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Recent Guidance from Federal Circuit on Doctrine of Equivalents in Cases Involving Chemical Compositions

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In ***Mylan Institutional LLC, et al. v. Aurobindo Pharma Ltd.*, *et al.***, Case No. 2017-1645, the ***Federal Circuit*** affirmed the district court's grant of a preliminary injunction as to one of three patents-in-suit, while finding that there was error in granting the injunction with respect to the other two patents.

The patents-in-suit related to ISB, a dye used to map lymph nodes, with two of the patents (the '992 and '616 patents) directed to the process for preparing ISB, and one of the patents (the '050 patent) directed to an ISB compound "having a purity of at least 99.0% by [high performance liquid chromatography]." Apicore is the owner of, and Mylan is the exclusive licensee of, the patents-in-suit.

Some years after Lymphazurin® (1% injectable solution of ISB) entered the market, Apicore developed an improved process for synthesizing ISB, and in 2004 partnered with Mylan's predecessor (Synerx Pharma LLC) to develop and market a generic form of Lymphazurin®. In 2007, Apicore filed a patent application that led to the patents-in-suit. Relying on the new process for synthesizing ISB, Synerx (later acquired by Mylan) sought FDA approval—which was approved in 2010—to market a generic form of Lymphazurin®. Mylan was the only supplier of the 1% ISB product until Aurobindo entered the market in 2016.

Aurobindo sought FDA approval to market a generic form of Lymphazurin® and Mylan proceeded to sue Aurobindo and seek a preliminary injunction. In conducting the preliminary injunction analysis, the district court addressed the likelihood of success on the merits and concluded that Aurobindo likely infringed the '992 and '616 patents under the doctrine of equivalents. Meanwhile, the district court found that Aurobindo did not raise a substantial question as to the validity of the '050 patent while giving credit to Mylan's evidence of secondary considerations of non-obviousness. The district court went on to find that Apicore would be irreparably harmed in the absence of the injunction, that there was a causal nexus between the harm and the infringement, and that the balance of equities and public interest favored granting the preliminary injunction. The district court reasoned that the loss to Apicore of its business would impact its ability to fund ongoing research and development, and that the public interest in lower priced pharmaceuticals did not justify eliminating the exclusionary

rights of patent owners.

In reviewing the district court's decision, however, the Federal Circuit found "that the district court's analysis of equivalence . . . was flawed, no doubt because of the sparse and confusing case law concerning equivalents, particularly the paucity of chemical equivalence case law, and the difficulty of applying the legal concepts to the facts." As the Federal Circuit stated, this case is unusual given that it addresses the grant of a preliminary injunction based on the doctrine of equivalents, and further in view of the fact that the Federal Circuit considered the application of the doctrine of equivalents "not clear" as applied in the chemical arts.

The Federal Circuit discussed the two frameworks used to assess the doctrine of equivalents: (1) the function, way, result test ("FWR test"); and (2) the insubstantial differences test. Noting that the FWR test is often not suited for non-mechanical cases, the Federal Circuit emphasized that the Supreme Court has "blessed the two equivalents tests," and leaves to the lower courts the decision of which test to apply.

The Federal Circuit explained that in this particular case the district court erred in applying the FWR test, noting that the use of the FWR test is questionable with chemical compositions because often it is not possible to clearly evaluate the *function* of a chemical composition or the *way* it functions in the human body. Here, because the district court did not appropriately consider the *way* the oxidation worked, the FWR analysis was incomplete. What is particularly interesting in this case is the Federal Circuit's statement that "the FWR test may be less appropriate for evaluating equivalence in chemical compounds if it cannot capture substantial differences between a claimed and accused compound." The Federal Circuit provided further guidance indicating that the insubstantial differences test might have been more appropriate to apply. This is instructive and serves as a reminder to keep both tests in mind when addressing the application of the doctrine of equivalents to chemical compositions.

Given the defect in the application of the FWR test, the Federal Circuit concluded that the district court's grant of a preliminary injunction based on the process patents was improper. However, because Aurobindo did not appeal the court's finding that it more likely than not infringes the '050 patent and because Aurobindo did not raise a substantial question as to the validity of the '050 patent, the Federal Circuit affirmed the grant of the preliminary injunction premised on the '050 patent alone.

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