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Federal Circuit Affirms Summary Judgment of Non-Obviousness and Findings of No Inequitable Conduct In Aciphex Litigations

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The Federal Circuit issued its opinion yesterday in companion cases *Eisai v. Dr. Reddy* (07-1397) and *Eisai v. Teva* (03-1398) following several years of litigation relating to Eisai's Aciphex® (rabeprazole sodium) product – a billion dollar per year proton pump inhibitor. Writing for the Court, Judge Rader ruled that the trial court – Judge Lynch of the U.S. District Court for the Southern District of New York – properly granted summary judgment of patent validity after finding the patent not obvious. The Court also affirmed the district court's findings that the patent was enforceable despite allegations by defendants that Eisai had committed inequitable conduct during the patent's prosecution.

Summary Judgment of Non-Obviousness

In October 2006, following a summary judgment motion of patent validity by Eisai, the Court had ruled that defendant Teva (defendant Reddy had already stipulated to the patent's validity)[2] had failed to show that a person of ordinary skill in the art would have been motivated to select the known compound lansoprazole as a lead compound and then modify it in a certain way to achieve the claimed compound, rabeprazole.

In granting summary judgment, the district court rejected Teva's arguments concerning the alleged teachings of the three references relied upon by Teva (Takeda's European Patent No. 174,726; Astra's U.S. Patent 4,255,431; and an article by A. Brändström, titled "Structure Activity Relationships of Substituted Benzimidazoles"). In particular, the district court pointed out that the only data from these references relied upon by Teva to support its selection of lansoprazole as a lead compound was of questionable value to a person of skill in the art. The district court also rejected Teva's argument that a person of ordinary skill in the art would have selected lansoprazole as a lead compound due to its lipophilicity. According to Teva, such a person would have been attracted to lansoprazole for its lipophilicity, which was evidenced by the existence of fluorine atoms on lansoprazole's pyridine ring. But the district court found that Teva's argument was flawed because a skilled person would not have selected lansoprazole for its fluorine atoms and resulting lipophilicity, only to remove those fluorine atoms to get rabeprazole. Finally, the district court considered and rejected Teva's argument that a person of ordinary skill would have focused on the molecular weight of lansoprazole to drive its selection as a lead compound. Here, the district court found that minimizing the molecular weight of a compound was evidence of motivation to modify lansoprazole, not to select it as a lead compound. Having found that Teva's evidence of a "good" or "reasonable" starting point was not sufficient to prove that a person of ordinary skill would have selected

lansoprazole as a lead compound, the district court found that Teva's asserted combination would not have occurred and thus the record could not support a finding of obviousness.

On appeal, Teva made the same arguments regarding obviousness, except that it emphasized to the Federal Circuit that the district court's summary judgment decision did not account for the flexible obviousness inquiry mandated by the recently-issued Supreme Court decision in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). Teva argued that the district court was too rigid in its obviousness inquiry, requiring it to prove that a person of ordinary skill necessarily would have selected lansoprazole as a lead compound based on the totality of the data available concerning that compound.

The Federal Circuit began by recognizing that *KSR* did mandate a flexible obviousness inquiry, and that "the requisite motivation can come from any number of sources and need not necessarily be explicit in the art." The Court found, however, that the district court had applied the requisite flexibility to the obviousness inquiry, particularly because the district court did not force Teva to select a single lead compound. Instead, the Federal Circuit recognized that "Teva alone selected lansoprazole as the anchor for its obviousness theory." The Federal Circuit also agreed with the district court's analysis that a person of ordinary skill in the art would select lansoprazole for its lipophilicity, then "drop the very feature, the fluorinated substituent, that gave this advantageous property."

Importantly for chemical compound cases generally, the Federal Circuit addressed *KSR*'s comment that an invention may be obvious where "there [was] … a design need or market pressure to solve a problem and there [were] … a finite number of identified, predictable solutions." Recognizing that the Supreme Court's *KSR* analysis relies on several assumptions about the prior art landscape (such as (1) the existence of starting reference points to identify a problem and potential solutions; (2) knowledge to make particular modifications to achieve the claimed compound, and (3) reasons to narrow the prior art universe to a "finite number of identified, predictable solutions"), the Federal Circuit clarified that "[t]o the extent an art is unpredictable, as the chemical arts often are, *KSR*'s focus on these 'identified, predictable solutions' may present a difficult hurdle because potential solutions are less likely to be genuinely predictable." Accordingly, the Federal Circuit concluded that "post-*KSR*, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound." In this case, because the record contained no evidence that a person of ordinary skill would have modified lansoprazole by removing the fluorinated substituent, the district court properly concluded as a matter of law that the patent could not be found obvious.

This decision provides an important insight into the Federal Circuit's post-*KSR* obviousness analysis for chemical compound cases. In particular, it is one of the first Federal Circuit decisions to provide guidance on the Supreme Court's *KSR* comment that the existence of a "small and finite number of alternatives" may suggest obviousness and, in particular, how the Federal Circuit will apply that comment to chemical compound patents. The Federal Circuit expressly recognized that chemical arts are often unpredictable, and that such unpredictability may "present a difficult hurdle" to the Supreme Court's direction to focus on "identified, predictable solutions" because "potential solutions are less likely to be genuinely predictable." Accordingly, a chemical compound patent holder would be well-advised to focus on debunking a defendant's characterization of not only the predictability of the chemical arts in general and a particular chemical field, but also the basic assumptions concerning the prior art landscape upon which the *KSR* analysis relies.

No Inequitable Conduct

The Federal Circuit also affirmed the finding of the district court that the patent was enforceable. On appeal, Teva and Dr. Reddy's alleged that Eisai

misled the PTO in five ways: 1) concealing lansoprazole from the examiner; 2) failing to disclose Eisai's own co-pending patent application, which claimed the "ethyl homolog" of rabeprazole; 3) withholding rejections of that co-pending patent application; 4) failing to disclose the prior art "Byk Gulden" patent; and 5) submitting an allegedly misleading inventor declaration (the "Fujisaki Declaration").

Following Eisai's motion for summary judgment of no inequitable conduct, the district court rejected the allegation that the patent was unenforceable due to the non-disclosure of lansoprazole. The district court found that the defendants had failed to present evidence of either deceptive intent or evidence to support an inference of materiality. The Federal Circuit affirmed this finding, reasoning that an Eisai employee's statement that the similarity of rabeprazole and lansoprazole "bothers me" was a "vague, subjective statement [that] is not sufficient by any means to establish materiality, let alone intent." The Federal Circuit's view was further bolstered by its ruling on lansoprazole and its relation to the patent's validity.

The remaining inequitable conduct issues were decided after a bench trial in March 2007, following which the district court rejected each of defendants' remaining inequitable conduct allegations. In particular, the district court found that found the failure to disclose the existence of the co-pending application was explained by the fact that the inventors did not see the two compounds as being mere homologs. Further, the district court found credible Eisai's employees' beliefs that the related compounds were considered separately patentable. Defendants' allegations that disclosure of the co-pending application could have led to a provisional double-patenting rejection also carried little weight with the district court. Rather, the district court found the co-pending application's materiality was low because applicants can routinely overcome such a rejection.

The Federal Circuit also agreed with the district court that Eisai's failure to disclose the co-pending application was not fatal. First, it recognized that the district court had ample evidence from which to conclude the materiality of the co-pending application was low. Second, the record was "devoid of any real suggestion of intent to deceive the Patent Office, much less the clear and convincing evidence required to support a finding of inequitable conduct." On this point, the Federal Circuit recognized that credibility determinations lie squarely within the realm of the district court's discretion, stating that the facts alleged in this case "certainly do not rise to the level of 'culpability' this court required in *Kingsdown*, 863 F.2d at 876, to establish intent to deceive, or even gross negligence."

The Federal Circuit had no difficulty affirming the district court's findings with respect to the materiality and lack of intent concerning the Byk Gulden patent. The Federal Circuit found the district court was well within its discretion to conclude that the reference was not material because the defendant's own expert conceded that the reference was cumulative to information already before the examiner. The Court further stated that "[e]ven if Byk Gulden had been material, the lack of clear and convincing evidence of intent to deceive would nonetheless have imposed an insurmountable bar to finding inequitable conduct."

Finally, with regard to the Fujisaki Declaration, although the district court found it to be highly material, it did not find the comparisons made therein misleading. The Fujisaki Declaration compared rabeprazole to the closest prior art compound, as well as two other non-prior art compounds. The defendants alleged it was misleading to not also compare rabeprazole with the "ethyl homolog" compound. The district court found, and the Federal Circuit agreed, that the defendants' argument was "contorted" because the declaration indisputably compared rabeprazole to the prior art compound called out by the examiner. Accordingly, although the Federal Circuit affirmed the district court's finding that the declaration was

highly material, it concluded "the lack of deceptive intent rendered stillborn yet another allegation of inequitable conduct."

The Federal Circuit's comments on the inequitable conduct allegations in this case suggest frustration in certain Court members with the frequency that inequitable conduct allegations appear in patent cases. Judge Rader cites *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (en banc), for the proposition that "[t]o satisfy the 'intent' prong for unenforceability, 'the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of deceptive intent," concluding "[t]his is a high bar." These comments echo Judge Rader's recent dissent in *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334 (Fed. Cir. 2008). In *Aventis*, the majority affirmed a finding of inequitable conduct based primarily on a deferential standard to the district court's findings, but Judge Rader, citing *Kingsdown* several times, commented that, in his view, inequitable conduct has "taken on a new life as a litigation tactic," "too often emphasiz[ing] materiality almost to the exclusion of any analysis of the lofty intent requirement." Whether these recent cases represent the beginning of a shift toward a new skepticism of inequitable conduct allegations (à la *Kingsdown*'s "absolute plague" characterization of this defense), only time will tell.

Eisai was represented in this case by Paul Hastings partners Joseph M. O'Malley, Jr. and Bruce M. Wexler, and associates David M. Conca, Gary G. Ji and Quinn E. Clancy.

To read the full text of the decision, please visit: http://www.cafc.uscourts.gov/opinions/07-1397.pdf

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[2] Mylan had initially been sued as well, but later stipulated to be bound by the outcome of the proceedings against Teva and Dr. Reddy.