THE FEDERAL CIRCUIT WEIGHS IN ON THE DOCTRINE OF EQUIVALENTS FOR CHEMICAL INVENTIONS

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In *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*,[1] the Federal Circuit affirmed the district court granting a preliminary injunction based on infringement of U.S. Patent No. 9,353,050 (the product patent), directed to an isosulfan blue ("ISB") compound in a purity "of at least 99.0% by HPLC," but reversed the district court's finding that Mylan Institutional LLC ("Mylan") was likely to succeed in proving infringement under the doctrine of equivalents of patents covering a process for making ISB, U.S. Patent Nos. 7,622,992 and 8,969,616 (the process patents). The Federal Circuit's reversal hinged on the district court's deficient function-way-result ("FWR") analysis on the process patents.

BACKGROUND

ISB is a lymphatic imaging agent. It was developed and sold under a New Drug Application by Covidien Ltd. ("Covidien") under the name Lymphazurin®.[2] Covidien was the sole supplier for over 30 years, but had supply problems throughout the early 2000s, and wound up developing its own ISB manufacturing process in 2010.[3]

In the meantime, around 2003, Apicore US LLC began developing an improved process for synthesizing ISB, and after partnering with Synerx Pharma LLC ("Synerx"), filed a patent application in 2007 that ultimately led to the process patents and the product patent.[4] The process patents are directed to a process for preparing ISB by reacting isoleuco acid with silver oxide, and the product patent is directed to an ISB compound having a purity greater than 99.0%, as measured by high performance liquid chromatography ("HPLC").[5] Based on the claimed process, Synerx filed an Abbreviated New Drug Application ("ANDA") to market a generic Lymphazurin®, which the FDA approved in 2010.[6] Mylan acquired Synerx in 2012 and is the exclusive licensee of the product and process patents and the ANDA product.[7]

Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc., and Auromedics Pharma LLC (together, "Aurobindo") entered the market after receiving FDA approval for their ISB generic in February 2016.[8] Aurobindo's process used manganese dioxide, rather than silver oxide as claimed in the process patents, and resulted in ISB having 5–10% impurities, which was then purified to greater than 99.5% by preparatory HPLC.[9]

THE DISTRICT COURT DECISION

In May 2016, Mylan sued Aurobindo for infringement of the process patents and the product patent in the U.S.

District Court for the Eastern District of Texas, and moved for a preliminary injunction.[10] In granting the injunction, the district court held that Aurobindo likely infringed the process patents under the doctrine of equivalents based on the court's finding that the accused process using manganese dioxide was equivalent to the claimed process using silver oxide.[11]

THE FEDERAL CIRCUIT DECISION

The Federal Circuit affirmed the preliminary injunction, but faulted the district court's doctrine of equivalents infringement analysis for the process patents.[12] The Federal Circuit held that the district court's analysis of equivalents was incomplete because the district court evaluated equivalents under the FWR framework (whether the accused product performs substantially the same function in substantially the same way to obtain the same result), and did not perform a complete analysis under that test.[13] First, the Federal Circuit found that the district court correctly evaluated the "function" prong of the FWR test by deciding that the function of silver oxide was to oxidize the precursor isoleuco acid to ISB acid—the same function as manganese dioxide.[14] But the district court failed to properly consider the "way" prong in evaluating the "way" oxidation works.[15] The Federal Circuit noted three key differences in the "way" oxidation in the reaction works with silver oxide versus manganese dioxide: the two have different oxidation strengths with silver oxide being a weaker oxidizing agent than manganese dioxide;[16] the process using manganese dioxide requires the use of an acid for oxidation, but silver dioxide does not; and the two result in different yields of ISB.[17] Because the district court's analysis of the "way" prong was lacking, the Federal Circuit reversed the district court's determination that manganese dioxide was equivalent to silver oxide.[18]

The Federal Circuit noted that the "insubstantial differences test" may be the more appropriate test to apply here. The Federal Circuit stated that this appeal was unusual because it arose from a grant of a preliminary injunction based on doctrine of equivalents infringement, and called the case law on the doctrine of equivalents as applied to chemical materials "sparse and confusing."[19] To guide future doctrine of equivalents analyses for chemical inventions, the Federal Circuit[20] observed that the FWR test may not be well suited for evaluating equivalents in the chemical arts.[21] Often, the "function" or "way" is not clear for each claim limitation of a chemical composition or process, and in some cases, the "function" and "way" may overlap or be synonymous.[22] The Federal Circuit offered that the insubstantial differences test (whether the accused product or process is substantially different from what is patented) may be more appropriate in chemical cases, particularly if the FWR test cannot capture substantial differences between a claimed and accused compound.[23] It cautioned that a compound or process may appear to be equivalent under the FWR test, but not under the insubstantial differences test, in which case the insubstantial differences test may be the more appropriate test to apply.[24] The Federal Circuit instructed the district court to provide further analysis under the FWR test (if the district court determines that test should be used) and to consider whether the insubstantial differences test is a more appropriate framework for evaluating equivalence given the specific facts of this case.[25]

LOOKING FORWARD

It remains to be seen whether *Mylan Institutional LLC v. Aurobindo Pharma Ltd.* will alter how courts apply the doctrine of equivalents in chemical cases, but the case provides alternatives that each party should consider in litigating a doctrine of equivalents case.

Notes:

1 No. 2017-1645, slip op. (Fed. Cir. May 19, 2017).
2 *Id.* at 4.
3 *Id.* at 4–5.
4 *Id.* at 5.
5 *Id.* at 2–4.
6 *Id.* at 5.
7 *Id.* at 2, 5.
8 *Id.* at 5.
9 *Id.* at 5–6.
10 *Id.* at 6.
11 *Id.*
12 The Federal Circuit ultimately affirmed the district court's injunction because it found that the district court did not err in finding that Aurobindo likely infringed the product patent.
13 *Id.* at 17.
14 *Id.* at 16.
15 *Id.* at 15–16.
16 Aurobindo argued that it had raised a substantial question of infringement of the process patents under the doctrine of equivalents because manganese dioxide is a strong oxidizing agent, whereas silver oxide is a weak oxidizing agent. *Id.* at 11.
17 *Id.* at 16.
18 The Federal Circuit declined to decide whether the district court's treatment of the "result" prong constituted reversible error, but instead relied on the district court's handling of the "way" prong to reverse the district court. *Id.* at 14 n.5, 15–16.
19 *Id.* at 12.
20 The Federal Circuit extensively cited Graver Tank & Mfg. Co. v. Linde Air Prod. Co., 339 U.S. 605 (1950) and Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997) for the FWR and insubstantial differences tests, respectively.
21 *Id.* at 13.
22 *Id.* at 14–15.
23 *Id.* at 17.
24 *Id.*
25 *Id.* at 18.

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