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Federal Circuit Patent Bulletin: *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*

May 22, 2017

"[T]he substantial differences test may be more suitable than FWR for determining equivalence in the chemical arts."

On May 19, 2017, in *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, the U.S. Court of Appeals for the Federal Circuit (Lourie,* Moore, Reyna) affirmed the district court's preliminary injunction enjoining Aurobindo from activity alleged to infringe U.S. Patents No. 7,622,992, No. 8,969,616, and No. 9,353,050, which related to a triarylmethane dye, isosulfan blue (ISB), used to map lymph nodes. The Federal Circuit stated:

"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." . . . To establish a likelihood of success on the merits, a patentee must show that it will likely prove infringement of the asserted claims and that its infringement claim will likely withstand the alleged infringer's challenges to patent validity and enforceability. A preliminary injunction should not issue if the accused infringer "raises a substantial question concerning either infringement or validity." . . .

In Graver Tank, the Supreme Court set out two frameworks for evaluating equivalence—the familiar FWR test (viz., whether the accused product performs "substantially the same function in substantially the same way to obtain the same result") and the insubstantial differences test (whether the accused product or process is substantially different from what is patented). The Supreme Court's most recent visit with this branch of the law was in Warner-Jenkinson, which dealt with whether a process of purification performed at a pH

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Practice Areas

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Patent

of 5 was equivalent to one performed at a pH of 6–9. The Court noted that equivalence is not a "prisoner of formula," but also observed that non-mechanical cases may not be well-suited to consideration under the FWR test. . . . Thus, the Court seemingly blessed two equivalents tests, leaving to the lower courts in future cases the choice of which to apply. . . .

Especially when evaluating an equivalents dispute dealing with chemical compositions having many components, chemical compounds with many substituents (which are usually claimed as separate limitations), and those having a medical or biological use, it is often not clear what the "function" or "way" is for each claim limitation. How a particular component of a composition, or substituent of a compound, functions in a human or animal body, or in what way, may not be known or even knowable (although, as technology evolves, that may change). And precedent requires that, for infringement under the doctrine of equivalents, each limitation must satisfy an equivalence test. The "result" of using a claimed compound may be more easily evaluated, as the structure and uses of one compound may be directly compared with those of another. [But] that is not how infringement under FWR is determined. It must be determined on a limitation-by-limitation basis. Similarly, in the case of a chemical process claim, as in this case, the "result" of a process producing a chemical compound maybe clear—why else would a claim for infringement of a process claim be brought if the claimed result is not obtained? But the "function" and "way" of a particular limitation of a chemical process claim may remain vague and often overlap. In some cases, "way" and "function" may be synonymous. . . .

For example, consider the well-known compounds aspirin and ibuprofen, which chemists would not usually consider to be structural equivalents under the insubstantial differences test. Chemical compounds are characterized by their structures, and these two compounds differ substantially in structure (see appendix). However, the two compounds would seem to be substantial equivalents under the FWR test. They each provide analgesia and anti-inflammatory activity ("function") by inhibiting prostaglandin synthesis ("way") in order to alleviate pain, reduce fevers, and lessen inflammation ("result"). Thus, a compound may appear to be equivalent under the FWR test, but not under the substantiality of the differences test. Hence, the substantial differences test may be more suitable than FWR for determining equivalence in the chemical arts.

In this case, the district court conducted an incomplete FWR analysis while essentially bypassing the substantial differences test, in a situation where the latter test might seemingly be more appropriate. The claims in the process patents recite a method for preparing a specifically named compound by combining another specifically depicted compound with a third specific compound, viz., silver oxide. Each of these compounds is expressly named, and an infringement analysis must not take lightly the specific recitation of these materials. The district court found that the accused process using manganese dioxide was equivalent to the claimed process using silver oxide. But the court failed to consider whether the key reagent in the process, manganese dioxide, was substantially different from the claimed reagent, silver oxide, and hence whether the substitution for, and omission of, silver oxide left the accused infringer outside of the bounds of the claims. . . . In sum, we conclude that the court's equivalents analysis was deficient in its FWR analysis. Because, on the record, there remains a substantial question concerning infringement, we conclude that the court's grant of a preliminary injunction based on the process patents constituted an abuse of discretion. Thus, we modify the

court's grant of the preliminary injunction to premise it only on its evaluation of the '050 patent [for which Aurobindo did not dispute infringement]. . . .

The district court rejected Aurobindo's argument that the '050 patent claims are anticipated by Sigma's manufacture and sale of ISB because it found that the Sigma Certificate of Analysis related to a compound named "Patent Violet Blue" and it was not clear that, at the time of the issuance of the Certificate, Sigma used that term to refer to ISB. Additionally, the Certificate contradicts other Sigma documents that report different purity levels for samples from the same Lot. . . . The district court also rejected Aurobindo's obviousness argument, finding that Aurobindo did not raise a substantial question regarding motivation to combine the references or a reasonable expectation of success. . . . Finally, the district court rejected Aurobindo's argument that the '050 patent claims are invalid as indefinite. . . . We see no error in the district court's analysis. We have previously acknowledged that "a purified compound is not always prima facie obvious over the [prior art] mixture" if the process to arrive at the purified compound is itself of patentable weight. Moreover, if the prior art teaches a mixture containing a compound but does not enable its purification, then the purified form of the compound may not have been obvious over the prior art mixture. . . . Furthermore, the district court credited Mylan's evidence of secondary considerations—specifically, long-felt but unmet need, commercial success, copying/praise of others, and unexpected results. The court relied on record evidence showing the failure of Allied, Sigma, Innovassynth, and others in the art to "reliably" produce "high-purity" ISB for 30 years, and that Aurobindo "admitted to the FDA" that it had copied the '992 patent. There is no clear error in the court's findings. . . . Thus, we see no error in the court's legal analysis or its factual findings pertaining to validity of the '050 patent, particularly at the preliminary injunction stage of the litigation.