Last Month at the Federal Circuit

November 2010

Federal Circuit Affirms TTAB Decision Finding That Chippendales' "Cuffs & Collar" Trade Dress Is Not Inherently Distinctive for Adult-Entertainment Services

In re Chippendales USA, Inc.
No. 09-1370 (Fed. Cir. Oct. 1, 2010)
[Appealed from TTAB]

Subsequent Paragraph IV Filer Has Legally Cognizable Interest in When First-Filer's Exclusivity Period Begins

Teva Pharmaceuticals USA, Inc. v. Eisai Co.
No. 09-1593 (Fed. Cir. Oct. 6, 2010)
[Appealed from D.N.J., Chief Judge Brown]

Spotlight Info

Looking Ahead

Reproducing an Invention in the United States Does Not Constitute Inventorship Under 35 U.S.C. § 102(g)(2)

Solvay S.A. v. Honeywell International, Inc.
No. 09-1161 (Fed. Cir. Oct. 13, 2010)
[Appealed from D. Del., Judge Robinson]

Abbreviations

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

any of our attorneys.

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Last Month at the Federal Circuit

Back to Main

November 2010

Spotlight Info

In *Solvay S.A. v. Honeywell International, Inc.*, No. 09-1161 (Fed. Cir. Oct. 13, 2010), the Federal Circuit held, inter alia, that the district court erred in ruling that certain claims of U.S. Patent No. 6,730,817 ("the '817 patent") were invalid under 35 U.S.C. § 102(g)(2). Solvay S.A.'s ("Solvay") '817 patent is directed to methods for making a compound used in the preparation of expanded polymeric materials. Solvay sued Honeywell Specialty Materials L.L.C. and Honeywell International, Inc. (collectively "Honeywell") for infringement of the '817 patent based on Honeywell's process of producing the compound. But Honeywell argued that the '817 claims were invalid because it was "another inventor" under § 102(g)(2). The Federal Circuit, however, found that Honeywell was not "another inventor" because it had merely obtained instructions from a Russian company to duplicate the claimed process in the United States. The Court held that this did not constitute conception and, therefore, Honeywell could not be an inventor for purposes of § 102(g)(2). Accordingly, the Federal Circuit held that the district court erred in ruling that certain claims of the '817 patent were invalid by reason of prior inventorship. See the full summary in this issue.

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Last Month at the Federal Circuit

Back to Main

November 2010

Looking Ahead

Under the patent laws, a patent applicant who is dissatisfied with the decision of the Board regarding his application may file a civil action in district court, and the district court will determine whether the applicant "is entitled to receive a patent for his invention . . . as the facts in the case may appear." 35 U.S.C. § 145. On November 8, 2010, in *Hyatt v. Kappos*, No. 07-1066, the Federal Circuit issued an en banc decision that resolves several issues related to the introduction of new evidence in a trial under 35 U.S.C. § 145. The Court, in a 7-2 split decision, held "that 35 U.S.C. § 145 imposes no limitation on an applicant's right to introduce new evidence before the district court, apart from the evidentiary limitations applicable to all civil actions contained in the Federal Rules of Evidence and Federal Rules of Civil Procedure." Slip op. at 5. In so holding, the Court rejected the PTO's proposal that only "new evidence that could not reasonably have been provided to the agency in the first instance" is admissible in a § 145 action. *Id*. (citation omitted). A full summary of the Federal Circuit's en banc decision will appear in next month's edition of *Last Month at the Federal Circuit.*

On November 9, 2010, the Federal Circuit, sitting en banc, heard oral arguments in *Therasense, Inc. v. Becton, Dickinson & Co*., No. 08-1511, which focuses on the legal standards for proving the defense of inequitable conduct—particularly the tests for proving materiality and intent, and to what extent intent may be found based on materiality. A decision is expected in the first half of 2011.

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Last Month at the Federal Circuit

Back to Main

November 2010

Federal Circuit Affirms TTAB Decision Finding That Chippendales' "Cuffs & Collar" Trade Dress Is Not Inherently Distinctive for Adult-Entertainment Services

Stephanie H. Bald

Judges: Dyk (author), Friedman, Moore

[Appealed from TTAB]

In *In re Chippendales USA, Inc.*, No. 09-1370 (Fed. Cir. Oct. 1, 2010), the Federal Circuit affirmed the TTAB's decision finding that Chippendales USA, Inc.'s ("Chippendales") "Cuffs & Collar" trade dress is not inherently distinctive for adult-entertainment services because it was merely a refinement of the earlier-used Playboy bunny costume.

Chippendales applied to register its trade dress consisting of wrist cuffs and a bowtie collar without a shirt ("Cuffs & Collar") for adult-entertainment services. The PTO determined that Chippendales was entitled to registration based only on acquired distinctiveness, and Chippendales thereafter obtained a registration on that limited basis. Chippendales subsequently filed a second application seeking registration for the Cuffs & Collar trade dress based on inherent distinctiveness. The PTO refused registration and, on appeal, the TTAB held that the Cuffs & Collar trade dress was not inherently distinctive based on, among other things, its common basic shape design, the fact that it is not unusual for exotic dancers to wear costumes that are revealing and provocative, and the fact that the Cuffs & Collar mark was not unique in its field. The TTAB concluded, alternatively, that the Cuffs & Collar mark was not unique or unusual in the particular field of use because it was inspired by the ubiquitous Playboy bunny suit, which included cuffs, a collar and bowtie, a corset, and a set of bunny ears. Chippendales appealed.

The Court first considered whether the fact that Chippendales already owned a registration for the Cuffs & Collar mark based on acquired distinctiveness mooted this proceeding. It found that it did not because, although registrations secured through inherent and acquired distinctiveness have equal standing on the Register, whether a particular mark is inherently distinctive may affect the scope of protection accorded in an infringement proceeding, which created a live controversy in this proceeding.

"Each such trademark must be evaluated individually under the *Seabrook* factors. The 'mere refinement or variation' test is not satisfied by showing

that costumes generally are common in the industry." Slip op. at 16.

Next, turning to the issue of inherent distinctiveness, the Court began with *Seabrook Foods, Inc. v. Bar-Well Foods, Ltd.*, 568 F.2d 1342 (C.C.P.A. 1977), and subsequent case law about the inherent distinctiveness standard. The *Seabrook* test asks four questions, namely, (1) whether it was a "common" basic shape or design; (2) whether it was nonunique or unusual in the particular field; (3) whether it was "a mere refinement of a commonly-adopted and well-known form of ornamentation for a particular class of goods viewed by the public as dress or ornamentation for the goods"; or (4) whether it was capable of creating a commercial impression distinct from the accompanying words. Before applying the *Seabrook* test, the Court agreed with the TTAB that the proper time for measuring inherent distinctiveness is at the time of registration, not when the mark is first used. However, the Court noted that the TTAB had erred by stating that "[t]heoretically, if a mark was inherently distinctive when [Chippendales] began use, it remained so thereafter." Slip op. at 14 n.13 (quoting *In re Chippendales USA, Inc.*, 90 U.S.P.Q.2d 1535, 1538 n.6 (T.T.A.B. Mar. 25, 2009)). The Court explained that a term that was once inherently distinctive may lose its distinguishing characteristics over time.

Turning to the *Seabrook* test, the Court held that the TTAB had appropriately considered evidence of the current situation as well as evidence of earlier uses. However, the Court found that the TTAB erred in suggesting that *any* costume in the context of adult entertainment would lack inherent distinctiveness. Specifically, the Court found that just because the live adult-entertainment industry generally involves "revealing and provocative" costumes does not mean that there cannot be any such costume that is inherently distinctive. Rather, each such trademark must be evaluated individually under *Seabrook.*

The Court found that the TTAB did not err, however, in concluding that the Cuffs & Collar mark was not inherently distinctive under the *Seabrook* test. The Court found that the first and fourth *Seabrook* factors were inapplicable, and that it did not need to consider whether the second *Seabrook* factor was applicable. Regarding the third *Seabrook* factor—whether the Cuffs & Collar trade dress was a mere variant or refinement of a particular costume—the Court agreed with the TTAB that this test had been satisfied. Specifically, the Court found that the use of the Playboy bunny mark (which includes cuffs and collar together with bunny ears) constituted substantial evidence supporting the TTAB's determination that the Cuffs & Collar mark was not inherently distinctive because, among other things, it was widely used for almost twenty years before Chippendales' first use of its trade dress, the Cuffs & Collar trade dress was very similar to the Playboy bunny costume, and the mark was within the relevant field of use.

Chippendales argued that it was unfair for the TTAB to raise the issue of the Playboy bunny costume sua sponte, preventing Chippendales from having the opportunity to respond, but the Court disagreed based on the fact that it was Chippendales' own expert who provided an article attached to his affidavit stating that the Cuffs & Collar trade dress was inspired by the bunny suit. Further, the Court found that it could take judicial notice of trademark registrations covering the Playboy bunny, under Fed. R. Evid. 201(c), as it determined that the registration documents were "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Slip op. at 17-18 (quoting Fed. R. Evid. 201(b)(2)).

Finally, the Court rejected Chippendales' argument that *Seabrook* should be overruled because the Supreme Court's decision in *Wal-Mart Stores, Inc. v. Samara Bros., Inc.*, 529 U.S. 205 (2000), was fundamentally at odds with that decision. The Court found that nothing in *Wal-Mart* questioned or undermined the *Seabrook* test, and the Supreme Court did not express any disagreement with

Seabrook. Thus, the Court was bound by *Seabrook* and concluded that substantial evidence supported the TTAB's decision that the Cuffs & Collar trade dress was not inherently distinctive.

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Last Month at the Federal Circuit

Back to Main

November 2010

Subsequent Paragraph IV Filer Has Legally Cognizable Interest in When First-Filer's Exclusivity Period Begins

Patricia M. Mitchell

Judges: Rader, Dyk, Prost (author)

[Appealed from D.N.J., Chief Judge Brown]

In *Teva Pharmaceuticals USA, Inc. v. Eisai Co.*, No. 09-1593 (Fed. Cir. Oct. 6, 2010), the Federal Circuit held that a subsequent Paragraph IV filer has a legally cognizable interest in when the first-filer's exclusivity period begins. Accordingly, the Court held that delay in triggering that period qualifies as an "injury-in-fact" sufficient to provide subject matter jurisdiction under Article III of the Constitution for a DJ action for patent invalidity. The Court also found that the district court abused its discretion in declining DJ jurisdiction.

Teva Pharmaceuticals USA, Inc. ("Teva") and its unincorporated division, Gate Pharmaceuticals ("Gate"), sought to manufacture and market two generic versions of donepezil, an approved drug. Eisai Co. and Eisai Medical Research, Inc. (collectively "Eisai") hold the approved NDA for the drug and own the five patents listed for the drug in the Orange Book. The first ANDA for a generic form of donepezil was filed by Ranbaxy Laboratories Ltd. ("Ranbaxy") in 2003. Ranbaxy submitted a Paragraph III certification for U.S. Patent No. 4,895,841 ("the '841 patent"), agreeing not to market a generic version of the drug until after the '841 patent expires in November 2010. Because Ranbaxy filed the first Paragraph IV certification for the four DJ patents, Ranbaxy is eligible for 180 days of market exclusivity upon FDA approval of its ANDA, beginning when Ranbaxy begins commercially marketing its drug or upon issuance of a court judgment holding the DJ patents invalid or not infringed.

Teva and Gate subsequently filed two separate ANDAs for generic donepezil. Both ANDAs made Paragraph IV certifications against all five of Eisai's Orange Book-listed patents. Because under the Hatch-Waxman Act, filing a Paragraph IV certification constitutes an act of patent infringement, Eisai sued Teva for infringement of the '841 patent, but not the four DJ patents. Though filed separately, these two infringement actions were consolidated, and Teva and Gate stipulated that its generic forms of the drug infringe various claims of the '841 patent unless the patent is invalid or unenforceable. Eisai moved for a preliminary injunction to prevent Teva and Gate from marketing any form of the generic drug after the expiration of the thirty-month stay, and the motion was granted. The preliminary injunction bars Teva and Gate from marketing any drug containing the active ingredient as claimed in the '841 patent.

Teva subsequently filed the DJ action, seeking a DJ that the manufacture, use, offer for sale, sale, or importation of generic donepezil covered by the Gate ANDA will not infringe four of the listed Orange Book patents ("the DJ patents"). Eisai never brought suit to enforce any of the DJ patents against Teva. Instead, before the DJ action arose, Eisai filed statutory disclaimers with the PTO regarding two of the DJ patents, thereby barring their enforcement.

Eisai moved to dismiss the DJ action for lack of subject matter jurisdiction. While Eisai's motion to dismiss the DJ action was pending, Teva and Eisai negotiated a covenant-not-to-sue covering the two other DJ patents. All four DJ patents, however, remained listed in the Orange Book. Teva's amended complaint acknowledged the statutory disclaimers and covenant-not-to-sue. Teva, however, maintained that it suffers an injury under Article III because the DJ patents remain listed in the Orange Book and, thus, approval of Teva's ANDA cannot occur until the exclusivity period of the first-filer, Ranbaxy, has run. The district court dismissed the DJ action for lack of jurisdiction—specifically, for lack of a justiciable controversy under Article III of the U.S. Constitution.

On appeal, the Federal Circuit explained that, under the Hatch-Waxman Act, a party that files an ANDA with Paragraph IV certifications may bring suit under the Declaratory Judgment Act, and that the Declaratory Judgment Act provides that in the case of an actual controversy, any court of the United States may declare the rights and other legal relations of any interested party seeking such declaration. The Court further reminded that federal courts have subject matter jurisdiction over cases brought by ANDA filers to the extent consistent with the Constitution, and that the Constitution requires an Article III case or controversy.

The Court reviewed two of its earlier decisions that set out the framework for determining whether an Article III controversy exists in a DJ action arising under the Hatch-Waxman Act. The Court explained that it previously held in *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, 527 F.3d 1278 (Fed. Cir. 2008), that the exclusion of noninfringing generic drugs from the market can be a judicially cognizable injury-in-fact. Because a company is not free to manufacture or market drugs until it receives FDA approval, under the Hatch-Waxman framework, an "injury" occurs when the NDA holder takes action that delays FDA approval of subsequent ANDAs. In *Caraco*, the action was listing particular patents in the Orange Book. "But-for" the defendant's decision to list a patent in the Orange Book, FDA approval of the generic drug company's ANDA would not have been independently delayed by that patent. A DJ of patent invalidity redresses this alleged injury, because it eliminates the potential for the corresponding listed patent to exclude the generic drug from the market.

"Here, as in *Caraco*, a favorable judgment 'would eliminate the potential for the [DJ patents] to exclude [Teva] from the drug market.'" Slip op. at 12 (alterations in original) (quoting *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1293 (Fed. Cir. 2008)).

The Court next explained that its decision in *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008), reaffirmed *Caraco*'s holding that the injury-in-fact must stem from the actions of the company that listed the patents in the Orange Book, not the inherent framework of the Hatch-Waxman Act. The Court explained that in *Janssen*, where the subsequent filer had stipulated to the validity, infringement, and enforceability of another patent listed in the Orange Book for the same drug, even if the subsequent filer had prevailed in its DJ action, it could not have launched its generic drug before

expiration of the patent covered by the stipulation. The Court explained that the alleged harm in *Janssen*—inability to enter the market—was not fairly traceable to the NDA holder's listing of the subject patents in the Orange Book, but to the stipulation instead. In *Janssen*, the Court found that a first-filer's exclusivity period in itself does not give rise to an injury-in-fact because the resulting exclusion of other generic companies from the market results from the inherent framework and intended workings of the Hatch-Waxman Act.

Under the framework laid out by *Caraco* and *Janssen*, the Court held that the current DJ action presents an actual controversy. "Here, as in *Caraco*, a favorable judgment 'would eliminate the potential for the [DJ patents] to exclude [Teva] from the drug market.'" Slip op. at 12 (alterations in original) (quoting *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1293 (Fed. Cir. 2008)). Unlike the generic drug company in *Janssen*, Teva had not stipulated to the validity or enforceability of any other patent listed in the Orange Book for the drug. Nor was Teva subject to any final judgment regarding an Orange Book patent for the drug that would prevent Teva from selling products covered by the ANDA. The preliminary injunction in the separate '841 patent infringement litigation was only "preliminary," and there was no final determination as to the validity, infringement, or enforceability of the '841 patent.

Next, the Court analyzed whether the district court had abused its discretion in declining to entertain the suit pursuant to its broad discretion under the Declaratory Judgment Act. The Court reviewed the language of 35 U.S.C. § 271(e)(5), analyzed how it impacts a district court's general grant of discretion in 28 U.S.C. § 2201, and upheld discretionary decisions declining jurisdiction in DJ actions. However, the Court also found that, "while the Declaratory Judgment Act does 'confer on federal courts unique and substantial discretion' to decide whether to exercise jurisdiction, that discretion is not unbounded." Slip op. at 15 (citations omitted).

Here, the Federal Circuit found that it was an abuse of discretion to decline jurisdiction because the district court erroneously concluded that it lacked subject matter jurisdiction. The Court reasoned that the district court should not have considered whether it had subject matter jurisdiction in making the subsequent, discretionary decision of whether to exercise jurisdiction over the case, because the existence of jurisdiction in itself is not probative of the relevant factors under § 2201(a), such as whether the DJ remedy will be useful or whether the case is fit for resolution.

Further, the Court found that the district court's exercise of discretion was not supported by the facts. The district court had concluded that the relationship between Teva and Gate, combined with multiple ANDAs, amounted to thinly disguised, improper gamesmanship. However, the Court noted that nothing in the Hatch-Waxman Act bars a company from filing multiple ANDAs covering different formulations of the same drug. Nor did the Court find it improper for those ANDAs to be filed under different corporate names, particularly since that filing decision was made at the FDA's request. The Court found that none of the typical factors that might warrant the exercise of discretion to decline jurisdiction existed.

Because the case presented an actual controversy justiciable under Article III and no well-founded basis for declining jurisdiction was established, the Court reversed and remanded the district court's decision.

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Last Month at the Federal Circuit

Back to Main

November 2010

Reproducing an Invention in the United States Does Not Constitute Inventorship Under 35 U.S.C. § 102(g)(2)

Shana K. Cyr

Judges: Dyk, Mayer, Schall (author)

[Appealed from D. Del., Judge Robinson]

In *Solvay S.A. v. Honeywell International, Inc.*, No. 09-1161 (Fed. Cir. Oct. 13, 2010), the Federal Circuit held that the district court erred in ruling that certain claims of U.S. Patent No. 6,730,817 ("the '817 patent") were invalid under 35 U.S.C. § 102(g)(2). The Court also held that the district court did not err in ruling that certain claims were infringed while certain other claims were not infringed.

Solvay S.A.'s ("Solvay") '817 patent is directed to methods for making a pentafluoropropane compound used in the preparation of expanded polymeric materials. Solvay sued Honeywell Specialty Materials L.L.C. and Honeywell International, Inc. (collectively "Honeywell") for infringement of the '817 patent based on Honeywell's process of producing the pentafluoropropane compound.

Over one year before the priority date of the '817 patent, Honeywell contracted with a Russian company to conduct process development studies for the commercial production of the pentafluoropropane compound. The Russian company consequently conceived the invention claimed in the '817 patent and reduced it to practice in Russia. Honeywell used the information from the Russian company to duplicate the process in the United States prior to the priority date of the '817 patent.

The parties cross-moved the district court for SJ on the issues of invalidity and infringement. The district court granted Honeywell's motion for SJ of invalidity, finding that Honeywell was a prior inventor under § 102(g)(2) and that it did not abandon, suppress, or conceal the invention. The district court granted, as an alternative, Solvay's motion for SJ of infringement of the claims it ruled invalid, and granted Honeywell's motion for SJ of noninfringement of certain other claims. The district court dismissed Solvay's suit, entering judgment in favor of Honeywell, and Solvay appealed.

The Federal Circuit held that the § 102(g)(2) language that "the invention was made in this country" requires the act of inventing to occur in the United States, and that Honeywell was not an inventor of the process claimed in the '817 patent. The Court reasoned that because Honeywell did not originate the invention and merely reproduced it in the United States following instructions from the Russian company,

Honeywell did not conceive of the invention and did not qualify as "another inventor" under § 102(g)(2). Thus, the district court erred in ruling that certain claims of the '817 patent were invalid by reason of prior inventorship.

"[R]eproduction cannot be conception because, if it were, the result would be that one who simply followed another inventor's instructions to reproduce that person's prior conceived invention would, by so doing, also become an 'inventor.'" Slip op. at 17.

Turning to the issue of infringement, the Federal Circuit found that Honeywell infringed certain claims of the '817 patent. The Court held that the district court properly construed the term "isolating" as not requiring purification of the pentafluoropropane compound, as Honeywell asserted. Because Honeywell did not dispute that its accused process satisfied the "isolating" limitation, the Court found that the district court did not err in ruling that certain claims of the '817 patent were infringed.

As for Solvay's appeal of the district court's grant of SJ of noninfringement of certain other claims of the '817 patent, the Court affirmed the district court's construction of the limitation "to keep in the reactor in the liquid state" to mean that the reactants must stay in the reactor in the liquid state until they leave as a gas and cannot return after being reprocessed. Although the specification was broad enough to include unconverted and partially converted reactants that return to the reactor for further use in the process, the Court found that statements made by Solvay to overcome prior art during prosecution precluded such a broad construction. Accordingly, because it was undisputed that Honeywell's process did not satisfy the limitation, the Court found no error in the district court's ruling that Honeywell did not infringe those claims of the '817 patent.

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