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Patents

Stakeholders Agree With Fed. Cir.'s Discount Of Severe Patent Exhaustion Consequences

he biotechnology and pharmaceutical industries received a win with the Federal Circuit majority opinion downplaying the concerns of high-tech sector and retaining its current standards on the reuse and resale of patented products. *Lexmark Int'l, Inc. v. Impression Prods., Inc.*, No. 2014-1617 (Fed. Cir. Feb. 12, 2016) (see related story reviewing the court's opinions).

Biopharma was worried that a change in the standard would allow imports of lower priced drugs from foreign markets. Electronics companies complained that there was a chance of unintentional infringement when importing complex products covered by hundreds of different patents.

The appeals court's precedent has allowed patentees to make "conditional" sales—putting restrictions on a buyer's resale and reuse—since 1992, "And yet we have been given no reliable demonstration of widespread problems not being solved in the marketplace," the court said.

The court's 2001 Jazz Photo Corp. v. ITC opinion has further been serving as a bar to importation into the U.S. of goods made overseas that would infringe a U.S. patent. Electronics industry stakeholders filed amicus briefs in the case, claiming that they are liable for "innocent infringement," not knowing which of the hundreds of parts they use are patented. But the court said there was "no reliable evidence that the possibility of unintended infringement in that scenario is actually a significant issue in practice."

Sources in the electronics industry did not respond immediately to Bloomberg BNA's request for comment on the court's rejection of their concern.

Good for BioPharma. Patent owners in the life sciences industry, on the other hand, lobbied the court to maintain the current standards, which allow variable drug pricing depending on the country. The 99-page, detailed majority opinion, if anything, reinforced their argument.

"Innovative biotechnology companies rely upon the dependability of America's patent system to support massive investment in the next generation of cures and treatments for patients living with deadly and debilitating disease, renewable sources of energy, and sustainable agricultural technologies," said Hans Sauer, deputy general counsel for intellectual property at the Biotechnology Industry Organization. "This Federal

Circuit ruling rightly protects innovators from the unauthorized reselling of their own products by third-party distributors, and is a welcome clarification of the law."

The majority opinion expressed concern for the "likely disruption" in the drug industry should it change the standards. Jordan Sigale of Dunlap Codding P.C., Chicago, agreed with the court's view.

"In the absence of this rule, drug companies would presumably have to minimize the disparity in drug prices between the U.S. and non-U.S. markets," he told Bloomberg BNA in an e-mail. "Whether that would result in a benefit to U.S. citizens or a detriment to the rest of the world is the subject of a PhD dissertation. More importantly for this court, basing any decision on that type of argument would seem more suited for Congress than the judiciary."

Little Evidence to Support Complaints. Blair M. Jacobs of Paul Hastings LLP, Washington, also saw little to argue with in the majority's opinion on that point. He further agreed with the court's response to those concerned with unintended infringement.

"The strict liability provisions of 35 U.S.C. § 271(a) certainly make any complaints about innocent infringers less palpable," he said in an e-mail. Further noting that Congress could certainly have changed it by now if the public so desired, Jacobs added, "There certainly has not been rampant allegations of unintended infringement since Jazz Photo, so this hardly seems like a reason to change or modify the law."

Some amicus briefs supporting a change in the patent exhaustion law extended the concern to individual buyers who purchase any item in an overseas market and bring it back to the U.S.

"The number of foreign buyers who unintentionally bring patented goods into the United States cannot be so significant as to let the tail wag the dog," Sigale said.

Fodder for Supreme Court Review? Both Sigale and Jacobs anticipated that alleged infringer Impression Products Inc. will file a petition for Supreme Court review. Jacobs's one complaint about the majority's opinion was its "strained logic" in trying to distinguish patent law from the parallel copyright decision the high court made—with the opposite outcome as to the copyright first-sale doctrine—in *Kirtsaeng v. John Wiley & Sons Inc.* in 2013.

"The Supreme Court has not adopted attempts such as this to distance patents from copyright analysis in the past," he said. "This strikes me as another piece of Federal Circuit logic that the higher court will have a difficult time accepting."

Sigale, however, noted that the decision here—sticking with existing standards, absent evidence of se-

rious problems with them— "sounds a lot" like the Supreme Court's 2015 ruling in *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2015 BL 197538, 114 U.S.P.Q.2d 1941 (2015) (90 PTCJ 2470, 6/26/15). The *Kimble* court acknowledged that there had been major changes in antitrust law in the 50 years since the high court established a rule on royalties after patent expiration, but the justices rejected the call to upgrade the patent standard.

Similarly, Sigale said, "non-exhaustion of U.S. patent rights based on a first foreign sale enjoys a long and un-

varied history. And notwithstanding that history of non-exhaustion, doomsday predictions have not materialized."

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