wiley

ALERT

Federal Circuit Patent Bulletin: *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*

May 7, 2015

"[I]nstructions need to evidence 'intent to encourage infringement.' The question is not just whether instructions 'describ[e] the infringing mode,' but whether the 'instructions teach an infringing use of the device such that we are willing to infer from those instructions an affirmative intent to infringe the patent.'"

On May 6, 2015, in *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, the U.S. Court of Appeals for the Federal Circuit (Newman, Dyk,* Hughes) affirmed the district court's denial of Takeda's preliminary injunction motion seeking to enjoin Hikma from launching Mitigare, its generic version of Takeda's Colcrys, and infringing U.S. Patents No. 7,964,648, No. 7,981,938, No. 8,097,655, No. 8,440,722, and No. 7,964,647, which related to treating gout with colchicine products. The Federal Circuit stated:

In general, a party seeking a preliminary injunction must establish that it is likely to succeed on the merits, that it is likely to suffer irreparable harm in the absence of relief, that the balance of equities is in its favor, and that an injunction is in the public interest. . . .

Congress intended "that a single drug could have more than one indication and yet that [an] ANDA applicant could seek approval for less than all of those indications." A patent certification such as a Paragraph IV certification need not be provided "for a patent

Authors

Lawrence M. Sung
Partner
202.719.4181
lsung@wiley.law

claiming a use for which the ANDA applicant is not seeking approval." In such a situation, a generic manufacturer may avoid infringement by proposing a label that does not claim a patented method of use, ensuring that "one patented use will not foreclose marketing a generic drug for other unpatented ones." . . .

Since Hikma did not seek FDA approval to market Mitigare for treatment of acute gout flares, Mitigare's label stated that Mitigare is "indicated for prophylaxis" and that the "safety and effectiveness of [it] for acute treatment of gout flares during prophylaxis has not been studied." The label also said that "[i]f you have a gout flare while taking [Mitigare], tell your healthcare provider." Takeda argued that this latter statement induced infringement because, in the case of the patient taking Mitigare for prophylaxis, the physician would likely tell the patient to use the Mitigare product to treat the acute flare. The district court concluded that the latter instruction was not sufficient to establish induced infringement. We agree.

"Whoever actively induces infringement of a patent shall be liable as an infringer." "[The] sale of a lawful product by lawful means, with the knowledge that an unaffiliated, third party may infringe, cannot, in and of itself, constitute inducement of infringement." The accused infringer must have "knowingly aided and abetted" direct infringement. [T]here is no indirect infringement "when a defendant merely sells a commercial product suitable for some lawful use." Infringement only exists where there is evidence that "goes beyond a product's characteristics or the knowledge that it may be put to infringing uses." Inducement can be found where there is "[e]vidence of active steps taken to encourage direct infringement," which can in turn be found in "advertising an infringing use or instructing how to engage in an infringing use." But such instructions need to evidence "intent to encourage infringement." The question is not just whether instructions "describ[e] the infringing mode," but whether the "instructions teach an infringing use of the device such that we are willing to infer from those instructions an affirmative intent to infringe the patent." Merely "describ[ing]," an infringing mode is not the same as "recommend[ing]," "encourag[ing]," or "promot[ing]," an infringing use, or suggesting that an infringing use "should" be performed. . . .

The principles that can be distilled from these cases are applicable in the Hatch-Waxman Act context where, as here, it is alleged that the drug label induces infringement by physicians. The label must encourage, recommend, or promote infringement. The mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient for inducement. "[M]ere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." This requirement of inducing acts is particularly important in the Hatch-Waxman Act context because the statute was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses.

Takeda concedes that mere knowledge of off-label infringing uses of Mitigare's product would not establish inducement. Similarly insufficient is Hikma's knowledge, acquired from the FDA, that colchicine is used to treat acute gout flares. The FDA has previously told healthcare providers to prescribe Colcrys for acute gout flares, and the FDA told Hikma that "it may be natural for the provider to use [Mitigare] for acute treatment." So too the guidelines from the American College of Rheumatology ("ACR") that recommend prescribing Colcrys for acute gout flares are irrelevant to the question of inducement. All of this, without more, is mere knowledge of infringing uses and does not establish inducement.

But Takeda argues that Mitigare's label, though indicated only for prophylaxis of gout, induces infringement by stating that "[i]f you have a gout flare while taking Mitigare, tell your healthcare provider." Although this is neither an explicit nor implicit instruction to take Mitigare for acute gout treatment, Takeda argues that the instruction to "tell your healthcare provider" will "inevitably" lead to physicians who are consulted to advise patients taking Mitigare for prophylaxis to simply increase their dose of Mitigare to treat acute gout flares, and that Hikma was aware of or willfully blind to this possibility. Hikma argues that the label's statement that the "safety and effectiveness" of Mitigare "for acute treatment of gout flares during prophylaxis has not been studied" bars a finding of inducement . . . . We need not address whether or not lack of approval language precludes a finding of inducement.

Given the statutory scheme explained above, vague label language cannot be combined with speculation about how physicians may act to find inducement. This would seem to too easily transform that which we have held is "legally irrelevant,"- mere knowledge of infringing uses-into induced infringement. But we need not decide whether evidence as to the invariable response of physicians could ever transform a vague label into active encouragement. Here, even if we do look outside the label, there is no evidence that the label would necessarily lead doctors who are consulted by patients taking Mitigare to prescribe an off-label use of it to treat acute gout flares.