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In This Issue

- Federal Circuit Reverses Dismissal Of Declaratory Judgment Action
- Federal Circuit Clarifies Meaning of "Another Inventor" Under 35 U.S.C. §102(g)(2)
- Federal Circuit Affirms TTAB's Determination that Mark Was Not Inherently Distinctive

Federal Circuit Reverses Dismissal Of Declaratory Judgment Action

In *TEVA PHARMACEUTICALS v. EISAI CO*, Teva requested a declaratory judgment that its generic version of donepezil does not infringe four Orange Book patents, U.S. Patent Nos. 5,985,864; 6,140,321; 6,245,911; and 6,372,760. The district court dismissed the case for lack of jurisdiction.

In this case, Teva was not the first Paragraph IV filer. The case turned on whether a subsequent Paragraph IV filer has a legally cognizable interest in when the first-filer's exclusivity period begins, such that delay in triggering that period qualifies as "injury-in-fact" for the purposes of Article III.

Before this case arose, Eisai had filed statutory disclaimers regarding the '321 and '864 patents. Eisai subsequently unconditionally agreed not to assert the '911 and '760 patents against Teva or its successors. However, all four of the DJ patents remained listed in the Orange Book.

The Federal Circuit reversed the district court's dismissal for lack of subject matter jurisdiction holding that an actual controversy existed because a favorable judgment would eliminate the potential for the DJ patents to exclude Teva from the drug market. The holding was in part based on the facts that Teva had not stipulated to the validity, infringement, or enforceability of any other patent listed in the Orange Book for donepezil, and that Teva was not subject to any final judgment regarding an Orange Book patent that would prevent Teva from selling products covered by the ANDA.

Federal Circuit Clarifies Meaning of "Another Inventor" Under 35 U.S.C. § 102(g)(2)

In *SOLVAY S.A. v. HONEYWELL INT'L, INC.*, Solvay appealed a district court decision invalidating Solvay's U.S. Patent No. 6,730,817 (the '817 patent) on the grounds that Honeywell had invented the claimed invention before Solvay. Honeywell's invalidity defense was based on 35 U.S.C. § 102(g)(2). In relevant part, this section states "A person shall be entitled to a patent unless . . . before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned suppressed or concealed it" (emphasis added). It was not disputed that before Solvay invented the claimed process (a process for manufacturing the fluorocarbon HFC-245fa), Honeywell had used the inventive process in the United States. The issue was whether Honeywell was an inventor within the meaning of the statute.

Honeywell's use of the invention came about in the following manner. In 1994, Honeywell entered into a research contract with the Russian Scientific Center for Applied Chemistry ("RSCAC"). Among other things under the contract, RSCAC developed an improved manufacturing method for HFC-245fa, and Honeywell implemented the method in a manufacturing plant in the U.S. Solvay independently developed the same process, and filed its patent application in the United States shortly after Honeywell's activities.

On appeal, Solvay argued that RSCAC, not Honeywell, was the inventor of the process, such that the manufacturing process was not invented in this country, and RSCAC's activities do not constitute prior art. Honeywell argued that it constitutes an inventor because it "appreciated" the inventive nature of the

process at the time it was practiced in the United States.

In rejecting Honeywell's argument, the Federal Circuit reasoned that § 102(g)(2) is a prior inventor defense, and not a prior user defense. It was clear that Honeywell was a prior user. However, RSCAC was the inventor of the process, and because RSCAC is located in Russia, its activities do not qualify as prior art under § 102(g)(2). Therefore, the Federal Circuit reversed the district court's finding of invalidity of Solvay's '817 patent.

Federal Circuit Affirms TTAB's Determination that Mark Was Not Inherently Distinctive

In *IN RE CHIPPENDALES USA, INC.*, Chippendales appealed to the Federal Circuit from a decision of the Trademark Trial and Appeal Board ("TTAB"). The TTAB affirmed the examining attorney's refusal to register the "Cuffs & Collar Mark" as inherently distinctive.

The Federal Circuit noted that whether an asserted mark is inherently distinctive involves both a legal question as to the correct standard to apply and a factual determination. The issue of inherent distinctiveness is a factual determination, and the PTO has the burden to establish a prima facie case of no inherent distinctiveness. Once the PTO sets forth a sufficient prima facie case, the burden shifts to the applicant to come forward with evidence to rebut the prima facie case.

The Federal Circuit applies a four-part test for determining inherent distinctiveness: [1] whether it was a "common" basic shape or design, [2] whether it was not unique 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 a dress or ornamentation for the goods, or [4] whether it was capable of creating a commercial impression distinct from the accompanying words. If a mark satisfies any of these tests, it is not inherently distinctive. The Federal Circuit held that the proper time for measuring inherent distinctiveness is at the time of registration. The Federal Circuit stated that the TTAB erred to the extent that it suggested that any costume would lack inherent distinctiveness in the context of the live adult entertainment industry. The Federal Circuit continued: "It is incorrect to suggest that no costume in the context of the live adult entertainment industry could be considered inherently distinctive. Simply 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. Each such trademark must be evaluated individually..."

The Federal Circuit concluded that the TTAB did not err in concluding that the Cuffs & Collar mark is not inherently distinctive in view of Playboy's mark, a Playboy bunny suit which includes cuffs and a collar, which was widely used for almost twenty years before Chippendales' first use of its Cuffs & Collar trade dress.

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