MYLAN INSTITUTIONAL LLC. v. AUROBINDO PHARMA LTD., Appeal No. 2017-1645 (Fed. Cir. May 19, 2017). Before Lourie, Moore, and Reyna. Appealed from E.D. Tex. (Judge Schroeder).

Background:

Mylan manufactures a generic version of the 1% ISB drug product Lymphazurin, and following Lymphazurin's withdrawal from the market in 2012, Mylan became the sole supplier of that type of drug product. In 2016, Aurobindo sought FDA approval for another generic version of Lymphazurin. Mylan accordingly sued, alleging that Aurobindo infringed three patents of which Mylan was the exclusive licensee. The district court granted Mylan a preliminary injunction against Aurobindo. Aurobindo appealed.

Issue/Holding:

Did the district court err by granting Mylan a preliminary injunction? No, affirmed.

Discussion:

A party seeking a preliminary injunction must establish that (i) it is likely to succeed on the merits, (ii) it is likely to suffer irreparable harm in the absence of preliminary relief, (iii) the balance of equities tips in its favor, and (iv) an injunction is in the public interest. On appeal, Aurobindo disputed the district court's findings that (i) it "more likely than not" infringed Mylan's two process patents under the doctrine of equivalents, (ii) it did not raise a substantial question as to the validity of the remaining product patent, and (iii) there was irreparable harm to Mylan. The Federal Circuit addressed each of these positions on appeal.

The Federal Circuit first held that the district court erred in its doctrine of equivalents analysis by misapplying the "function, way, result" test to conclude that Aurobindo's use of manganese dioxide is equivalent to Mylan's process patents' use of silver oxide. It commented that, particularly in chemical cases, it is often not clear what the "function" or "way" is for each claim limitation, and the Federal Circuit argued that the district court significantly erred in its analysis of the "way." The Federal Circuit also suggested that the district court should have considered the insubstantial differences test to evaluate equivalence, which may be more appropriate in chemical cases and could yield different results.

The Federal Circuit then held that Aurobindo pointed to no legal error underlying the district court's conclusion that Mylan's remaining product patent is valid; Aurobindo only alleged that the district court erred in "misreading the factual content of the prior art." The Federal Circuit also found Mylan's evidence of secondary considerations to be persuasive to validity. And in connection with the irreparable harm requirement, the Federal Circuit found no clear error in the district court's determination that Mylan has, and will continue to, suffer from lost sales, lost research and development, price erosion, and having to compete with an infringer.

So in view of the above determinations and because Aurobindo did not challenge the district court's finding that it "more likely than not" infringed the remaining product patent, the Federal Circuit affirmed the district court's grant of the preliminary injunction.