The Latest Intellectual Property News

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Hello from everyone in Lowe Hauptman & Ham, LLP, and welcome to The Latest Intellectual Property News, a newsletter for updating you with recent information about Intellectual Property.

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"TINY MARKET" FAVORS FINDING IRREPARABLE HARM

By Tony Chang, Esq. (tchang@ipfirm.com)

Trebro sued FireFly for infringement of the U.S. Patent No. 8,336,638 (the '638 patent) and moved for a preliminary injunction. The technology at issue concerns "sod harvesters." The district court denied Trebro's motion, and Trebro filed an interlocutory appeal to the United States Court of Appeals for the Federal Circuit. The Federal Circuit vacated the preliminary injunction denial and remanded for further proceedings. *Trebro Manufacturing, Inc. v. Firefly Equipment, LLC*, slip op. 13-1166 (Fed. Cir. Apr. 13, 2014).

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2009). With regard to the "irreparable harm" prong, the district court found no irreparable harm, because (1) Trebro failed to show actual harm; and (2) the evidence of alleged loss of market share and customers was dismissed as "purely monetary relief." The Federal Circuit held that the district court abused its discretion in determining that Trebro did not show a likelihood of irreparable harm.

The Federal Circuit found the district court clearly erred in finding the harm Trebro is likely to suffer as speculative. The Federal Circuit agreed with Trebro's position that the sod harvester market is a tiny market. For example, Trebro sells only roughly eight sod harvesters per year, and every sale to FireFly is essentially a lost sale to Trebro. Also, once a farmer buys a sod harvester, she is unlikely to replace it for many years.

Furthermore, the Federal Circuit found the district court committed legal error by giving no weight to Trebro's evidence of likely loss of market share and customers and stated that the alleged loss can be compensated by monetary damages. The Federal Circuit stated that

evidence showing likely loss of market share and loss of access to customers is pertinent to the irreparable harm inquiry. The district court's blanket dismissal of evidence regarding such factors was an error of law. Also, being able to estimate Trebro's loss of profit does not automatically render money damages adequate. The Federal Circuit found that the record supports Trebro's position that losing market share and customers and likelihood of laying people off due to FireFly's alleged infringement are losses that Trebro is not likely to recover.

LATER-ISSUED PATENT QUALIFIES AS DOUBLE PATENTING REFERENCE

By Michael P. McComas (mmccomas@ipfirm.com)

A Federal Circuit panel agreed with accused infringer Natco Pharma, Ltd. (Natco) that a later-issued patent qualifies as an obviousness-type double patenting reference against accuser Gilead Sciences, Inc. (Gilead). *Gilead Sciences, Inc. v. Natco Pharma, Ltd.*, slip op. 2013-1418 (Fed. Cir. Apr. 22, 2014).

Gilead is the owner of two patents that disclose similar content but do not claim priority to a common patent application. U.S. Patent No. 5,763,483 ("'483 patent") issued on June 9, 1998, with an expiration date of December 27, 2016, and U.S. Patent No. 5,952,375 ("'375 patent") issued on September 14, 1999, with an expiration date of February 27, 2015.

A majority of the panel agreed with Natco's position that, despite the later issuance, the '375 patent's earlier expiration qualifies it as a reference in their attempt to invalidate certain '483 patent claims under an obviousness-type double patenting argument. The panel noted that the double patenting doctrine has always been implemented to support the "bedrock principal" that expiration of a patent applies to patentably indistinct modifications of an invention as well as to the invention itself. Under this rationale, the expiration date of a potential reference has primary significance.

While Gilead cited prior cases in which the issue date was seen as controlling, the panel pointed out that patent terms in those cases were tied to the issue dates, having been governed by laws prior to the Uruguay Rounds Agreement Act. For those patents, "later issued patents expired later," so the panel considered the issue date as merely a "stand-in" for an expiration date.

NO IMMEDIATE REVIEW OF DECISION WHETHER TO GRANT AN IPR

By Joshua L. Pritchett, Esq. (jpritchett@ipfirm.com)

In a series of cases the Federal Circuit unequivocally stated that no immediate review is available for the Director's decision whether to institute an *inter partes* review (IPR). In *St. Jude Medical Cardiology Division, Inc. v. Volcano Corp.,* slip op. 2014-1183 (Fed. Cir. Apr. 24, 2014), the Federal Circuit laid out the analysis for why no immediate review is available. The Federal Circuit relied heavily on the wording of the statute which states, "[t]he determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable." 35 U.S.C. § 314(d).

In the *St. Jude* case, the Board denied the IPR, because *Volcano* filed a counter claim alleging infringement more than one year prior to the petition to grant the IPR was filed. The Board construed the counterclaim as qualifying as a complaint alleging infringement of the patent.

In a similar case, *In re Dominion Dealer Solutions, LLC.,* slip op. 2014-109 (Fed. Cir. Apr. 24, 2014), the Federal Circuit held that a *writ of mandamus* cannot be granted for a decision refusing to institute an IPR. Dominion had timely filed the petition to grant the IPR; however, the Board stated that there was no reasonable likelihood that the petitioner would prevail.

Dominion argued that unrebutted evidence demonstrated a reasonable likelihood in a request for rehearing. However, the Board denied the rehearing. Using similar logic as in the *St. Jude* case, the Federal Circuit held that the decision by the Board refusing to institute the IPR was not an appealable issue.

The Federal Circuit maintained this position for decisions which institute an IPR in *In re The Proctor & Gamble Company,* slip op. 2014-121 (Fed. Cir. Apr. 24, 2014). A timely petition to institute an IPR was filed and granted. P&G argued that a previous declaratory-judgment action barred institution of the IPR. However, the Board reasoned that because the declaratory-judgment action was dismissed without prejudice the action was treated as never existing. Similar to the *St. Jude* and *In re Dominion* cases, the Federal Circuit held that immediate review of the decision whether to institute the IPR was not appealable.

The Federal Circuit did leave open the possibility of review of a decision to institute an IPR following a final written decision by the Board. The Federal Circuit declined to answer this question until an appeal of a final written decision reaches the Federal Circuit.

BONIVA® MONTHLY DOSAGE DEEMED OBVIOUS

By Sean A. Passino, Ph.D., Esq./Partner (spassino@ipfirm.com)

An infrequent dosing schedule is a known problem to be used in obviousness determinations concerning reasons to modify and make other dosing regimens. *Hoffmann-La Roche Inc. V. Apotex Inc.*, slip ops. 2013-1128, -1161-64 (Fed. Cir. Apr. 11, 2014). Roche owns U.S. Patent No. 7,718,634 ("the '634 patent") directed to uses of ibandronate, which is commercially available as Roche's once-monthly (150 mg) Boniva®. Roche sued generics who filed an ANDA seeking approval of a generic version of the once-monthy Boniva®.

The district court granted the defendants' motion for summary judgment of invalidity of the '634 patent due to obviousness under 35 U.S.C. § 103(a). As to the frequency of dosing, the court found that once monthly oral dosing of ibandronate was established in the prior art as obvious to try. The Federal Circuit affirmed in a split decision.

Citing Fosamax®, the panel noted that a relatively infrequent dosing schedule has long been viewed as a potential solution to the problem of patient compliance stemming from the inconvenience of oral bisphosphonate regimens. One prior art document, Riis, suggested the total-dose concept whereby "the efficacy of ibandronate depends on the total oral dose given rather than on the dosing schedule." Riis, according to the panel, teaches that, in setting the dosage level for an intermittent ibandronate regimen, one need only scale up a known-effective dose.

To arrive at the once-monthly150 mg dose, the panel cited another prior art reference, Daifotis, which shows a total-dose equivalent to 5 mg of ibandronate per day.

The panel combined these reference to prove that it was obvious to try, with a reasonable expectation of success, to modify the total-dose equivalents of the 5 mg daily dose, i.e., (5mg/day x 30 days per month =) to result in a 150 mg per month dosage from. According to the panel, based on the prior art, there were only a "finite number of identified, predictable solutions."

COMBINATION OF KNOWN INGREDIENTS IS NON-OBVIOUS

By Sean A. Passino, Ph.D., Esq./Partner (spassino@ipfirm.com)

A combination of old drug ingredients can be nonobvious. *Sanofi-Aventis Deutchland v. Glenmark Pharmaceuticals*, slip op. 2012-1489 (Fed. Cir. Apr. 21, 2014). The Sanofi-Aventis Deutschland GmbH owns U.S. Patent No. 5,721,244 (the '244 patent) directed to an

antihypertension drug that combines two active ingredients into a single dosage: an angiotensin converting enzyme (ACE) inhibitor trandolapril, and a calcium channel blocker verapamil hydrochloride. The corresponding brand name drug is Tarka®, and Glenmark filed an ANDA Paragraph IV Certification to market a generic version. After the 30-month stay, Glenmark launched at risk. Glenmark admitted infringement, and a jury held that the '244 patent had not been proved invalid as obvious. Glenmark appealed the jury verdict, and the Federal Circuit affirmed.

Glenmark argued that if a combination of classes of components is already known, all selections within such classes are obvious to try, as a matter of law. Glenmark also argued that it is irrelevant that the combination is ultimately found to have unpredicted or superior properties if those properties, though unknown in the prior art, could be attributed to one of the prior art components of the combination.

The Federal Circuit reasoned that in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) the United States Supreme Court explained that "obvious to try" may apply when "there are a finite number of identified, predictable solutions" to a known problem. The identified path must "present a finite (and small in the context of the art) number of options easily traversed to show obviousness." Here, there was no prior knowledge that the combination of an ACE inhibitor with a calcium antagonist would be longer lasting than the hypertension treatments at the time. Patentability may consider all of the characteristics possessed by the claimed invention, whenever those characteristics become manifest. Thus, the Federal Circuit let the decision stand.

As a side note, the jury awarded $15,200,000 in lost profits and $803,514 in price erosion damages for launching at risk.

ADDITIONAL INFORMATION

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