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Vague Drug Label Instructing Physician Consultation is Insufficient to Find Induced Infringement

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In upholding the denial of a preliminary injunction, the Federal Circuit held that a drug manufacturer's label instructing the use of a generic drug for prophylactic use coupled with an instruction to consult a physician in the event of an acute condition arising is insufficient to find induced infringement. *Takeda Pharmaceuticals U.S.A., Inc. v. Hikma Americas, Inc.* 15-1139 (Fed. Cir., May 6, 2015) (Judge Dyk, authoring the majority opinion).

The Court stated that where it is alleged that a drug label induces infringement by physicians, "[t]he label must encourage, recommend, or promote infringement." The existence of direct infringement by physicians, while a necessary element in finding liability, is not sufficient for inducement. Citing its decision in *Warner-Lambert Co. v. Apotex Corp*., 316 F.3d 1348, 1364 (Fed Cir. 2003), the Court noted that "mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." The Court further stated that this principle was "particularly important" in the Hatch-Waxman 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."

The patents at issue relate to methods of administering colchicine products to treat gout. Colchicine itself is not covered by the patents, having been in use for centuries. The "acute-gout patents" are directed to methods of treating acute gout flares, involving a specific timed dosage of colchicine.

Hikma received FDA approval to market its drug Mitigare, a colchicine capsule for prophylaxis of gout flares. Hikma did not seek FDA approval for any use of colchicine covered by the patents. Mitigare's label stated that the drug 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 stated that "[i]f you have gout flare while taking [Mitigare], tell your healthcare provider." The Court found as irrelevant to the question of inducement the fact that Hikma had knowledge that colchicine is used to treat gout flares, that the FDA had previously told healthcare providers to prescribe the patent owner's drug for gout flare, that the FDA told Hikma that it may be natural for the provider to use Mitigare for acute treatment, and that the American College of Rheumatology (ACR) recommended the use of the patent owner's drug for acute gout flare. The Court concluded that these facts amounted only to knowledge of infringing uses and not inducement. The Court also rejected the patent owner's argument that the instruction to "tell your healthcare provider" in the event of gout flare would inevitably lead to physicians to increase the dose of Mitigare to treat acute gout flare because it relied on speculation about how physicians may act to find inducement.

The court declined to rule on whether evidence of an inevitable response of physicians could ever transform a vague label into active encouragement. The decision leaves open the possibility of establishing inducement where a drug label instructs physician consultation and there is evidence of an

inevitable response of physicians to prescribe an off-label infringing use.

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