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Federal Circuit Provides Additional Guidance for Induced Infringement in Hatch-Waxman Cases

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On November 9, 2017, the Federal Circuit confirmed that the overall content of a generic drug manufacturer's labeling, as well as real-world evidence of physician practices, inform the induced infringement analysis in Hatch-Waxman cases. *Sanofi v. Watson Labs. Inc.*, No. 2016-2722 (Fed. Cir. Nov. 9, 2017). Specifically, Chief Judge Prost and Circuit Judges Wallach and Taranto unanimously affirmed the District Court of Delaware's trial finding of inducement based on various sections of the proposed product labeling, as well as expert testimony that showed how actual practices were consistent with the labeling. *Sanofi v. Watson*, slip op. at 10-16. In addition, the Federal Circuit held that there was "no legal or logical basis" for limiting inducement liability where the pharmaceutical product has substantial noninfringing uses permitted by the product labeling. *Id.* at 15-16. As explained in further detail below, this decision provides practitioners with additional guidance for evaluating infringement of pharmaceutical method-of-use patents.

I. Background of the Decision

Multaq® is an antiarrhythmic medication sold by Sanofi. *Id.* at 2. The active ingredient in Multaq® is a chemical compound called dronedarone. *Id.* The underlying patent infringement action was precipitated by Watson Laboratories Inc. ("Watson") and Sandoz Inc. ("Sandoz") when they submitted Abbreviated New Drug Applications ("ANDAs") seeking to market generic dronedarone tablets. *Id.* Sanofi sued Watson and Sandoz for infringement of two patents, including U.S. Patent No. 8,410,167 ("the '167 patent"). *Id.* The '167 patent claims methods of reducing cardiovascular hospitalization by administering dronedarone to a class of patients with certain medical histories and various cardiovascular risk factors. *Id.* at 1, 8-9. After a three-day bench trial, the district court found, among other things, that Watson's and Sandoz's proposed sale of their generic products, with their proposed labeling, would induce physicians to infringe all but one asserted claim of the '167 patent. *Id.* at 3.

II. The Federal Circuit's Affirmance on Induced Infringement

A party is liable for infringement if it directly infringes a patent, such as by selling or using the patented invention without authority, or if it indirectly infringes the patent, such as by actively inducing another to infringe the patent. In the pharmaceutical industry, drug manufacturers generally do not themselves practice patented methods of using drugs. Instead, patented methods of using drugs may be practiced by healthcare providers, such as physicians, or by patients who purchase drug products from drug manufacturers. As a result, a patent holder typically relies on a claim of inducement in order to enforce of method-of-use patents against another drug manufacturer.

Liability for induced infringement exists if an inducing party possesses a specific intent to encourage another's acts while knowing that these acts constitute direct infringement of a patent. *Id.* at 10-11. The "specific intent" of the inducing party may be established by circumstantial evidence. *Id.* at 12-13. This includes encouragements, recommendations, or promotions in the labeling that accompanies the marketing of a drug. *Id.* at 13. Notably, Watson and Sandoz disputed the existence of the "specific intent" element, but not the "knowledge" element of induced infringement. *Id.* at 11.

In affirming the district court's decision, the Federal Circuit found that the "Indications and Usage" section of the drug labeling states which patient populations are covered by the FDA-approved indication. *Id.* at 13-14. The Federal Circuit further noted that the "Indications and Usage" section, by way of a parenthetical reference, expressly directs a reader to the "Clinical Studies" section for elaboration of the patient population. *Id.* at 14. The Federal Circuit also found that the "Clinical Studies" section features a leading subsection that describes a clinical trial called "ATHENA". *Id*. The ATHENA trial is the only clinical trial that supported the approved indication and it identified a class of patients with the same risk factors that are claimed in the '167 patent. *Id.* In addition, the Federal Circuit found that the "Clinical Studies" section also describes two other clinical trials, both of which serve as a "negative warning" about patient risk factors. *Id.* Taken together, the Federal Circuit found that the "label thus directs medical providers to information identifying the desired benefit for only patients with the patent-claimed risk factors." *Id.*

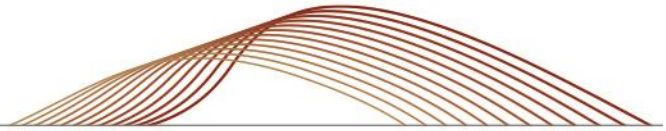
Significantly, the Federal Circuit also found that expert testimony confirmed that physicians look to drug labeling for information about the use of drugs in specific populations, and that approximately 77% of Multaq® prescriptions were written for patients with the claimed risk factors. *Id.* at 14-15. In light of this real-world evidence, the Federal Circuit concluded that the "content of the label in this case permits the inference of specific intent to encourage the infringing use." *Id.* at 16. The Federal Circuit noted that "inducement law permits the required factual inferences about intended effects to rest on circumstantial evidence in appropriate circumstances." *Id.*

Watson and Sandoz further argued on appeal that the labeling for Multaq® permitted substantial noninfringing uses and therefore the district court could not find intent to encourage an infringing use. *Id*. at 15. The Federal Circuit resoundingly rejected this contention, stating that there is "no legal or logical basis" for limiting inducement as argued by Watson and Sandoz. *Id*. at 15-16. As the Federal Circuit aptly noted, Section 271(b), which concerns inducement, does not contain the "substantial noninfringing use" restriction of Section 271(c), which concerns contributory infringement. *Id*. at 15.

III. Practical Takeaways

Sanofi v. Watson confirms that the drug product labeling as a whole may be used to support a claim of induced infringement. Traditionally, district courts have relied on explicit instructions in the drug labeling, typically found in the "Indications and Usage" and "Dosage and Administration" sections, to evaluate whether a drug manufacturer intends to encourage patients and/or healthcare providers to perform infringing acts. The Federal Circuit's *Sanofi v. Watson* decision makes plain that, in appropriate circumstances, liability for induced infringement may exist when the overall content of the labeling infers a drug company's specific intent to encourage infringement. This guidance provides an important road map for enforcing method-of-use patents as new uses for drugs are discovered and with the explosion of targeted patient therapies.

Sanofi v. Watson also confirms what could constitute credible evidence in a suit for induced infringement of method-of-use patents. In presenting evidence of inducement to a court, practitioners



should take note of any internal references in a product's labeling. These references may establish a narrative that reflects of how healthcare providers are educated and how they are made aware of the uses and benefits of pharmaceutical products. In addition, expert testimony concerning how physicians and other healthcare providers read and understand the FDA-approved instructions and recommendations within a product's labeling cannot be overlooked in litigation. Further, actual data of physician practices coupled with supporting statements in product labeling can be compelling evidence.

Finally, *Sanofi v. Watson* highlights the importance of the clinical trial information included in a drug manufacturer's product labeling. The protocols and clinical study results, inclusive of positive and negative results as well as product safety information, can be important evidence of encouragement and may serve as a basis for inferring the intent of an accused generic drug manufacturer.

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If you have any questions concerning these developing issues, please do not hesitate to contact the following Paul Hastings lawyer:

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