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## Last Month at the Federal Circuit

February 2010

### Claim Terms Should Be Construed in View of the Originating Disclosure When Challenged for Written Description Support in Interference Proceeding

*Koninklijke Philips Electronics N.V. v. Cardiac Science Operating Co.*

No. 09-1241 (Fed. Cir. Jan. 5, 2010)

[Appealed from W.D. Wash., Judge Pechman]

### PTO Incorrectly Calculated Patent Term Adjustments in Situations of Overlapping PTO Delays

*Wyeth v. Kappos*

No. 09-1120 (Fed. Cir. Jan. 7, 2010)

[Appealed from D.D.C., Judge Robertson]

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[Appealed from N.D. Cal., Judge Alsup]

### 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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## February 2010

### Spotlight Info

In *Wyeth v. Kappos*, No. 09-1120 (Fed. Cir. Jan. 7, 2010), the Federal Circuit rejected the PTO's interpretation of patent term adjustment ("PTA") under 35 U.S.C. § 154(b). Under the statute, patent applicants are entitled to PTA for each day the PTO does not meet certain examination deadlines and for each day the PTO fails to issue a patent within three years of the actual filing date of the application. The statute also restricts PTA when periods of delay overlap. But the Court noted that the two types of delays only overlap after the three-year mark. The PTO, however, interpreted § 154(b) as allowing PTA only for the greater of the two types of delays, but never a combination of the two. The Court found the PTO's interpretation of § 154(b) was contrary to the unambiguous language of the statute and that *Chevron* deference did not apply. Accordingly, the Court affirmed the grant of plaintiffs' motion for SJ, extending the patent term of their patents according to the proper interpretation of the statute. See full summary below.

**February 2010**

## **Looking Ahead**

On February 5, 2010, in *ResQNet.com, Inc. v. Lansa, Inc.*, Nos. 08-1365, -1366, 09-1030, the Federal Circuit, in a per curiam opinion, affirmed the district court's finding that Lansa, Inc. ("Lansa") infringed ResQNet.com, Inc.'s ("ResQNet") U.S. Patent No. 6,295,075, and that Lansa did not infringe U.S. Patent No. 5,831,608. The Court, however, vacated the district court's award of damages and remanded for a redetermination of damages. The Court found that the district court's accepted royalty rate of 12.5% is artificially inflated and disagreed with the process used to arrive at that rate. The Federal Circuit also reversed the district court's imposition of Rule 11 sanctions on ResQNet and its counsel. Look for a complete summary in the next month's edition of *Last Month at the Federal Circuit*.

On February 17, 2010, the Federal Circuit vacated its August 11, 2009, opinion in *Hyatt v. Doll*, No. 07-1066, in which the Federal Circuit upheld the district court's exclusion of evidence in a proceeding against the PTO brought pursuant to 35 U.S.C. § 145. The Federal Circuit has reinstated the appeal, which will be heard en banc, and requested briefing on several issues related to § 145 proceedings. No date for oral argument has yet been set.

**February 2010**

## **Claim Terms Should Be Construed in View of the Originating Disclosure When Challenged for Written Description Support in Interference Proceeding**

*David Albagli*

**Judges: Michel, Friedman, Gajarsa (author)**

**[Appealed from W.D. Wash., Judge Pechman]**

In *Koninklijke Philips Electronics N.V. v. Cardiac Science Operating Co.*, No. 09-1241 (Fed. Cir. Jan. 5, 2010), the Federal Circuit reversed the district court's sua sponte dismissal of Koninklijke Philips Electronics N.V.'s ("Philips") suit seeking to overturn the Board's cancellation of all patent claims in an interference proceeding. The Federal Circuit remanded with instructions to construe the claims pursuant to *Agilent Technologies, Inc. v. Affymetrix, Inc.*, 567 F.3d 1366 (Fed. Cir. 2009), and to address Philips's written description challenge and challenges under 35 U.S.C. §§ 102 and 103.

Philips is the assignee of U.S. Patent No. 6,241,751 ("the '751 patent"), which is directed to a cardiac defibrillator that delivers electrical shocks to a patient's heart using two parameters—patient transthoracic impedance and desired energy level. Cardiac Science Operating Co. ("Cardiac Science") filed a continuation application, No. 10/159,806 ("the Owen application"), covering a multiple-capacitor cardiac defibrillator, which claimed priority to a parent application filed before the priority date of Philips's '751 patent. To provoke an interference, Cardiac Science copied the claims of the '751 patent into the Owen application and claimed an earlier priority date. The PTO declared an interference and formulated one count.

In the interference, the Board denied five motions filed by Philips challenging the patentability of the Owen application, awarded priority to the Owen application, and canceled all claims in Philips's '751 patent. In so doing, the Board disregarded the '751 patent in construing a disputed claim term in the Owen application, citing 37 C.F.R. § 41.200(b), which states, "A claim shall be given its broadest reasonable construction *in light of the application or patent in which it appears.*" Slip op. at 4.

Philips sought review of the Board's ruling in district court, moving for a claim construction hearing. In its last brief before the district court, Philips asserted that, if the district court denied Philips's motion for a claim construction hearing, Philips would introduce evidence to the district court at trial. The district court denied Philips's motion for a claim construction hearing and sua sponte dismissed Philips's complaint with prejudice. In the order dismissing the complaint, the district court affirmed the Board, finding that its reasons for ruling against each motion were "grounded in the application of the Board's own procedures

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**“We remind the district court and the Board that they must follow judicial precedent instead of 37 C.F.R. § 41.200(b) when a party challenges another’s written description during an interference proceeding because the PTO lacks the substantive rulemaking authority to administratively set aside judicial precedent.” Slip op. at 17.**

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Philips appealed on three grounds. First, Philips argued that the sua sponte dismissal of its complaint was an improper de facto SJ. Second, Philips argued that the district court erred by affirming the Board’s erroneous application of 37 C.F.R. § 41.200(b). Third, Philips argued that the district court improperly dismissed its claim that the Board erred in denying Philips’s contingent motion to find certain claims anticipated by or obvious over the prior art.

With regard to the first issue, the Federal Circuit concluded that the district court did not satisfy either of the two standards that must be met for proper entry of SJ. Because the question of whether the de facto SJ was proper raises a procedural issue and not one unique to patent law, the Federal Circuit applied regional circuit law. In the Ninth Circuit, a court may enter SJ (1) if the losing party had a full and fair opportunity to present its case, and (2) the parties have no genuine dispute over a material fact.

Philips brought its district court action under 35 U.S.C. § 146, which permits a party to seek review of an interference proceeding and to present new evidence. Thus, in a § 146 action, a party is not limited to the evidentiary record before the Board. The Federal Circuit concluded that the district court denied Philips a full and fair opportunity to present its case when the district court ignored Philips’s request to present new testimony and never heard Philips’s argument for priority of the ’751 patent over the Owen application.

The Court also found that the district court ignored the parties’ genuine dispute as to issues of material fact relating to written description and anticipation. The parties disagreed as to whether the Owen application has adequate written description support for the term “impedance-compensated defibrillation pulse,” and as to whether the claim was anticipated. Philips asserted that the Owen application did not disclose both patient impedance and desired energy level as parameters for the defibrillator, whereas the ’751 patent defines the term “impedance-compensated defibrillation pulse” by these parameters. Cardiac Science denied these assertions of fact in its answer. Similarly, Philips alleged in its complaint that claim 38 of the Owen application was anticipated by at least two prior art references, but Cardiac Science denied Philips’s assertions of fact as to anticipation in its answer. Because it found that neither standard for SJ under Ninth Circuit law was met, the Court concluded that the district court erred in dismissing the complaint.

The Federal Circuit next concluded that the district court erred in affirming the Board’s application of § 41.200(b) to Philips’s written description challenge. Philips argued that the Owen application claims (except claim 38) were unpatentable for lack of written description. Those claims, copied from the ’751 patent, include the term “impedance-compensated defibrillation pulse,” which the ’751 patent defines as including both patient impedance and desired energy level. The Owen application, however, does not disclose desired energy level as a parameter. The Court concluded that the district court erred in concluding that, under § 41.200(b), the ’751 patent written description was irrelevant. The Federal Circuit

held that applying § 41.200(b) and disregarding the original disclosure when assessing a challenge to written description support in an interference is contrary to the holding in *Agilent* and *In re Spina*, 975 F.2d 854 (Fed. Cir. 1992). The Court acknowledged “that the Board may believe that there is a conflict between this court’s holdings and § 41.200(b). However, any conflict between the two must be resolved as directed in *Agilent*.” Slip op. at 13.

The Federal Circuit noted that *Agilent* reiterated how the analysis differs between a written description challenge and a validity challenge for an interference. “[W]hen a party challenges written description support for an interference count or the copied claim in an interference, the *originating disclosure provides the meaning of the pertinent claim language*,” but “[w]hen a party challenges a claim’s validity under 35 U.S.C. § 102 or § 103, however, this court and the Board must interpret the claim in light of the specification in which it appears.” *Id.* at 14 (alterations in original). Thus, “*Agilent* made clear that 37 C.F.R. § 41.200(b) does not apply in an interference proceeding when one party challenges another’s written description.” *Id.* at 15.

The Federal Circuit vacated the SJ ruling because the dismissal of Philips’s written description challenge on procedural grounds was based on an erroneous conclusion of law and thus constituted an abuse of discretion. The Federal Circuit remanded with instructions to construe the term “impedance-compensated defibrillation pulse” in light of the ’751 patent written description and then determine whether the Owen application’s written description supports that construction.

The Federal Circuit further commented that the legal errors by the Board and the district court “stem from a failure to appreciate the consequences of the PTO’s rulemaking authority.” *Id.* at 16. The Federal Circuit “remind[ed] the district court and the Board that they must follow judicial precedent instead of 37 C.F.R. § 41.200(b) when a party challenges another’s written description during an interference proceeding because the PTO lacks the substantive rulemaking authority to administratively set aside judicial precedent.” *Id.* at 17.

As to the third issue on appeal, the Federal Circuit held that the district court erred in dismissing Philips’s claim that the Board erroneously denied Philips’s contingent motion to consider the patentability of certain claims in the Owen application under §§ 102 and 103. The district court concluded that the Board properly dismissed Philips’s motion because “the contingency on which it was premised never arose.” *Id.* at 18. The Federal Circuit found, however, that the contingency never materialized because the Board failed to resolve the written description challenge as a properly raised issue of patentability. Moreover, the Court directed that, under *Agilent*, the district court should have addressed the motion challenging the claims under §§ 102 and 103 regardless of whether it construed claim terms in light of the ’751 patent written description. This is so because “when a party challenges a claim’s patentability under § 102 or § 103—in contrast to a written description challenge—a court ‘must interpret the claim in light of the specification in which it appears.’” *Id.* at 19 (quoting *Agilent*, 567 F.3d at 1375). Accordingly, the Court directed the district court to address Philips’s arguments under §§ 102 and 103 if the district court concludes that the Owen application provides an adequate written description on remand.

**February 2010**

## **PTO Incorrectly Calculated Patent Term Adjustments in Situations of Overlapping PTO Delays**

*David J. Martens*

**Judges: Rader (author), Plager, Moore**

**[Appealed from D.D.C., Judge Robertson]**

In *Wyeth v. Kappos*, No. 09-1120 (Fed. Cir. Jan. 7, 2010), the Federal Circuit affirmed the district court's determination that Wyeth and Elan Pharma International Limited (collectively "Wyeth") were entitled to extended patent term adjustments ("PTA") under 35 U.S.C. § 154(b) due to the PTO's delay in prosecuting their patent applications.

Congress passed the American Inventors Protection Act ("AIPA") in 1999, promising patent applicants a full PTA for any delay during prosecution caused by the PTO. The promise included two guarantees to patentees. Paragraph A of 35 U.S.C. § 154(b)(1) (the "A guarantee" or the "A clause") promises prompt PTO responses by extending the term of the patent one day for each day the PTO does not meet certain examination deadlines, including a fourteen-month deadline to issue a first response to a filed application. Paragraph B of § 154(b)(1) (the "B guarantee" or "B clause") extends the term of the patent one day for each day issuance is delayed due to the PTO's failure to issue a patent within three years after the actual filing date of the application. The A and B clauses are expressly subject to the general limitation that restrict the period of adjustment when any of the "periods of delay" overlap. 35 U.S.C. § 154(b)(2)(A). Under the PTO's definition, the "period of delay" caused the B guarantee to start with the filing of the application and not three years later. Under that interpretation, "overlap" between A adjustments and B adjustments could arise and begin during the pendency of the patent application. Thus, the PTO used either the greater of the A delay or the B delay to determine the appropriate adjustment but never combined the two.

Wyeth owns U.S. Patent Nos. 7,179,892 ("the '892 patent") and 7,189,819 ("the '819 patent") for inventions that treat Alzheimer's disease. During prosecution of these patents, the PTO undisputedly caused delays in issuing the patents that entitled Wyeth to both A and B guarantees.

The PTO calculated 462 days of PTA for the '892 patent and 492 days of PTA for the '819 patent, using the greater-of-A-or-B rubric. Wyeth contended that § 154(b) entitled it to PTAs of 756 days and 722 days, respectively, because the "period of delay" for purposes of the B clause could not have started until

three years after the application's filing date. Wyeth first sought reconsideration of the PTA determination with the PTO. Upon denial of reconsideration, Wyeth challenged the PTA determination by filing suit in the U.S. District Court for the District of Columbia under 35 U.S.C. § 154(b)(4)(A). Both parties filed motions for SJ. The district court granted Wyeth's motion, finding that, even if *Chevron* deference was applicable, the PTO's interpretation is contrary to the plain language of the statute.

On appeal, the Federal Circuit began with statutory construction. The Court detected no ambiguity in the terms "periods of delay" and "overlap" in the context of § 154(b). The Court found that the "period of delay" for the A clause runs from the date the PTO misses the specified deadline to the date of response to the underlying action. The Court also found that the "period of delay" under the express language of the B clause runs from the three-year mark after filing until the application issues. The Court therefore held that no "overlap" can transpire between the A delay and the B delay before the three-year mark because the B delay has yet to begin or take effect.

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**"Of course, it is elementary that 'no deference is due to agency interpretations at odds with the plain language of the statute itself.'" Slip op. at 13 (quoting *Smith v. City of Jackson, Miss.*, 544 U.S. 228, 267 (2005)).**

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The PTO argued that the B delay could occur anytime after the application is filed. The Court rejected this interpretation as contrary to the language of the statute. In response, the PTO argued that it would be double counting if A and B delays were both used for PTA because A delays "cause" B delays. Slip op. at 9. The Court, however, noted that the statute requires as much.

The Court also examined the legislative history of the AIPA but found nothing to support the PTO's arguments. The Court noted that, from the legislative history, it was apparent that the statutory language should provide a minimum seventeen-year term for most patents. The PTO also argued that because the B guarantee was added to the draft sections of § 154(b) after the A delay, Congress did not intend to give patentees already eligible for A adjustments additional compensation during the first three years of prosecution. The Court rejected this argument, finding it did not amount to an extraordinary showing of contrary intentions, as required when the language of the statute is clear.

Finally, the Court rejected the PTO's claim to deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). The Court held that because the language of the statute was unambiguous, there was no reason to afford special deference to the PTO's interpretation. Accordingly, the Court affirmed the judgment of the district court.

February 2010

## Federal Circuit Vacates SJ of Noninfringement After Finding Claim Construction Too Narrow

Jin Zhang

**Judges: Linn (author), Friedman, Dyk (concurring in the result and dissenting-in-part)  
[Appealed from S.D.N.Y., Judge McMahon]**

In *Schindler Elevator Corp. v. Otis Elevator Co.*, No. 09-1146 (Fed. Cir. Jan. 15, 2010), the Federal Circuit concluded that the district court erred in construing the terms “information transmitter” and “recognition device” to exclude any “personal action” by an elevator user other than “walking into the monitored area.” The Federal Circuit vacated the district court’s entry of SJ of noninfringement of U.S. Patent No. 5,689,094 (“the ’094 patent”) in favor of Otis Elevator Co. (“Otis”) and remanded for further proceedings.

The ’094 patent is directed to an elevator system that recognizes a user when he or she enters a building, then dispatches an elevator to take the user to a destination floor based on user-specific data. The system recognizes the user in one or two ways—either a user carrying an “information transmitter” brings the transmitter within range of a “recognition device” mounted in the building’s entry location, or the recognition device recognizes the user by “individual features,” such as facial contours. Once the system has recognized the user, the system identifies the user’s destination floor, dispatches an elevator to the user’s starting floor, and informs the user which elevator to take. The user thus arrives at a destination floor without having to press any button outside or inside the elevator to designate a floor.

Schindler Elevator Corp. and Inventio AG (collectively “Schindler”) sued Otis for infringing all claims of the ’094 patent. The district court construed the term “information transmitter” to mean “a device that communicates with a recognition device via electromagnetic waves, after being actuated by that recognition device, without requiring any sort of personal action by the passenger.” The district court construed the term “recognition device” to mean “a device that actuates and reads data transmitted by an information transmitter without requiring any sort of personal action by the passenger.” After claim construction, the parties cross-moved for SJ on the issue of infringement. Otis argued, and the district court agreed, that neither of these claim limitations is met by the accused system because the use of a passenger’s hands to bring a radio frequency identification (“RFID”) card within the effective range of a card reader constitutes prohibited “personal action.” In its SJ ruling, the district court refined its understanding of “personal action” to require something more than walking into the monitored area and

granted SJ of noninfringement in favor of Otis.

On appeal, Schindler argued that the district court improperly limited the terms “information transmitter” and “recognition device” by requiring those devices to operate “without any sort of personal action by the passenger” and by further defining “personal action” to mean any action “other than walking into the monitored area.” The Federal Circuit agreed that the district court’s construction was too narrow. The Court noted that relevant statements in the specification and prosecution history were directed to elevator operations that occur only after the information transmitter is already within range of the recognition device, not to the initial act of bringing the information transmitter within range of the recognition device.

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**“We modify the district court’s construction of ‘information transmitter’ and ‘recognition device’ by striking the phrase ‘without requiring any sort of personal action by the passenger’ from each construction.” Slip op. at 17.**

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The Federal Circuit focused its analysis on the claim language, the specification, and the prosecution history. First, the Federal Circuit found that the district court overlooked several important aspects of the claim language, which shed light on whether and to what extent an elevator user undertakes “personal action” in the invention. The Court, for example, found that claim 1 explicitly provides that the transmitter is “carried by an elevator user” and that carrying a transmitter is thus a type of “personal action” that is expressly required in the claims. Further, the Court found that claim 7, which depends from claim 1, is directed to an embodiment in which the recognition device may be mounted near a “time clock,” and an elevator is dispatched when a user clocks in or out of work. The Court found that, because a user would need to use his hands to bring the transmitter key within range of the recognition device to unlock the door, or to clock in or out of work, these types of personal action are implicitly permitted in claim 7 and, by extension, in claim 1. Accordingly, the Court held that the claims appear to permit at least those types of personal action that are necessary to bring the information transmitter within range of the recognition device.

The Court also found that the one place that the phrase “personal action” appears in the specification provides no information about how the passenger initially brings the transmitter (or fingerprints) within recognition range, but merely that, once in range, the user need not use personal action to communicate a destination to the elevator control. Moreover, contrary to the district court’s prohibition against all actions other than walking, the Court found that the specification itself provides examples where a user would need to do more than just walk to bring the transmitter into recognition range. The Court noted that unlocking a door and pushing a cart are two “personal actions,” other than simply walking, which are disclosed in the specification as actions needed to bring a transmitter within range of the recognition device. Once in range, the transmitter is actuated by the recognition device and transmits its encoded data without personal action by the user.

Finally, the Federal Circuit looked to the prosecution history. The Court noted that during prosecution, Schindler amended the claims in response to an obviousness rejection, adding the “information transmitter” limitation and requiring that the transmitter be “actuated” by the recognition device. The district court read statements in the prosecution history as unambiguously disavowing the use of a passenger’s hands for any and all purposes. The Federal Circuit disagreed, finding that the prosecution statements do not constitute a “clear and unmistakable” disavowal of personal action for the limited purpose of bringing the transmitter within range of the recognition device. The Court, therefore, modified

the district court's construction of "information transmitter" and "recognition device" by striking the phrase "without requiring any sort of personal action by the passenger" from each construction.

Under the modified constructions, the Court held that Schindler's evidence was sufficient to create a genuine issue of material fact that the RFID cards of the accused system communicate with a card reader via electromagnetic waves after being actuated by the card reader, and that the card reader actuates and reads data transmitted by the RFID cards. Thus, the Court vacated the grant of SJ and remanded for further proceedings.

In a concurring opinion, Judge Dyk agreed that the "without requiring any sort of personal action" construction imposed by the district judge unduly limited the scope of the claims. Judge Dyk disagreed with the majority, however, that there is no requirement of hands-free or automatic action until the transmitter is within range of the recognition device. Judge Dyk found that the specification and prosecution history make no such distinction and consistently emphasize the hands-free and automatic nature of the device without regard to whether it is in range or not. In Judge Dyk's view, the majority's claim construction artificially eliminates any disclaimer by limiting it to actions taken after the transmitter is in range of the recognition device.

**February 2010**

## **Safe-Harbor Provision of 35 U.S.C. § 121 Applies to a Divisional of a Divisional— Even One Filed Voluntarily, Claiming Several Nonelected Inventions**

*Armon B. Shahdadi*

**Judges: Linn (author), Dyk (dissenting-in-part), Prost**  
**[Appealed from D. Del., Judge Farnan]**

In *Boehringer Ingelheim International GmbH v. Barr Laboratories, Inc.*, No. 09-1032 (Fed. Cir. Jan. 25, 2010), the Federal Circuit reversed the district court's finding of invalidity, holding that (1) a retroactive terminal disclaimer cannot overcome obviousness-type double patenting; (2) the safe-harbor provision of 35 U.S.C. § 121 properly applies to a divisional of a divisional of the application in which a restriction requirement was entered, even where the subsequent divisional application was filed voluntarily; and (3) the safe-harbor provision of 35 U.S.C. § 121 applies to a divisional application that claims more than one of the nonelected inventions from the original application.

Boehringer Ingelheim International GmbH ("Boehringer") manufactures and sells MIRAPEX®, an FDA-approved drug for the treatment of signs and symptoms of idiopathic Parkinson's disease. Boehringer brought suit against two ANDA filers for infringing U.S. Patent No. 4,886,812 ("the '812 patent") by attempting to obtain FDA approval for generic versions of the drug.

The '812 patent belongs to a chain of related patents that share common specifications. The original patent—U.S. Patent No. 4,731,374 ("the '374 patent")—issued after the PTO required the applicants to elect one of at least five independent and distinct inventions claimed in the application. After making an election, the applicants filed a divisional application which claimed more than one of the nonelected inventions. This divisional later issued as U.S. Patent No. 4,843,086 ("the '086 patent"). Before the '086 patent issued, the applicants voluntarily filed a second divisional application based on the previous divisional application. The second divisional application issued as the '812 patent. A patent term extension added 1,564 days to the '812 patent's term.

At the time of trial, both the '374 and '086 patents had expired. In an attempt to avoid invalidity due to obviousness-type double patenting, Boehringer filed a terminal disclaimer on the last day of trial. The district court concluded that Boehringer's terminal disclaimer was ineffective to overcome obviousness-type double patenting because the disclaimer was filed after the '086 patent had expired. The district court also held that the safe-harbor provision of § 121 did not apply to the '812 patent because (1) the

provision does not apply to a divisional of a divisional of an application that required restriction, and (2) the second divisional was not “a result of” the original restriction requirement. Based on these holdings, the district court went on to find the '812 patent invalid.

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**“[35 U.S.C. § 121] is not concerned with any overlap in non-elected inventions prosecuted within any particular divisional application or in how any such applications are filed.” Slip op. at 23.**

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The Federal Circuit began its analysis by holding that a terminal disclaimer cannot overcome obviousness-type double patenting when the disclaimer is filed after the expiration of the original patent. The Court reasoned that by failing to terminally disclaim a later patent prior to the expiration of an earlier related patent, a patentee enjoys an unjustified advantage—a purported time extension of the right to exclude from the date of the expiration of the earlier patent. Boehringer argued that it did not enjoy any unjustified advantage because it had properly obtained a term extension of the '812 patent that would have kept it in force. The Court was not persuaded, however, responding that since the rights of a patentee during a term extension are limited in ways that do not normally apply to granted patents, the '812 patent had enjoyed an unjustified extension of its term. Accordingly, the Court found Boehringer's terminal disclaimer ineffective.

Next, the Court held that the safe-harbor provision of 35 U.S.C. § 121 may apply to a divisional of a divisional of the application in which a restriction requirement was entered. Section 121 provides a safe harbor against double patenting rejections for divisional applications filed as a result of a restriction requirement. The Court pointed to previous holdings in *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569 (Fed. Cir. 1991), and *Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340 (Fed. Cir. 2009), where it held that § 121 applies to continuing applications deriving from a divisional application filed as a result of a restriction requirement. Similarly, the Court found that the safe-harbor provision applies equally to a divisional of a divisional application filed as a result of a restriction requirement.

The Court also held that the “as a result of” requirement of § 121 is met when an application simply traces its lineage to an application that elicited a restriction requirement. Here, the fact that the applicants voluntarily filed the second divisional application did not affect the applicability of the safe-harbor provision. The Court reasoned that but for the original restriction requirement, the applicants would have been free to pursue all of the claims in the '812 patent. The Court agreed that “it makes no difference . . . whether the applicant responds to the examiner's restriction requirement by filing one or more divisional applications from the original application, or instead files a single divisional application followed by successive additional divisionals.” Slip op. at 22.

Finally, the Court held that the language of § 121 does not require a divisional—or a divisional of a divisional—to be restricted to only one of the examiner's demarcated inventions in order to preserve the right to rely on the safe-harbor provision of § 121. The application must only trace its lineage back to the application in which a restriction requirement was entered and claim some subset of the nonelected subject matter. According to the Court, § 121 is not concerned with any overlap in nonelected inventions prosecuted within any particular divisional application or in how any such applications are filed.

Although Boehringer's terminal disclaimer remained ineffective, the Federal Circuit reversed the district court's judgment of invalidity and remanded the case for further proceedings consistent with its

interpretation of 35 U.S.C. § 121.

Judge Dyk dissented-in-part, arguing that the Court's construction of 35 U.S.C. § 121 significantly expanded the statute's coverage. Judge Dyk's dissent focused on the purpose of the statute and reasoned that it is not enough that the original divisional application was filed as a result of the restriction requirement; the subsequent contested patent application itself must have been the result of a restriction requirement as well. Judge Dyk also opined that § 121 was never intended to apply to a divisional that elects more than one independent and distinct invention as identified by the examiner.

**February 2010**

## **Federal Circuit Finds Inequitable Conduct Based on Applicant's Conflicting Statements Made to the EPO**

*Jessica A. Keesee*

**Judges: Linn (concurring-in-part and dissenting-in-part), Friedman, Dyk (author)**

**[Appealed from N.D. Cal., Judge Alsup]**

In *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 08-1511, -1512, -1513, -1514, -1595 (Fed. Cir. Jan. 25, 2010), the Federal Circuit affirmed the district court's decision that claims 1-4 of U.S. Patent No. 5,820,551 ("the '551 patent") were invalid due to obviousness and the entire patent was unenforceable due to inequitable conduct, affirmed the district court's grant of SJ of noninfringement of all asserted claims in U.S. Patent Nos. 6,143,164 ("the '164 patent") and 6,592,745 ("the '745 patent"), and affirmed the district court's findings that nearly all of the asserted claims of the '745 patent were invalid due to anticipation.

Becton, Dickinson and Co. ("Becton") sued Therasense, Inc. (now Abbott Diabetes Care, Inc.) seeking a DJ of noninfringement of the '164 and '745 patents. Abbott Diabetes Care, Inc. and Abbott Laboratories (collectively "Abbott") are the owners of the patents-in-suit, all of which relate to disposable blood glucose test strips utilizing electrochemical biosensors to measure the level of glucose in a sample of blood.

Abbott countersued Becton alleging infringement of the '164, '745, and '551 patents. Abbott also initiated an infringement action against Nova Biomedical Corp. ("Nova"), Becton's supplier, alleging infringement of the same patents for the same products. Abbott also sued Bayer Healthcare LLC ("Bayer") alleging that its blood glucose strips infringed the '551 and '745 patents. The cases were consolidated, with all defendants asserting that their products did not infringe Abbott's patents and that Abbott's patents were invalid.

The district court granted SJ of noninfringement of all asserted claims in the '164 and '745 patents, and found nearly all of the asserted claims of the '745 patent invalid due to anticipation. Following a bench trial, the district court held claims 1-4 of the '551 patent invalid due to obviousness and the entire '551 patent unenforceable due to inequitable conduct during prosecution.

On appeal, the Court first addressed the district court's holding that claims 1-4 of the '551 patent were obvious in light of U.S. Patent Nos. 4,545,382 ("the '382 patent") and 4,225,410 ("the '410 patent"). The

central question for obviousness of the '551 patent claims was whether the prior art disclosed a glucose sensor without a membrane for use in whole blood, as required by the claims. The Court upheld the district court's obviousness determination and held that the lower court did not err in finding that the '382 patent disclosed electrochemical sensors in which "a protective membrane was optional in all cases except the case of live blood, in which case the protective membrane was preferred—but not required." Slip op. at 6.

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**“To deprive an examiner of the EPO statements—statements directly contrary to Abbott’s representations to the PTO—on the grounds that they were not material would be to eviscerate the duty of disclosure.” Slip op. at 26.**

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The Court next addressed whether the '382 patent, in combination with the '410 patent, could have enabled the membraneless sensor of the '551 invention. Abbott argued that the oxygen sensitivity of the '382 patent rendered it ineffective when testing whole blood without a membrane, and, therefore, the combination of the '382 patent with the '410 patent could not have enabled the '551 patent. The district court made no explicit finding that the '382 patent would have enabled one having ordinary skill in the art to make and use a membraneless sensor. The district court did find, however, that the '382 patent exhibited "very low oxygen sensitivity" comparable to that disclosed in the '551 patent, and, therefore, "the '382 patent would not have any issues with oxygen sensitivity." *Id.* at 13. On appeal, the Court held this finding was not clearly erroneous. Although the Court identified conflicting testimony on the issue, it held that the district court could properly credit Bayer's expert testimony that the '382 patent showed that there would be no greater than 5% oxygen sensitivity when testing with whole blood.

The Court also upheld the district court's determination that one skilled in the art would have been motivated to combine the '382 patent and the '410 patent to create the membraneless sensor for whole blood of the '551 patent. The Court reasoned that in light of its conclusions that (1) the district court did not clearly err in finding that the '382 patent disclosed a membraneless sensor and (2) that those with ordinary skill in the art would have expected such a membraneless sensor to work, the district court did not err in finding that those with ordinary skill would have been motivated to combine this sensor in a disposable form (the contribution of the '410 patent).

The Court also held that the district court's finding that Abbott failed to demonstrate a sufficient nexus between the claims of the '551 patent and the commercial success of Abbott's Exactech product was not clearly erroneous because of uncontroverted evidence that the Exactech product's success was due to features already in the prior art, such as the '382 patent. Thus, the Court held that the district court did not err in rejecting Abbott's assertion that commercial success supported a finding of nonobviousness.

In sum, the Court found no error with the district court's conclusion that claims 1-4 of the '551 patent would have been obvious in light of the prior art.

The Court also affirmed the district court's decision finding the '551 patent unenforceable due to inequitable conduct based on a failure to disclose statements made to the European Patent Office ("EPO") during proceedings involving the European counterpart to the '382 patent. The Court upheld the conclusion that statements made by Abbott's predecessor to the EPO were highly material to the prosecution of the '551 patent because they contradicted representations Abbott made to the PTO regarding the membraneless sensor disclosed in the '382 patent.

The original application that led to the '551 patent was filed in 1984. The application was repeatedly rejected over the '382 patent. Thirteen years into the prosecution of the application, Abbott drafted new claims including electrochemical sensors lacking a membrane. During an interview with the examiner, Abbott's patent attorney presented the new claims along with argument that the amended claims were not anticipated or obvious because they taught a new glucose sensor that did not require a protective membrane when testing whole blood. Abbott submitted a declaration to the PTO stating that, at the time of the invention, such a membrane was considered essential for whole blood and that one skilled in the art would read the '382 patent's "optionally, but preferably" language not as a technical teaching but rather as "patent phraseology." *Id.* at 20. Shortly thereafter, the PTO allowed the '551 patent with the new claims for a membraneless sensor.

During prosecution of European Patent EP 0 078 636 ("the '636 patent")—a counterpart to the '382 patent with a virtually identical specification—Abbott's patent counsel submitted a brief to the EPO stating that the '636 patent "is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood." *Id.* at 22 (emphasis omitted).

The Court upheld the district court's findings that the EPO statements contradicted the PTO representations in at least two significant ways. First, by describing the "[o]ptionally, but preferably" language as "unequivocally clear," Abbott's EPO representations contradicted Abbott's representations to the PTO that a person having ordinary skill in the art would have understood the phrase as mere "patent phraseology" that did not convey a clear meaning. Second, the EPO documents clearly explained that membranes were merely preferred for live blood and that a membrane was not necessary for testing whole blood *in vitro*.

The Court concluded that to deprive an examiner of the EPO statements—statements directly contrary to Abbott's representations to the PTO—on the grounds that they were not material would be to eviscerate the duty of disclosure. Moreover, if this could be regarded as a close case, which the Court found it was not, the Court stated that "the duty of disclosure requires that the material in question be submitted to the examiner rather than withheld by the applicant." *Id.* at 26.

Abbott, nonetheless, contended that attorney arguments about prior art were not information material to patentability, and that since both the EPO and the PTO representations were merely argument, any inconsistency between the two could not be material. The Court, however, distinguished this case from those involving patentees making representations to the PTO about prior art. Here, the applicant made contradictory arguments in another forum that were withheld from the PTO. The Court found that an applicant's earlier statements about prior art, especially the applicant's own prior art, were highly material to the PTO when those statements directly contradicted the applicant's position regarding that prior art in the PTO.

The Court also affirmed the holding that Abbott intended to deceive the PTO by withholding the EPO documents. The Court confirmed the following findings of the district court: (1) that the statements made to the PTO concerning the prior art '382 patent were absolutely critical in overcoming the examiner's earlier rejections of the claims of the '551 patent; (2) that the EPO statements would have been very important to an examiner because they contradicted the representations made to the PTO; (3) that Abbott's representatives both knew of the EPO statements and consciously withheld them from the PTO; (4) that neither of Abbott's representatives provided a credible explanation for failing to submit the EPO documents to the PTO; and (5) that Abbott's representatives' explanations for withholding the EPO

documents were so incredible that they suggested intent to deceive.

The first and third findings were undisputed, and the second was not clearly erroneous, as previously explained by the Court. The fourth and fifth findings both involved witness credibility. Based on the lower court's assessment of witness credibility and given its opportunity to observe Abbott's representatives' testimony, the Court found the record clearly supported the findings of lack of witness credibility. Thus, the Court concluded that the district court's findings that the EPO submissions were highly material to the prosecution of the '551 patent and that Abbott's representatives intended to deceive the PTO by withholding those submissions were not clearly erroneous, and, therefore, the lower court did not abuse its discretion in holding the '551 patent unenforceable.

The Court also affirmed the district court's grant of SJ with respect to noninfringement of the '164 and '745 patents. A limitation in each of Abbott's asserted claims in the '164 and '745 patents requires that the blood sample being analyzed be held within the strip in a "non-flowing manner."

The district court construed the term narrowly, precluding all motion, including convective flow. The Court rejected the district court's claim construction, finding that any reasonable construction must allow for fluid motion that is inherent within liquids, including convective flow and Brownian motion. The Court therefore interpreted the recitation of a "non-flowing manner" to mean that a sample "is not moving in the sample chamber during the measurement," other than motion attributable to convective flow, Brownian motion, or other qualities inherent to all liquids. *Id.* at 35. The Court held that under this claim construction, SJ of noninfringement was still appropriate. Expert testimony and uncontroverted evidence supported the conclusion that the test strip at issue demonstrated that blood sample flowed in a swirling motion within the strip's measurement zone during the entire measurement period, and therefore did not infringe Abbott's '164 and '745 patents.

The Court also affirmed the district court's grant of SJ as to anticipation of the '745 patent based on PCT application WO 98/35225 ("the '225 reference"). On appeal, Abbott challenged whether the '225 reference disclosed the "diffusible redox mediator" limitation and the "background signal" claim limitation of the '745 patent. Because Abbott did not argue the "background signal" limitation to the district court, the Court held that Abbott waived the issue. The Court then found that the language of the '225 reference implied that diffusible mediators are contemplated, though they are not preferred. The Court also looked to claim 127 of the '225 reference describing a method calling for a "redox mediator," in combination with dependent claim 128 reciting "[t]he method of claim 127, wherein the redox mediator is a non-leachable redox mediator," i.e., a nondiffusible mediator, compelled the conclusion that the '225 reference claims diffusible and nondiffusible mediators in claim 127. *Id.* at 37-38. Accordingly, the Court found there was no triable issue of material fact for a jury to consider on the issue of whether the '225 reference disclosed diffusible mediators. As such, the Court held SJ was proper.

In a separate opinion, Judge Linn dissented from the Court's inequitable conduct ruling. Judge Linn also stated that he concurred with the result and with much of the majority's reasoning in affirming the judgments of obviousness and anticipation, but disagreed with the majority's reference to the claims of the prior art as a measure of what the prior art discloses.

With respect to inequitable conduct, Judge Linn argued that the question for purposes of materiality here is not whether Abbott's arguments to the PTO were meritorious (i.e., that the word "preferably" in the '382/'636 patent would actually have been interpreted by a skilled artisan to mean "required"), but rather

whether anything in Abbott's EPO submissions "refutes, or is inconsistent with," its arguments to the PTO. Judge Linn also asserted that even if this information were material, the individuals who owed a duty of disclosure to the PTO produced a good-faith explanation as to why they withheld the EPO submissions. Judge Linn stated that such an explanation should defeat a charge of inequitable conduct if it was "plausible" that the individuals subjectively believed that the reference was immaterial at the time they withheld it. Judge Linn believed the district court erred in finding the statements were material and made with an intent to deceive the PTO. As to invalidity, Judge Linn noted that he agreed with the holding of invalidity of the '551 and '745 patents, but that the descriptive portions of the prior art patents were alone sufficient to invalidate the claims-in-suit. Thus, Judge Linn believed that it was unnecessary and improper to look to the claims of the prior art patents as a measure of what the prior art disclosed for purposes of obviousness and anticipation.

**February 2010**

## **Erroneous Jury Instructions Not Grounds for Overturning a Verdict Where Jury Is Not Prejudiced**

*Richard M. Hanna*

**Judges: Linn (author), Friedman, Dyk**

**[Appealed from N.D. Cal., Judge Alsup]**

In *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 09-1008, -1009, -1010, -1034, -1035, -1036, -1037 (Fed. Cir. Jan. 25, 2010), the Federal Circuit affirmed the district court's denial of JMOL. The Court found that the district court's legally erroneous jury instruction on the law of anticipation did not prejudice the jury's verdict of "anticipation or obviousness," where the claims in question would have been obvious as a matter of law, and therefore affirmed the district court's judgment.

Therasense, Inc. (now known as Abbott Diabetes Care, Inc.) and Abbott Laboratories (collectively "Abbott"), the owners of U.S. Patent No. 5,628,890 ("the '890 patent"), sued Becton, Dickinson & Co. and Nova Biomedical Corp. (collectively "BD/Nova") for infringement of claims 11 and 12 of the '890 patent by making, using, and selling a product called BD™ Test Strips. BD/Nova denied infringement and asserted that the claims were invalid under 35 U.S.C. §§ 102, 103, and 112. Specifically, BD/Nova asserted that the claims were anticipated or rendered obvious in light of U.S. Patent No. 5,120,420 ("Nankai") and U.S. Patent No. 5,582,697 ("Ikeda"). The jury found that BD/Nova had infringed claims 11 and 12 under the DOE, and also that claims 11 and 12 were invalid under § 102 or § 103, and § 112. Slip op. at 1.

The jury used a special verdict form and checked "Yes" to the following two questions: (1) "Have defendants proven by clear and convincing evidence that Claims 11 and 12 of the '890 patent are invalid by reason of anticipation or obviousness?" and (2) "Have defendants proven by clear and convincing evidence that Claims 11 and 12 of the '890 patent are invalid by reason of inadequate written description?" *Id.* at 4-5. The district court entered judgment in favor of BD/Nova on all counts relating to the '890 patent and denied Abbott's post-trial motions for JMOL and a new trial.

Abbott appealed the judgment and challenged the district court's denial of its motions for JMOL and for a new trial. Abbott's appeal sought to overturn the jury's two verdicts of "anticipation or obviousness" and "inadequate written description." *Id.* at 6. BD/Nova also cross-appealed the jury's finding of infringement, but its cross-appeal was dismissed as improper because judgment had been entered in favor of BD/Nova on all counts.

**“The erroneous jury instruction on the law of anticipation could not have changed the verdict of ‘anticipation or obviousness,’ and obviousness based on Nankai alone is sufficient to support that verdict as a matter of law.” Slip op. at 17.**

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With regard to the “anticipation or obviousness” issue, Abbott contended that the verdict encompassed the separate legal theories of anticipation and obviousness, and that if either theory was legally flawed or unsupported, the verdict must be reversed or a new trial granted. Particularly, Abbott argued that the jury instructions regarding the law of anticipation were legally erroneous and that the jury could not have found the claims obvious under either of BD/Nova’s two obviousness contentions. The Court determined that a jury verdict could only be set aside if the jury instructions were both legally erroneous and prejudicial.

In addressing the first issue, the Court examined the jury instructions regarding the law of obviousness. The jury had been instructed that, for anticipation to apply, it is not necessary that the prior art reference expressly lay out the elements in the exact way laid out in the claim, and that it is sufficient if the single reference would have informed those skilled in the art that all of the claimed elements could have been arranged as in the claimed invention. *Id.* at 7. The Court found these instructions to be legally erroneous, noting that for a claim to be anticipated, each element of the claim must be disclosed, either expressly or inherently, in a single prior art reference, and the claimed arrangement or combination of those elements must also be disclosed, either expressly or inherently, in that same prior art reference. *Id.* at 10. The Court then moved on to determine whether the erroneous instructions had a prejudicial effect.

The Court held that the erroneous jury instructions on the law of anticipation could not have changed the result in this case because the claims at issue would have been obvious as a matter of law, such that no reasonable jury could have returned a verdict that the claims were not obvious. The Court decided that only one legal theory upon which the jury’s decision was based was required to be supported in law and in fact. The Court examined the Nankai patent and determined that it disclosed all of the features and limitations of claims 11 and 12 of the ’890 patent, in an arrangement sufficiently similar to that of the claims to render the claims obvious as a matter of law. Because the jury must at least have found the claims obvious over the Nankai patent, the Court declined to address whether the alternative legal theories of obviousness over Nankai in view of Ikeda, or anticipation over Nankai were supported. *Id.* at 16. The Court further declined to address Abbott’s challenge to the verdict that claims 11 and 12 of the ’890 patent were invalid based on inadequacy of written description.