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Federal Circuit Patent Bulletin: *Sanofi v. Watson Labs. Inc.*

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"[Where a label] directs medical providers to information identifying the desired benefit for only patients with the patent-claimed risk factors[, a court may] draw the required inducement inferences."

On November 9, 2017, in *Sanofi v. Watson Labs. Inc.*, the U.S. Court of Appeals for the Federal Circuit (Prost, Wallach, Taranto*) affirmed the district court's judgment that the defendants induced infringement of U.S. Patents No. 8,318,800 and No. 8,410,167, which related to the cardiovascular antiarrhythmic drug dronedarone that Sanofi markets as Multaq®, and that the '800 and '167 patents were not invalid for obviousness. The Federal Circuit stated:

Under 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." Here, the district court found, the inducing act will be the marketing by Watson and Sandoz of their generic dronedarone drugs with the label described above. And the induced act will be the administration of dronedarone by medical providers to patients meeting the criteria set forth in the '167 patent claims. "In contrast to direct infringement, liability for inducing infringement attaches only if the defendant knew of the patent and that 'the induced acts constitute patent infringement.'" Neither of those two knowledge requirements is disputed here. If and when Watson and Sandoz receive FDA approval and market dronedarone with the label at issue, they will know of the '167 patent (they already do) and that a medical provider's administration of the drug to the claimed class of patients is an act of infringement (which Watson and Sandoz do not dispute).

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The dispute in this case involves an aspect of the connection between the marketing and the medical providers' infringement that is different from the two knowledge requirements and is inherent in the word "induce" as it has been understood in this area. . . . The term "induce" means "[t]o lead on; to influence; to prevail on; to move by persuasion or influence." The addition of the adverb 'actively' suggests that the inducement must involve the taking of affirmative steps to bring about the desired result. . . . [F]or a court to find induced infringement, "[i]t must be established that the defendant possessed specific intent to encourage another's infringement." The court has articulated certain necessary conditions: the plaintiff must show "that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements." And the court has repeatedly explained that, for the finder of fact to find the required intent to encourage, "[w]hile proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice." When proof of intent to encourage depends on the label accompanying the marketing of a drug, "[t]he label must encourage, recommend, or promote infringement." . . . The label itself has a short "Indications and Usage" section, one sentence long. It states what dronedarone is indicated for: it "is indicated to reduce the risk of hospitalization for atrial fibrillation." . . . The label thus directs medical providers to information identifying the desired benefit for only patients with the patent-claimed risk factors. . . . On the record in this case, the district court could draw the required inducement inferences.

Watson and Sandoz contend that, because Multaq® has substantial noninfringing uses not forbidden by the proposed labels, the district court could not permissibly find intent to encourage an infringing use. But there is no legal or logical basis for the suggested limitation on inducement. Section 271(b), on inducement, does not contain the "substantial noninfringing use" restriction of section 271(c), on contributory infringement. . . . The content of the label in this case permits the inference of specific intent to encourage the infringing use. As noted above, inducement law permits the required factual inferences about intended effects to rest on circumstantial evidence in appropriate circumstances. . . . The evidence in this case supports the finding of intentional encouragement of infringing use and, therefore, of inducement.

Obviousness under 35 U.S.C. § 103 is a question of law based on underlying questions of fact. Watson and Sandoz accept the legal framework under which they had to establish that, as of February 2008, a person of ordinary skill in the art would have had a reasonable expectation that the processes claimed would succeed in their (claimed) aims, a factual issue. On appeal, Watson and Sandoz make no argument as to obviousness independent of their challenge to the district court's finding of no such expectation. We reject the contention that the district court adopted an incorrect legal standard on the issue, and we are unpersuaded that the district court was clearly erroneous in determining that Watson and Sandoz failed to prove the required reasonable expectation. . . . Although the evidence might well have supported the opposite finding, we cannot conclude that the district court clearly erred in its finding that Watson and Sandoz did not carry their burden of showing that a person of ordinary skill in the art in February 2008 would have had a reasonable expectation that dronedarone would succeed in reducing cardiovascular hospitalization in the ATHENA patient population. . . .

In seeking to reverse the finding of infringement of the '800 patent, Watson and Sandoz raise just one issue. They argue that the district court erred by failing to limit the claims of the '800 patent to exclude polysorbate surfactants. They point to the fact that, while prosecuting the parent application, which issued as U.S. Patent No.7,323,493, Sanofi amended the sole independent claims (hence all claims) so as expressly to exclude pharmaceutical compositions with a "polysorbate surfactant" from the claims of the '493 patent. Based on that amendment, Watson and Sandoz contend that Sanofi made a "prosecution disclaimer" that also limits the scope of the claims of the '800 patent, despite the absence of any limiting language in the '800 patent's claims. We review the district court's rejection of this prosecution-disclaimer argument de novo. We agree with the district court.

A prosecution disclaimer occurs "when a patentee, either through argument or amendment, surrenders claim scope during the course of prosecution." But "[w]hen the purported disclaimers are directed to specific claim terms that have been omitted or materially altered in subsequent applications (rather than to the invention itself), those disclaimers do not apply." "In general, a prosecution disclaimer will only apply to a subsequent patent if that patent contains the same claim limitation as its predecessor."

In this case, all that Sanofi did, in prosecuting the application that issued as the '493 patent, was to write an express limitation into the claims: "provided that the pharmaceutical composition does not contain a polysorbate surfactant." That language does not appear in the '800 patent claims at issue. As the district court noted, Sanofi did not argue during prosecution that the unamended claim language of the '493 patent, or the disclosed invention generally, excluded polysorbate surfactants. In these circumstances, the process in this case fit a familiar pattern: an applicant adopts an explicit claim-narrowing limitation to achieve immediate issuance of a patent containing the narrowed claims and postpones to the prosecution of a continuation application further arguments about claims that lack the narrowing limitation. Without more than exists here, that process does not imply a disclaimer as to claims, when later issued in the continuation, that lack the first patent's express narrowing limitation. We therefore affirm the district court's ruling that the scope of the claims of the '800 patent should not be limited so as to exclude polysorbate surfactants.