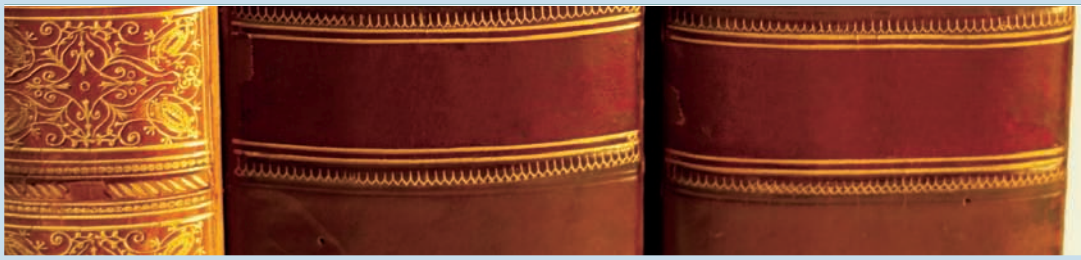
Last Month at the Federal Circuit



April 2008

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FEDERAL CIRCUIT CASES:

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Spotlight Info

- On April 1, 2008, Judge Cacheris in the U.S. District Court for the Eastern District of Virginia struck down the highly controversial PTO rules that limited the number of claims and continuation applications that may be filed. Judge Cacheris found the rules to be substantive in nature and, thus, beyond the PTO's rulemaking authority. *Tafas v. Dudas*, No. 1:07cv846 (E.D. Va. 2007).
- In *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 07-1271 (Fed. Cir. Mar. 7, 2008), the Federal Circuit held that a CIP application filed in response to an examiner's restriction requirement is not protected by the safe harbor provision of 35 U.S.C. § 121, which prevents a parent application from being used as a prior art reference against a divisional application. See the full summary below.

Safe Harbor of Section 121 Applies to Divisionals Only, Not CIPs

Bart A. Gerstenblith

Judges: Michel, Dyk (author), Kennelly (District Judge sitting by designation)

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

In *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 07-1271 (Fed. Cir. Mar. 7, 2008), the Federal Circuit, considering three patents asserted by Pfizer, Inc. et al. (collectively "Pfizer")—U.S. Patent Nos. 5,760,068 ("the '068 patent"); 5,466,823 ("the '823 patent"); and 5,563,165 ("the '165 patent")—found the asserted claims of the '068 patent invalid for obviousness-type double patenting, claim 9 of the '823 patent and claim 17 of the '165 patent not invalid in light of the best mode requirement, and all three patents not unenforceable for inequitable conduct.

Pfizer owns the patents-in-suit, which encompass a broad genus of nonsteroidal anti-inflammatory compounds, compositions using those compounds, and methods of using those compositions. The claims of the patents include celecoxib—the active ingredient in Pfizer's Celebrex, a nonsteroidal anti-inflammatory drug ("NSAID") for the treatment of osteoarthritis and rheumatoid arthritis. Pfizer filed U.S. Patent Application No. 08/160,594 ("the '594 application") with the PTO claiming a broad range of those compounds, compositions including those compounds, and methods of using them, including claims to celecoxib. Celecoxib is a cyclooxygenase-2 ("COX-2") inhibitor, which selectively targets the COX-2 enzyme to treat pain and inflammation without inhibiting the COX-1 enzyme, a distinct COX enzyme associated with the "good housekeeping functions inside the body," such as good gastrointestinal physiology.

Responding to a restriction requirement between the compound, composition, and method claims, as well as to a request that it "elect a single disclosed species" from those identified by the examiner, Pfizer elected to prosecute the generic compound claims and, within that genus, the single compound species, celecoxib. Those compound claims were ultimately allowed, when the '594 application issued as the '823 patent.

Subsequent to the above actions, but before issuance of the '823 patent, Pfizer filed several continuation applications claiming priority to the '594 application and covering its nonelected subject matter, in particular, a divisional application, including the restricted-out composition claims, that issued as the '165 patent, and a CIP, including the restricted-out method claims, that issued as the '068 patent.

Teva Pharmaceuticals USA, Inc. ("Teva"), a generic drug manufacturer, filed an ANDA with the FDA addressed to a proposed drug identified as "Celecoxib Capsules." Because the patents covering celecoxib are listed in the Orange Book, Teva filed a paragraph IV certification challenging the validity of Pfizer's patents covering celecoxib. In response, Pfizer initiated this litigation by filing a patent infringement action against Teva pursuant to 35 U.S.C. § 271(e). In the district court, Teva did not argue noninfringement; rather, it asserted the affirmative defenses of invalidity and unenforceability. Teva did not counterclaim.

Following an eighteen-day bench trial, the district court rejected Teva's positions: its obviousness position, which it did not appeal, and its best mode defense. Finally, the district court held that Pfizer had not committed inequitable conduct. Thus, the district court issued a judgment, concluding that Teva infringed each of the patents-in-suit and enjoined Teva from the manufacture, use, offer to sell, sale, or importation into the United States of any product comprising the chemical compound celecoxib. Teva appealed.

The Federal Circuit began by examining 35 U.S.C. § 121 to determine whether the district court had correctly interpreted its safe harbor provision. The third sentence of section 121 provides a safe harbor following a restriction requirement by precluding the use of certain patents and applications as references against a "divisional application . . . if the divisional application is filed before the issuance of the patent on the other application." 35 U.S.C. § 121 (2000).

"[W]e may properly decide the issue, even if not raised below, since the issue of whether section 121 applies to CIPs is a predicate legal issue necessary to a resolution of the issues before the court." Slip op. at 9 n.5.

The Federal Circuit then addressed Teva's argument that section 121 applies exclusively to "divisional applications" and not to CIPs, even though the district court found that Teva had raised this issue too late in the proceedings and, therefore, had not considered it. The Federal Circuit noted that it could "properly decide the issue, even if not raised below, since the issue . . . is a predicate legal issue necessary to a resolution of the issues before the court." Slip op. at 9 n.5. Addressing that question, the Court concluded that the safe harbor of section 121 is limited to divisional applications, excluding CIPs.

First, the applications are themselves different in that a CIP introduces new subject matter not disclosed in the prior application. A divisional, however, is carved out of a pending application and, thus, discloses and claims only subject matter disclosed in the earlier or parent application. Second, section 121 uses the specific term "divisional application" four times, but does not refer to a CIP. Third, the legislative history of section 121 also refers only to "divisional" applications, even though the difference between CIPs and divisionals was known at the time Congress enacted the 1952 Patent Act. In particular, that history reflects that the language of section 121 was changed to prevent the PTO and courts from rejecting an application filed as a result of a requirement for restriction based on the very same application from which the subsequent application was divided. The Court also noted

that its interpretation of section 121 was consistent with that of the PTO, which had interpreted section 121 as limited to divisional applications.

Because the Court's interpretation of section 121 permitted the '165 patent to be used as a reference against the '068 patent, the Court then proceeded to address the merits of Teva's obviousness-type double patenting argument, reiterating the two-step analysis: (1) construing the claims in both the earlier and later patent, and determining the differences; and (2) determining whether those differences render the claims patentably distinct. In particular, the Court reiterated that it has found a claim to a method of using a composition not patentably distinct from an earlier claim to the composition in a patent disclosing the identical use. The Court noted that the district court had held that if section 121 did not block the use of the '165 patent, it would have found the relevant claims of the two patents not patentably distinct. The Federal Circuit agreed, finding that the relevant '068 patent claims recite methods of administering a "therapeutically-effective amount" of the compositions found in claim 5 of the '165 patent. That same term is also found in claim 1 of the '165 patent, and the parties stipulated that it means the same thing in both patents. Thus, the Court agreed with the district court that the '068 patent merely claims a particular use described in the '165 patent and is therefore not patentably distinct over the claims of the '165 patent. Thus, because the safe harbor of section 121 did not apply, the Court held the '165 patent invalid for obviousness-type double patenting.

Turning to Teva's best mode defense, the Court first addressed Teva's challenge to the generic claims of the compound and composition of the '823 and '165 patents. Teva argued that the generic claims of the '823 and '165 patents do not teach one of skill in the art how to arrive at the preferred embodiment because they do not reveal Pfizer's preference for compounds that demonstrate COX-2 selectivity. Teva asserted that, without the knowledge of the preference for COX-2 selectivity, one of ordinary skill in the art would not be able to identify a preferred embodiment (compound or composition) in the generic claims and that selectivity was relevant to using the claimed invention.

Although it was undisputed that Pfizer preferred COX-2 selectivity, the Federal Circuit declined to address Teva's contentions as to the generic claims because they raised "a difficult issue that . . . need not [be] resolve[d] to decide this case." *Id*. at 20. Because the best mode inquiry is undertaken on a "claim by claim basis," the Court focused solely on the celecoxib-specific claims.

In so doing, the Federal Circuit avoided Teva's argument that Pfizer failed to disclose its preference for COX-2 selective compounds because those specific claims were directed to just one compound, which was COX-2 selective. Teva's remaining argument was that Pfizer failed to disclose the criteria for selecting the correct dosage, which somehow requires knowledge of Pfizer's preference for COX-2 selectivity. The Court agreed with Teva that dosage range could be a preferred method of use that materially affects the properties of the invention under *Bayer AG v. Schein Pharmaceuticals, Inc.*, 301 F.3d 1306 (Fed. Cir. 2002). However, it was undisputed that dosages were disclosed in the specification, and there was no evidence that the inventors preferred any other dosage.

Further, contrary to Teva's assertion that COX-2 selectivity could affect dosage, there was no evidence that at the time of filing the inventors planned to use the COX-2 selectivity criterion to arrive at a preferred dosage (in contrast to their intent to use COX-2 selectivity to arrive at the right compounds). Thus, there was no evidence that they concealed a preferred method of determining the right dosage.

The Court thus agreed that the celecoxib-specific claims in the '823 and '165 patents did not violate the best mode requirement. Having found these claims valid, the Court did not address the generic claims because Teva had not counterclaimed for invalidity. Under *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83 (1993), the Court was not required to address the validity of those claims, and a finding that the other claims were invalid would not change the practical effect of the district court's judgment since that court's order is directed to the use of celecoxib. In other words, there was no practical difference whether Teva's ANDA filing infringes other claims in the '823 and '165 patents.

Finally, the Federal Circuit addressed Teva's argument of unenforceability due to inequitable conduct. Before the district court, Teva had argued that Pfizer committed inequitable conduct by failing to disclose two Merck publications during the prosecution of the applications that led to the patents-in-suit. The district court found that neither reference was material and that Teva had failed to meet the threshold showing of intent.

On appeal, Teva argued that the materiality of the references standing alone, in the absence of a credible explanation for withholding them, was sufficient to establish intent. The district court, however, had found that Pfizer had offered a good-faith explanation for failing to disclose the Merck references based on the testimony of a Pfizer witness who was one of the inventors of celecoxib. The inventor testified that Pfizer had studied the Merck references and concluded that none of the compounds disclosed in the Merck references were similar to the compounds disclosed in Pfizer's own patent applications. This is because the compounds disclosed in the Merck references had a different heterocyclic core than the compounds of the Pfizer applications and that this was a significant distinction. Pfizer noted both that the PTO recognizes that such differences are significant, and that it presented evidence below of its own highly consistent pattern of disclosing references having the same heterocyclic core in the prosecution of hundreds of its other patent applications. Specifically, Pfizer established that, in connection with the prosecution of a separate patent application that had the same heterocyclic core, it did in fact disclose the reference withheld here.

The district court credited this "highly consistent pattern" as strong evidence supporting Pfizer's good-faith explanation for not disclosing the Merck references. The Federal Circuit agreed, finding that it had no basis for overturning that finding and, given the existence of a credible reason for withholding those references, the materiality of the references standing alone was not sufficient to establish intent. Thus, the district court did not clearly err in finding that Teva failed to prove by clear and convincing evidence that Pfizer intended to deceive the PTO by not disclosing the Merck references.

35 U.S.C. § 271(e)(1) Safe Harbor Extends to Products Produced by Patented Processes in Section 337 Actions

Jenna M. Morrison

Judges: Newman (author), Lourie, Linn (concurring-in-part and dissenting-in-part)

[Appealed from ITC]

In *Amgen, Inc. v. International Trade Commission*, No. 07-1014 (Fed. Cir. Mar. 19, 2008), the Federal Circuit affirmed the ITC's ruling that the safe harbor provided by 35 U.S.C. § 271(e)(1) applies in section 337 proceedings to imported products made by patented processes. The Court also reversed the ITC's ruling that it had no jurisdiction, absent a sale or offer to sell the imported product, to determine violations of section 337 of the Tariff Act.

Amgen, Inc. ("Amgen") requested the ITC to initiate an investigation, alleging that certain importations of recombinant human erythropoietin and its derivatives (collectively "EPO") violated section 337 of the Tariff Act by infringing at least one claim of Amgen's six EPO patents. Moving for summary determination of noninfringement, intervenors Roche Holding Ltd., F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively "Roche") submitted that the imported EPO qualified for the FDA safe harbor exemption under 35 U.S.C. § 271(e)(1), as the imported EPO was used to develop and submit information regarding the manufacture, sale, and use of drugs. The ITC granted the motion for noninfringement.

> "We affirm the Commission's ruling that the safe harbor provided by §271(e)(1) applies in proceedings under the Tariff Act relating to process patents as well as product patents, for imported product that is used for exempt purposes."
> Slip op. at 2.

On appeal, Amgen argued that the safe harbor exemption of § 271(e) did not extend to section 337 violations based on foreign practice of patented processes. Amgen argued that the 1988 enactment of 35 U.S.C. § 271(g), which provides a remedy in the district courts for offshore practice of a patented process but explicitly applies the safe harbor exemption of § 271(e), showed congressional intent to limit the safe harbor to process patents that would be enforced in district courts and did not extend to section 337 violations.

The Federal Circuit disagreed, holding that the safe harbor provision of 35 U.S.C. § 271(e) applies in section 337 actions to imported products produced by patented processes. In particular, the Court noted the "broadly stated congressional policy" found in the legislative history of 35 U.S.C. § 271(g), which stated that "the Committee does not intend that it shall be an act of infringement to import a product which is made by a process patented in the United States 'solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.' See 271(e)(1) of title 35, United States Code." Slip op. at 8. Moreover, the Federal Circuit referred to *Merck KgaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), and *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990), which noted the congressional purpose of removing patent-based barriers for

federal regulatory approval of medical products.

Nonetheless, the Court remanded for consideration of the exempt status of each Roche study using the imported EPO. Amgen asserted that at least some of the imported Roche EPO was not exempt because its actual use did not comply with the requirement of § 271(e)(1). It submitted that Roche had completed its submission to the FDA and had shifted its activities to infringement analysis, market-seeding trials, and litigation-related studies that were not protected by the safe harbor.

The Federal Circuit found that the ITC appeared to have assumed that all otherwise infringing activities are exempt if conducted during the period before regulatory approval was granted. The Court held that assumption to be incorrect because "[e]ach of the accused activities must be evaluated separately to determine whether the exemption applies." Slip op. at 10 (alteration in original) (citing *Merck*, 545 U.S. at 200).

Finally, the Court considered the jurisdiction of the ITC to investigate. The ITC held that it lacked jurisdiction to investigate an importation subject to a safe harbor, absent an actual sale or contract for sale of the imported product. Amgen asserted that the ITC's jurisdiction was appropriate because the importation and potential injury to the domestic industry were real and that Roche's sale was imminent. In addition, Amgen submitted that Roche's application for FDA approval established an intent to sell the imported EPO.

Agreeing with Amgen, the Court noted that the projected FDA approval established the ITC's jurisdiction to investigate and provide a remedy that takes effect after FDA approval is granted, and the safe harbor exemption no longer applies. Moreover, "[w]hen it has been shown that infringing acts are reasonably likely to occur, the Commission's obligation and authority are properly invoked." *Id*. at 15.

In a concurring-in-part and dissenting-in-part opinion, Judge Linn focused on the plain language of the statutes. While Judge Linn agreed that it makes sense for the safe harbor provision to apply to section 337, he noted that "the problem remains that if that is what Congress intended, it is not what Congress unambiguously said." Linn op. at 2. Judge Linn expressed that synchronizing the safe harbor provision of section 271 with the Tariff Act was not a decision for the Court to make.

The Claim Terms "Portable Computer" and "Portable Computer Microprocessing System" Did Not Encompass Laptops Where Laptops Were Disclaimed During Prosecution

Joyce Craig

Judges: Michel, Plager, Rader (author)

[Appealed from W.D. Wis., Judge Crabb]

In *Computer Docking Station Corp. v. Dell, Inc.*, Nos. 07-1169, -1316 (Fed. Cir. Mar. 21, 2008), the Federal Circuit affirmed the district court's grant of SJ of noninfringement because the patentee disavowed an interpretation of "portable computer" that would encompass a computer with a built-in display or keyboard, i.e., a laptop. The Court also affirmed the district court's finding that the case was not exceptional and that attorneys' fees were not warranted under 35 U.S.C. § 285.

Computer Docking Station Corporation ("CDSC") owns U.S. Patent No. 5,187,645 ("the '645 patent"). The '645 patent is directed to a portable microprocessor system that is capable of connecting to peripheral devices, such as a keyboard or mouse, either through individual connectors or through a docking connector. The specification explains that a keyboard and visual display are optional. CDSC sued Dell, Inc., Gateway, Inc., Toshiba America, Inc., and Toshiba America Information Systems, Inc. (collectively "Defendants"), alleging that laptops and docking stations produced by them infringed the '645 patent. Each accused laptop has a built-in display or keyboard.

"Here the sum of the patentees' statements during prosecution would lead a competitor to believe that the patentee had disavowed coverage of laptops. CDSC cannot recapture claim scope disavowed during prosecution to prove infringement." Slip op. at 17-18 (citations omitted).

Each of the claims of the '645 patent that CDSC asserted requires a "portable computer" or "portable computer microprocessing system" ("the portable computer limitation") and a "single connector for making all connections from the microprocessor to said specific computer peripheral devices" ("the all connections limitation"). The district court determined that the prosecution history and the specification of the '645 patent distinguished the claimed invention from a laptop computer. Specifically, the district court found the applicants' statements made to overcome the examiner's rejections based on U.S. Patent No. 5,030,128 to Herron et al. ("Herron patent") amounted to a clear and unmistakable disavowal of computers with built-in displays or keyboards. Accordingly, the district court construed the phrases "portable computer" and "portable computer microprocessing system" to mean "a computer without a built-in display or keyboard that is capable of being moved or carried about." The district court also construed the phrase "said single connector for making all connections for the microprocessor to said specific computer peripheral devices" to require "that all individual peripheral device connections on the housing that connect to the microprocessor also pass through the single connector."

Based on these claim interpretations, CDSC moved for entry of final judgment of noninfringement, conceding that none of the accused products met the court's construction of the portable computer limitation. CDSC also noted that some of the accused products did not satisfy the all connections limitation. Defendants opposed the motion because the parties could not agree on the form of judgment for the all connections limitation. The district court denied CDSC's motion. Defendants then moved for SJ of noninfringement based on both limitations. Because Defendants introduced new documents in support of their motion, CDSC filed a Rule 56(f) motion for additional discovery related to the all connections limitation. The district court denied CDSC's Rule 56(f) motion, granted Defendants' motion for SJ, and denied Defendants' motion for attorneys' fees and costs under section 285. CDSC appealed the district court's claim construction, its grant of SJ, and its denial of CDSC's Rule 56(f) motion. Defendants appealed the denial of the motion for attorneys' fees and costs.

On appeal, the Federal Circuit first addressed claim construction. As a threshold matter, the Court concluded, and the parties did not dispute, that the phrases "portable computer" and "portable computer microprocessing system" in the preambles of the asserted

claims limited the scope of the asserted claims. Turning to the construction of these phrases, the Federal Circuit agreed with the district court that the sum of the applicants' statements during prosecution clearly and unambiguously disavowed computers with built-in displays and keyboards, such as laptops, for several reasons. First, during prosecution, the applicants explained that interface connectors for the keyboard and display were located on the rear of the housing. The Court found that if the keyboard and display were built-in, such peripheral connections would not be necessary. Next, the applicants told the examiner that the invention conceded portability of displays and keyboards in favor of processing power and memory. Further, the applicants distinguished their system from the laptop computer of the Herron patent, which had its own flat panel display and keyboard, arguing that the laptops did not have the memory capacity, utility, and functionalities of the applicants' system. Finally, the applicants described their system as able to fit vertically in the docking station, which the Court concluded it could not do if the keyboard and display were built-in.

The Court added that the examiner's citation of the single connection limitation, and not the portable computer limitation in the reasons for allowabilty, did not "erase the applicants' clear disavowal of laptops." Slip op. at 15. The Court reasoned that the applicants distinguished their invention from the prior art in multiple ways and a disavowal, if clear and unambiguous, could lie in a single distinction among many. The Court also noted that the specification of the '645 patent did not cut against the clear disavowal of laptops because the specification did not provide an express definition of "portable computer" that would override or make the distinctions in the prosecution history ambiguous. Indeed, the Court found that the specification contrasted the microcomputer system with a laptop computer and explained that a keyboard and visual display were optional. Accordingly, the Court affirmed the district court's determination that the portable computer limitation required "a computer without a built-in display or keyboard that is capable of being moved or carried about."

CDSC stipulated that, if the claims are construed to require a computer without a built-in display and keyboard, Defendants' accused laptops and docking stations would not infringe. Because there was no factual dispute regarding the portable computer limitation, which was required by every asserted claim, the Federal Circuit found that Defendants were entitled to SJ of noninfringement. Given this conclusion, the Court declined to reach the issues related to the all connections limitation, including the district court's denial of CDSC's Rule 56(f) motion.

Turning next to the issue of attorneys' fees, the Federal Circuit observed that a court may award reasonable attorneys' fees to prevailing parties under 35 U.S.C. § 285, and that factors relevant to this inquiry include the closeness of the question, prefiling investigation and discussions with the Defendants, and litigation behavior. The Court, however, determined that the district court did not clearly err in finding that the case was not exceptional under section 285. The Court found support in the record for the district court's findings that the applicants' disavowal of laptops was not self-evident at the beginning of the claim construction analysis and that CDSC engaged in a serious effort to evaluate the likelihood of success on its patent claims. The Court also found that, if the district court's construction of the portable computer limitation were reversed on appeal, CDSC might have been able to prevail on the all connections limitation. Thus, the Court concluded that the district court's finding that CDSC's lawsuit was not objectively baseless was not clearly erroneous and affirmed the denial of attorneys' fees and costs under section 285.

Rat Zapper Patent Held to Be Obvious Despite Objective Evidence of Nonobviousness

Bradley E. Edelman

Judges: Bryson, Moore (author), Wolle (Senior District Judge sitting by designation)

[Appealed from E.D. Pa., Senior Judge Kelly]

In *Agrizap, Inc. v. Woodstream Corp.*, Nos. 07-1415, -1421 (Fed. Cir. Mar. 28, 2008), the Federal Circuit affirmed the jury's verdict that Woodstream Corporation ("Woodstream") was liable for fraudulent misrepresentation, and reversed the jury's verdict that U.S. Patent No. 5,949,636 ("the '636 patent") was not invalid for obviousness. In finding the '636 patent obvious, the Federal Circuit held that Agrizap, Inc.'s ("Agrizap") objective evidence of nonobviousness was insufficient to overcome the overwhelming strength of Woodstream's prima facie case of obviousness.

Agrizap is the assignee of the '636 patent, directed to a method and apparatus for electrocuting pests, such as gophers and rats. The invention operates by sensing the presence of a pest with a resistive switch, which triggers a generator that electrocutes the pest. Agrizap sued Woodstream, alleging fraudulent misrepresentation and infringement of the '636 patent. A jury returned a verdict in favor of Agrizap and awarded damages of $1,275,000 for fraudulent misrepresentation and $1,425,000 for infringement. The district court denied Woodstream's motions for JMOL on fraudulent misrepresentation and the affirmative defenses, but granted the JMOL for noninfringement.

The Federal Circuit first reviewed the fraudulent misrepresentation verdict, holding that Agrizap offered sufficient evidence for a jury to find Woodstream liable for fraudulent misrepresentation under Pennsylvania law. The Court also upheld the jury's damages award for fraudulent misrepresentation. Although "Agrizap never propounded a specific dollar amount for its fraud damages and instead left it up to the jury to extrapolate an amount from the various pieces of evidence submitted at trial," the Court nonetheless held that "Agrizap introduced sufficient facts for the jury to fairly estimate an amount of damages, ..." Slip op. at 7. The Court noted that "[a]n award of damages is not precluded simply because of some uncertainty as to the precise amount of damages occurred." *Id.*

> The inclusion of "objective considerations of nonobviousness . . . , including substantial evidence of commercial success, praise, and long-felt need, [may be] inadequate to overcome a strong showing of primary considerations that render[] the claims at issue invalid." Slip op. at 12.

In addressing the patent issues, the Federal Circuit found the claims invalid as obvious, and because the obviousness issue was dispositive, declined to address the other issues raised on appeal. The Court noted that during prosecution, the PTO had initially rejected the claims of the '636 patent under obviousness-type double patenting based on U.S. Patent No. 5,269,091 ("the '091 patent") to the same inventors as the '636 patent, and in view of two other patents. The '091 patent disclosed all of the limitations of the '636 patent claims except for the use of a mechanical switch instead of a resistive switch. The two other patents described the use of a resistive switch having separate contact points, set off by animals upon touching the two contact points. In response to the filing of a terminal disclaimer, however, the rejections were removed, and the '636 patent issued.

The Court then noted that at two separate trade shows prior to the filing date of the '636 patent, Agrizap demonstrated a "Gopher Zapper" product that embodied the '091 patent. The PTO was not aware of the trade shows during prosecution of the '636 patent. As a result, the Court relied on the Gopher Zapper product, as well as the two additional patents the PTO previously relied on in finding obviousness.

The Court cited *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), stating that "[t]his is a textbook case of when the asserted claims involve a combination of familiar elements according to known methods that does no more than yield predictable results." Slip op. at 11. The Court held that (1) the asserted claims merely substitute a resistive electrical switch for a mechanical pressure switch employed by the Gopher Zapper, (2) the use of a resistive switch to complete a circuit for the generation of an electric charge was already known in the prior art, and (3) both of the cited resistive switch patents were directed to solving the same problem as the '636 patent—the malfunction of mechanical switches in environments prone to dirt and dampness.

The Court considered objective evidence of nonobviousness, such as commercial success of the Rat Zapper, copying by Woodstream, and a long-felt need for electronic rat traps, all considered by the jury. However, despite this evidence, and citing to *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007), the Court held that the evidence was "insufficient to overcome the overwhelming strength" of Woodstream's prima facie case of obviousness. Slip op. at 11. The Court thus held that in some situations, objective considerations of nonobviousness are "inadequate to overcome a strong showing of primary considerations that rendered the claims at issue invalid." *Id.* at 12. Consequently, the Court reversed the jury's verdict regarding invalidity, finding all of the claims of the '636 patent invalid for obviousness.

Patent Held Invalid for Failing to Disclose Algorithm Corresponding to Means-Plus-Function Claim Term

Timothy P. McAnulty

Judges: Lourie, Schall, Bryson (author)

[Appealed from D. Nev., Judge Sandoval]

In *Aristocrat Technologies Australia Pty Ltd. v. International Game Technology*, No. 07-1419 (Fed. Cir. Mar. 28, 2008), the Federal Circuit affirmed the district court's holding that all claims of Aristocrat Technologies Australia Pty Limited and Aristocrat Technologies, Inc.'s (collectively "Aristocrat") patent were invalid for indefiniteness. In particular, the Federal Circuit held that the patent was invalid for failing to recite an algorithm corresponding to the means-plus-function terms recited in the asserted claim.

Aristocrat asserted U.S. Patent No. 6,093,102 ("the '102 patent") against International Game Technology and IGT (collectively "IGT"). The '102 patent is directed to an electronic slot machine that allows a player to select winning combinations of symbol positions. The district court noted, and the parties agreed, that the term "game control means" or "control means," used in several instances in claim 1, was a means-plus-function term that invoked 35 U.S.C. § 112, ¶ 6. The district

court held the claims of the '102 patent invalid because the specification lacked any specific algorithm or any step-by-step process for performing the claimed functions of the claimed "control means."

"Although the examples given in the '102 patent might enable one of ordinary skill to make and use the invention, they do not recite the particular structure that performs the function and to which the means-plus-function claim is necessarily limited." Slip op. at 14.

On appeal, Aristocrat first argued that the district court erred by failing to construe the functions of the term "control means" under section 112, ¶ 6 and, thus, could not have properly determined whether the specification recited adequate corresponding structure. The Federal Circuit disagreed, noting that the district court effectively gave a construction of the functions of the "control means limitation" when it described the claimed functions and stated that the specification contained no algorithm that described or recited those functions.

Aristocrat also contended that the language of claim 1 of the '102 patent, when referring to the game control means, implicitly disclosed an algorithm for the microprocessor. The Court rejected this contention because the language simply described the function to be performed and not the algorithm by which it is performed. The Court also found that other language pointed to by Aristocrat merely described the outcome of performing a function and was not an algorithm that described how the function is performed. The Court further rejected Aristocrat's contention that the description of embodiments within the '102 patent delineated the appropriate programming because it was instead simply a description of the outcome of the claimed functions and not a description of the structure.

The Federal Circuit also rejected Aristocrat's contention that it is not necessary to disclose a particular algorithm in order to disclose sufficient structure for a means-plus-function limitation in a computer-implemented invention. The Court distinguished *In re Dossel*, 115 F.3d 942 (Fed. Cir. 1997), where the patent at issue provided "an extremely detailed disclosure of all information necessary to perform the function, except for basic mathematical techniques that would be known to any person skilled in the pertinent art." Slip op. at 13.

The Federal Circuit also rejected Aristocrat's contention that that disclosure of a microprocessor with "appropriate programming" was sufficient to enable one of ordinary skill in the art to build the claimed device. The Court found this argument conflated the enablement requirement under section 112, ¶ 1 and the requirement to disclose the structure that performs the recited function under section 112, ¶ 6. The Court explained that "[a]lthough the examples given in the '102 patent might enable one of ordinary skill to make and use the invention, they do not recite the particular structure that performs the function and to which the means-plus-function claim is necessarily limited." *Id*. at 14.

Ownership of a Patent May Be Changed by Operation of Law Such as State Probate Law or Japanese Law

Meredith H. Schoenfeld

Judges: Newman, Archer (author), Linn

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

In *Akazawa v. Link New Technology International, Inc.*, No. 07-1184 (Fed. Cir. Mar. 31, 2008), the Federal Circuit vacated the

district court's grant of SJ to Link New Technology International, Inc. ("Link") based on lack of standing and remanded. The Court found that issues of Japanese intestacy law had to be resolved by the district court to determine whether Akira Akazawa ("Akira") owned U.S. Patent No. 5,615,716 ("the '716 patent") and, therefore, possessed standing to bring the lawsuit.

Yasumasa Akazawa ("Yasumasa"), a Japanese citizen, is the only named inventor of the '716 patent. Yasumasa was the sole owner of the patent until his death. He did not have an executed will when he died. Thus, under Japanese law, Hitomi Akazawa ("Hitomi"), Yuki Akazawa ("Yuki"), and Fumi Akazawa ("Fumi"), his wife and daughters respectively, are Yasumasa's only heirs. In an "Inheritance Agreement," the daughters assigned their interest in the '716 patent to their mother, Hitomi, who executed an assignment transferring all rights in the patent to Akira.

In 2003, Akira and Palm Crest, Inc. ("Palm") brought suit against Link for infringement of the '716 patent. Link moved for SJ on the basis that Akira did not have standing to file the suit. The district court noted that Japanese law may determine to whom the '716 patent could be transferred upon Yasumasa's death, but that the Patent Act determined the manner by which the assignment must be made. It found that when Yasumasa died, title to the '716 patent was held by his estate until properly assigned in writing by the legal representative of the estate and that it was Akira's burden to prove that such a writing existed or that some other chain of title gave Akira ownership of the '716 patent. The district court held that Akira had not met his burden and granted SJ to Link. In so holding, the district court relied on 35 U.S.C. § 261, which states that "[a]pplications for patent, patents, or any interests therein, shall be assignable in law by an instrument in writing." Akira and Palm appealed.

On appeal, the Federal Circuit noted that the district court's focus on section 261 was erroneous. The Court observed that 35 U.S.C. § 154(a)(1) states that "[e]very patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, ..." The Court reasoned that while section 261 requires assignments to be in writing, "there is nothing that limits assignment as the only means for transferring patent ownership." Slip op. at 4. It explained that "ownership of a patent may be changed by operation of law." *Id.* It noted that patent title may be transferred according to state probate law and that state law, not federal law, typically governs patent ownership. The Court determined that applying this principle to the present case would require looking to foreign law, as opposed to state law, because Yasumasa was a resident of Japan at the time of his death. Thus, the Court noted that "interpreting Japanese intestacy law, not United States patent law, [was] the first step in determining whether Akira possessed standing to bring the present suit." *Id.* at 7.

The Court determined that the translation of Japanese intestacy law suggested that at the time of Yasumasa's death, Hitomi, Yuki, and Fumi became owners of the '716 patent. However, noted the Court, whether an administrator was required under Japanese law, the role of such an administrator, and whether the existence of an administrator would affect the transfer of the '716 patent to Yasumasa's heirs was less clear. Rather than decide these issues in the first instance on appeal, the Court vacated the district court's grant of SJ and remanded.

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

Connie Y. Chang

Judges: Michel, Rader (author), Linn

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

In *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, No. 07-1223 (Fed. Cir. Mar. 31, 2008), the Federal Circuit held that the district court correctly construed the claim term "and" in U.S. Patent No. 4,513,006 ("the '006 patent") owned by Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil"); affirmed its dismissal of Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc.'s (collectively "Mylan") invalidity defenses based on obviousness, inequitable conduct, and nonenablement; and found that the district court had not erred in resetting the effective date of Mylan's ANDA.

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

> "In retrospect, [the inventor's] pathway to the invention, of course, seems to follow the logical steps to produce these properties, but at the time of [the] invention, the inventor's insights, willingness to confront and overcome obstacles, and yes, even serendipity, cannot be discounted." Slip op. at 10.

On appeal, Mylan argued that the district court erred in construing the word "and" to mean "or" in claim 1 of the '006 patent and that under the proper construction, the claim did not cover topiramate. The Federal Circuit disagreed. The Court explained that as used in the claim, "and" conjoined mutually exclusive possibilities and that the claim did not use "and" in isolation but in a larger context that clarified its meaning. The Court noted that construing claim 1 to require a conjunctive meaning of "and" would render several dependent claims meaningless and that the specification also supported the district court's reading of "and." It added that dictionary definitions also supported the district court's reading of the term. Accordingly, the Court held that the district court properly construed the claim.

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

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

The Court explained that after *KSR*, a flexible teaching, suggestion, or motivation ("TSM") test remains the primary guarantor against a nonstatutory hindsight analysis such as occurred in this case. It reasoned that "[t]he TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence – teachings, suggestions (a tellingly broad term), or motivations (an equally broad term) – that arise before the time of invention as the statute requires." Slip op. at 11. The Court reiterated that those teachings, suggestions, or motivation need not always be written references, but may be found within the knowledge and creativity of ordinary skilled artisans. The Court determined that here, the record amply supported the district court's finding of nonobviousness, which included consideration of objective criteria showing nonobviousness. Accordingly, the Court affirmed the district court's dismissal of Mylan's obviousness defense.

The Court also rejected Mylan's argument that claims 6-8 were not enabled because the drug's effective amount was unclear and its determination would require undue experimentation. In so doing, the Court noted that the disclosure adequately enabled the claims and that even if clinical trials informed the effective amount, the record did not show that extensive or undue tests would be required to practice the invention. It thus concluded that the district court was correct in summarily dismissing Mylan's nonenablement defense.

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

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

- On May 8, 2008, the Federal Circuit will hear oral argument en banc in *In re Bilski*, No. 07-113, a case that will address the scope of patentable subject matter under 35 U.S.C. § 101. The Court plans to consider, inter alia, the following issues: (1) what standard should govern in determining whether a process is patent-eligible subject matter under section 101; (2) when does a claim that contains both mental and physical steps create patent-eligible subject matter; and (3) whether it is appropriate to reconsider *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), and *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999), in this case and, if so, whether those cases should be overruled in any respect.

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