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Federal Circuit Affirms Skinny Label Carve Outs

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In *H. Lundbeck A/S, et al. v. Lupin Ltd., et al.*, Nos. 2022-1194, 2022-1208, and 2022-1246 (December 7, 2023), the Federal Circuit held that generic pharmaceutical companies may continue to use skinny labels to avoid infringement of method of treatment claims as long as they do not engage in advertising or promotional activities that encourage infringement of the patents.

This case affirms settled law that had become somewhat uncertain due to the Federal Circuit's 2021 *Glaxo* opinion. The Federal Circuit explicitly limited its holding in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 7 F.4th 1320, 1333 (Fed. Cir. 2021) to situations in which a generic pharmaceutical company engages in advertising or promotional activities for an infringing use. In the absence of such advertising or promotional activities, 21 U.S.C. § 355(j)(2)(A)(viii) ("section viii") allows carving out infringing uses from generic labels.

Background

A number of generic pharmaceutical companies (collectively, "Defendants") filed Abbreviated New Drug Applications ("ANDAs") to market generic versions of the Trintellix® antidepressant. The approved NDA is held by Takeda Pharmaceuticals U.S.A., Inc.

Plaintiffs (H. Lundbeck A/S, Takeda Pharmaceutical Company Ltd., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International AG, and Takeda Pharmaceuticals America, Inc.) sued to enjoin Defendants from marketing generic versions on the basis of inducing and/or contributorily infringing various patents, including U.S. Patent Nos. 9,278,096 (the "'096 patent") and 9,125,910 (the "'910 patent"). The '096 patent claims using vortioxetine (the active ingredient in Trintellix®) in patients who have previously taken certain other antidepressants and had to cease due to sexually related adverse events ("TESD" or "Treatment Emergent Sexual Dysfunction"). The '910 patent claims using vortioxetine to treat cognitive impairment.

Plaintiffs appealed the district court's determination that defendants' ANDAs did not infringe either patent following a bench trial. Some of the defendants conditionally cross appealed the district court's judgment that the two patents are not invalid. Additionally, Lupin Ltd. and Lupin

Pharmaceuticals, Inc. (collectively, “Lupin”) cross appealed the district court’s finding that their ANDA infringes Plaintiff’s U.S. Patent No. 9,101,626 (the “’626 patent”) that covers a process for making vortioxetine.

Issue(s)

Whether section 271(e)(2)(A) of the Hatch-Waxman Act creates a separate cause of action that does not require a showing of direct, induced, or contributory infringement by the ANDA filer.

Whether infringement can be found because clinicians will allegedly prescribe the generic medication for uses claimed in the ’096 and ’910 patents.

Holding(s)

Judgment of non-infringement by all defendants of the ’096 and ’910 patents was upheld.

Judgment of infringement by Lupin of claim 12 of the ’626 patent was upheld.

Reasoning

The Federal Circuit stated that precedent, including *Warner-Lambert* and its progeny, established that “‘the use . . . claimed in a patent’ under section 271(e)(2)(A) must be the use for which an applicant is seeking marketing approval” in order to find infringement. *Lundbeck v. Lupin* at 12.

The Federal Circuit distinguished this case from *Glaxo*. *Id.* at 14. In *Glaxo*, the Court found infringement even though Teva submitted a section viii carve out statement, on the ground that Teva used marketing and promotional materials to advertise infringing uses of its generic drug. *Id.* In contrast, in the present case the Court found that “plaintiffs’ inducement case relied solely on Defendants’ proposed ANDA labels as the inducing conduct. … [P]laintiffs did not identify any advertising or promotional materials that encouraged infringement.” *Id.* The Federal Circuit concluded that, “it cannot be, as plaintiffs’ suggest, that a patentee can bar the sale of a drug for a use covered only by patents that will have expired simply by securing a new patent for an additional, narrower use.” *Id.*

Here, the labels described only one indication—the treatment of Major Depressive Disorder (“MDD”) in adults. The Federal Circuit noted that Defendants’ ANDA labels carved out “the superiority data in the clinical studies portion of the label and the cross-reference to that data” without “even referenc[ing] the patient class recited” in claim 7 of the ’096 patent. *Id.* at 16-17. Thus, the generic labels carved out, pursuant to section viii with FDA approval, the TESD and cognitive impairment indications that are covered by the ’096 and ’910 patents.

The Court rejected Plaintiffs’ contributory infringement claim based on knowledge of possible infringement. Plaintiff’s argument defies the purpose of the Hatch-Waxman Act to allow “the sale of drugs for unpatented uses even though those sales result in some infringing uses” and the “additional requirement that there be no substantial non-infringing use” in order to find infringement. *Id.* at 18. The Federal Circuit further found that the district court did not err in relying on evidence about recommended doses in addition to evidence that applies to all doses to find no contributory infringement under 35 U.S.C. § 271(c). *Id.* at 18-19. Additionally, the Federal Circuit found no error in the district court’s reliance on “the existence of substantial non-infringing uses to find no contributory infringement.” *Id.* at 20, 19-21.

Finally, the Federal Circuit affirmed the district court's construction of "reacting" due to a lack of intrinsic evidence supporting Lupin's narrow proposed construction to affirm the finding of infringement of the '626 patent.

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