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Axinn IP Update: Where is the Federal Circuit Heading in the Skinny Labeling Case?

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ATTORNEYS

Landmon, Chad

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Intellectual Property

Chad Landmon
Axinn Update

The Federal Circuit held a rehearing last week in *GlaxoKlineSmith LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347 (Fed. Cir. 2020) (No. 18-1976).

In October 2020, the Federal Circuit had issued a divided opinion vacating the District Court's decision to set aside the jury verdict against Teva for induced infringement. The reason the District Court had set aside that jury's verdict was, in view of Teva's skinny label, "there [was] not legally sufficient evidence to support a finding that Teva, by listing its carvedilol as AB rated to Coreg® in product catalogs and reference guides, encouraged infringement."

The Federal Circuit's opinion received harsh criticism from many generic firms and other commentators, each expressing fears that it effectively eliminates the practice of skinny labeling. Even former Congressman Waxman filed an amicus brief warning that "[t]he Majority opinion, if left standing, 'would allow a pioneer drug manufacturer to maintain de facto indefinite exclusivity over a pharmaceutical compound by obtaining serial patents for approved methods of using the compound and then wielding [the threat of infringement actions] "as a sword against any competitor's [application] seeking approval to market an off-patent drug for an approved use not covered by the patent."'" Brief of Amicus Curiae Former Congressman Henry A. Waxman in Support of Petition for Rehearing En Banc [Corrected] at 10, Appeal No. 18-1967 (second and third alterations in original) (quoting *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012)). A few weeks ago, when the original three-member panel of the Federal Circuit granted the rehearing, many hoped it was a sign that this controversial precedent would quickly be reversed. But, if last week's rehearing is any indication, the practice of skinny labeling may not be out of the woods yet.

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Based on questions/remarks at the rehearing, it seems neither Judge Newman (author of the majority opinion) nor Chief Judge Prost (author of the dissent) has significantly changed her views. For example, Judge Newman voiced her concerns that any type of skinny labeling undermines the incentive for branded pharmaceutical companies to conduct further clinical trials to secure additional indications for already-approved products. Setting aside the fact that Congress already addressed such concerns when the Hatch-Waxman Act was drafted and enacted in 1984, Judge Newman's remarks suggest that she still believes there was substantial evidence to support the jury's findings of induced infringement. And on the other side of this issue, it was clear from Chief Judge Prost's questions/remarks that she still holds the views expressed in her dissent. The fate of the practice of skinny labelling, then, likely lies in the hands of Judge Moore.

While Judge Moore's questions/remarks at the rehearing suggest she may be willing to take a more nuanced approach than that espoused in the majority opinion she previously joined, Judge Moore nonetheless showed a willingness to entertain second-guessing of the content of a generic's skinny labeling. For example, Judge Moore challenged GSK's counsel to admit that marketing statements that merely mention "AB-rating," "therapeutic equivalence," and the reference listed drug "Coreg" are not enough—by themselves—to show induced infringement. Yet Judge Moore repeatedly stressed that the Court is not the arbiter of whether a branded pharmaceutical company properly or fully complied with FDA's rules requiring identification of the language in the drug label that is covered by patents. By stressing that a brand company's sworn statements made pursuant to FDA rules are not dispositive in a patent infringement case, and even characterizing those rules as a "sideshow," Judge Moore struck at the heart of the skinny labeling process: the public's (including FDA and generic applicants) reliance on a branded pharmaceutical company's assertions of which parts of its label are and are not patent protected. In response, Chief Judge Prost queried, without any follow-up, whether such reliance affects intent.

The reason we think the practice of skinny labeling may not yet be out of the woods is because most of the colloquy at the rehearing focused on Teva's actions (e.g., distributing press releases, including information in product catalogues) rather than Teva's intent. It is axiomatic that "*specific intent* and action to induce infringement must be proven." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003). But if reliance on the brand pharmaceutical company's sworn statements to FDA about

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which language must be omitted from a generic's label in order to avoid patent infringement is *not* sufficient to rebut a finding of specific intent, then every section viii carve-out will create the same risk of patent litigation as a Paragraph IV certification. The practical effect may be to curtail the practice of skinny labelling, thereby frustrating Congress's intent in enacting section viii in the first place.

Axinn is continuing to monitor the case closely and will provide further updates on notable developments.

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