Last Month at the Federal Circuit

July 2007

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FEDERAL CIRCUIT CASES:

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Spotlight Info

- Speaking at the 9th Federal Circuit Bar Association Bench & Bar Conference on June 28, 2007, Chief Judge Michel noted that filings of patent infringement appeals have steadily increased over the last ten years and have become one of the largest portions of the Court's pending cases. He also noted that the Court's Mediation Program continues to evolve and participation is now mandatory for all cases selected by the Court's staff.

There Is No Jurisdiction over an Appeal of a Civil Contempt Order That Did Not Modify or Continue a Preliminary Injunction

Lisa M. Matovcik

Judges: Gajarsa, Linn, Moore (author)

[Appealed from D. Mass., Judge O'Toole, Jr.]

In *Entegris, Inc. v. Pall Corp.*, Nos. 04-1440, 05-1265, -1266, 06-1374 (Fed. Cir. June 13, 2007), the Federal Circuit dismissed for lack of jurisdiction Pall Corporation's ("Pall") appeal of the district court's contempt order, and affirmed the district court's dissolution of a preliminary injunction that the district court had granted to Entegris, Inc. ("Entegris").

The subject patents, directed to filtration systems used in semiconductor manufacture, are assigned to Entegris. Entegris sued Pall for infringement of these patents and obtained a preliminary injunction enjoining Pall from making, using, selling, or offering to sell its filter assembly. In response, Pall ceased sales of the enjoined filters, began selling a modified product, and sought a DJ that its modified product did not infringe Entegris's patents. Entegris in turn moved the district court to hold Pall in contempt for violating the injunction by selling the modified product. Pall also sought to dissolve the injunction on the basis that newly discovered prior art raised a substantial question regarding the validity of the asserted patents. The district court held Pall in contempt for violating the injunction and granted Pall's motion to dissolve the injunction. Both parties appealed.

> "Although 'the distinction between an order interpreting an injunction and one modifying an injunction is not always clear,' the distinction defines a boundary of appellate jurisdiction under section 1292." Slip op. at 7 (citation omitted).

On appeal, the Federal Circuit first addressed the issue of whether it had jurisdiction over Pall's appeal of the contempt order. Pall argued that the Court had jurisdiction over its appeal because it is an interlocutory appeal under 28 U.S.C. § 1292(c)(1), which provides jurisdiction over "interlocutory orders of the district courts . . . continuing, modifying, . . . or dissolving injunctions, ..." According to Pall, the Federal Circuit had jurisdiction because the district court "continued or modified" the injunction to include Pall's modified product. The Federal Circuit rejected this argument, finding that the contempt order did not amount to either a modification or continuation of the injunction. Characterizing the difference between modifying and interpreting an injunction as a "distinction [that] defines a boundary of appellate jurisdiction under section 1292," the Federal Circuit found that the district court was interpreting, not modifying, the injunction when it found that Pall's modified product was expressly covered by the original injunction. Slip op. at 7-8.

Neither did the contempt order "continue" the injunction within the meaning of 28 U.S.C. § 1292(a), held the Court. Citing previous rulings of the First and Ninth Circuits, the Federal Circuit adopted as its own standard that "continuing" an injunction requires an order to "effectively prolong or extend an existing injunction." *Id.* at 8. Applying this standard to this case, the Court held that the contempt order did not prolong, extend, or in any other way impact the duration of the preliminary injunction, and thus could not be interpreted as "continuing" the injunction.

The Federal Circuit also rejected Pall's alternative argument that there was jurisdiction over Pall's appeal under the final judgment rule, codified as 28 U.S.C. § 1295(a). Pall argued that the contempt order was final within the meaning of § 1295(a) because a fine had been assessed against Pall. The Federal Circuit observed that § 1295(a) grants the Court exclusive jurisdiction over an appeal from a final decision of a district court. Citing Supreme Court precedent that civil contempt orders are not final judgments, regardless of whether a fine is assessed, the Federal Circuit rejected Pall's argument and considered the district court litigation to be ongoing and not final.

Finally, Pall asserted that the Federal Circuit could exercise pendent jurisdiction over its appeal because it had jurisdiction over Entegris's cross-appeal of the dissolution of the preliminary injunction. While acknowledging that an appellate court may appropriately exercise pendent jurisdiction over an appeal, which is "inextricably intertwined" with another over which it does have jurisdiction, the Federal Circuit found that the two questions in this case were not "inextricably intertwined." The Court explained that the question of whether the district court properly dissolved the injunction in view of invalidity concerns raised by newly cited prior art does not overlap with or impact, let alone resolve, the question of whether Pall's modified product was a colorable imitation of the enjoined product. Accordingly, finding no basis for jurisdiction, the Court dismissed Pall's appeal of the district court's contempt order.

With respect to Entegris's cross-appeal of the district court's decision to dissolve the preliminary injunction, the Federal Circuit first addressed Pall's jurisdictional challenge to Entegris's cross-appeal. Pall contended that the district court dissolved the injunction on two independent grounds and that the Court lacked jurisdiction because Entegris failed to challenge one of those two grounds. The Federal Circuit disagreed, concluding that Entegris had properly challenged the district court's dissolution of the injunction. The Federal Circuit, however, affirmed, holding that the district court had not abused its discretion in granting Pall's motion to dissolve the injunction based upon the substantial question of invalidity raised by the prior art. The references appeared to present analogous prior art and contained all of the elements of one of the relevant claims. Accordingly, the Federal Circuit concluded that Pall had asserted an invalidity defense that Entegris had not proved lacked substantial merit.

Means-Plus-Function Claim Held Invalid as Indefinite for Failure to Identify Corresponding Structure

Larry L. Ilag

Judges: Rader, Archer (author), Gajarsa

[Appealed from W.D. Wash., Chief Judge Lasnik]

In *Biomedino, LLC v. Waters Technologies Corp.*, No. 06-1350 (Fed. Cir. June 18, 2007), the Federal Circuit affirmed the district court's judgment that claims 13-17 and 40 of U.S. Patent No. 6,602,502 are invalid for indefiniteness under 35 U.S.C. § 112, ¶ 2.

The claim term at issue was "control means for automatically operating said valving" or valves. The only references in the specification to the "control means" were a box labeled "Control" in Figure 6 and a statement that the regeneration process of the invention "may be controlled automatically by known differential pressure, valving and control equipment."

> "[A] bare statement that known techniques or methods can be used does not disclose structure. To conclude otherwise would vitiate the language of the statute requiring 'corresponding structure, material, or acts described in the specification.'" Slip op. at 11.

The district court noted that if a claim element contains the term "means" and recites a function, as does "control means" in this case, there is a presumption that § 112, ¶ 6 applies. This particular statutory provision permits broad means-plus-function language in the claims, and at the same time, requires that the patent specification disclose some structure that performs the specified function. In the absence of such disclosure, means-plus-function claims are deemed to have failed to particularly point out and distinctly claim the invention as required by the second paragraph of § 112, and will thus be invalid as indefinite.

The district court concluded that inclusion of the word "control" did not identify structure and, thus, did not overcome the presumption that § 112, ¶ 6 applies. Concluding that "[t]he specification says nothing more than that unspecified equipment may be used to control the regeneration process," the district court held that "[t]he failure to disclose a structure corresponding to the 'control means' function makes claims 13-17 and claim 40 of indefinite scope in violation of § 112, ¶ 2 of the Patent Act." Slip op. at 4.

On appeal, Biomedino, LLC ("Biomedino") asserted that the term "control" to describe "means" recited sufficient structure well understood by those of skill in the art, obviating the need for § 112, ¶ 6. The Federal Circuit disagreed and noted with approval the district court's observation that the reference to "control" was simply an adjective describing "means" and did not denote a structure or material capable of performing the identified function. The Court thus concluded that "control means" was a means-plus-function claim limitation under § 112, ¶ 6.

The Federal Circuit first identified the function of the limitation. Here, there was no dispute that the claimed

function is "automatically operating said valving" or "automatically operating valves." The Court then determined whether the specification described a corresponding structure for that function. The parties agreed that the only references in the specification to the "control means" were the box labeled "Control" in Figure 6 and a statement that the regeneration process may be "controlled automatically by known differential pressure, valving and control equipment." Biomedino argued that there were many known ways to operate valves in the art, including pneumatically, hydraulically, mechanically, and electrically, and that the specification provided adequate guidance for one skilled in the art. This case thus presented the following question: "For purposes of § 112, ¶ 6, is sufficient corresponding structure disclosed when the specification simply recites that a claimed function can be performed by known methods or using known equipment where prior art of record and the testimony of experts suggest that known methods and equipment exist?" *Id*. at 7-8.

The Federal Circuit considered this issue by looking at two of its earlier decisions regarding § 112, ¶ 6, *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205 (Fed. Cir. 2003), and *Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374 (Fed. Cir. 1999). In *Medical Instrumentation*, the Federal Circuit disagreed with the district court's identification of software as a corresponding structure for § 112, ¶ 6 because software was not clearly linked in the specification or prosecution history to the claimed function. In *Atmel*, the Federal Circuit found that an article title in the specification disclosed sufficient structure because "the article's title alone was sufficient to indicate to one skilled in the art the precise structure of the means recited in the specification." Slip op. at 9. Accordingly, the Federal Circuit concluded that the district court improperly granted SJ that the patent was invalid for indefiniteness.

In the present case, the Federal Circuit found nothing to suggest a structure for the claimed control means. The Federal Circuit explained that while the patentee need not disclose details of structures well known in the art, the specification must nonetheless disclose some structure. "The inquiry is whether one of skill in the art would understand the specification itself to disclose a structure, not simply whether that person would be capable of implementing a structure." *Id*. at 11. The Federal Circuit thus affirmed the district court's indefiniteness holding.

Patent Attorney's Complicity in Deceptive Invention Promotion Scheme Justified Exclusion from PTO Practice

Venk B. Krishnamoorthy, Ph.D.

Judges: Rader, Plager, Linn (author)

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

In *Bender v. Dudas*, No. 06-1243 (Fed. Cir. June 21, 2007), the Federal Circuit affirmed a district court's verdict that upheld the PTO's exclusion of registered patent attorney S. Michael Bender from practice based on his complicity in a deceptive invention promotion scheme run by American Inventors Corporation ("AIC").

AIC, using the services of patent attorney Leon Gilden, preyed on unsuspecting inventors utilizing its fee-based "invention promotion" services by providing a "money-back guarantee" if it failed to procure a patent on their behalf. To avoid refunding inventors, Gilden allegedly filed over a thousand design patent applications ("the Gilden applications") embellished with design ornamentation often in the face of invention disclosures reflecting a desire to patent functional features. The PTO awarded Gilden a five-month disciplinary suspension for his role in the embellishment scheme.

> "The background of this case reads like a novel but represents the true story of hopes dashed, fees wasted, and dreams lost by hundreds of individual inventors caught up in the world of self-interested promoters who promise the world and deliver very little." Slip op. at 2.

Subsequently, AIC retained Bender to continue the prosecution of the Gilden applications. Although Bender removed Gilden's improperly added embellishments, he continued to prosecute the design applications without ascertaining whether the inventors wished to pursue utility applications. In addition, his generic engagement letter failed to adequately inform

inventors of the distinctions between design and utility patent applications, or provide case-specific information. As a consequence of complaints related to Bender's actions, the PTO commenced an investigation, ultimately finding Bender in violation of several sections of the code of professional responsibility.

Specifically, the PTO determined that Bender neglected an entrusted legal matter and violated 37 C.F.R. § 10.77(c) by failing to inform his inventor clients of the differences between design and utility patents. The PTO also found that Bender violated 37 C.F.R. § 10.62(a) by not disclosing the conflict of interest created by his financial relationship with AIC in view of AIC's money-back guarantee. Bender was further found to have violated 37 C.F.R. § 10.68(a)(1) by failing to fully disclose and obtain the consent of his inventor clients for payments received from AIC. Finally, the PTO held that Bender engaged in conduct that was prejudicial to the administration of justice and violated 37 C.F.R. § 10.23(b)(5) by providing evasive answers to the PTO's requests for information ("RFI") during its investigation. On account of the above violations, the PTO ordered Bender excluded from practice.

The Federal Circuit appeal ensued after the U.S. District Court for the District of Columbia entered SJ for the PTO in response to Bender's petition challenging the PTO's exclusion order. In reviewing the district court's SJ decision de novo, the Federal Circuit found substantial evidence to support the PTO's exclusion order.

In particular, the Federal Circuit affirmed the 37 C.F.R. § 10.77(c) violation, finding that Bender did not adequately address the issues raised by Gilden's wholesale filing of embellished design applications driven by AIC's money-back guarantee in his engagement letter. Further, in arriving at its decision to uphold the PTO's determination that Bender violated 37 C.F.R. § 10.62(a), the Court deferred to the PTO's interpretation of "full disclosure" as requiring Bender to disclose (i) that he was being compensated by AIC, and (ii) the potentially divergent interests of AIC in filing and prosecuting the pending applications as design applications. The Federal Circuit also affirmed both the PTO's decision holding Bender in violation of 37 C.F.R. § 10.68(a)(1), and its interpretation of "full disclosure" under that section as requiring disclosure of the amount that Bender was being paid by AIC. Additionally, the Court found that Bender did not respond meaningfully to questions in the RFI (i) directed to his relationship with AIC, and (ii) disclosure of that relationship to clients, thereby violating 37 C.F.R. § 10.23(b)(5). The Federal Circuit found the sanction of exclusion from practice before the PTO proper in view of Bender's lack of remorse and his refusal to recognize his misconduct, which created the likelihood of recurrence.

It Is Incorrect to Compare Marks by Eliminating Portions and Simply Comparing the Residue

Naresh Kilaru

Judges: Newman (author), Friedman, Rader

[Appealed from TTAB]

In *China Healthways Institute, Inc. v. Wang*, No. 06-1464 (Fed. Cir. June 22, 2007), the Federal Circuit reversed the TTAB's decision to deny China Healthways Institute, Inc.'s ("Chi Institute") opposition to registration of Xiaoming Wang's mark CHI PLUS, holding that there is likelihood of confusion between Wang's mark CHI PLUS and Chi Institute's mark CHI & Design.

Wang applied to register the mark CHI PLUS for an electric massage apparatus. Chi Institute opposed registration of the mark based on its prior use of the mark CHI & Design in connection with its electric therapeutic massagers. Although noting that the goods covered by the parties' marks were "legally identical," the TTAB found no likelihood of confusion. Relying on dictionary definitions of the term "chi" as meaning vital energy and vital force, the TTAB found "CHI" to be "highly suggestive, if not merely descriptive," when used in connection with massage devices. Slip op. at 4. On this basis, the TTAB reasoned that the common CHI component of the marks is a relatively weak contributor to trademark status, and analyzed likelihood of confusion based on the differences, not the similarities, of the marks. The TTAB concluded that the additional wording "PLUS" in Wang's mark and the design element in Chi Institute's mark were sufficient to avoid a likelihood of confusion.

In reversing the TTAB's decision, the Federal Circuit noted that the word CHI is a significant component of the marks when viewed in their entirety and has significant descriptive aspects that raise a likelihood of confusion and weigh against registration of multiple marks for identical goods. The Court stated that "[i]t is incorrect to compare marks by eliminating portions

thereof and then simply comparing the residue." *Id*. at 5. The word CHI, reasoned the Court, is an integral part of both marks and must be given appropriate weight.

The Court noted that the word "chi" does not mean an electric massage apparatus and that when the marks are viewed in their entirety, the addition of "PLUS" to a mark already established and in use in commerce is indeed likely to cause confusion. The Court found it significant that Chi Institute had sold tens of thousands of electric massagers under its CHI & Design mark, while Wang had only recently entered the market. Accordingly, the Court reversed the TTAB's decision, holding that confusion is likely as to the source of electronic massagers associated with the mark CHI & Design and the mark CHI PLUS.

Statements in Parent Application Prosecution History Did Not Act as Disclaimers Where Claims Differed from Child Application

Edward J. Naidich

Judges: Michel, Bryson (author), Dyk

[Appealed from E.D. Va., Judge Brinkema]

In *Saunders Group, Inc. v. Comfortrac, Inc.*, No. 06-1576 (Fed. Cir. June 27, 2007), the Federal Circuit reversed and remanded the district court's grant of SJ of noninfringement. Specifically, the Federal Circuit held that the district court erred in construing the claims of U.S. Patent No. 6,899,690 ("the '690 patent") to require the presence of at least one pressure activated seal, a limitation that was not present in the accused devices.

> "When the purported disclaimers are directed to specific claim terms that have been omitted or materially altered in subsequent applications (rather than to the invention itself), those disclaimers do not apply." Slip op. at 10.

The Saunders Group, Inc. ("Saunders") competes with the defendants in the market for relatively inexpensive and lightweight cervical traction devices, the subject of the '690 patent. Cervical traction is a physical therapy treatment in which a device is used to generate a sustained force pulling upward on the patient's neck so as to relieve pressure on enflamed or enlarged nerves. Saunders filed an action against the defendants for infringement of the '690 patent. The district court held that the term "pneumatic cylinder" in the asserted claim was limited to a pneumatic cylinder containing at least one pressure activated seal. At the same time, the district court granted SJ of noninfringement.

On appeal, the Federal Circuit held that the district court erred in narrowly construing the claim term "pneumatic cylinder" to require at least one pressure activated seal. The Court noted that it was not disputed that the ordinary meaning of "pneumatic cylinder" does not require the presence of pressure activated seals. The Court also found that nothing in the text of the '690 patent and its prosecution history justified such a restrictive construction of the term.

Moreover, the Court explained that the strongest indication that the term "pneumatic cylinder," as used in the '690 patent, was not meant to include pressure activated seals as a matter of definition could be found in a comparison of independent claim 1 and claim 6, which depends from claim 1. The Court noted that claim 1 does not expressly require a "pressure activated seal," whereas claim 6 adds a further limitation reciting a pressure activated seal. The Court concluded that the doctrine of claim differentiation supports the inference that claim 1 encompasses cylinders without pressure activated seals.

The Court also found that the prosecution history of the '690 patent further supported the conclusion that the term "pneumatic cylinder" is not restricted to ones that use pressure activated seals. The parent application specifically required at least one pressure activated seal in all of its claims. When the patentees filed a continuation application, they omitted that limitation from some, but not all, of the new claims. The Court concluded that this was a strong indication that the claims not reciting pressure activated seals were not intended to require them.

The Court also concluded that the Petition to Make Special was significant because the applicants asserted in that document that the defendants' device lacking a pressure activated seal infringed the independent claims of the application. Furthermore, although the specification did not describe any pneumatic cylinders without pressure activated seals, the Court nevertheless noted that a patent that only describes a single embodiment is not necessarily limited to that embodiment. Although the specification contained passages that described the traction device as comprising at least one pressure activated seal, the Court noted that those passages did not expressly state

that the pressure activated seal was an "essential component of the invention." Slip op. at 9. The Court concluded that "[w]hile the restrictive language of the specification might be sufficient in other contexts to limit the scope of the claims, it is not sufficient in this case, where the language of the claims so clearly distinguishes between those claims that require the presence of a pressure activated seal and those that do not." *Id.*

Nor was the Court persuaded by the defendants' argument that the prosecution history of the parent application unambiguously disclaimed pneumatic cylinders lacking pressure activated seals. The Court noted that the claims in the parent application explicitly required at least one pressure activated seal, and the alleged disclaimer in the prosecution history distinguished the prior art focused on a particular claim limitation, the "pressure activated seal," found in the claims of the parent application—and was not directed to the invention as a whole. The Court thus held that "[w]hen the purported disclaimers are directed to specific claim terms that have been omitted or materially altered in subsequent applications (rather than to the invention itself), those disclaimers do not apply." *Id.* at 10. Moreover, the Court found that statements in the parent application prosecution history that argued that prior art pneumatic cylinders were unable to maintain the required traction force did not establish that the cylinder in the '690 patent must contain a pressure activated seal.

Lastly, the Federal Circuit held that the district court erred in applying the maxim that claims should be construed to preserve their validity and also erred in concluding that if claims 1 and 16 were construed broadly, they would not be enabled because the specification only described a pneumatic cylinder having at least one pressure activated seal. The Federal Circuit explained that in light of the structure of the claims (with some reciting pressure activated seals and others lacking that information), the focus of the Petition to Make Special on the defendants' device, and the absence of any clear disclaimer in the specification or prosecution history, the claim term "pneumatic cylinder" unambiguously encompasses cylinders that do not use pressure activated seals. The Court noted that any validity issues that the defendants had preserved could be addressed on remand.

"Near" Is Not Indefinite and Belated Disclosure in Time for Examiner's Consideration Does Not Render the Patent Unenforceable

Jill MacAlpine

Judges: Lourie (author), Prost, Moore

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

In *Young v. Lumenis, Inc.*, No. 06-1455 (Fed. Cir. June 27, 2007), the Federal Circuit reversed the district court's judgment of invalidity for indefiniteness, holding that the term "near" did not render the claims of U.S. Patent No. 6,502,579 ("the '579 patent") indefinite. The Court also reversed the district court's grant of SJ of unenforceability, holding that no affirmative misrepresentation of material fact occurred and that there was not a failure to timely disclose material information.

William P. Young is the inventor of the '579 patent, which is directed to a surgical method for removing a claw from a domesticated cat. Young sued Lumenis, Inc. ("Lumenis") for infringement. Lumenis requested reexamination of the '579 patent and the PTO rejected the claims in a first office action in view of certain prior art references, including a chapter in a veterinary textbook ("the Fossum Reference"). In response, Young argued that the references did not teach the claimed invention. Meanwhile, in the litigation, the author of the Fossum Reference, Professor Hedlund, provided testimony concerning the Fossum Reference. Lumenis alleged that Young failed to submit Professor Hedlund's testimony to the PTO and that Young made false statements regarding the Fossum Reference to the PTO in his response to the first office action. Based on these two grounds,

> "Claims are considered indefinite when they are 'not amenable to construction or are insolubly ambiguous . . . .'" Slip op. at 14 (citation omitted).
>
> "[W]e cannot agree that there was inequitable conduct resulting from the 'failure to disclose material information' when that information was disclosed to the PTO in time for the examiner to consider it." *Id.* at 21.

Lumenis filed a motion for SJ of unenforceability, asserting that Young engaged in inequitable conduct during the reexamination. After Lumenis filed its SJ motion, but before the PTO issued a second office action, Young submitted Professor Hedlund's testimony to the PTO.

The district court granted Lumenis's motion for SJ of unenforceability, finding that Young had committed inequitable conduct because his statements regarding the Fossum Reference to the PTO were misleading in light of Professor Hedlund's testimony and because he failed to submit her testimony to the PTO. In so doing, the district court rejected Young's argument that his eventual submission of the testimony to the PTO cured the misconduct. In addition, the district court held that the '579 patent was invalid for indefiniteness under 35 U.S.C. § 112, ¶ 2, based on the word "near" in the phrase "forming a first circumferential incision in the epidermis near the edge of the ungual crest of the claw." Relying on *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991), the district court reasoned that the word "near" was indefinite for failing to distinguish the claimed subject matter from the prior art.

On appeal, the Federal Circuit reversed the district court's judgment of invalidity, holding that the word "near" did not render the claims of the '579 patent indefinite. The Court noted that claims are considered indefinite when they are "not amenable to construction or are insolubly ambiguous" and that "[i]ndefiniteness requires a determination whether those skilled in the art would understand what is claimed." Slip op. at 14. It observed that general principles of claim construction are used to make that determination. *Id.* Applying these principles, the Court found that the term "near," as evidenced by the claim language, specification, and drawings, had its ordinary and customary meaning of "close to or at the edge" and was not "insolubly ambiguous." *See id.* at 17. The Court noted that, unlike *Amgen*, the intrinsic evidence here provided guidance on the meaning of the term "near" and that the term "near" had not been inserted in the claims in order to overcome the prior art. The Court explained that "[w]hen intrinsic evidence resolves the claim construction, a term is not 'insolubly ambiguous,' and thus reference to the prior art is not needed." *Id.*

The Federal Circuit also reversed the district court's grant of SJ that the '579 patent was unenforceable, holding that the district court erred in determining that the statements made in response to the first office action were affirmative misrepresentations of material fact and that Young had not failed to timely disclose information to the PTO. With respect to the alleged misrepresentations, the Court found that the statements regarding the Fossum reference, which were allegedly inconsistent with Professor Hedlund's testimony, were "attorney argument, attempting to distinguish the claims from the prior art, not gross mischaracterizations or unreasonable interpretations" of the Fossum Reference. *Id.* at 19-20. Because the examiner had the Fossum Reference and "was free to reach his own conclusions and accept or reject Young's arguments," those arguments were not affirmative misrepresentations of material fact. *Id.* at 20.

As for the district court's conclusion based on the failure to disclose Professor Hedlund's testimony, the Federal Circuit noted that, because the testimony was submitted "at a time when it could be considered by the examiner," the duty of disclosure was satisfied. *Id.* at 19-21. The Court observed that "[t]he essence of the duty of disclosure is to get relevant information before an examiner in time for him to act on it, and that did occur here." *Id.* at 21.

The PTO Is Not Required to Identify Every Conceivable Deficiency in the Claim to Establish a Prima Facie Case of Lack of Written Description

Jeffrey E. Danley

Judges: Michel (author), Archer, Dyk

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

In *Hyatt v. Dudas*, No. 06-1171 (Fed. Cir. June 28, 2007), the Federal Circuit reversed the district court, holding that the PTO had set forth a sufficient prima facie basis for rejection of Gilbert P. Hyatt's claims for failing to satisfy the written description requirement of 35 U.S.C. § 112. In reaching its decision, the Federal Circuit also held that it had jurisdiction to hear the appeal, notwithstanding that the district court had not rendered a final judgment, but had instead remanded for further proceedings at the PTO.

This case involved five of Hyatt's continuation applications "with lineages that can be traced back for decades." Slip op. at 1. All five of these applications, which share the same specification, generally claim devices of various configurations of electronic components. During prosecution of these applications, Hyatt withdrew the pending claims and replaced them with over 1100 new claims. The PTO rejected a number of these claims for failing the written description requirement, noting that while each individual element was disclosed in the specification, nowhere did Hyatt specify the particular configurations or combinations of elements claimed. The PTO relied on and followed

M.P.E.P. § 2163.04(I)(B) to set forth the basis for its initial rejection, i.e., the PTO's prima facie case. Rather than respond to the rejection on the merits, Hyatt challenged the propriety of the PTO's prima facie case. Unpersuaded by Hyatt's response, the PTO made a final rejection. Hyatt appealed to the Board, which upheld the rejection.

"In the context of the written description requirement, an adequate prima facie case must . . . sufficiently explain to the applicant what, in the examiner's view, is missing from the written description." Slip op. at 7.

"A statement of a prima facie case need not be a full exposition on every conceivable deficiency of a claim." *Id*. at 6.

Hyatt then filed an action under 35 U.S.C. § 145 in the district court to challenge the Board's decision. The district court agreed with Hyatt, held that the PTO's explanation of its prima facie case was inadequate, and remanded to the PTO for further prosecution. The PTO appealed to the Federal Circuit.

The Federal Circuit initially addressed the issue of whether it had jurisdiction over the appeal because the district court had not entered a final judgment, but instead had remanded to the PTO for further prosecution. It noted that a court generally does not have jurisdiction when a final judgment has not been entered. The Court observed, however, that an exception to the final judgment rule exists "where denying appellate review would likely result in the permanent loss of the agency's ability to appeal." *Id*. at 4. The Court held that this case presented such a situation because if it were to deny review, the PTO will likely permanently lose its ability to appeal on the issue of whether or not meeting the requirements of M.P.E.P. § 2163.04(I)(B) forms a proper and adequate basis for a prima facie case. As a result, the Court concluded that it had jurisdiction over the appeal.

With respect to the merits of the appeal, the Federal Circuit observed that the PTO is not required to identify every deficiency in the claims to establish an adequate prima facie case. Instead, it only needs to "sufficiently explain to the applicant what, in the examiner's view, is missing from the written description." *Id*. at 7. The Court noted that the PTO has expressed this requirement in M.P.E.P. § 2163.04(I)(B) and held that § 2163.04(I)(B) as written is a lawful formulation of prima facie standard for a lack of written description rejection. The Court explained that the only thing the PTO can reasonably be expected to do is to point out the nonexistence of written description and that § 2163.04(I) expressly instructs the examiner to specify which claim limitation is lacking adequate support in the written description.

Applying these principles, the Court held that the examiner's initial rejection complied with § 2163.04(I)(B) because the examiner not only explained that the written description failed to support the specific claims combinations, but also listed each element of the allegedly unsupported combination. The Court observed that the examiner specifically noted that the lack of adequate description applied to the claimed combination, not to the individual elements of the combination. According to the Court, the burden then properly shifted to Hyatt to respond to the examiner's rejection and Hyatt could not avoid that burden by only challenging the PTO's position that it had properly established a prima facie case. Because Hyatt refused to properly and timely respond, the Court concluded that the PTO properly rejected the claims.

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

Scott M. K. Lee

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

[Appealed from S.D.N.Y., Judge Cote]

In *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, No. 06-1329 (Fed. Cir. June 28, 2007), the Federal Circuit affirmed the district court's judgment that the asserted claims of U.S. Patent No. 4,687,777 ("the '777 patent") were not obvious.

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

The generic drug manufacturer Alphapharm Pty., Ltd. and three other generic manufacturers (collectively "Alphapharm") filed ANDAs pursuant to the Hatch-Waxman Act seeking FDA approval under 21 U.S.C. § 355(j) et seq. to manufacture and sell generic versions of pioglitazone. Because Takeda had listed the '777 patent in the FDA's Orange Book as covering ACTOS®, Alphapharm filed pursuant to 21 U.S.C. § 505(j)(2)(B)(ii) a certification with its ANDA, asserting that the relevant claims of Takeda's '777 patent were invalid as obvious. In response, Takeda sued Alphapharm, alleging that Alphapharm had infringed or would infringe claims 1, 2, and 5 of the '777 patent.

"While the KSR Court rejected a rigid application of the teaching, suggestion, or motivation ('TSM') test in an obviousness inquiry, the Court acknowledged the importance of identifying a 'reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination." Slip op. at 10, quoting *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1731 (2007).

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

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

That test for prima facie obviousness for chemical compounds, the Court held, is consistent with the legal principles enunciated in *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007). The Federal Circuit explained that while the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness inquiry, "[it] acknowledged the importance of identifying 'a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination." Slip op. at 10, quoting *KSR*, 127 S. Ct. at 1731. Moreover, the Federal Circuit noted that the *KSR* Court held that the TSM test can provide helpful insight to an obviousness inquiry as long as the test is not applied as a rigid and mandatory formula. Thus, the Federal Circuit held, "in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." *Id.*

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

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

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

The Federal Circuit then rejected Alphapharm's contention that, under *KSR,* the claimed compounds would have been obvious because the prior art compound fell within "the objective reach of the claim," and the evidence demonstrated that using the techniques of homologation and ring-walking would have been "obvious to try." According to the Court, this was not a situation, as identified in *KSR*, with a problem having a finite number of identified and predictable solutions. Instead, compound b, the closest prior art, "exhibited negative properties that would have directed one of ordinary skill in the art away from that compound." *Id*. at 15. Thus, the Court concluded, "this case fails to present the type of situation contemplated by the [*KSR*] Court when it stated that an invention may be deemed obvious if it was 'obvious to try.'" *Id.*

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

The Federal Circuit went on to state that even if Alphapharm had established that the prior art would have led to the selection of compound b as the lead compound, Alphapharm's obviousness argument failed on a second ground. Specifically, the district court found nothing in the prior art to suggest making the specific molecular modifications to compound b that would be necessary to achieve the claimed compounds. First, the district court found that the process of modifying lead compounds was not routine at the time of the invention. Second, the district court found that nothing in the prior art provided a reasonable expectation that adding a methyl group to compound b would reduce or eliminate its toxicity. There was also no reasonable expectation in the art that changing the positions of a substituent on a pyridyl ring would result in beneficial changes.

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

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

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

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

- A patent reform bill unanimously passed the House Judiciary Committee on July 18, 2007. Among other things, the bill institutes a first to file system, restricts the venue in which a patent litigation may be filed, apportions damages in infringement suits to the profit resulting from the patented portion of a product rather than the entire product, and allows interlocutory appeals from claim construction rulings.

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