FDA Reexamination

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Patients, doctors and insurers have all felt the distress of rising drug prices over the past decade. Underlying much of these cost increases are the exclusive rights granted by patents. Many firms recognize that patents play a key role in their ability to charge supra-competitive pricing, and thus have been filing many more patents in order to prevent competition and extend the life of their patents. In order to address some of these issues, President Biden recently issued an executive order requesting that the Food & Drug Administration (FDA) and the United States Patent & Trademark Office (USPTO) communicate more to create a more efficient regulatory process.

The USPTO and the FDA play two important but different roles in regulating pharmaceuticals. The USPTO promotes the progress of science and the useful arts by granting patent rights to their inventions. For the pharmaceutical industry, patents play a crucial role to incentivize manufacturers to take on costly up-front risks associated with brining a new drug to market.[1] In contrast, the FDA's mission is to protect the public health by ensuring safety, efficacy and security of human drugs, biological products and medical devices. Although the USPTO and FDA have different missions they both rely on similar scientific and technical information provided by the applicant/drug sponsor (hereinafter applicant).

A problem occurs, however, when an applicant makes separate but contradictory statements to each agency. For example, in a recent case[2] the Federal Circuit invalidated a drug patent because the patentee made representations to the PTO that directly conflicted with statements made in a prior FDA submission. A similar situation occurs when a drug or device sponsor withholds a material reference from the PTO while submitting that same reference to the FDA.[3]

The way to typical way to prevent this type of behavior is to invalidate the patent through the doctrine of inequitable conduct. The problem, however, is complicated by the fact that the rules for inequitable conduct were heighted post-*Therasense*. Specifically, after *Therasense*, alleged infringers must plead inequitable conduct with

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[1] Olivier J. Wouters, Martin McKee, Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 JAMA 844 (2020) (showing that the median capitalized research and development investment to bring a new drug to market was estimated at $985.3 million).

[2] *Belcher Pharmaceuticals, LLC v. Hospira, Inc*., 2021 WL 3889810 (Fed. Cir. 2021)

[3] See *Baxter Int'l, Inc. v. CareFusion Corp*., 2017 U.S. Dist. LEXIS 39323 (holding that the patentee identified three devices that the FDA has approved as "substantially equivalent" to patentee's pump, but did not disclose these prior art references to the PTO); *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs*., 394 F.3d 1348 (Fed. Circ. 2005) (affirming the district court holding that patentee had failed to disclose to the PTO information on several invalidating prior art references that the patentee had submitted to the FDA in seeking approval to sell a medical device covered by the patent; *Merck & Co. v. Danbury Pharmacal, Inc*. 873 F2d 1418 (Fed. Circ. 1989) (holding that the patentee withheld prior art from the PTO while submitting the same prior art to the FDA).

particularity and the material reference must be withheld with intent to deceive the PTO.

The first problem with FDA information under the new inequitable conduct standard is that FDA information is, for the most part, held confidential, and thus cannot be plead with particularly without discovery. The second problem is that this information must be material. This type of analysis is normally achieved through an expert patent examiner at the PTO, however, in court this analysis is done by the court or a jury who does not have the type of training needed to evaluate these important patents. Finally, inequitable conduct must be undertaken with the intent to deceive the PTO. This mens rea requirement is not required when analyzing a patent at the PTO.

For these reasons, we suggest that Congress create a new FDA Reexamination procedure by which information from the FDA can be passed along to the PTO. This would be easily accomplished if FDA approval precedes PTO approval. However, a new process must be created if the FDA approval comes after the PTO grants a patent. A new FDA reexamination could be created where FDA information is passed back to the PTO for a team of examiners to determine if the PTO should reopen prosecution. This FDA reexamination process could be confidential until the PTO determines if the patent is valid or invalid. The process could mirror ex parte reexamination.

This new FDA reexamination process would not suffer from the problems associated with the current inequitable conduct rules. First, this process would occur automatically after the FDA approves a drug, which would mean that no "pleading with particularly" is necessary. Second, this patent and the FDA information would be examined by experts in both the law and scientific evidence associated with drug patents. Finally, there would be no mens rea element necessary because the process would happen sua sponte at the PTO.