Last Month at the Federal Circuit

April 2007

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Spotlight Info

- In *Whirlpool Corp. v. LG Electronics, Inc.*, No. 07-1088 (Fed. Cir. Mar. 1, 2007), the Federal Circuit granted a motion to dismiss the appeal filed by LG Electronics, Incorporated and LG Electronics U.S.A., Incorporated (collectively "LG").

  Whirlpool Corporation and Whirlpool Patents Company (collectively "Whirlpool") sued LG for infringement of two patents. LG filed counterclaims seeking DJs of noninfringement and invalidity of both patents and unenforceability of one. The parties filed SJ motions, but LG did not file SJ motions relating to all the issues underlying the DJ counterclaims. The district court granted SJ of noninfringement of one patent and invalidity of the other. The district court denied the other SJ motions as moot and entered a judgment. Whirlpool appealed.

  The Federal Circuit dismissed the appeal because LG's motions for SJ did not raise all of the DJ issues and, therefore, the district court did not decide all of the relief sought by the counterclaims. Because all the claims were not disposed of and no judgment under Fed. R. Civ. P. 54(b) was entered, there is no final judgment and the appeal is premature.

A § 1659 Stay Granted by a District Court Must Remain in Effect Until a Related ITC Judgment Can No Longer Be Appealed

Brannon C. McKay

Judges: Bryson, Linn, Dyk (author)

[Appealed from S.D.N.Y., Judge Brieant, Jr.]

In *In re Princo Corp.*, Misc. No. 841 (Fed. Cir. Mar. 1, 2007), the Federal Circuit held that, with regard to a stay granted under 28 U.S.C. § 1659, a district court must continue to stay proceedings until a judgment in a related ITC proceeding is no longer eligible for appeal.

This case stems from six patents owned by U.S. Philips Corporation ("Philips") relating to the manufacture of recordable compact disks ("CD-Rs") and rewritable compact disks ("CD-RWs"). Philips licenses these patents as part of a licensing package that includes other patents that allegedly are not essential for manufacturing CD-Rs and CD-RWs. Licensing royalties under the package are based on the number of discs manufactured, irrespective of how many of the patents are used. Although Princo Corporation ("Princo") initially licensed the package from Philips in 1997, Princo eventually stopped paying the licensing fees.

Philips terminated the licensing agreement and brought an infringement suit against Princo in January 2002 in the Southern District of New York. Princo raised a patent misuse defense, asserting that Philips's licensing package unlawfully tied nonessential patents to the six essential patents for manufacturing CD-Rs and CD-RWs. Based on the same six patents, the ITC initiated an investigation in July 2002 into the importation of CD-Rs and CD-RWs pursuant to 19 U.S.C. § 1337. Shortly thereafter, Princo intervened in the ITC proceedings as a respondent and raised the same patent misuse defense that it had raised in the district court.

Princo then requested a § 1659 stay in the district court. 28 U.S.C. § 1659 states, *inter alia*, that the "district court shall stay, until the determination of the [ITC] becomes final, proceedings in the civil action with respect to any claim that involves the same issues . . . before the [ITC]." Because Princo's request was timely and met the other requirements of § 1659, the district court issued the stay.

In 2004, the ITC held that Philips engaged in patent misuse because none of the six essential patents could be licensed apart from the nonessential patents. Because the ITC had made its ruling, the district court lifted its § 1659 stay. Subsequently, Philips appealed the ITC's decision and Princo requested that the district court continue to stay proceedings, pending Philips's appeal. However, the district court did not continue the stay, and in early 2005 the district court granted two SJ motions against Princo, ruling that Princo infringed Philips's patents and denying Princo's patent misuse defense. Princo then appealed to the Federal Circuit on the patent misuse issue, but did not argue at that time that the district court should have continued the stay. This resulted in both the district court and the ITC cases being simultaneously before the Federal Circuit.

In September 2005, the Federal Circuit reversed and remanded the ITC's finding that Philips committed patent misuse. *See U.S. Philips Corp. v. Int'l Trade Comm'n*, 424 F.3d 1179, 1193 (Fed. Cir. 2005). While the ITC proceedings were pending on remand, in March 2006, the Federal Circuit also vacated the district court's findings against Princo and remanded that case

for further consideration. *See U.S. Philips Corp. v. Princo Corp.*, 173 Fed. App'x 832 (Fed. Cir. 2006). With both cases on remand, Princo renewed its motion to stay proceedings in the district court. The district court again denied the motion, interpreting the Federal Circuit opinion as compelling the district court to move forward with the case, and again granted Philips's SJ motion on the patent misuse issue.

> "[B]oth the Supreme Court and the other circuits have invariably interpreted 'becomes final' or similar language to mean that the determination is final when it can no longer be appealed." Slip op. at 12.

In response, Princo filed a petition for a writ of mandamus (from which this decision arises) in November 2006, asking the Federal Circuit to vacate the district court's order and stay proceedings under § 1659 until the related ITC proceedings were complete.

Prior to this decision, the Federal Circuit had never addressed whether a § 1659 stay of district court proceedings ends after an initial ruling by the ITC or must continue until the ITC ruling is no longer eligible for appeal. 28 U.S.C. § 1659 states that the stay will remain "until the determination of the [ITC] becomes final," thus turning the issue on the meaning of "becomes final." Based on interpretations of similar language in other statutes and the purpose behind § 1659, the Federal Circuit held that a district court must continue a § 1659 stay until the related ITC decision can no longer be appealed.

The Court relied on previous interpretations of "becomes final" in other statutes for guidance on its interpretation of 28 U.S.C. § 1659. For example, with regard to a criminal law statute for postconviction relief, the Supreme Court has previously interpreted "becomes final" as meaning that the determination can no longer be appealed. *See Clay v. United States*, 537 U.S. 522, 527 (2003). Similarly, the Third Circuit has construed the terms "have become final" in a statute for narcotics violations to mean "no longer subject to direct appellate review." *See United States v. Allen*, 556 F.2d 1193, 1194 (3d Cir. 1977). The Fourth, Fifth, Sixth, Ninth, and Eleventh Circuits have also construed "becomes final" or similar language in the Internal Revenue Code to mean the appeal period has run. In contrast, statutes intending finality after an immediate decision have used language such as "final decisions of the district courts." *See* 28 U.S.C. § 1291; *see also* 28 U.S.C. § 1295(a).

Further, according to the Court, the legislative intent behind § 1659 is "to address the possibility that infringement proceedings may be brought against imported goods in two forums at the same time." H.F. REP. NO. 103-826(I), at 141 (1994). Therefore, the Court reasoned that § 1659 would better serve its purpose if "becomes final" is construed to mean that the decision is no longer eligible for appeal.

The Court also rejected several additional arguments made by Philips. First, the fact that damages were the only remaining issue in the district court proceedings was irrelevant. A stay under § 1659 requires "proceedings" on a "claim" involving issues also before the ITC, but does not require that the proceedings themselves be the same. Second, despite Philips's contentions, the issues in the ITC and the district court were sufficiently related under § 1659 because both proceedings involved patent infringement of the same six patents. Third, Princo did not waive its right to request a stay because Princo initially requested the stay within "30 days after the court action is filed," as required by 28 U.S.C. § 1659. Finally, filing for SJ in the district court did not waive Princo's right to file a petition for writ of mandamus because Princo had unsuccessfully requested a stay prior to filing for SJ.

Consequently, the Court concluded that § 1659 requires that the stay of district court proceedings continue until the ITC proceedings are no longer subject to judicial review. Because the related ITC proceedings were still ongoing, the Court ordered the district court to stay its pending infringement proceedings. Additionally, the Court set aside all proceedings occurring in the district court after May 2, 2006 (the date Princo's stay should have been granted), including the district court's grant of SJ to Philips.

Dismissal of First Suit Without Prejudice or Conditions Is Proper Where Second Action on Same Issues Is Pending

Larry L. Ilag

Judges: Gajarsa, Moore, Jordan (author, sitting by designation)

[Appealed from M.D.N.C., Judge Tilley, Jr.]

In *Walter Kidde Portable Equipment, Inc. v. Universal Security Instruments, Inc.*, No. 06-1420 (Fed. Cir. Mar. 2, 2007), the Federal Circuit affirmed the district court's dismissal of the complaint without prejudice and without conditions.

Walter Kidde Portable Equipment, Inc. ("Kidde") filed two infringement suits against Universal Security Instruments, Inc. ("USI"), amidst questions regarding Kidde's standing to sue. On June 11, 2003, Kidde filed the first infringement action ("*Kidde I*") in the United States District Court for the Middle District of North Carolina, alleging infringement of U.S. Patent No. 4,972,181 ("the '181 patent"). In its answer and counterclaims, USI asserted noninfringement, invalidity, unenforceability for inequitable conduct, unenforceability for fraud on the PTO, a violation of Section 2 of the Sherman Act, and unfair competition in violation of the Lanham Act and North Carolina statutory and common law.

USI filed a motion to dismiss for improper venue, or alternatively, to transfer the case. In its reply brief, USI also asserted that Kidde did not have standing to bring suit because another company, Management Investment & Technology Company, Ltd. ("MITCL"), not Kidde, owned the '181 patent. In response, Kidde submitted a Confirmatory Assignment of the '181 patent executed by MITCL on October 8, 2003, which purported to confirm a transfer of rights in the '181 patent to Kidde pursuant to a purchase agreement dated January 24, 1997. The district court dismissed USI's venue motion and did not address the standing issue.

Prior to trial, the district court granted USI's motion in limine excluding Kidde's expert reports served on May 1, 2005, from use at trial. According to Kidde, the parties mutually agreed to extend the deadline for the exchange of expert reports to May 1, 2005. USI, however, filed a motion to exclude the reports from being introduced at trial, claiming that the reports were untimely served. The district court granted USI's motion, finding that the parties had no authority without court approval to alter the April 15, 2005, discovery deadline, and admission of the untimely expert reports would have necessitated either moving the trial date (to grant USI more time to submit rebuttal expert reports) or forcing the district court to face dispositive motions on the eve of trial, neither of which the district court was willing to do.

USI later filed a motion in limine to exclude evidence and testimony as to the ownership and chain of title of the '181 patent. Concerned that Kidde did not have legal title to the '181 patent, the district court asked the parties to fully brief and further develop the record regarding ownership of the '181 patent. In an attempt to eliminate questions about its standing, Kidde filed a motion for voluntary dismissal without prejudice. On the same day, Kidde filed a new action in the same court ("*Kidde II*") with the belief that the Confirmatory Assignment of the '181 patent executed before the new suit was filed would confer standing. USI submitted a cross motion to dismiss with prejudice, or in the alternative, to dismiss without prejudice but with conditions. The Court granted Kidde's motion to dismiss without comment and without prejudice or conditions. This appeal followed.

On appeal, the Federal Circuit first analyzed whether the district court's order was a final appealable judgment. The Court held that the district court's statement in the order dismissing the "action" terminated not only the complaint but also USI's counterclaims; therefore, the Court had jurisdiction over the appeal.

Turning to the dismissal, the Federal Circuit applied the law of the regional circuit because voluntary dismissal pursuant to Fed. R. Civ. P. 41(a)(2) is not unique to patent cases. Applying Fourth Circuit precedent, the Federal Circuit held that the district court did not abuse its discretion in dismissing Kidde's claims without prejudice and without conditions. In so deciding, the Federal Circuit considered USI's allegations of prejudice and found them to be conclusory or without merit. The Court found that USI was not prejudiced by the expenditure of resources and effort because USI can use the discovery and work product obtained in *Kidde I* in *Kidde II*. The Court also was not swayed by USI's argument that the dismissal nullifies the favorable in limine rulings it received in *Kidde I* with regard to Kidde's expert reports. The in limine rulings had nothing to do with substantive rights or even with the quality of the evidence but, rather, were expressly founded on a scheduling concern. Additionally, USI remains free to argue that the in limine rulings should also apply in *Kidde II*.

The Federal Circuit found that the district court's dismissal of USI's counterclaims was harmless legal error. The Court explained that the district court had erred in dismissing USI's antitrust and unfair competition counterclaims because the counterclaims were pleaded prior to Kidde's motion to dismiss. Moreover, the district court apparently had subject matter jurisdiction over the claims, as neither party had contended otherwise, and in fact, USI objected to their dismissal. Kidde could have properly defended itself against those counterclaims without owning the '181 patent.

While the Federal Circuit declined to decide whether the district court's dismissal of the patent counterclaims was legal error because the district court never resolved whether Kidde owned the '181 patent, the Court held

that the dismissal of USI's counterclaims was harmless legal error because it did not affect USI's substantial rights. The Court explained that USI's substantial rights were not affected by the dismissal because USI appeared free to assert all of its counterclaims in *Kidde II*. Rather than explain how USI's substantial rights might be adversely affected by the dismissal, USI instead contended, citing precedent, that the "mere fact that it is conceivable that there may be some legal significance to the timing of the counterclaims is enough to warrant reversal." Slip op. at 18. The Federal Circuit countered that precedent did not hold that "a defendant need not articulate the ramifications of a district court's dismissal of counterclaims, ..." *Id*. Separately, USI also contended that the dismissal was unfair because USI would lose the benefit of the favorable in limine ruling in *Kidde I*. As explained *supra*, this argument did not persuade the Court because the ruling was made apparently out of procedural necessity at the time, without examination of the expert reports' merits. Additionally, USI is also free to argue in *Kidde II* that the same restrictions on expert evidence set by the in limine ruling in *Kidde I* should apply in *Kidde II*.

The Federal Circuit also held that the district court had erred in deciding the dismissal motion before resolving the standing issues; however, the Court held that this error was also harmless. The Court explained that because the parties would find themselves in the same position as they are now if the case were remanded and subject matter determined, the interest of judicial economy dictates that the district court's order should be upheld.

Deliberate Choice to Accept Later Filing Date Not a Correctable Error Through Reissue

Meredith H. Schoenfeld

Judges: Lourie (author), Schall, Gajarsa

[Appealed from the Board]

In *In re Serenkin*, No. 06-1242 (Fed. Cir. Mar. 6, 2007), the Federal Circuit affirmed the Board's sustaining of the examiner's rejection of claims 1-11 of Reissue Application No. 10/134,550 ("the '550 application").

After failing to include drawings in a PCT application submitted to the PTO in its capacity as the United States Receiving Office ("USRO"), Arnold Serenkin, the applicant, chose to accept a later filing date and forego a priority claim to his provisional application in exchange for the ability to submit the missing drawings. After issuance of a U.S. patent in the national stage of the PCT application, Serenkin attempted to add the priority claim through reissue. The examiner issued a final rejection of the application, concluding that the error identified by Serenkin is not one upon which a reissue can be based. The Board sustained the rejection because, under PCT law and applicable U.S. statutes, Serenkin failed to perfect his claim of priority and that failure was a deliberate choice. Serenkin appealed.

> "[W]e note that the present case, in essence, is not about the failure of an applicant to perfect a claim for priority," but rather, "an applicant who intentionally . . . surrendered his right to a claim of priority, in exchange for a benefit, and now is unhappy with his choice." Slip op. at 9.

The Federal Circuit held that the Board properly concluded that it is not permissible for Serenkin to claim the benefit of the earlier filing date through the reissue process. The Court explained that the action for which the patent applicant sought correction—selecting one of two prosecution options presented by the PTO—was a "conscious decision" and a "deliberate choice," not an error in accordance with 35 U.S.C. § 251. "[T]he deliberate action of an inventor or attorney during prosecution generally fails to qualify as a correctable error under § 251." Slip op. at 7. The remedial function of § 251 is not without limits.

Consistent with precedent, the Federal Circuit explained that Serenkin cannot rely on the reissue statute in order to undo the consequences of deliberate choices made during prosecution. In this case, Serenkin did not fail to perfect priority, but intentionally and knowingly surrendered his right to priority. The Court distinguished this case from precedent wherein the Court determined that the reissue process was appropriate for seeking claims narrower in scope than claims deliberately canceled during prosecution. The Court explained that Serenkin is not using reissue to obtain claims that differ in scope from claims that he previously cancelled. The nature of the so-called errors differ greatly. Thus, the Court concluded that the Board did not err in sustaining the examiner's rejection, and affirmed.

The "Tangentially Related" Exception to Estoppel Under *Festo* Is Narrowly Applied

Maryann T. Puglielli

Judges: Rader, Schall, Prost (per curiam)

[Appealed from C.D. Cal., Judge Taylor]

In *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, No. 05-1415 (Fed. Cir. Mar. 20, 2007), the Federal Circuit reversed the district court's finding that the modified surgical screw of Medtronic Sofamor Danek, Inc. ("Medtronic") infringed the claimed seat means limitation under the DOE, and affirmed the district court's grant of SJ of noninfringement on a claimed anchor seat.

In claim 5 of U.S. Patent No. 5,474,555 ("the '555 patent"), Cross Medical Products, Inc. ("Cross Medical") described a fixation device for stabilizing vertebrae comprising at least two anchors, an anchor seat means, an elongated stabilizer, and a securing means. The seat means included "a vertical axis and first threads which extend in the direction of said vertical axis toward said lower bone interface to a depth below the diameter of the rod . . . ." Claim 7 of the '555 patent recited an "anchor seat including external threads . . . said threads extending toward the rod contacting surface to a thread run-out, the distance between the rod [contacting] surface and the thread run-out being less than the diameter of the rod, ..."

Cross Medical sued Medtronic for infringement of the '555 patent based on Medtronic's polyaxial screw design. The district court granted SJ of infringement and validity of claim 5 to Cross Medical and issued a permanent injunction. Medtronic appealed despite ongoing district court proceedings. While that appeal was pending, Medtronic redesigned its polyaxial screws to replace the threading with an undercut. However, Cross Medical asserted that the redesigned screws also infringed claim 5 and that both the original screw design and the redesigned screw infringed claim 7 of the '555 patent. Without the benefit of the Federal Circuit's guidance in the first appeal, the district court issued a second permanent injunction based on its finding that the redesigned screws also infringe claim 5. The district court found that Medtronic's redesigned screws did not infringe claim 7 of the '555 patent. Medtronic filed a second appeal, which is the basis for this action.

After Medtronic filed its initial brief in the second appeal, the Federal Circuit issued an opinion in the first appeal, overturning the first permanent injunction. The parties agreed that the second permanent injunction could not stand in view of the decision in the first appeal; however, the parties contended that various issues remained for resolution in the second appeal.

In addressing the remaining contentions, the Federal Circuit affirmed the finding regarding no infringement of claim 7; however, the Court did not review the district court's analysis of infringement of claim 7 by Medtronic's original screw design because the Court concluded in the first appeal that genuine issues of material fact remained unadjudicated. As a result, the Federal Circuit vacated and remanded the district court's finding of SJ of infringement and validity of claim 7 for reconsideration in light of the first appeal.

> "[T]he inquiry into whether a patentee can rebut the *Festo* presumption under the 'tangential' criterion focuses on the patentee's objectively apparent reason for the narrowing amendment and that the reason 'should be discernible from the prosecution history of record, if the public notice function of a patent and its prosecution history is to have significance.'" Slip op. at 10.

Upon reviewing the district court's finding of infringement, the Federal Circuit first considered whether Medtronic's redesigned polyaxial screws literally infringed claim 5 of the '555 patent. Cross Medical argued that the groove in Medtronic's redesigned screws was effectively a thread because the groove could act as a root of a thread. The Federal Circuit agreed with the district court's conclusion that Cross Medical's argument stretched the meaning of "thread" too far. As the Federal Circuit reasoned, "[s]imply because the undercut appears adjacent to a thread form does not convert that independent structure into a thread." Slip op. at 8. Accordingly, the Federal Circuit affirmed the district court's finding of no literal infringement of claim 5. Having found no literal infringement, the Federal Circuit then reviewed the district court's finding of infringement under the DOE.

During prosecution of the '555 patent, claim 5 was rejected for lack of antecedent basis, lack of written description support, and for double patenting. Cross Medical amended claim 5 to describe first threads "which extend in the direction of said vertical axis

toward said lower bone interface to a depth below the diameter of the rod when it is in the rod receiving channel, ...” The district court concluded that this amendment did not trigger prosecution history estoppel under *Festo* because, as Cross Medical argued, the reason for this amendment was no more than tangentially related to the accused equivalent. Specifically, the district court reasoned that the rationale behind the amendment was to describe and enable the claimed device and not to overcome prior art using an undercut. In the district court’s opinion, the amendment did not relate to an undercut. The Federal Circuit disagreed.

Under *Festo*, a narrowing claim amendment, whether to overcome prior art to satisfy 35 U.S.C. § 112 or to better describe the invention, can give rise to a presumption that prosecution history estoppel bars the patentee from recapturing the surrendered subject matter. The patentee can overcome this presumption by showing one of three things: (1) that the alleged equivalent was unforeseeable when the amendment was made; (2) that the alleged equivalent was tangential to the purpose of the amendment; or (3) that there was a reason why the patentee could not have described the insubstantial substitute in question.

When considering whether Cross Medical’s narrowing amendment was tangential to the undercut present in Medtronic’s screws, the Federal Circuit considered the applicant’s statements as to why the amendment was made. The applicant explained that the amendment was made “to define the anchor seat means having a channel and threads which cooperate with the securing means . . . so as to capture the stabilizer between the channel and the securing means since the [anchor] seat threads extend toward the channel to a depth below the top of the stabilizer . . . .” Based on this explanation, the Federal Circuit surmised that the thread depth limitation was added to capture the way in which the stabilizer operated, thus overcoming the § 112 rejections. With this rationale in mind, the Court concluded that the accused equivalent, which did not have threads that “extend . . . to a depth below the top of the stabilizer,” did not “capture” this aspect of the invention.

Cross Medical also argued that the alleged equivalent was not foreseeable at the time the amendment was made. The Federal Circuit also rejected this argument, noting that in its argument to support literal infringement, Cross Medical admitted that an undercut was known in the art to act as a thread. Thus, the Federal Circuit found that Cross Medical did not overcome the *Festo* presumption under either exception, and reversed the district court’s finding of infringement of claim 5 under the DOE.

Intent to Deceive May Be Inferred from a Declaration Containing a Disingenuous Statement

Qingyu Yin

Judges: Linn, Dyk, Moore (author)

[Appealed from D. Del., Judge Jordan]

In *eSpeed, Inc. v. BrokerTec USA, L.L.C.*, No. 06-1385 (Fed. Cir. Mar. 20, 2007), the Federal Circuit affirmed the district court’s decision that U.S. Patent No. 6,560,580 (“the ’580 patent”), asserted by plaintiffs eSpeed, Inc., Cantor Fitzgerald, L.P., CFPH, L.L.C., and eSpeed Government Securities, Inc. (collectively “Cantor”), was unenforceable due to inequitable conduct.

Traders in the secondary market for fixed income securities generally do not want to reveal the full volume that they are willing to trade at a given price because this information might be used against them by other market participants. To foster liquidity in the market, exclusive workup rights are given to customers who initiate the trade to allow such customers to incrementally increase purchase volume. Under the traditional “old rules,” when the first buyer or seller has completed his transaction, new buyers or sellers are sequentially given the exclusive workup rights. A problem was that a few participants could tie up the market for long periods of time.

> “An inference of intent [to deceive] may arise where material false statements are proffered in a declaration or other sworn statement submitted to the PTO.” Slip op. at 15

Between 1987 and 1992, Cantor employees developed software code known internally as the “Super System.” The Super System included code that allowed brokers to use either the old rules or some new rules. The new rules limited the exclusivity of the workup rights. The code for the new rules was accessible to brokers using the Super System, but was not commercially implemented when the Super System was used in 1993 to conduct trades because of its slow speed. Improvements were later made to the Super System.

The ’580 patent describes new rules that limit the exclusive workup rights to the initial traders. In particular, after the initial traders finish their transactions, orders that were placed while the initial traders had exclusivity would then be rapidly executed

in time-priority order. The new rules preserve incentive for traders to initiate trades while at the same time avoiding a long queue of traders waiting for their chance to trade.

The ’580 patent issued from U.S. Patent Application No. 09/294,526 (“the ’526 application”), which claimed priority to U.S. Patent Application No. 08/766,733 (“the ’733 application”). The ’733 application was filed on December 13, 1996, and issued as U.S. Patent No. 5,905,974 (“the ’974 patent”) on May 18, 1999. Neither the Super System nor any improvement to that system was disclosed to the PTO during the prosecution of the ’733 application.

Shortly after the ’974 patent issued, Cantor asserted the ’974 patent in a lawsuit, but later dismissed after Cantor’s counsel learned that the Super System had not been disclosed to the PTO. Then, in an effort to purge the possible inequitable conduct with regard to the ’974 patent and avoid a similar problem with any patent that might issue based on the ’526 application, each of the three inventors of the ’526 application submitted a declaration stating that they were not aware of the duty to disclose the Super System during the prosecution of the ’733 application. One such declaration stated that “[t]he Super System . . . did not include new rules” and that “[t]he Super System code was based on ‘old rules.’” The declarations were accompanied by exhibits of over 1000 pages, which included portions of the Super System source code. The ’526 application later issued as the ’580 patent.

Cantor filed suit against BrokerTec USA, L.L.C., Garban, L.L.C., OM Technology US, Inc., and OM Technology AB (collectively “BrokerTec”) in the U.S. District Court for the District of Delaware on June 30, 2003. Cantor asserted that BrokerTec infringed claims 20-23 of the ’580 patent.

The district court ruled, among other things, that the ’580 patent was unenforceable because of inequitable conduct on two separate grounds. First, the failure to disclose the Super System constituted inequitable conduct during the prosecution of the ’733 application, which infected the ’526 application. Inventor declarations in the ’526 application failed to cure the inequitable conduct. Secondly, the three inventor declarations themselves included material misrepresentations. Specifically, the declarations included statements “that the Super System did not contain any code for the ‘new rules’ of trading,” which the district court found to be not true. In addition, the district court inferred intent to deceive, partly because the declarations were worded in a way to make the examiner believe that there were no “new rules” in the Super System. Cantor appealed.

The Federal Circuit’s opinion addressed only the second ground for the finding of inequitable conduct. On the issue of materiality of the misrepresentations in the declarations, the Court concluded that the false statements in the declarations were material under the “reasonable examiner” standard. The Court noted that “[f]alse statements are more likely material when embodied in declarations or affidavits submitted to the PTO.” Slip op. at 11 (citations omitted). Here, the statement that “the Super System did not contain any code for the ‘new rules’ of trading” was found to be false, and would have been important to a reasonable examiner in deciding whether to allow the ’526 application. By the statement in the declaration, the examiner was “left . . . with the impression that the examiner did not need to conduct any further . . . investigation.” *Id.* at 14 (citation omitted).

Next, the Court noted that “[a]n inference of intent may arise where material false statements are proffered in a declaration or other sworn statement submitted to the PTO.” *Id.* at 15. Cantor argued that the applicants acted in good faith by submitting portions of the source code with their declarations. However, instead of explaining the relevance of the new rules code buried in the exhibit of over 1000 pages, applicants made outright false statements in the declarations that the Super System did not contain any code for the new rules. These declarations may be considered “the chosen instrument of an intentional scheme to deceive the PTO,” because “[t]he affirmative act of submitting an affidavit must be construed as being intended to be relied upon.” *Id*. at 16 (citations omitted).

Accordingly, the Court concluded that the district court did not abuse its discretion in finding inequitable conduct.

Failure to Enable Claimed Invention Without Unrecited Elements May Invalidate Otherwise Enabled “Comprising” Claims

William B. Raich

Judges: Lourie (author), Rader, Bryson

[Appealed from S.D. Ohio, Judge Beckwith]

In *Liebel-Flarsheim Co. v. Medrad, Inc*., Nos. 06-1156, -1157 (Fed. Cir. Mar. 22, 2007), the Federal Circuit affirmed the district court’s grant of SJ in favor of Medrad, Inc. (“Medrad”), holding that two patents

asserted by Liebel-Flarsheim Company and Mallinckrodt, Inc. (collectively "Liebel") are invalid for lack of enablement and two others are invalid for anticipation.

U.S. Patent Nos. 5,456,669 and 5,658,261 (collectively "the front-loading patents") share a common specification and are directed to a front-loading fluid injector with a replaceable syringe capable of withdrawing high pressures for delivering a contrast agent to a patient. The claims in the originally filed application that gave rise to these patents expressly recited a "pressure jacket" associated with the high-pressure injector, and all of the disclosed embodiments included a pressure jacket. During prosecution, Liebel removed the references to a pressure jacket, and the issued claims do not explicitly recite a pressure jacket but recite the inclusive transitional phrase "comprising." Notably, the injector in Medrad's accused product did not include a pressure jacket.

U.S. Patent Nos. 5,662,612 and 5,928,197 (collectively "the syringe-sensing patents") also share a common specification but are directed to a computer-controlled injector wherein a motor advances and retracts a plunger located within the syringe. The claims in the syringe-sensing patents recite a detector for detecting "physical indicia" on a syringe, where the indicia are related to the capacity of the syringe.

In an earlier appeal to the Federal Circuit, *Liebel-Flarsheim Co. v. Medrad, Inc*., 358 F.3d 898 (Fed. Cir. 2004) ("*Liebel I*"), the Court reversed the district court's claim construction that the claims required a pressure jacket and determined that the asserted claims of the front-loading patents did not require a pressure jacket. The Court reasoned that none of the asserted claims expressly mention a pressure jacket, the disclosure does not clearly disavow embodiments lacking a pressure jacket, and the prosecution history indicates that the claims purposefully did not claim a pressure jacket.

On remand, in light of the claim construction in *Liebel I*, the district court concluded that Medrad's devices infringed the asserted claims of the front-loading patents, but held that the claims were invalid as failing to comply with the written description and enablement requirements of 35 U.S.C. § 112.

With regard to enablement, the district court noted that the inventors of the front-loading patents admitted to their own unsuccessful experiments with jacketless systems. The district court also relied on the testimony of Liebel's engineers that a jacketless system was not a mere design option and that one of skill in the art would not know how to make a jacketless system. Finally, the district court found that no prototypes of a jacketless injector had been made or described at the time of filing, and that the state of the art was such that a jacketless system would have been a "true innovation." Slip op. at 6. The district court also explained that the claims were invalid for lack of written description because the specification of the front-loading patents did not describe a jacketless injector.

On appeal, the Federal Circuit affirmed the district court's holding that the asserted claims of the front-loading patents were invalid for lack of enablement and reiterated that claims must be enabled across their full scope. The Court agreed with Medrad that, although every embodiment need not be disclosed in the specification, the disclosure must teach the full range of embodiments in order for the claims to be enabled, and here the specification did not teach an injector without a pressure jacket. Moreover, the specification taught away from a jacketless injector by describing jacketless syringes as "impractical." The Court also cited to the testimonial evidence, noting that the inventors themselves admitted that they tried unsuccessfully to produce a jacketless system, and that they decided not to pursue such a system because it was "too risky." *Id*. at 13.

> "The irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet. The motto, 'beware of what one asks for,' might be applicable here." Slip op. at 15.

Citing precedent, the Court emphasized that the quid pro quo of the patent bargain required the applicant's specification to enable one of ordinary skill in the art to practice the full scope of the claimed invention. The Court suggested that Liebel overreached in amending its claims during prosecution to read on jacketless injectors, stating that "having won that battle," enablement presented a challenge that Liebel "could not meet." *Id.* at 15.

Because the Court resolved the case on the enablement ground, the Court did not consider the written description holding of invalidity.

With regard to the syringe-sensing patents, the Federal Circuit in *Liebel I* held that the district court correctly determined that the claim term "physical indicia" was not limited to indicia related to the length of an extender because the claims recited syringe properties other than the length of the extender.

On remand and in light of the claim construction, the district court found that Medrad's device infringed the asserted claims of the syringe-sensing patents, but that those claims were invalid as anticipated and for lack of adequate written description. The district court found that there was nothing in the written description that described an invention for detecting indicia, other than a limited reference to a physical indicia relating to the length of the extender. With regard to anticipation, the district court found that the asserted claims of the syringe-sensing patents were anticipated by Medrad's U.S. Patent No. 5,383,858 ("the '858 patent"). In particular, the district court held that the '858 patent disclosed "physical indicia" related to the "capacity" of the syringe by describing the use of a bar code that stored information about the device, such as information relating to the "dimensions" of the syringe. The district court found that distinctions between "capacity" and "dimensions" were "semantic differences" that did not affect its conclusion of anticipation.

On appeal, the Federal Circuit held that the district court correctly determined that there was no genuine issue of material fact that the '858 patent anticipated the asserted claims of the syringe-sensing patents. The Federal Circuit agreed with the district court that detecting "dimensions" of the syringe, as disclosed in the '858 patent, permitted calculation of capacity using a basic volumetric formula. The Court again noted that Liebel argued for a broad meaning during prosecution, and succeeded, but consequently "suffer[ed] a Pyrrhic victory." *Id.* at 20.

A Prima Facie Case of Obviousness Was Found over the Same Prior Art References Considered by the Examiner During the Prosecution

Ningling Wang

Judges: Michel (author), Mayer, Linn (concurring)

[Appealed from N.D. Ill., Judge Rosenbaum]

In *Pfizer, Inc. v. Apotex, Inc.*, No. 06-1261 (Fed. Cir. Mar. 22, 2007), the Federal Circuit reversed the district court's holding of validity and infringement, and held claims 1-3 of U.S. Patent No. 4,879,303 ("the '303 patent") invalid for obviousness.

Claim 1 of the '303 patent is directed to "[t]he besylate salt of amlodipine." Claims 2 and 3 are directed, respectively, to a pharmaceutical composition and a tablet formulation comprising the besylate salt of amlodipine of claim 1. Amlodipine besylate (or amlodipine benzene sulphonate) is an acid addition salt form of amlodipine formed from the reaction of amlodipine, a weak base, and benzene sulphonic acid. Pfizer, Inc. ("Pfizer") sells an amlodipine besylate drug product in tablet form under the tradename Norvasc®.

Pfizer's scientists discovered amlodipine and its antihypertensive and anti-ischemic pharmacological properties before 1982. Pfizer obtained U.S. Patent No. 4,572,909 ("the '909 patent"), claiming certain dihydropyridine compounds and their pharmaceutically acceptable acid addition salts. The '909 patent discloses pharmaceutically acceptable acid addition salts of amlodipine, which do not specifically include besylate, and that the preferred salt is maleate. However, Pfizer's scientists later found that amlodipine maleate is chemically unstable and sticks to manufacturing equipment. To solve these problems, Pfizer's scientists identified seven alternative anions, including besylate, and found that amlodipine besylate tablet formulations exhibited "clear superiority" in stability and in their processing characteristics, particularly nonstickiness.

> "Since we must presume a patent valid, the patent challenger bears the burden of proving the factual elements of invalidity by clear and convincing evidence. That burden of proof never shifts to the patentee to prove validity." Slip op. at 16 (citation omitted).

Pfizer filed a U.S. patent application directed to amlodipine besylate. During the prosecution, the examiner initially rejected all of the claims as obvious over the '909 patent in view of two prior art references, Spiegel and Schmidt. Schmidt discloses that aryl sulphonic acid salts, which include besylate, are superior to the preferred maleate of the '909 patent. Spiegel provides an example of a pharmaceutical compound wherein the besylate form is specifically identified as the preferred embodiment. The examiner further maintained the rejection and cited another prior art reference, Berge, which shows fifty-three FDA-approved, commercially marketed anions, including besylate, that are useful for making pharmaceutically acceptable salts. To overcome the obviousness rejection, Pfizer filed a Rule 132 declaration by one of its scientists, which stated that the besylate salt of amlodipine was "found to possess a highly desirable combination of physicochemical properties," including good solubility, stability, nonhygroscopicity, and processability, which are

"unpredictable both individually and collectively." Consequently, the examiner allowed the pending claims, which issued as the '303 patent.

Pfizer filed a suit against Apotex, Inc. ("Apotex"), alleging that Apotex's filing of its ANDA seeking approval to commercially sell amlodipine besylate tablets, i.e., Norvasc®, before the expiration of the term of the '303 patent infringed claims 1-3 of that patent. Apotex denied infringement and counterclaimed for DJ that the claims of the '303 patent are invalid for anticipation and obviousness, and that the '303 patent is unenforceable due to Pfizer's alleged inequitable conduct. Apotex admitted, however, that if the '303 patent were held valid and enforceable, its ANDA product would literally infringe claims 1-3 of the '303 patent. After a bench trial, the district court entered judgment for Pfizer, holding the '303 patent valid, enforceable, and infringed. Apotex appealed.

Relying on the same prior art references that were considered by the examiner during the prosecution of the application that issued as the '303 patent, the Federal Circuit reversed the district court's holding of validity. Initially, the Court noted that the district court improperly held that the examiner's interim finding of prima facie obviousness renders the issued claims prima facie obvious. Specifically, the Federal Circuit stated that "a court is never bound by an examiner's finding in an ex parte patent application proceeding" and that "deference to the decisions of the PTO takes the form of the presumption of validity under 35 U.S.C. § 282." Slip op. at 15-16. The Federal Circuit further stated that "[t]he *basis* (as opposed to the mere existence) of an examiner's initial finding of prima facie obviousness of an issued patent is therefore, at most only one factual consideration that the trial court must consider in context of the totality of the evidence 'in determining whether the party asserting invalidity has met its statutory burden by clear and convincing evidence.'" *Id*. at 17 (emphasis in original) (citation omitted).

The Federal Circuit then moved on to the obviousness analysis. While Pfizer argued that the '909 patent does not suggest or motivate the skilled artisan to make amlodipine besylate because none of the anions listed in the '909 patent have a cyclic structure as does besylate, the Court disagreed. The Court explained that a suggestion, teaching, or motivation to combine the prior art teachings to achieve the claimed invention does not have to be found explicitly in the prior art references, but rather, it may be found in other sources, including common knowledge, the prior art as a whole, or the nature of the problem itself. The Federal Circuit held that clear and convincing evidence established that, out of the list of fifty-three anions disclosed in Berge, one of ordinary skill in the art, facing the problems of the maleate tablet form, would have been motivated to use besylate, because of its known acid strength, solubility, and other known chemical properties disclosed in the prior art references and to combine it with the teachings of the '909 patent to produce the besylate salt of amlodipine.

With regard to the district court's finding of no expectation of success in making amlodipine besylate, the Federal Circuit explained that "obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Id*. at 24.

Pfizer also argued that amlodipine in its besylate salt form would at most be obvious to try, but the Federal Circuit disagreed. The Court held that what Pfizer had done in selecting the besylate salt was routine testing because the prior art provided not only the means of creating acid addition salts but also predicted the results. The Federal Circuit further held that Pfizer's showing of superior results of amlodipine besylate were not sufficiently unexpected to rebut Apotex's showing of a prima facie case of obviousness.

Because the Federal Circuit reversed the district court's nonobviousness judgment, it did not determine whether the '303 patent is unenforceable due to Pfizer's alleged inequitable conduct before the PTO. Judge Linn concurred in the Court's decision without a separate opinion.

License Negotiations Created Case or Controversy for DJ Action Despite Promises Not to Sue

Christopher T. Kent

Judges: Bryson (concurring), Linn (author), Dyk

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

In *SanDisk Corp. v. STMicroelectronics, Inc.*, No. 05-1300 (Fed. Cir. Mar. 26, 2007), the Federal Circuit vacated the district court's dismissal of SanDisk's DJ claims for lack of subject matter jurisdiction and remanded the case.

SanDisk Corporation ("SanDisk") and STMicroelectronics, Inc. ("ST") are competitors in the flash memory storage market, and each has patent portfolios related to flash memory storage products.

Beginning with an April 2004 letter from ST to SanDisk requesting a meeting with representatives of SanDisk to discuss a cross-licensing agreement based on a number of ST's patents, ST and SanDisk exchanged letters for several months concerning the scheduling and agenda for the meeting. The exchange of letters resulted in a licensing meeting between ST and SanDisk held on August 27, 2004.

During the licensing meeting, ST presented a slide show, which listed SanDisk's various "unlicensed activities." The ST slide show was followed by a four- to five-hour presentation by ST's technical experts, during which they identified and discussed specific claims of each ST patent and alleged that they were infringed by SanDisk's products. In particular, the presentation included an element-by-element analysis of how SanDisk's products purportedly infringed claims of the fourteen ST patents. Thereafter, SanDisk made a presentation describing several of SanDisk's patents and analyzing how a semiconductor chip product sold by ST purportedly infringed the SanDisk patents. At the end of the licensing meeting, ST's vice president of IP and licensing handed SanDisk's counsel a packet of materials containing, for each of ST's fourteen patents presented, a copy of the patent, reverse engineering reports for SanDisk's products, and diagrams showing how elements of ST's patent claims covered SanDisk's products. According to SanDisk's counsel, ST's counsel indicated that

> I know that this is material that would allow SanDisk to DJ [ST] on. We have had some internal discussions on whether I should be giving you a copy of these materials in light of that fact. But I have decided that I will go ahead and give you these materials.

Slip op. at 5. ST's counsel further told SanDisk's counsel that "ST has absolutely no plan whatsoever to sue SanDisk," to which SanDisk's counsel replied, "SanDisk is not going to sue you on Monday." *Id.*

Following the licensing meeting, ST and SanDisk exchanged copies of the materials presented during the meeting, and on September 15, 2004, SanDisk sent ST a confidential cross-licensing offer, indicating that the offer would expire if not accepted by September 27, 2004. Thereafter, despite ST's repeated requests for a nonconfidential version of the offer, SanDisk refused to send ST a nonconfidential version of the offer. On September 27, 2004, SanDisk indicated to ST that SanDisk did not need any additional information about ST's patents because SanDisk was "quite comfortable with its position" and that it was "time to let our business people talk and see if a peaceful resolution is possible." *Id*. at 6.

After several failed attempts by business representatives to schedule another meeting, SanDisk filed a lawsuit on October 15, 2004, alleging infringement of one of SanDisk's patents and seeking a DJ of noninfringement and invalidity of the fourteen ST patents. The district court granted ST's motion to dismiss SanDisk's DJ claims for lack of subject matter jurisdiction on the basis that there was no actual controversy at the time SanDisk filed its complaint. In particular, the district court reasoned that under the Federal Circuit's existing two-part test for determining whether an actual controversy exists to support DJ jurisdiction under the DJ Act, 28 U.S.C. § 2201(a), ST's conduct did not create in SanDisk a reasonable apprehension of suit by ST. The district court noted that "SanDisk has presented no evidence that ST threatened it with litigation at any time during the parties' negotiations, nor has SanDisk shown other conduct by ST rising to a level sufficient to indicate an intent on the part of ST to initiate an infringement action." *Id.* at 7. The district court further found that the infringement analysis, which ST provided to SanDisk, did not constitute the required "express charges [of infringement] carrying with them the threat of enforcement." *Id.* SanDisk appealed.

"We hold only that where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights." Slip op. at 15.

On appeal, the Federal Circuit vacated the district court's dismissal of SanDisk's request for a DJ of noninfringement and invalidity of the fourteen ST patents and remanded the case. Referring to footnote 11 in the Supreme Court's recent opinion in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007), the Federal Circuit repudiated its own two-part test to determine whether an actual controversy exists, and held "that where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights." Slip op. at 15. In particular, the Federal Circuit found that in footnote 11,

the Supreme Court "specifically addressed and rejected our reasonable apprehension test." *Id.* at 14.

Applying the facts of ST and SanDisk's licensing negotiations under the new rule, the Federal Circuit held that SanDisk had demonstrated the existence of an Article III controversy giving rise to DJ jurisdiction. In support, the Federal Circuit cited ST's detailed infringement analysis, including a presentation given by seasoned litigation experts detailing how ST's patent claims purportedly read on one or more of SanDisk's products based on its element-by-element analysis, ST's liberal reference to SanDisk's activities as "ongoing infringement" of ST's patents and the need for SanDisk to obtain a license to those patents, and ST's provision of materials to SanDisk containing, for each of ST's fourteen patents, copies of each of the patents, reverse engineering reports for SanDisk's products, and diagrams showing a detailed infringement analysis of SanDisk's products.

The Federal Circuit further noted that SanDisk maintained that it could continue its conduct without payment of license royalties to ST, thereby establishing a legal controversy. The Federal Circuit quoted *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941), and concluded that "the conditions of creating 'a substantial controversy, between parties having adverse legal interest, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment' were fulfilled." Slip op. at 17. The Federal Circuit further explained its rationale, commenting that "SanDisk need not 'bet the farm' . . . and risk a suit for infringement by cutting off licensing discussions and continuing in the identified activity before seeking a declaration of its legal rights." *Id.* at 17-18.

Concerning ST's explicit promise not to sue SanDisk, the Federal Circuit concluded that ST's promise did not eliminate a justiciable controversy because ST's conduct showed a preparedness to and willingness to enforce its patent rights despite the promise. Calling ST's conduct "extra-judicial patent enforcement with scare-the-customer-and-run tactics," the Federal Circuit found such tactics to be the type of conduct that the DJ Act was intended to obviate. *Id.* at 18. Referring to the district court's alternative indication that it would exercise its discretion and decline to hear the DJ case, the Federal Circuit noted that such discretion has limits, and further, that the district court's decision was made in the context of the Federal Circuit's now repudiated "reasonable apprehension" test. As a result, the Federal Circuit indicated that there would be little basis for the district court to exercise such discretion in the absence of additional facts in this case.

In a concurring opinion, Judge Bryson agreed with the Federal Circuit's opinion in light of footnote 11 in the Supreme Court's *MedImmune* decision, but noted that "it would appear that under the [Federal Circuit]'s standard virtually any invitation to take a paid license relating to the prospective licensee's activities would give rise to an Article III case or controversy if the prospective licensee elects to assert that its conduct does not fall within the scope of the patent." Bryson Concurring Op. at 3. In short, Judge Bryson sees no practical basis for preventing grant of a DJ action in virtually any case in which the recipient of an offer to take a patent license decides to dispute the need for a license and bring a DJ action.

Hatch-Waxman Patent Term Extension May Be Applied to a Patent Subject to a Terminal Disclaimer

A. Denise Main

Judges: Linn (author), Friedman, Plager

[Appealed from D.N.J., Judge Cooper]

In *Merck & Co. v. Hi-Tech Pharmacal Co.*, No. 06-1401 (Fed. Cir. Mar. 29, 2007), the Federal Circuit affirmed the district court's holding that a patent term extension under the Hatch-Waxman Act, 35 U.S.C. § 156, may be applied to a patent subject to a terminal disclaimer filed to overcome an obviousness-type double-patenting rejection.

Merck & Company, Inc. ("Merck") is the owner of U.S. Patent No. 4,797,413 ("the '413 patent"), filed on June 26, 1987, which covers the drug dorzolamide, a carbonic anhydrase inhibitor, marketed by Merck under the trademark TRUSOPT®. During prosecution of the '413 patent, the applicants filed a terminal disclaimer under 35 U.S.C. § 253 to overcome an obviousness-type double-patenting rejection over an earlier Merck patent, U.S. Patent No. 4,677,115 ("the '115 patent"), which issued on June 30, 1987. Pursuant to the terminal disclaimer, any term of the '413 patent extending beyond June 30, 2004 (seventeen years from the '115 patent issuance), was relinquished.

Following the 1994 enactment of the Uruguay Round Agreement Act ("URAA"), the term of a patent in force was extended to the greater of twenty years from the filing date or seventeen years from the date of issue. As provided by the new law, the expiration dates of both the '115 patent and the '413 patent were extended to

December 12, 2004 (twenty years after the filing date of the '115 patent).

After the FDA's regulatory review and approval of TRUSOPT®, Merck listed the '413 patent in the Orange Book, providing notice that TRUSOPT® was covered by a patent as required by the FDA. Merck then requested and was granted from the PTO a Hatch-Waxman extension pursuant to 35 U.S.C. § 156, resetting the expiration date of the '413 patent to April 28, 2008. Section 156 provides for the patent term of a patent listed in the Orange Book to be extended for the period of time the related product is delayed from the market by the FDA's regulatory review.

On January 18, 2006, Merck sued Hi-Tech Pharmacal Company, Inc. ("Hi-Tech"), alleging infringement of the '413 patent after Hi-Tech filed two ANDAs seeking FDA approval to market dorzolamide as eye drops before the expiration of the '413 patent. Hi-Tech filed a motion to dismiss on the ground that the '413 patent was unenforceable, having expired on December 12, 2004. Merck cross-moved for judgment that the terminal disclaimer did not disclaim the Hatch-Waxman term extension.

Denying Hi-Tech's motion to dismiss and granting Merck's motion for judgment on the pleadings, the district court enjoined Hi-Tech from marketing its generic dorzolamide product until April 28, 2008, the expiration date of the '413 patent.

On appeal, the Federal Circuit analyzed the language of § 156, explaining that § 156 is silent as to whether a patent with a terminal disclaimer is excluded from the benefit of a Hatch-Waxman extension, yet § 154 explicitly states that the patent will not benefit from patent term adjustment for PTO delay. Thus, the Court concluded that it can be inferred that § 156 does not exclude the benefit of a Hatch-Waxman extension. In support of its conclusion, the Court cited the ruling in *Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168 (1993), where the Supreme Court held that an express requirement in a federal rule not included in a later federal rule indicates that the later federal rule does not have the same requirement. Additionally, the Court noted that "the mandate in § 156 that the patent term *shall* be extended if the requirements enumerated in that section are met, support[s] the conclusion that a patent term extension under § 156 is not foreclosed by a terminal disclaimer." Slip op. at 9 (emphasis in original).

Rejecting Hi-Tech's argument that to allow the Hatch-Waxman extension was to nullify the terminal disclaimer, the Federal Circuit found that there was no conflict between the terminal disclaimer under § 253 and the Hatch-Waxman extension under § 156. Rather, the two statutes are applied together where the Hatch-Waxman extension is calculated from the expiration date resulting from the terminal disclaimer, not from the date the patent would have expired without the terminal disclaimer.

Under *MedImmune*'s Article III Justiciable Controversy Test, DJ Jurisdiction Is Proper for ANDA Filers

Brenda J. Huneycutt

Judges: Mayer, Friedman (concurring), Gajarsa (author)

[Appealed from D.N.J., Judge Linares]

In *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.,* No. 06-1181 (Fed. Cir. Mar. 30, 2007), the Federal Circuit reversed the district court's decision dismissing the DJ action by Teva Pharmaceuticals USA, Inc. ("Teva").

Novartis Pharmaceuticals Corporation ("Novartis") holds a New Drug Application for its pharmaceutical Famvir®. Novartis listed five patents with the FDA in the Orange Book: U.S. Patent No. 5,246,937 ("the '937 patent"), drawn to the active ingredient in Famvir®, famciclovir, and four other patents covering various methods of therapeutic use. In 1994, Teva filed an ANDA to market generic famciclovir tablets and certified under paragraph IV that its proposed product did not infringe the five listed Famvir® patents or that the patents were invalid. Novartis sued Teva within the statutory forty-five-day period for infringement of the '937 patent alone. In response, Teva filed a DJ action on the four remaining method patents to declare the patents invalid or not infringed by Teva's proposed product.

Novartis filed and the district court granted Novartis's motion to dismiss Teva's DJ action for lack of subject matter jurisdiction. Utilizing the Federal Circuit's two-part DJ test as recited in *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.,* 395 F.3d 1324 (Fed. Cir. 2005) ("*Pfizer*"), the district court concluded that Teva had failed to show that it was under a reasonable apprehension of imminent suit.

In determining whether subject matter jurisdiction was proper, the Federal Circuit followed the standards recently articulated by the Supreme Court in *MedImmune, Inc. v. Genentech, Inc.,* 127 S. Ct. 764 (2007), and looked to the legislative history and intent

of the DJ provisions. Initially, the Federal Circuit acknowledged that, although the district court's use of the two-part reasonable-apprehension-of-suit test was correct, the test had since been overruled by the Supreme Court in *MedImmune*, in which the test was characterized as conflicting with Supreme Court precedent.

"A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents." Slip op. at 18-19.

In articulating the proper DJ jurisdictional standard, the Court noted that (1) jurisdiction under the DJ Act, 28 U.S.C. § 2201(a), extended to ANDA suits by 35 U.S.C. § 271(e)(5), requires an "actual controversy"; (2) the Supreme Court in *MedImmune* reaffirmed that the DJ Act's "actual controversy" requirement is the same as the Article III "cases and controversy" requirement; and (3) thus, the standard inherently requires both that the plaintiff have standing and the issue be ripe. Taken together, the Federal Circuit concluded that "a declaratory judgment plaintiff is only required to satisfy Article III, which includes standing and ripeness, by showing under 'all the circumstances' an actual or imminent injury caused by the defendant that can be redressed by judicial relief and that is of 'sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" Slip op. at 9 (citation omitted).

Following this *MedImmune* standard, the Federal Circuit determined that Teva has a justiciable controversy because under "all the circumstances," it has a concrete injury-in-fact. *Id*. at 12. The Court disagreed with Novartis that because Novartis had neither filed suit nor threatened suit on the four method patents, there was no actual controversy. Instead, the Court found that by suing Teva on the '937 patent, Novartis created an actual controversy by "placing into actual dispute the soundness of Teva's ANDA and Teva's ability to secure approval of the ANDA." *Id.* The Court explained that Novartis's failure to sue Teva on the method patents within the statutory forty-five-day period does not preclude Novartis from later suing Teva during the life of the patents. Therefore, Teva remains under the threat of an infringement suit. The Court concluded that "[i]n light of Novartis'[s] pending suit on the same ANDA, this threat of litigation is a present injury creating a justiciable controversy." *Id.* at 14.

Conceding that several of Teva's grounds for alleging an "actual controversy" might not be sufficient standing alone, the Federal Circuit held that the circumstances taken as a whole establish a justiciable controversy. The Court proceeded to discuss three circumstances it found dispositive.

First, the Court noted that by listing its Famvir® patents in the Orange Book, Novartis represented that it could reasonably assert a claim of patent infringement on those patents if someone not licensed by Novartis engaged in the manufacture, use, or sale of generic famciclovir.

Second, because Teva's ANDA filing was an act of infringement and, therefore, created a justiciable controversy for one party, it "logically follows that if such an action creates a justiciable controversy for one party, the same action should create a justiciable declaratory judgment controversy for the opposing party." *Id.* at 15.

Third, the purposes of the Hatch-Waxman Act, the "civil action to obtain patent certainty" under 21 U.S.C. § 355(j)(5)(C), and the ANDA DJ provision under 35 U.S.C. § 271(e)(5), all support a finding that a justiciable controversy exists. The Federal Circuit explained that in the situation in which the patentee sues on less than all the ANDA certified patents, the patentee is afforded the thirty-month stay while relieved of its statutory duty to, in exchange for the stay, cooperate in the expeditious determination of the validity of *all* the patents. In essence, the patentee has insulated its other patents from validity challenges, thereby creating the exact uncertainty the DJ provisions were enacted to resolve. The Court noted that it is clear from the legislative history of 21 U.S.C. § 355(j)(5)(C) that this provision intended to grant DJ jurisdiction to virtually all situations where an ANDA filer has been sued for patent infringement and then files a DJ action on the remaining certified patents. In addition, the practical result of Novartis's actions is to delay the introduction of generic drugs, further frustrating the purposes of the statutory provisions and arguing for a finding of a justiciable controversy. Finally, the fact that Teva may be subject to multiple suits based on the same ANDA by the same patentee creates a present and real harm relevant to the analysis.

After consideration of all the circumstances, the Federal Circuit concluded that Teva had suffered a direct injury—the uncertainty as to the legal status of its ANDA and, thus, its legal rights regarding its freedom to market its product. To hold otherwise would subject Teva to the exact type of uncertainty the DJ provisions were enacted to prevent. Therefore, Teva had succeeded in demonstrating a present injury sufficient for a justiciable DJ controversy.

Abbreviations | Acronyms

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 & Drug Administration
IDS	Information Disclosure Statement
IP	Intellectual Property
ITC	International Trade Commission
JMOL	Judgment as a Matter of Law
MPEP	Manual of Patent Examining Procedure
PCT	Patent Cooperation Treaty
PTO	United States Patent and Trademark Office
SEC	Securities and Exchange Commission
SJ	Summary Judgment
SM	Special Master
TTAB	Trademark Trial and Appeal Board

Looking Ahead

- Further to the update in the February issue, Judge Brewster of the U.S. District Court for the Southern District of California has now issued a final judgment against Microsoft Corporation ("Microsoft"), affirming the jury's verdict and previous orders that Microsoft pay $1.5 billion in damages to Alcatel-Lucent for infringement of two Alcatel-Lucent patents relating to audio MP3 files. Microsoft continues to plan to appeal the judgment, particularly in view of the recent Supreme Court decision in *Microsoft Corp. v. AT & T Corp.*, No. 05-1056 (S. Ct. Apr. 30, 2007), in which the Court overturned the Federal Circuit's decision holding Microsoft liable for damages on Windows operating systems sold abroad.

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Last Month at the Federal Circuit

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