FEDERAL CIRCUIT PATENT LAW CASE UPDATE

Ferring B.V. v. Barr Labs., Inc., 05-1284 (Fed. Cir. Feb. 15, 2006) (Dyk, J.)

Based on Barr's ANDA filing to sell a generic antidiuretic compound, Ferring sued under its patent for an antidiuretic claiming gastrointestinal absorption. The court affirmed the inequitable conduct determination of unenforceability on summary judgment because Ferring submitted highly material declarations about the meaning of a key prior art reference, but four of the five declarants "were written by scientists who had been employed or had received research funds from Ferring, and [an inventor] participated in the drafting of two of the four declarations submitted by non-inventors." This supported the inference of intent to mislead. Judge Newman dissented, arguing that the majority's approach was contrary to precedent and revives misuse of inequitable conduct defense.

Ferring owns U.S. Pat. No. 5,407,398, for an "antidiuretic composition for humans comprising a gastrointestinally absorbable, antidiuretically effective, amount of [the peptide] . . . and a pharmaceutically acceptable carrier in solid oral dosage form for absorption in the gastrointestinal tract of said humans."

The court affirmed the inequitable conduct determination arising from the patent's prosecution. Inventors Vilhardt and Hagstam filed on Dec. 17, 1985. On May 28, 1986, Vilhardt attended an interview with the examiners.

> At the interview, the examiners discussed certain prior art references, including U.S. Patent No. 3,497,491 (filed Sept. 14, 1967) ("'491 patent" or "Zaoral patent"). Ferring was the exclusive licensee of '491 patent until its expiration in 1987. The '491 patent taught, for antidiuretic purposes, that [the peptide] "may be used . . . for the parenteral, peroral, intranasal, subcutaneous, intramuscular, or intravenous application." '491 patent at col.3 l.15-23, col.5 l.15-20 (emphasis added). The examiners were concerned that the '491 patent's disclosure of the "peroral" application of the peptide may have suggested the oral administration of the peptide for gastrointestinal absorption. Vilhardt argued that the term "peroral" as used in the '491 patent did not teach the oral administration of the peptide for gastrointestinal absorption, but rather for absorption through the walls of the mouth. As the examiners were not entirely convinced, they "suggested that applicants obtain evidence from a non-inventor" to support their interpretation of the term "peroral." J.A. at 3460 (emphasis added).

Ferring submitted four declarations, "two from Vilhardt himself, one from a Dr. Myron Miller, and one from a Dr. Paul Czernichow." They expressed the opinion "that the term 'peroral' in the '491 patent meant that the compound could be administered 'through the mouth,' but only for absorption through the cheek of the mouth or under the tongue."

> However, the declarations failed to disclose that Czernichow had been receiving research funding from Ferring from 1985-86. Specifically, Czernichow received research funding to conduct a clinical investigation relating to a particular drug (DDAVP) preparation.

The Board affirmed the examiner's obviousness rejection by bringing in another reference, an article by Vavra.

> On November 21, 1990, the inventors submitted five more declarations to persuade the examiners that the Vavra reference would not, when read with the '491 patent, suggest the gastrointestinal absorption of the peptide. As before, the inventors submitted declarations from Vilhardt, Miller, and Czernichow. They also submitted declarations from a Dr. Iain Robinson and a Dr. Tomislav Barth. Each of these declarations explained why, in the declarant's own professional judgment,

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> the Vavra reference did not suggest that the peptide could be absorbed gastrointestinally. Just as before, the inventors did not inform the examiners that Czernichow had been receiving funds from Ferring. . . . Czernichow's declaration did include an extensive CV. However, it did not mention his research with Ferring.

Robinson and Barth had connections to Ferring not dissimilar to those of Czernichow. Vilhardt sent Barth and Robinson "draft declarations" and provided input on the statements.

> After these declarations were submitted, the examiners allowed the previously rejected claims, and the '398 patent issued on September 10, 1991. The PTO did not provide any explanation for its allowance.

The court affirmed the findings on materiality and intent.

> The general law of evidence has long recognized that the testimony of any witness may be rendered suspect by a past relationship with a party. . . . A witness's interest is always pertinent to his credibility and to the weight to be given to his testimony, and relevant interests are not limited to direct financial interests. Under Refac and Paragon, a declarant's past relationships with the applicant are material if (1) the declarant's views on the underlying issue are material and (2) the past relationship to the applicant was a significant one. Here we think that each of these requirements was satisfied on the summary judgment record.

Like the materiality prong, in this case it was also appropriate to decide the intent prong under summary judgment.

> We need not in this case attempt to lay down a general rule as to when intent may be or must be inferred from the withholding of material information by an applicant. Suffice it to say that we have recognized, in cases such as Paragon, that summary judgment is appropriate on the issue of intent if there has been a failure to supply highly material information and if the summary judgment record establishes that (1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding. . . . Here, all three conditions are satisfied.

In particular, Vilhardt's actions satisfied all three conditions. "Far from there being a credible explanation for the withholding, there is evidence in the summary judgment record supporting a conclusion that the past relationships were deliberately concealed:" the selective submission of CVs. Given the preceding analysis, the court had little trouble affirming the weighing step of the inequitable conduct inquiry under an abuse of discretion standard.

Judge Newman dissented, introducing the dissent by recalling the history of misuse of the inequitable conduct defense.

> My colleagues on this panel have regressed to that benighted era, rejecting the efforts of Kingsdown to bring objectivity to charges of inequitable conduct, instead reviving the culture of attack on inventor rights and attorney reputations based on inference and innuendo. My colleagues, endorsing several novel and unsupportable presumptions of wrongdoing, do injury to the reasonable practice of patent solicitation, even as they defy the rules of summary judgment. . . . The most reasonable inference, to which Ferring is entitled on summary judgment, is that Dr. Czernichow's relationship with Ferring was so remote as to not be worthy of a listing in his CV. Further, as my colleagues acknowledge, the summary judgment record contains no evidence that Dr. Vilhardt was aware of this prior relationship.

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