For the claim terms “electronic mail” or “electronic mail message,” the Court concluded that the broadest reasonable construction of these terms is “a message that has a destination address and the capability for entry of message content, an identification of an originating processor, and a subject.” *NTP Seven* slip op. at 9. With respect to the term “electronic mail system,” the Court held that the broadest reasonable construction is the construction the Court provided in the previous RIM litigation. Accordingly, the Court vacated the Board’s decisions as to the invalidity of the patents-in-suit and remanded to the Board to apply the correct claim constructions to the prior art.

Next, the Federal Circuit considered the Board’s finding that NTP could not antedate several references using affidavits that NTP submitted under 37 C.F.R. § 1.131. Section 1.131 allows a party to antedate a reference based on prior reduction to practice by presenting evidence of the actual reduction to practice of the invention prior to the effective date of the reference, which is typically an affidavit of the inventor accompanied by corroborating evidence. The critical date for the prior art that NTP sought to antedate was October 29, 1990. NTP submitted inventor affidavits alleging reduction to practice prior to that date, along with allegedly corroborating evidence.

The Court explained that it “does not reweigh evidence [of reduction to practice] on appeal, but rather determines whether substantial evidence supports the Board’s fact findings.” *Id.* at 18. The Court concluded that substantial evidence supported the Board’s findings that NTP’s documents do not evidence a reduction to practice prior to the critical date and that the allegedly corroborative evidence did not corroborate the testimony of the inventors, who also had an interest in the outcome of the reexaminations.

The Federal Circuit next considered whether the “Telenor” reference is a printed publication under 35 U.S.C. § 102(b). The reexamination requester located Telenor in the library of the Norwegian University of Science and Technology and submitted the reference to the PTO. The copies of Telenor submitted to the PTO indicate that they were received and cataloged more than a year before the critical date of NTP’s patents. NTP argued that the Telenor document was not authentic or reasonably accessible to those of skill in the art, and thus, the Board erred in using it in its invalidity analysis as a “printed publication” under § 102(b).

With regard to the authenticity of the Telenor documents, the Federal Circuit held that substantial evidence supported the Board’s finding that the Telenor documents are authentic. The Court, as it did in *In re Hall*, 781 F.2d 897 (Fed. Cir. 1986), relied on competent evidence of general library practice to establish an approximate time when a document became available. Here, a letter from the director of the library extensively discussed the library’s cataloging practices. The Court also agreed with the Board that the Telenor reference was reasonably accessible because the subject matter categories assigned to Telenor by the library, i.e. “computer networks” and “communication protocols,” would have allowed one of ordinary skill in the art exercising reasonable diligence to find the reference.

The Federal Circuit next considered four specific prior art rejections, including one based on the Telenor reference, that did not depend on the claim constructions being remanded to the Board. The Court reversed one of the Board’s obviousness rejections because it was based on improper hindsight reasoning, reversed another obviousness rejection because the combination was insufficient in scope, and affirmed a third obviousness rejection. With regard to the Telenor reference, NTP argued that Telenor “does not enable one with ordinary skill in the art to build a system for transmission of originated information from an RF information transmission network to an RF receiver.” *NTP Seven* slip op. at 34. The Court disagreed, concluding that Telenor is a sufficiently enabling disclosure as a matter of law.

The Court explained, “Simply because Telenor did not include every possible implementation does not mean one of ordinary skill in the art would not recognize the description as enabled.” *Id.* at 35. The Court reversed the Board’s anticipation decision with respect to certain claims containing limitations that the Court found Telenor does not disclose, but affirmed the Board’s invalidity decision in other respects.

Finally, the Federal Circuit reviewed various concessions that NTP made in its appeal brief and ruled that NTP may not reargue those points on remand. Given that it raised the issues but then conceded them, the Court bound NTP by the concessions.

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A Claim Error Obvious and Correctable from the Perspective of a Person of Ordinary Skill in the Art Held Not Invalid

Ruby J. Natnithithadha

Judges: Lourie (author), Bryson, Linn

[Appealed from N.D. Ga., Judge Thrash, Jr.]

In *CBT Flint Partners, LLC v. Return Path, Inc.*, Nos. 10-1202, -1203 (Fed. Cir. Aug. 10, 2011), the Federal Circuit reversed the district court's SJ of invalidity of claim 13 of U.S. Patent No. 6,587,550 ("the '550 patent") because the district court had authority to correct the supposed error found in the claim, vacated the district court's rulings on costs, and denied CBT Flint Partners, LLC's ("CBT") cross-appeal for attorneys' fees.

CBT owns the '550 patent and U.S. Patent No. 6,192,114 ("the '114 patent"), which both relate to methods and systems for charging a fee for sending unsolicited and unwanted e-mail (known as "spam"). In a preferred embodiment of the '550 patent system, when a party sends a spam message to an intended receiving party, the Internet Service Provider determines whether the sender of the e-mail is an authorized sending party, and, if authorized, forwards the spam e-mail to the receiving party. If, however, the sending party is not authorized, the system sends a message to the sending party with an option to pay a fee and have the spam message forwarded to the recipient. Claim 13 of the '550 patent, the only claim-at-issue in the appeal, recites, inter alia, "[a]n apparatus for determining whether a sending party . . . is an authorized sending party, the apparatus comprising: a computer in communication with a network, the computer being programmed to *detect analyze* the electronic mail communication sent by the sending party to determine whether or not the sending party is an authorized sending party or an unauthorized sending party" Slip op. at 3-4 (citation omitted).

CBT sued Cisco Ironport Systems, LLC ("Cisco") and Return Path, Inc. ("Return Path") for infringement of the '550 and '114 patents. The accused system analyzes each incoming e-mail message to determine whether the e-mail came from an authorized computer, and, if so, forwards it. The accused system, however, does not have any mechanism to permit the forwarding of e-mail from unauthorized computers to a recipient, even if the unauthorized sending party is willing to pay a fee.

The district court agreed with the parties that claim 13 contained a "drafting error"; specifically, the claim recites "the computer being programmed to *detect analyze* the electronic mail communication." *Id.* at 4 (citation omitted). The district court determined that there were at least three reasonable corrections to rectify the drafting error: (1) delete the word "detect," (2) delete the word "analyze," or (3) add the word "and" between the words "detect" and "analyze." The district court held that since the appropriate correction was subject to reasonable debate, it was therefore not authorized to correct the so-called drafting error, and, thus, the claim was invalid for indefiniteness. Cisco moved for a finding of an exceptional case and an award of attorneys' fees, and submitted its bill of costs. The district court

awarded costs but denied Cisco's motion for declaration of an exceptional case and its request for attorneys' fees. CBT appealed the district court's SJ of invalidity of claim 13 of the '550 patent and the court's award of costs to Cisco. Cisco cross-appealed the district court's denial of its motion for designation as an exceptional case and attorneys' fees.

On appeal, the Federal Circuit agreed with CBT that claim 13 was not indefinite because there was "an obvious and correctable error in the claim, the construction of which is not subject to reasonable debate." *Id.* at 8. First, the Court noted that in *Novo Industries L.P. v. Micro Molds Corp.*, 350 F.3d 1348 (Fed. Cir. 2003), it held that a "district court can correct a patent only if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims." Slip op. at 9 (quoting *Novo Indus.*, 350 F.3d at 1357).

"A court therefore must consider how a potential correction would impact the scope of a claim and if the inventor is entitled to the resulting claim scope based on the written description of the patent." Slip op. at 10.

Second, the Federal Circuit concluded that the district court erred by holding that it was not authorized to "correct" the supposed "detect analyze" error. In particular, the district court failed to consider the three alternative corrections from the point of view of one skilled in the art. From that perspective, a person of skill in the art would find the claim to have "the same scope and meaning under each of the three possible meanings that the court found reasonable," *id.* at 10, because each requires that the computer be programmed to "detect and analyze" the subject e-mail.

With respect to the district court's first possible interpretation, the Federal Circuit noted that if the word "detect" were deleted, the claim would require that the computer be programmed to analyze the e-mail, but "the system would necessarily have to first detect the e-mail." *Id.* Deleting the word "analyze," in accordance with the district court's second possible interpretation, would require that the computer be programmed to detect the e-mail and then "determine whether or not the sending party is an authorized sending party or an unauthorized sending party." *Id.* at 11. The Court concluded, however, that the "determining step must include some form of analysis of the e-mail," because "detecting an e-mail does not determine whether the user is an authorized sending party." *Id.*

The Federal Circuit thus found that the district court's final possible interpretation, inserting the word "and" between the words "detect" and "analyze," would be readily known by a person of skill in the art "[b]ecause each of the three proposed reasonable interpretations would result in the same claim scope." *Id.* Further, the specification supports this reading of the claim because it discloses a decoding step that the Court found "necessarily detect[ed] the e-mail message," and a "compar[ing]" step, which, according to the Court, was "one of analysis." *Id.* at 12. Thus, the district court was not required to guess which meaning was intended in order to make sense out of the patent claim.

In so finding, the Federal Circuit rejected Cisco's assertion that correction of a claim must precede claim construction. Rather, the Court held that "[a]ny correction of a claim has to be consistent with the invention 'described in the specification and drawings of the original patent,'" *id.* at 10 (citation omitted), and "[a] court therefore must consider how a potential correction would impact the scope of a claim and if the inventor is entitled to the resulting claim scope based on the written description of the patent," *id.*

Finally, the Federal Circuit found that the district court erred by relying too heavily on one portion of the inventor's testimony, which the district court misinterpreted, and by ignoring the inventor's testimony that the meaning of the claim would be the same under each of the three interpretations because both detection and analysis were necessary to determine whether the sending party was authorized.

Accordingly, the Federal Circuit reversed the district court's SJ of invalidity of claim 13 of the '550 patent, vacated the district court's rulings on costs because Cisco was no longer a prevailing party, denied the cross-appeal, and remanded to the district court for further proceedings consistent with the Court's opinion.

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Assignment of “Inventions and Discoveries” Disclosed in an Application Also Assigned Unrelated Application Covered by the Disclosure

Kevin D. Rodkey

Judges: Rader, Gajarsa (author), Prost
[Appealed from E.D. Tex., Judge Ward]

In *MHL Tek, LLC v. Nissan Motor Co.*, Nos. 10-1287, -1317, -1318 (Fed. Cir. Aug. 10, 2011), the Federal Circuit affirmed the district court’s decision that MHL Tek, LLC (“MHL”) lacked standing to assert two patents-in-suit, reversed the district court’s decision that MHL had standing to assert the third patent-in-suit, and vacated the district court’s decision granting SJ of noninfringement relating to the third patent-in-suit.

MHL sued Nissan Motor Co. (“Nissan”) and several other defendant automobile manufacturers (collectively the “defendants”), alleging infringement of U.S. Patent Nos. 5,663,496 (“the ‘496 patent”); 5,741,966 (“the ‘966 patent”); and 5,731,516 (“the ‘516 patent”) (collectively “the patents-in-suit”). The patents-in-suit relate to tire pressure monitoring systems (“TPMS”) and have the same inventors. A TPMS monitors a tire’s pressure and transmits pressure information to the vehicle’s operator. Both the ‘496 and ‘966 patents are divisionals of U.S. Patent Application No. 08/101,379 (“the Parent Application”). The later-filed ‘516 patent is not related to either of the two other patents-in-suit or the Parent Application.

The ‘496 patent generally claims a sensor inside of the tire that generates a signal related to the tire’s pressure and transmits the signal along a communications link to a receiver. The communications link allows the pressure signal to travel along the conductive components of the car. The preferred embodiment includes a piezo-resistive power source allowing for reduced energy expenditures when the tires are stationary. The ‘966 patent has similar claims to the ‘496 patent with the addition of a “processor control command” that allows remote-controlled command entry. The ‘516 patent claims a TPMS in which all of the components are contained within a “cylindrical housing” and together measure tire pressure and allow the signal to be transmitted.

Shortly after the Parent Application was filed, the inventors executed an assignment to Animatronics Inc. (“Animatronics”) assigning “the entire right, title and interest, domestic and foreign, in and to the inventions and discoveries in [the Parent Application]” to Animatronics. Slip op. at 10 (alteration in original) (citation omitted). Animatronics subsequently assigned “the entire right, title and interest, domestic and foreign, in and to the inventions and discoveries set forth in the [Parent] Application” to McLaughlin Electronics (“ME”). *Id.* (alteration in original) (citation omitted). The assignment from Animatronics to ME contained a carve out provision that the assignment “shall not cover any rights to the [Parent] Application that concern the Animatronics Proprietary Inventions.” *Id.* (alteration in original) (citation omitted). Instead, pursuant to a development agreement between ME and Animatronics,

Animatronics had an exclusive, irrevocable, royalty-free license to use the Animatronics Proprietary Inventions to make, use, and sell the TPMS, which did not prevent Animatronics from using the Animatronics Proprietary Inventions to make, use, and sell other non-TPMS products. The Animatronics Proprietary Inventions included “(1) the Communications Link; (2) a radio frequency transceiver and algorithm used in the Service Unit and Sensor Unit; and (3) a peizo [sic] resistive rubber pressure sensor for use in the Sensor Unit.” *Id.* at 11 (alteration in original) (citation omitted). Eventually, Animatronics and ME disputed ownership of the '496 and '966 patents under the development agreement, but the dispute was never resolved.

Fourteen years later, the inventors of the patents-in-suit purported to assign the patents-in-suit to MHL. MHL then brought a first suit against the defendants alleging patent infringement. Shortly thereafter, Animatronics purportedly assigned the patents-in-suit to MHL and MHL filed a second suit against the defendants in March 2008. The district court eventually dismissed MHL's claims relating to the '496 and '966 patents for lack of standing, holding that the '496 and '966 patents were not subject to the carve out provision of the license and therefore were assigned from Animatronics to ME. The district court then determined that the defendants did not infringe the asserted claims of the '516 patent. Both parties appealed.

On appeal, the Court first reviewed the scope of the assignment from Animatronics to ME and rejected ME's argument that the '496 and '966 patents were subject to the carve out provision, which concerned the Animatronics Proprietary Inventions. The Court determined that the Communications Link in the assignment was a “system,” whereas the '496 patent defined the communications link as an electromagnetic path. The Court stated that MHL's argument confused the patent specification with the patent assignment, which controls the scope of the assignment. The Court noted that MHL did not argue that the '496 patent claims covered the Communications Link of the patent assignment, even though one claim did include some components of the Communications Link. Rather, the Court agreed with the district court that the '496 patent claimed a TPMS. The Court held that MHL had not met its burden of showing that the claims of the '496 patent cover the Communications Link and, therefore, MHL lacked standing to assert the '496 patent.

“[T]he resolution of MHL Tek's standing to assert the '516 patent depends on whether the inventions claimed therein are the 'inventions and discoveries' set forth in the Parent Application. . . . Thus, so long as the written description of the Parent Application 'reasonably conveys to those skilled in the art' the invention claimed in the '516 patent, the '516 patent was assigned to Animatronics and then to ME.” Slip op. at 18-19 (citation omitted).

Turning next to the '966 patent, the Court rejected MHL's argument that the claims of the '966 patent cover the “Service Unit and its RF Link,” and are therefore subject to the carve out provision. The Court noted that the carve out provision covers only a “radio frequency transceiver and algorithm used in the Service Unit and Sensor Unit,” and that the communications link claimed in the '966 patent was not used in the Sensor Unit. The Court observed that the communications link was at most used with the Service Unit and not used in it, and was therefore not subject to the carve out provision.

Next, the Court addressed MHL's argument that the '966 patent claims the piezo-electric elements of the Animatronics Proprietary Inventions and is therefore subject to the carve out provision. The Court rejected this argument, noting that the carve out provision does not use the phrase “piezo electric.” Rather, the Court observed that Animatronics reserved the rights to a “peizo [sic] resistive rubber pressure sensor for use in the Sensor Unit.” *Id.* at 17 (alteration in original) (citation omitted). The Court determined that the piezo-resistive element of the carve out provision is a pressure sensor, whereas the claimed piezo-electric element supplies power. Furthermore, the Court noted that the '966 patent does not describe a rubber piezo-resistive element. Therefore, the Court held that MHL lacked standing to assert the '496 and '966 patents.

Finally, the Court addressed MHL's standing to sue under the '516 patent. The Court noted that the

inventors assigned the entire right, title, and interest “in and to the inventions and discoveries” in the Parent Application, and that similar language was used in assignment from Animatronics to ME. The Court rejected MHL’s argument that the ’516 patent is not subject to the assignment because it is not related to the Parent Application. The Court determined that the language of the assignment was not so narrow because it assigns “inventions and discoveries” disclosed in the Parent Application without requiring them to be in patents or applications related to the Parent Application. The Court further noted that the file history of a divisional application related to the ’516 patent stated that the inventors had assigned the application to Animatronics, expressing the view that the assignment covered more than applications related to the Parent Application. The Court then compared the claims of the ’516 patent to the specification of the Parent Application and stated that if the Parent Application reasonably conveyed to those skilled in the art the invention of the ’516 patent, then the ’516 patent had been assigned to Animatronics, then to ME. Findings that all of the elements of the claims of the ’516 patent were disclosed in the Parent Application, the Court determined that the ’516 patent had been assigned to Animatronics and was not subject to the carve out provision. The Court held that because the ’516 patent was assigned from the inventors to Animatronics, then to ME, MHL lacked standing to assert the ’516 patent.

Because MHL lacked standing to assert any of the patents-in-suit, the Court vacated the grant of SJ for noninfringement regarding the ’516 patent.

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Methods That Could Be Entirely Executed Mentally Found Unpatentable Under 35 U.S.C. § 101

Sulay D. Jhaveri

Judges: Bryson, Dyk (author), Prost
[Appealed from N.D. Cal., Judge Patel]

In *CyberSource Corp. v. Retail Decisions, Inc.*, No. 09-1358 (Fed. Cir. Aug. 16, 2011), the Federal Circuit affirmed the district court's grant of SJ of invalidity of claims 2 and 3 of U.S. Patent No. 6,029,154 ("the '154 patent") under 35 U.S.C. § 101 for failure to recite patent-eligible subject matter.

CyberSource Corporation ("CyberSource") owns the '154 patent, which recites a method and system for detecting fraud in a credit card transaction between a consumer and a merchant over the Internet. Claim 3 recites "[a] method for verifying the validity of a credit card transaction over the Internet comprising the steps of: a) obtaining information about other transactions that have utilized an Internet address that is identified with the . . . credit card transaction; b) constructing a map of credit card numbers based upon the other transactions and; c) utilizing the map of credit card numbers to determine if the credit card transaction is valid." Slip op. at 3 n.1. Claim 2 recites "[a] computer readable medium containing program instructions for detecting fraud in a credit card transaction between a consumer and a merchant over the Internet . . ." *Id.* at 3 n.2.

CyberSource brought suit against Retail Decisions, Inc. ("Retail Decisions"), alleging infringement. In response, Retail Decisions initiated an *ex parte* reexamination, which resulted in amended claims. After reexamination, Retail Decisions moved for SJ of invalidity under 35 U.S.C. § 101. The district court found that claim 3 recited an unpatentable mental process for collecting data and weighing values, which did "not become patentable by tossing in references to [I]nternet commerce," and found with respect to claim 2 that "simply appending 'A computer readable media including program instructions . . .' to an otherwise non-statutory process claim is insufficient to make it statutory." *Id.* at 5 (alterations in original) (citations omitted).

On appeal, CyberSource argued that the method of claim 3 is tied to a particular machine because it "would not be necessary or possible without the Internet." *Id.* at 9 (citation omitted). In *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008) (en banc), the Court held that a claimed process would only be "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." Slip op. at 6 (quoting *Bilski*, 545 F.3d at 954). The Court noted that regardless of whether the Internet is a machine, nothing in claim 3 requires an infringer to use the Internet to obtain that data. The Court also noted that the mere collection and organization of data regarding credit card numbers and Internet addresses is insufficient to meet the transformation prong of the test. Further, the Court agreed with the district court that claim 3 also fails to meet the machine-or-transformation test. But, the Court did not end its analysis there, because in *Bilski v. Kappos*, 130 S. Ct.

3218, 3226 (2010), the Supreme Court rejected use of the machine-or-transformation test as the exclusive test for the patentability of a claimed process.

“Here, the incidental use of a computer to perform the mental process of claim 3 does not impose a sufficiently meaningful limit on the claim’s scope. As such, the ‘computer readable medium’ limitation of claim 2 does not make the otherwise unpatentable method patent-eligible under § 101.” Slip op. at 19.

The Court further analyzed claim 3 in view of two Supreme Court cases, *Gottschalk v. Benson*, 409 U.S. 63 (1972), and *Parker v. Flook*, 437 U.S. 584 (1978), and found it drawn to an unpatentable mental process—a subcategory of unpatentable abstract ideas. The Court found that all three steps of claim 3 can be performed in the human mind or by a human using a pen and paper. For instance, step (a) can be performed by a human who simply reads records of Internet credit card transactions from a preexisting database; step (b) does not require the constructed “map” to consist of anything more than a list of a few credit card transactions; and step (c) is broadly written to encompass any method for detecting fraud based on the gathered transaction and Internet address data, including logical reasoning that can be performed entirely in the human mind. Finally, the Court noted that claim 2 is a “Beauregard claim” to a computer-readable medium (e.g., a disk, hard drive, or other data storage device) containing program instructions for a computer to perform a particular process. The Court, however, characterized the claim as nothing more than a computer-readable medium containing program instructions for executing the method of claim 3. The Court disagreed with CyberSource’s argument that claim 2 is patent eligible per se because it recites a “manufacture,” because the invention underlying the claims is a method for detecting credit card fraud, not a manufacture for storing computer-readable information. The Court compared this case to *In re Abele*, 684 F.2d 902 (CCPA 1982), where, although the claim invoked an “[a]pparatus,” the court treated it as a method claim for the purpose of its § 101 analysis. The Court also found that the claim failed the machine-or-transformation test. The Court noted that the machine did not play a significant part in permitting the claimed method to be performed, and, further, the mere manipulation or reorganization of data did not satisfy the transformation prong. The Court distinguished this case from two recent cases, *SiRF Technology, Inc. v. International Trade Commission*, 601 F.3d 1319, 1333 (Fed. Cir. 2010), and *Research Corp. Technologies v. Microsoft Corp.*, 627 F.3d 859 (Fed. Cir. 2010), where the machine was required for the method. Thus, the Court affirmed the district court’s finding that claims 2 and 3 were invalid under § 101.

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§ 102(b) On-Sale Bar Does Not Require an Invention to Be Ready for Patenting When Offered for Sale

Michael D. Stone

Judges: Dyk, Moore (author), O'Malley

[Appealed from D. Minn., Chief Judge Davis]

In *August Technology Corp. v. Camtek, Ltd.*, No. 10-1458 (Fed. Cir. Aug. 22, 2011), the Federal Circuit affirmed-in-part, vacated-in-part, and remanded for further proceedings. The Court affirmed the district court's denials of JMOL and a new trial on invalidity, while also affirming the district court's dismissal of Camtek, Ltd.'s ("Camtek") inequitable conduct defense and counterclaim. Finding the district court erred in its claim construction of the term "wafer," the Court vacated the district court's judgment of infringement, its award of damages, and its grant of a permanent injunction, and remanded for further proceedings.

August Technology Corporation and Rudolph Technologies, Inc. (collectively "August Tech") sued Camtek for infringing claims 1 and 3 of U.S. Patent No. 6,826,298 ("the '298 patent"). A jury found that Camtek literally infringed both claims, the infringement was not willful, and awarded damages. The jury also found Camtek failed to prove the asserted claims were obvious, and that August Tech's NSX-80 device was not on sale prior to the critical date of the '298 patent. The district court then permanently enjoined Camtek from making, using, selling, and offering for sale its infringing Falcon machines. The district court also held that there was no need for a separate trial on inequitable conduct, since the jury found that the NSX-80 device was not prior art. The district court then denied Camtek's post-trial motions for JMOL or a new trial on infringement, damages, and obviousness.

Claims 1 and 3 of the '298 patent are directed to a system and a method for inspecting integrated circuits printed on substrates such as wafers. The claim construction of the district court focused on two claim limitations, "wafer" and "strokes . . . based on velocity." The first claim construction dispute centered upon whether a "wafer" is also a "plurality of wafers." The district court construed a wafer to be "a thin slice of semiconductor material with circuitry thereon that is ready for electrical testing, *or any part thereof*." However, a "wafer" is not the same as a "die." Slip op. at 5 (citation omitted). The district court further explained that a "wafer should be construed to include a part of a wafer. Throughout the patent, reference is made to wafers, in whole or in part." *Id.* (citation omitted). The district court also explained that this definition does not improperly give the same meaning to "die" and "wafer" because it requires the wafer or portion of a wafer to include multiple dies. Since the claim included a "plurality of known good quality wafers" limitation, the district court's construction allowed a single wafer to be a plurality of wafers.

On appeal, the Federal Circuit began its review with the claim language itself. Though the claims' preambles listed example "wafers," the Court could not conclude that wafers were not discrete objects.

The Court found the claim itself distinguished between a single wafer and multiple wafers, where it uses “a wafer” and “a plurality of . . . wafers.” Other claims of the '298 patent lent further support that a single wafer is not also multiple wafers. Claims 18 and 26 required “each and every wafer” to be aligned at the exact same location and orientation. The Court noted that if a wafer included a plurality of wafers, then some of the wafers could not be aligned to the exact same location. The '298 patent specification consistently treated wafers as discrete objects. Based upon these readings, the Court concluded that “a wafer is a discrete object, and thus a single wafer, even though it may later be diced into hundreds of separate dies, is not itself also a plurality of wafers.” *Id.* at 10.

“The issue presented in this case is whether the invention must be ready for patenting at the time the alleged offer is made. We conclude that it does not.” Slip op. at 17.

The Court rejected assertions by August Tech that this claim construction was incorrect because it excluded the preferred embodiment. “The mere fact that there is an alternative embodiment disclosed in the [asserted patent] that is not encompassed by [our] claim construction does not outweigh the language of the claim, especially when the court’s construction is supported by the intrinsic evidence.” *Id.* at 11 (alterations in original) (quoting *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008)). This is “especially true where, as here, other unasserted claims in the parent patent cover the excluded embodiments.” *Id.*

The Court construed a “wafer” as “a thin, discrete slice of semiconductor material with circuitry thereon that is ready for electrical testing having one or more dies. A plurality of wafers means more than one physically distinct wafer.” *Id.* at 11-12. Based upon the district court’s flawed claim construction, the infringement verdict was vacated and remanded for a limited trial on infringement with respect to this claim element.

The district court additionally construed the claim limitation “strokes . . . based on velocity.” The district court found the limitation to require strobing based at least in part on “the rate of change of the position of the wafer.” *Id.* at 12 (citation omitted). As long as the strobing was based upon the wafer’s velocity, it did not matter whether the strobing also depended upon the wafer’s position. Both parties agreed that the claimed invention periodically strobed based on a wafer’s velocity. Camtek argued that the asserted claims precluded strobing based on the wafer’s position, because August Tech disclaimed that during prosecution.

The Federal Circuit found no clear disavowal of strobing according to position during prosecution and agreed with the district court’s construction of strobing based on velocity. The Court also rejected an argument by Camtek that no evidence supported the jury’s verdict of infringement with respect to the strobing limitation. The Court found no error in the district court’s analysis and concluded that “the jury was presented with substantial evidence that the Falcon strokes [were] based on the rate of change of the position of the wafer.” *Id.* at 14. Accordingly, the Court did not direct the district court to include the strobing limitation in its retrial on infringement.

The Court also reviewed the jury’s finding that Camtek failed to show that the asserted claims would have been obvious by clear and convincing evidence over U.S. Patent Nos. 5,859,698 and 5,298,963. The district court denied Camtek’s motion for JMOL, finding there was substantial evidence that the cited prior art failed to teach the strobing limitation. The Court agreed that there was substantial evidence, including expert testimony, supporting the jury’s fact-finding and affirmed the denial of a JMOL and a new trial on the issue.

The jury also found August Tech’s NSX-80 wafer inspection machine was not on sale prior to the critical date of the '298 patent, causing the district court to dismiss Camtek’s inequitable conduct charges based on nondisclosure of the NSX-80. The district court also denied JMOL and a new trial on invalidity for obviousness. Though the Court could not rule on whether the NSX-80 constituted prior art, the Court affirmed and noted no need for a retrial on the issue of whether the NSX-80 was on sale prior to the

critical date.

Camtek argued that the district court erred as a matter of law in the jury instructions, where it defined “on sale” to mean the NSX-80 must have been ready for patenting at the time an alleged offer for sale was made. The Federal Circuit first considered whether the NSX-80 qualified as § 102(b) prior art. The Court used a two-part test for determining whether the § 102(b) on-sale bar applies: (1) the product is the subject of a commercial offer for sale, and (2) the invention is ready for patenting. *Id.* at 16 (citing *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998)). The key issue was whether the invention must be ready for patenting at the time the alleged offer is made. The Court concluded it does not.

The Court noted that requiring that an invention must be ready for patenting at the time of an offer for sale would render the second prong of *Pfaff* “superfluous.” *Id.* at 17. Citing *Robotic Vision Systems v. View Engineering, Inc.*, 249 F.3d 1307, 1313 (Fed. Cir. 2001), the Court noted that completion of the invention prior to the critical date pursuant to an offer to sell would create a bar. While an invention need not be ready for patenting, the Court held that “there is no offer for sale until such time as the invention is conceived.” Slip op. at 18. Before that conception date, the seller is merely offering to sell an idea for a product.

Because the record on appeal was not clear as to whether August Tech conceived of the NSX-80 prior to the critical date, the Court left that question of fact to be decided by a fact-finder in the first instance. Nor could the Court evaluate whether the jury based their decision on the experimental use exception, as argued by August Tech. The Court did note the NSX-80 did not disclose the claimed strobing limitation, which was the missing element for purposes of the obviousness analysis. The Court concluded that even if the NSX-80 was on sale and prior art, as a matter of law based on the undisputed facts, it would not render the asserted claims obvious in view of the prior art. On this basis, the Court affirmed the district court’s denial of JMOL and a new trial on invalidity for obviousness. This same reasoning led the Court to conclude that the NSX-80 is not material prior art and affirmed the district court’s dismissal of Camtek’s inequitable conduct counterclaims.

Since the Court vacated and remanded for further proceedings under the correct claim construction, the Court did not reach the parties’ contentions regarding damages and the permanent injunction.

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Expiration of Patent Does Not Divest a Court of Jurisdiction in a § 291 Interference Proceeding

Justin A. Hendrix

Judges: Lourie (author), Plager, Dyk (concurring-in-part and dissenting-in-part)
[Appealed from D. Del., Judge Robinson]

In *Genetics Institute, LLC v. Novartis Vaccines & Diagnostics, Inc.*, No. 10-1264 (Fed. Cir. Aug. 23, 2011), the Federal Circuit affirmed the district court's dismissal of an interference action under 35 U.S.C. § 291 for lack of an interference in fact.

Genetics Institute, LLC ("Genetics") is the assignee of U.S. Patent No. 4,868,112 ("the '112 patent"). Novartis Vaccines and Diagnostics, Inc. ("Novartis") is the assignee of U.S. Patent Nos. 6,228,620 ("the '620 patent") and 6,060,447 ("the '447 patent") (collectively "the Novartis patents"). The patented technology-at-issue relates to truncated forms of a protein called Factor VIII, which is an essential blood-clotting protein that circulates freely in the blood in an inactive state. The Factor VIII protein contains several regions, or domains, including an A, B, and C domain. Each domain folds into a three-dimensional structure independent of the other domains. The C domain contains an acidic region, a3, as well as domains A3, C1, and C2.

Genetics sued Novartis to determine priority of invention under 35 U.S.C. § 291, alleging that an interference in fact existed between certain claims of the '112 patent and the Novartis patents. Genetics asserted that all three patents are directed to the same subject matter, truncated Factor VIII proteins lacking all or part of the B domain while retaining procoagulant activity. Novartis moved to dismiss, arguing that (1) the district court lacked subject matter jurisdiction because a 35 U.S.C. § 156 patent term extension of the '112 patent did not apply to all of its claims; and (2) there was no interference in fact between the asserted claims because the Novartis patents—unlike the '112 patent—are directed to truncated Factor VIII proteins that preserve the functional a3 acidic region. The district court granted Novartis's motion to dismiss, holding that while the patent term extension under § 156 applied to all of the '112 patent claims, there was no interference in fact as to any of the allegedly interfering claims. Genetics appealed.

"Unlike a disclaimed claim, however, an expired patent is not viewed as having 'never existed' . . . [and] ' . . . does have value beyond its expiration date.'" Slip op. at 13 (citation omitted).

The Federal Circuit rejected Novartis's argument, initially raised in a motion to dismiss Genetics' appeal, that expiration of the '112 patent divested the Court of jurisdiction over the appeal. In so doing, the Court declined to extend *Albert v. Kevelex Corp.*, 729 F.2d 757 (Fed. Cir. 1984), where the Court found that a patent disclaimer, directed to the patent claims addressed in a § 291 action, mooted the action

and required dismissal for lack of jurisdiction to circumstances involving expired patents. The Court explained that disclaiming claims under 19 U.S.C. § 253 “effectively eliminate[s] those claims from the original patent,” and the patent is treated “as though the disclaimed claim(s) had ‘never existed.’” Slip op. at 13 (alteration in original) (citation omitted). “Unlike a disclaimed claim, however, an expired patent is not viewed as having ‘never existed’ . . . [and] ‘. . . does have value beyond its expiration date.’” *Id.* (citation omitted).

Additionally, the Federal Circuit found that the expiration of the '112 patent did not deprive the appealed § 291 action of meaning because the outcome directly impacts a pending district court infringement suit. Finally, the Court noted that, unlike 35 U.S.C. § 135, which requires one pending application and “any pending application, or . . . any *unexpired* patent,” *id.* at 14 (alteration in original) (citation omitted), § 291 simply requires two “interfering patents,” indicating “one essential difference between these two statutes,” *id.* Accordingly, the Federal Circuit held that it had jurisdiction over the appeal.

The Federal Circuit also rejected Novartis’s assertion that the district court lacked jurisdiction over the interference proceeding because a § 156 patent term extension applies on a claim-by-claim basis, and thus did not apply to the '112 patent claims asserted in the interference. Relying on the plain language of § 156 and its legislative history, the Court found that “[a] patent as a whole is extended even though its effect may be limited to certain of its claims.” *Id.* at 17. The Court additionally rejected Novartis’s related argument that patents extended under § 156 cannot form the basis of a § 291 interference action, finding that neither the statutory text nor the legislative history of § 156 supported such a conclusion. Accordingly, the Federal Circuit held that the district court properly had jurisdiction over the proceeding.

Turning to the substance of the appeal, the Federal Circuit reiterated that an interference in fact under § 291 exists “if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa.” *Id.* at 19 (citation omitted). Thus, each leg of the “two-way test” must be satisfied.

The Federal Circuit agreed with the district court, finding no interference in fact between the asserted patent claims of the '112 patent and the '620 patent because, in analyzing the first leg of the test, the Court concluded that if the claims of the '112 patent had been prior art, they would not have rendered obvious the claims of the '620 patent. In reaching that conclusion, the Court first cited structural differences between the proteins claimed in the '112 and '620 patents. In particular, the claimed truncated Factor VIII proteins differed (1) in terms of the size of the permitted amino acid deletions; (2) the location of the permitted amino acid deletions; and (3) the degree of allowable amino acid substitutions.

Second, the Court agreed that Genetics failed to establish any such reason for “modifying the group of proteins claimed in the '112 patent to produce the group claimed in the '620 patent.” *Id.* at 23. The Court rejected Genetics’ arguments, finding that (1) it was not known prior to the filing of the '620 patent that particular amino acids were critical to maintain a particular binding function of the truncated Factor VIII protein; (2) the mere existence of *in vivo* cleavage points between particular amino acid residues, without more, would not have motivated the skilled artisan to make the particular truncated proteins claimed in the '620 patent; and (3) research objectives of those in the field of truncated Factor VIII proteins focused on finding a smaller protein that mimicked Factor VIII, not larger proteins, such as those claimed in the '620 patent.

Third, the majority responded to Judge Dyk’s dissent, noting that the dissent (1) “selectively parses the prior art disclosure with impermissible hindsight,” *id.* at 25; (2) challenges “well-established law requiring the identification of some reason that would have prompted a researcher to substantially modify a prior art compound to produce the claimed compound” based on an “oversimplification” of the differences in the claimed proteins, *id.* at 25-26; and (3) like Genetics, erroneously “attempts to shoehorn the facts of this case into [the Court’s] holding in [*In re*] *Peterson*, [315 F.3d 1325 (Fed. Cir. 2003)],” slip op. at 27, where “[t]he facts here present a case where the ‘disclosed range is so broad as to encompass a very large number of possible distinct compositions’ thus ‘requir[ing] nonobvious invention,’ not a case, as in

Peterson, where prior art “ranges that are not especially broad invite routine experimentation to discover optimum values,” *id.* at 28 (second alteration in original) (citation omitted).

Further, the Federal Circuit found that the district court did not err in crediting the unexpected results of the claimed invention of the '620 patent as part of its obviousness analysis. First, the Court reiterated that “every property of a claimed compound need not be fully recognized as of the filing date of the patent application to be relevant to nonobviousness.” *Id.* at 29 (citation omitted). Thus, regardless of whether the importance of some of the binding ability of the proteins claimed in the '620 patent were known at the time of filing, those effects may still be relied upon when considering unexpected results. Second, the Court rejected Genetics’ argument that the unexpected results were not commensurate with the full scope of the '620 patent claims because one particular amino acid substitution at one particular position eliminates the unexpected binding function; rather, the Court held that there does not need to be an “absolute identity” of scope. *Id.* at 32. “Indeed, a rigid requirement of absolute identity that ignores relevant properties of claimed compounds would defy the mandate of § 103 requiring consideration of the claimed ‘subject matter as a whole.’” *Id.*

Accordingly, because the '620 patent claims were not obvious in light of the '112 patent claims, the first leg of the two-way test was not satisfied, and the Court did not need to consider whether the '112 patent claims would not, if prior art, anticipate the '620 patent claims or the second leg of the test.

The Federal Circuit next concluded that there was no interference in fact between the asserted claims of the '112 patent and the '447 patent. First, the Court noted that Genetics raised the same alleged errors by the district court that the Federal Circuit rejected in the context of the '112 and '620 patents. Moreover, the Court found that Genetics failed to show why one of ordinary skill would modify the protein claimed in the '447 patent to make the three different proteins claimed in the '112 patent. Without some reason for making the necessary chemical modifications to arrive at the claimed compound, the '447 patent claims would not have rendered obvious the '112 patent claims, and, thus, there was no interference in fact between the claims of the two patents.

Accordingly, the majority found that the expiration of the '112 patent did not divest the Federal Circuit of appellate jurisdiction, and affirmed the district court’s judgment that (1) the patent term extension of the '112 patent applied to all of the allegedly interfering claims; and (2) there was no interference of fact between the relevant claims of the '112 patent and the '620 and '447 patents.

Judge Dyk concurred with the majority’s findings on jurisdiction, but dissented from the Court’s opinion regarding whether an interference in fact existed. Judge Dyk disagreed with the majority on four points: (1) there should be a requirement for a motivation to retain the binding region of the Factor VIII protein where, from an objective standpoint, no inventor—including the Novartis inventors themselves—could have been aware of the benefits of retaining the region at the time of the invention; rather, structural similarity was sufficient to establish *prima facie* obviousness; (2) the overlapping range of retentions in the Novartis patents and the '112 patent was insufficient in and of itself to establish *prima facie* obviousness; rather, Judge Dyk would find the analysis analogous to *In re Peterson* and the claims *prima facie* obvious; (3) retention of amino acids in the region responsible for the beneficial binding was contrary to the teachings of the '112 patent, where, in Judge Dyk’s view, the '112 patent and the Novartis patents all taught some variants that retained the region and some variants that did not; and (4) later-discovered, undisclosed benefits should be considered as unexpected results; rather, Judge Dyk would require that unexpected properties be set forth in the specification or contemporaneously known to the inventors.

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United States Waived Sovereign Immunity with Respect to DJ Patent Suits

Kevin D. Rodkey

Judges: Bryson (author), Schall, Prost

[Appealed from E.D. Cal., Senior Judge Wanger]

In *Delano Farms Co. v. California Table Grape Commission*, No. 10-1546 (Fed. Cir. Aug. 24, 2011), the Federal Circuit affirmed the district court's decision that the United States Department of Agriculture ("USDA") is a necessary party to a DJ suit, reversed the district court's decision that 5 U.S.C. § 702 does not waive sovereign immunity with respect to DJ suits, reversed the district court's decision that Delano Farms Co. ("Delano Farms") failed to properly plead inequitable conduct, and affirmed the district court's decision that Delano Farms failed to properly plead a violation of the Sherman Act.

The USDA is the owner of three table grape patents issued under the Plant Variety Protection Act: PP15,891 ("the Sweet Scarlet patent"); PP16,229 ("the Scarlet Royal patent"); and PP16,284 ("the Autumn King patent"). The USDA licensed the rights in the three patents to the California Table Grape Commission ("Grape Commission"), which is an agency of the State of California. The Grape Commission pays royalties to the USDA, which are collected from the growers sublicensed by the Grape Commission under a "Domestic Grower License Agreement."

The plaintiffs (collectively "Delano") are all California grape growers who purchased grapevines covered by the patents, signed the Domestic Grower License Agreement, and paid the licensing fee. Delano brought a DJ suit against the Grape Commission and the USDA seeking a ruling that the patents are unenforceable because of prior use, and that the Sweet Scarlet patent is unenforceable due to inequitable conduct during prosecution. Specifically, Delano alleged that one of the coinventors of the three varieties displayed fruit of the patented varieties at public meetings that were held before the critical dates for each patent and had distributed the varieties in advance of the critical dates. Delano also alleged that the USDA unlawfully obtained the patents and that the Grape Commission violated state and federal unfair competition laws through its licensing efforts.

The district court held that the USDA, as a patent owner who had retained substantial rights in the patents, was a necessary party to the DJ suit. The district court also determined that the USDA was an indispensable party and could not be joined because of sovereign immunity. The district court then granted the USDA's motion to dismiss because Delano had not exhausted its administrative remedies under the APA. The district court also dismissed the state unfair competition and Sherman Act claims brought by Delano. Delano appealed.

On appeal, the Federal Circuit first assessed whether the USDA was a necessary party to the DJ suit. The Court determined that, under the license agreement with the Grape Commission, the USDA had retained substantial rights in the patents and was therefore a necessary party. Analyzing the license

agreement, the Court determined that the Grape Commission had the exclusive right to use, propagate, and sell the patented varieties, as well as to grant sublicenses to growers. But the Grape Commission did not have the right to enforce the patents against suspected infringers. Rather, the Court concluded that the USDA retained the right to enforce the patents, but could grant that right to the Grape Commission. The Court found nothing in the license to curtail the USDA's right as patentee to sue on the patents. Moreover, the USDA retained a royalty-free right to practice the patents and reserved approval power over the Grape Commission's sublicenses. For these reasons, the Court held that the USDA retained substantial rights in the patents and was a necessary party to the DJ action.

“That Congress has consented to an action for money damages for patent infringement by the government does not in any way imply that Congress intended to bar equitable actions related to the validity of government-owned patents. Accordingly, . . . in Section 702 of the APA[,] Congress waived sovereign immunity for claims such as Delano’s declaratory judgment claims under the Patent Act.” Slip op. at 22.

The Court then turned to whether sovereign immunity barred Delano’s DJ claims based on the Patent Act. If Congress has not waived the federal government’s immunity for a particular claim, courts lack jurisdiction over that claim and must dismiss it. Here, the Federal Circuit examined the text and legislative history of 5 U.S.C. § 702 to determine whether the district court has jurisdiction over the claim.

The Court first explained that the APA can be said to do three things with respect to judicial review of actions or failures to act by government agencies or employees. First, it recognizes a right of judicial review for “agency action” made reviewable by another statute and provides rules governing such review. Second, it creates a right of judicial review, even in the absence of a review-authorizing statute, for “final agency action” for which there is no other adequate remedy in a court. Third, it waives sovereign immunity for any action stating a claim against the United States (or its officers or employees) and seeking relief other than money damages.

The United States and the Grape Commission argued that the waiver of sovereign immunity is limited to the first two categories—the types of judicial review recognized or created by the APA. Reviewing the legislative history, the Court observed that § 702 was intended to eliminate the sovereign immunity defense in all equitable actions for specific relief against a federal agency or officer acting in an official capacity. The Court rejected the defendants’ argument that § 702 was limited to actions arising under the APA. The Court instead noted that § 702 was intended to eliminate the defense of sovereign immunity with respect to any action in a court of the United States seeking relief other than money damages and based on an assertion of unlawful activity by a federal officer or employee. The Court concluded that § 702 of the APA waives sovereign immunity for nonmonetary claims against federal agencies, subject to the limitations of subsections 1 and 2, and that the waiver is not limited to “agency actions” or “final agency actions” as defined in the APA. Thus, the Court held that the waiver of sovereign immunity in § 702 is broad enough to allow Delano to pursue equitable relief against the USDA on its patent law claims. The Court reviewed decisions of several regional circuits and found them to be in accord with this determination.

The Court rejected the Grape Commission’s arguments that a pair of prior Federal Circuit cases held that § 702 did not waive sovereign immunity for actions arising outside of the APA. The Court determined that, in each of those cases, *Smith v. Secretary of the Army*, 384 F.3d 1288 (Fed. Cir. 2004), and *Christopher Village, L.P. v. United States*, 360 F.3d 1319 (Fed. Cir. 2004), a plaintiff cannot invoke the § 702 waiver to obtain judicial review under the APA when Congress had provided an alternative and exclusive forum for such a dispute. The Court further observed that in neither case did it hold that the waiver of immunity applies only to a cause of action based on the APA and does not apply to a cause of action based on another source, such as the DJ Act. The Court further observed that in *Nebraska Public Power District v. United States*, 590 F.3d 1357 (Fed. Cir. 2010) (en banc), § 702 waives sovereign immunity for actions seeking DJ under the Nuclear Waste Policy Act, and that,

because the right of judicial review arose under a statute other than the APA, § 702 waives sovereign immunity without the need to satisfy the requirements of the APA.

The Court also noted that while § 702 waives sovereign immunity with respect to nonmonetary actions, it does not have any effect on the exclusive jurisdiction of the United States Court of Claims over suits for monetary damages falling within that court's jurisdiction. The Federal Circuit observed, however, that this principle does not apply to DJ Patent Act claims, which are not within the exclusive jurisdiction of the Court of Claims.

Next, the Court rejected the argument that the Quiet Title Act bars other nonmonetary relief relating to patents and copyrights. The Court rejected this argument because nothing in the Quiet Title Act suggests that Congress intended to apply the act narrowly, and because the House report explained that waiver under § 702 should apply to equitable actions generally. The Court determined that nothing in Congress's consent to money damages for patent infringement by the government implied that Congress intended to bar equitable actions related to the validity of government-owned patents. For these reasons, the Court held that § 702 of the APA waived sovereign immunity for DJ claims arising under the Patent Act and that the USDA could be joined as a party in such claims.

The Federal Circuit next considered whether Delano's complaint provides an adequate factual basis from which the district court could conclude that anyone at the USDA made a deliberate decision to withhold the fact of prior use with the intent to deceive the PTO. The Court held that a reasonable jury could infer from Delano's allegations that the applicant knew of the prior use, appreciated that the prior use was material, and decided not to disclose the information to the PTO with deceptive intent. Accordingly, the Court held that Delano's complaint was sufficient to plead inequitable conduct.

Finally, the Court turned to Delano's claim that, by entering into sublicense agreements with grape owners for the Sweet Scarlet patent, the Grape Commission had enforced a fraudulently obtained patent in violation of section 2 of the Sherman Antitrust Act. The Court noted that to establish the antitrust portion of a *Walker Process* allegation such as this, a plaintiff must show that the defendant held monopoly power in the relevant market and willfully acquired or maintained that power by anticompetitive means. A plaintiff must also define the market within which the defendant engaged in the challenged conduct. Here, Delano contended that the Sweet Scarlet variety was its own market and that other grapevines could be reasonable substitutes for it. The Court concluded that Delano could not rely on "the naked assertion that noninfringing goods are not an adequate substitute for a patented product, especially when it is undisputed that other vines possess at least some of the [same] relevant characteristics." Slip op. at 26. Accordingly, the Court affirmed the district court's dismissal of the antitrust claim.

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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

Troy L. Gwartney

Judges: Rader (author), Moore, O'Malley
[Appealed from S.D.N.Y., Judge Patterson, Jr.]

In *Unigene Laboratories, Inc. v. Apotex, Inc.*, No. 10-1006 (Fed. Cir. Aug. 25, 2011), the Federal Circuit affirmed the district court's SJ of nonobviousness, denial of 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®, an FDA-approved pharmaceutical nasal spray with the active ingredient salmon calcitonin that treats, inter alia, postmenopausal osteoporosis. Unigene's NDA 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 ANDA 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" Slip op. at 4. 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 PTO 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 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." *Id.* at 9 (citation omitted). 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." *Id.* at 10 (citation omitted). Thus, the Federal Circuit found no abuse of discretion with the findings on intent, and did not need to reach the issue of materiality.

"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)." Slip op. at 15.

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." *Id.* at 11 (citation omitted). 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." *Id.* at 12.

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." Slip op. at 14. 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." *Id.* at 14-15. "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)." *Id.* at 15. Thus, the Court observed that the term "reference composition" is more appropriate than "lead compound" in this context. *Id.* at 16.

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.” *Id.* at 17. 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.” *Id.* at 18-19 (citation omitted). 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. *Id.* at 19 (citation omitted).

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.” *Id.* at 19-20. 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.” *Id.* at 20.

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.

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Speculative and Tentative Disclosures in the Prior Art May Not Sufficiently Direct or Instruct a Skilled Artisan

Erin M. Sommers

Judges: Rader (author), Linn, Dyk (concurring-in-part and dissenting-in-part)
[Appealed from D. Md., Senior Judge Garbis]

In *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, No. 10-1183 (Fed. Cir. Aug. 26, 2011), the Federal Circuit affirmed the district court's denial of Star Scientific, Inc.'s ("Star") JMOL of infringement and denial of Star's motion for a new trial, but reversed the district court's denial of Star's JMOL on validity.

Star is the exclusive licensee of U.S. Patent Nos. 6,202,649 ("the '649 patent") and 6,425,401 ("the '401 patent") (collectively "the Williams patents"), which claim methods for curing (drying) tobacco leaves. Since the 1970s, tobacco has been cured in direct-fired barns that heat and dry the tobacco in the presence of the combustion exhaust gases released by the heaters. The combustion gases can create an anaerobic, or oxygen-free, environment that can lead to the formation of a family of chemical compounds called tobacco-specific nitrosamines ("TSNAs"), known carcinogens, on curing tobacco leaves.

The Williams patents claim tobacco-curing methods that "substantially prevent" the formation of at least one TSNA during curing by creating a "controlled environment." Star filed a provisional patent application, and a year later filed a nonprovisional application, which issued as the '649 patent. The '401 patent issued from an application that was a continuation of the application that matured into the '649 patent.

Star sued R.J. Reynolds Tobacco Company ("RJR") for infringement of the Williams patents. RJR denied infringement and claimed that the patents were unenforceable for inequitable conduct and invalid for anticipation, obviousness, indefiniteness, and failure to disclose the inventor's best mode. After a bench trial, the district court found the patents unenforceable for inequitable conduct, granted SJ of invalidity for indefiniteness, and granted RJR's SJ motion that Star was not entitled to rely on the provisional application's priority date because the nonprovisional application contained new matter. Star appealed to the Federal Circuit. In an earlier decision, the Court reversed the findings of unenforceability and invalidity, and remanded for proceedings on infringement. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008).

On remand, the jury, via special verdict, found the Williams patents invalid as anticipated, as obvious, for failing to disclose the best mode, and indefinite, and that RJR's curing process did not infringe. The district court subsequently denied Star's motions for JMOL on direct and indirect infringement, and for JMOL to reverse the jury's findings of invalidity, and similarly denied Star's appeal of evidentiary rulings.

In the current appeal, the Federal Circuit first addressed and reversed the district court's SJ ruling that

the Williams patents were not entitled to the provisional application filing date because the nonprovisional application added new matter in the form of a new example requiring “air flow of approximately 25,000 CFM.” The Court found that the district court’s reliance on specifically disclosed air flow rates in the written description of the provisional application (e.g., the provisional application disclosed that the minimum air flow “may be about 28,000 CFM”) “improperly narrowed the scope of the provisional application” “[b]ecause the provisional application teaches one of ordinary skill that a minimum air flow ‘may vary’ . . . [such that] the conditions in a curing barn could demand an air flow of 25,000 CFM.” Slip op. at 11. The Court thus concluded that the new example did not add new matter, and, therefore, the claims were entitled to the provisional application’s priority date. The Court also noted that the PTO recently concluded an *ex parte* reexamination, requested by Star, which confirmed that the Williams patents were entitled to the provisional application’s priority date.

“Wiernik’s speculative and tentative disclosure of what ‘might’ or ‘may’ lead to nitrite and TSNA production does not sufficiently direct or instruct one of skill in the art.” Slip op. at 19.

Second, the Federal Circuit rejected Star’s challenges to the district court’s evidentiary rulings, finding that the district court did not commit reversible error because Star failed to show that any of the rulings affected its substantive rights.

Third, the Court reversed the district court’s denial of Star’s motion for JMOL on the issues involving the validity of the Williams patents. With respect to best mode, the Court reversed the district court’s finding of invalidity because (1) the Williams patents were entitled to the priority date of the provisional application, and (2) RJR conceded that Williams had not contemplated a best mode as of that date.

With respect to indefiniteness, the Federal Circuit held that the disputed claim term, “controlled environment,” was not “insolubly ambiguous.” The Court found that even in the absence of “exact numbers” measuring humidity, temperature, and airflow in a conventional curing barn, “a person of skill in the art of tobacco curing would possess adequate understanding to manipulate these variables to create a controlled environment.” *Id.* at 15. Specifically, “because conventional curing varies depending on the conditions for each cure, specific numerical values are not needed for one skilled in the art to implement conventional curing.” *Id.* Further, the ‘649 patent specification disclosed that “the controlled conditions described herein [are] according to conventional methods commonly and commercially used in the U.S.” *Id.* at 16 (alteration in original) (citation omitted). Thus, because tobacco-curing variables were well known in the tobacco industry, the term “controlled environment” was well within the bounds of ordinary skill in the art and, hence, not insolubly ambiguous and indefinite.

The Federal Circuit next reversed the district court’s determination of obviousness in light of two prior art references, Wiernik and Tohno. First, the Court concluded that “Wiernik’s speculative and tentative disclosure of what ‘might’ or ‘may’ lead to nitrite and TSNA production does not sufficiently direct or instruct one of skill in the art.” *Id.* at 19. Second, “Tohno does not mention TSNAs and does not provide a link between the oxygen levels (inherent in increasing air flow) and precursor tobacco alkaloids or the activation or inhibition of nitrate reductase—both critical targets of the Williams patents.” *Id.* Third, there was no evidence suggesting a motivation to combine an article on remedying a foul odor in tobacco (“Tohno”) with a summary of studies about TSNA formation (“Wiernik”). Fourth, neither reference taught the “air free of combustion gases” claim limitation of the Williams patents. Finally, many secondary considerations supported nonobviousness, including long-felt industry need for a curing method that minimized or eliminated the formation of TSNAs, decades of unsuccessful attempts at reducing TSNA levels to the extent achieved by the Williams patents, unexpected results, and commercial success evidenced by licenses worth millions of dollars.

Lastly, with respect to validity, the Federal Circuit found that the Williams patents were not anticipated by an RJR curing method and two alleged public uses. First, the RJR method was not used in the United States more than one year before the patent’s critical date, in light of the Court’s determination of priority. Second, the alleged first public use was not anticipatory because the tobacco cured in that

instance was not uncured, as required by the claims. Third, the second alleged public use was not anticipatory because the threshold detection level of the test used to detect the TSNA levels (0.15 ppm) was not able to accurately determine whether the TSNA levels were below 0.05 ppm or 0.10 ppm as required by the claims.

Fourth, with respect to infringement, the Federal Circuit agreed with the district court's denial of Star's JMOL, finding that it was not unreasonable for the jury to discredit Star's expert's testimony (Star's primary evidence of infringement) in light of RJR's conflicting expert testimony.

Finally, the Court found that the district court did not abuse its discretion in denying Star's motion for a new trial because (1) the Court's decision on validity moots any alleged errors pertaining to validity, and (2) the correction of any alleged errors with respect to infringement would not have changed the result because there was substantial untainted evidence before the jury to support a verdict of noninfringement.

Accordingly, the Federal Circuit affirmed the district court's denial of JMOL on noninfringement and reversed the district court's denial of JMOL on invalidity.

Judge Dyk concurred-in-part and dissented-in-part. He agreed with the majority with respect to noninfringement, but would have found the "controlled environment" term indefinite. In particular, Judge Dyk believed that the majority misinterpreted the specifications of the Williams patents and that, contrary to the majority's interpretation, "controlled environment" was not equated with conventional curing. Judge Dyk would have credited RJR's expert and found that the Williams patents describe the claimed "controlled environment" as something different from conventional curing methods, but fail to explain those differences in a way that would permit a skilled artisan to determine the bounds of the claim.

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Means-Plus-Function Claim Lacking Corresponding Structure Rejected as Indefinite

Jameson Q. Ma

Judges: Newman (dissenting), Gajarsa, Linn (author)

[Appealed from Board]

In *In re Aoyama*, No. 10-1552 (Fed. Cir. Aug. 29, 2011), the Federal Circuit affirmed the Board's rejection of claims 11 and 21 in U.S. Patent Application No. 10/798,505 assigned to Mitsui Bussan Logistics, Inc. ("Mitsui"). Because the Board erred in construing a means-plus-function limitation of claims 11 and 21, the Court affirmed the rejection of claims 11 and 21 for failure to satisfy the definiteness requirement of 35 U.S.C. § 112, ¶ 2.

Independent claims 11 and 21 recited a "reverse logistics means for . . . generating transfer data." The examiner construed the limitation as a means-plus-function limitation and concluded that the structure corresponding to the "reverse logistics means" for transferring was a computer implemented with software. Under this construction, the examiner rejected the claims on the ground of anticipation. Mitsui appealed, contending that Figure 8 and its accompanying description disclosed the corresponding structure for the means-plus-function limitation.

The Board disagreed that Figure 8 and its accompanying description provided a structure or algorithm for generating transfer data. The Board then "scoured the specification for any implied structure that could even arguably generate transfer data." Slip op. at 4. The Board, in giving "generating transfer data" a broad construction, focused on the application's disclosure of generating shipping data. The Board concluded that the structure for generating transfer data was "open ended." Under this construction, the Board affirmed the examiner's anticipation rejection.

On appeal, the Court agreed with Mitsui and the Board that the specification and prosecution history link the claimed "means for generating transfer data" with the flowchart of Figure 8. However, after finding that Figure 8 did not disclose sufficient structure for the claim limitations, the Court rejected the Board's construction of "transfer data" to include "shipping data." The Board erred by identifying structure that was not clearly linked or associated by the specification or prosecution history with the function actually recited in the claim, i.e., "generating transfer data." The only portion of the specification the Court found where Mitsui described the corresponding structure was the flowchart of Figure 8.

"The Board did not purport to announce that a flowchart can never, under any circumstances, provide sufficient structure to satisfy § 112 ¶ 6. . . . Instead, the Board simply concluded that the particular flowchart of Figure 8 and its accompanying description fail to provide any structure or algorithm whatsoever." Slip op. at 8-9.

Mitsui argued that the Board's determination that Figure 8 does not contain sufficient structure to support the limitation was equivalent to official notice that a flowchart algorithm can never provide the algorithmic structure for a means-plus-function element. The Court rejected this argument, stating that the Board simply concluded that this particular flowchart and its accompanying description failed to provide any structure or algorithm whatsoever. The Court further agreed with the Board that, while Figure 8 provided a high-level process flow, it did not describe any structure and "fail[ed] to describe, even at a high-level, how a computer could be programmed to produce the structure that provides the results described in the boxes." *Id.* at 9 (citation omitted).

Because the means-plus-function limitation of claims 11 and 21 lacked sufficient disclosure of structure, the Court deemed the claims unpatentable as indefinite under 35 U.S.C. 112, ¶ 2. Further, because a claim cannot be both indefinite and anticipated, the Court never reached the ground of rejection relied upon by the Board.

Mitsui contended that the Court may only review the grounds upon which the Board based its determination, citing *Securities & Exchange Commission v. Chenery Corp.*, 318 U.S. 80 (1943). However, the Court noted that *Chenery* itself made clear a decision should be affirmed, even on alternative grounds, so that it is within the power of the appellate court to formulate. The Court emphasized that, as a legal question, failure to satisfy the definiteness requirement is a ground of rejection within the power of the appellate court to formulate.

Moreover, the Court distinguished *In re Fleissner*, 264 F.2d 897 (CCPA 1959), which reached an opposite conclusion in a slightly different factual context. The Board in *Fleissner* rejected applicant's claims containing a means-plus-function limitation as anticipated in view of a prior art reference. On appeal, the PTO sought to affirm the rejection on the basis that the limitation lacked a corresponding structure in the specification. The predecessor court refused to make the indefiniteness rejection, stating that it was beyond their statutory authority to institute a ground of rejection not of record. The Federal Circuit distinguished *Fleissner* by stating that while claim construction and indefiniteness are now recognized as legal questions, at the time of *Fleissner*, these were not seen as legal in nature.

Finally, the Court recognized that if they were simply to affirm the Board's rejections, Mitsui would not be permitted to amend its claims. But, if the Board had correctly issued a section 112, ¶ 2 rejection, Mitsui would have had the opportunity to amend its claims or to submit new evidence rebutting the ground of rejection. To remedy this discrepancy, the Court afforded Mitsui the same protections as it would have had before the Board with respect to the rejected claims by remanding the case to the Board.

Judge Newman dissented with the majority because, while Mitsui was given the opportunity to amend the claims or submit new evidence in light of the rejection, Mitsui did not have the opportunity to argue the merits of the definiteness rejection. In Judge Newman's opinion, Figure 8 and its corresponding description supported the definiteness requirement for claims 11 and 21. Judge Newman would have also addressed whether one of ordinary skill in computer programming would understand Figure 8 and its descriptive text as a structural algorithm that could be routinely programmed to perform the function of generating transfer data.

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No Reissue Recapture Where Reissue Claims Not Deemed Broader and Applicant Is Own Lexicographer

Elana B. Fisher

Judges: Rader, Lourie (author), Bryson

[Appealed from M.D. Tenn., Judge Haynes, Jr.]

In *AIA Engineering Ltd. v. Magotteaux International S/A*, No. 11-1058 (Fed. Cir. Aug. 31, 2011), the Federal Circuit reversed the district court's SJ decision invalidating claims in U.S. Patent No. RE39,998 ("the '998 patent") under 35 U.S.C. § 251 for impermissible recapture and remanded.

On June 4, 2002, Magotteaux International S/A and Magotteaux, Inc. (collectively "Magotteaux") were granted U.S. Patent No. 6,399,176 ("the '176 patent") directed to a composite wear component containing a combination of ceramic materials. The combination of ceramic materials included a mixture of aluminum oxide (Al_2O_3) and zirconium oxide (ZrO_2). Among other things, independent claim 1 in the '176 patent contained the following language: "Composite wear component . . . consisting of . . . a porous ceramic pad, *the porous ceramic pad consisting of a homogenous solid solution of 20 to 80 % of Al_2O_3 and 80 to 20 % of ZrO_2 .*" Slip op. at 4 n.2.

During prosecution of the '176 patent, the applicant did not alter the portion of the claim setting forth the "homogeneous solid solution." The applicant did, however, submit a declaration under 37 C.F.R. § 1.132. The applicant used "solid solution" multiple times in the declaration, stating that a "homogeneous *solid solution* of both ceramics meets the advantages of both Al_2O_3 and ZrO_2 ." *Id.* at 4 (citation omitted).

Less than one year after issue, the patentee applied for reissue of the '176 patent, amending claim 1 and adding claims 12-21. In both amended claim 1 and new independent claim 12, the patentee changed "homogeneous solid solution" to "homogeneous ceramic composite," and in claim 12 also changed "consisting" to "comprising." Despite an anonymous third-party protest under 37 C.F.R. § 291 asserting that claims 1 and 12 should be rejected under 37 U.S.C. § 251 for impermissibly recapturing subject matter surrendered during prosecution of the '176 patent, the PTO issued the '998 patent.

AIA Engineering Ltd. ("AIA Engineering") sued Magotteaux for a DJ of noninfringement, invalidity, and unenforceability of the '998 patent; and Magotteaux filed a third-party complaint against Vega Industries, Ltd., Inc. ("Vega"), alleging that Vega infringed the '998 patent. AIA Engineering and Vega (collectively "AIA") then moved for SJ, asserting that the '998 patent claims were invalid due to impermissible recapture.

The district court held that the substitution of "ceramic composite" for "solid solution" in claims 1 and 12 of the '998 patent broadened the scope of the reissue claims. The district court further held that

Magotteaux relied on the “solid solution” limitation to overcome prior art during prosecution, thereby surrendering broader scope to a “ceramic composite.” Accordingly, the district court granted SJ in favor of AIA, holding the '998 patent claims invalid for impermissible recapture under 35 U.S.C. § 251.

On appeal, the Federal Circuit concluded that the district court erred in claim construction, and held that “homogeneous solid solution” was synonymous with “homogeneous ceramic composite.” *Id.* at 11.

“But where, as here, the specification reveals a special meaning for a term that differs from the meaning it might otherwise possess, that special meaning governs, particularly where it also serves to avoid an inoperable claim construction.” Slip op. at 24 (citing *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051 (Fed. Cir. 2010)).

The Court began its analysis by construing “homogeneous ceramic composite.” The Court noted that the district court did not explicitly set forth a construction for the term. On appeal, Magotteaux argued that “homogeneous ceramic composite” should be construed as “an aggregation of relatively consistent grains of at least Al_2O_3 and ZrO_2 wherein each of the Al_2O_3 and ZrO_2 retains a distinct composition and/or crystal structure.” *Id.* at 14 (citation omitted). In contrast, AIA did not propose a construction and contended that the district court correctly adopted a claim construction proposed by Magotteaux.

The Court agreed with the claim construction proposed by Magotteaux. Both parties’ experts also supported Magotteaux’s proposed claim construction.

The Court also analyzed the meaning of “homogeneous solid solution” in claim 1 of the '176 patent.

Both AIA and Magotteaux agreed that the plain meaning of “solid solution” was “a solid solution’ involving a solute in a solvent with a single, uniform structure.” *Id.* at 19. AIA argued, however, that “solid solution” in claim 1 of the '176 patent should be given its plain meaning, while Magotteaux argued that the patentee acted as his own lexicographer, giving a definition for “solid solution” that makes it synonymous with “ceramic composite.”

The Court first analyzed the intrinsic evidence and determined that the patentee did act as his own lexicographer, concluding that “solid solution” was synonymous with “ceramic composite.” The Court examined the specification and noted that it stated the “‘inserts’ in the ‘composite wear component’ are ‘made of a ceramic material, itself *composite*, consisting of a *solid solution* or homogeneous phase of 20 to 80% of Al_2O_3 and 80 to 20% of ZrO_2 .’” *Id.* at 20 (citation omitted).

The Court further noted that construing “solid solution” in terms of its plain meaning would contradict “a ceramic material, itself composite, consisting of a solid solution” because the ceramic material was two distinct crystalline structures, whereas the solid solution was agreed upon as having a plain meaning including only one distinct crystalline structure. The Court attempted to avoid such contradictions when possible and noted that construing “solid solution” to have the same meaning as “ceramic composite” avoided this problem.

Additionally, the Court supported its conclusion that the patentee was his own lexicographer by noting the district court’s description of the invention, which set forth that “once combined, Al_2O_3 and ZrO_2 retain their crystal structure.” *Id.* at 17. Accordingly, the district court’s description required that the “solid solution” have two distinct crystalline structures, which was inconsistent with the plain meaning of “solid solution.” The Court also pointed to the method disclosed in the specification and determined that the method did not teach preparation of a solid solution with only one distinct crystalline structure.

The Court also disagreed with the district court’s conclusion that the prosecution history supported the plain meaning construction of “solid solution.” The Court noted that the patentee used the term “solid solution” in a declaration; however, the statements using the term were only examples of the invention, and they did not limit the term to the plain meaning construction.

Both parties' experts agreed that if "solid solution" was construed in terms of its plain meaning, then the invention of claim 1 of the '176 patent would not be physically possible, which would have been apparent to one of ordinary skill in the art. The Court noted that it was skeptical of any claim construction that would render the invention inoperable. Further, the Court stated that when the specification reveals a definition for a term that differs from the plain meaning, the specification's definition governs, especially when the plain meaning would render the invention inoperable.

Rejecting AIA's request that the Court consider evidence from foreign prosecution histories, the Court noted that precedent "cautions against" relying on evidence from foreign claim construction analysis. *Id.* at 25.

Because the Court held that "solid solution" was synonymous with "ceramic composite," the Court determined that "ceramic composite" was not broader than "solid solution" and therefore did not consider whether any subject matter was surrendered during prosecution of the '176 patent. Accordingly, the Court concluded that there was no impermissible recapture of evidence under 35 U.S.C. § 251 and that the district court erred in granting AIA's motion for SJ invalidating the claims in the '998 patent. Therefore, the Court reversed and remanded the district court's decision.

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Majority Holds § 101 Does Not Exclude Claims Directed to a Specific, Tangible Application; Judge Moore Finds Majority's Analysis Incomplete

John S. Sieman

Judges: Rader (additional views, in which Judge Newman joins), Newman (author), Moore (dissenting)

[Appealed from D. Md., Judge Quarles]

In *Classen Immunotherapies, Inc. v. Biogen IDEC*, Nos. 06-1634, -1649 (Fed. Cir. Aug. 31, 2011), 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 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. Slip op. at 5. 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." Slip op. at 14. 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." *Id.* at 15.

“In contrast, the claims of the ’139 and ’739 patents require the further act of immunization in accordance with a lower-risk schedule, thus moving from abstract scientific principle to specific application.” Slip op. at 21.

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.” *Id.* 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.” Slip op. at 17. 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.” *Id.* at 18.

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.” *Id.*

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.” *Id.* at 21. “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.” *Id.*

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” *Id.* at 26 (quoting 35 U.S.C. § 271(e)(1)). 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 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*, ___ S. Ct. ___ (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." Moore Dissent at 3.

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. Rader Additional Views at 4. Second, Judge Rader explained that restrictions on subject matter patentability could drive innovation outside the United States.

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