Generic Skinny labels and Pioneer Secondary Patents Impact on Pharmaceuticals

By Kurt Jacobs

In the world of pharmaceuticals, generic drugs are encouraged as a means to decrease the cost of medications. The Hatch-Waxman act was developed to balance incentives for both pioneer and generic drugmakers.[1] The Hatch-Waxman act provides an abbreviated route for generic drug approval.[2] Abbreviated new drug application (ANDA) allows generic drugs to get through FDA approval and enter the market once the pioneer drug's patents have expired. It allows the use of the pioneer drug's approval to significantly reduce the costs of the FDA approval, which has incentivized more generic drugs.[3]

However, this process can be hindered when pioneer drugs receive secondary patents which effectively prolong a drugs patent protection beyond the life of the original patent.[4] This is often called patent evergreening, or is associated with patent thickets. The concern with evergreening is that the scientific and industrial benefits of secondary patents are seemingly minor compared to the societal costs of patent exclusivity. In an ideal patent system, all improvement should be incentivized, while unnecessary exclusion of competition should be minimized.

Our current patent system does allow for generic drug use for older inventions with expired patent terms. And the secondary patents that are problematic are able to be challenged in the USPTO review processes.[5] But frequently the secondary patents are not challenged. Often because patent challenges are considered cost prohibitive or are ineffective against drugs with a thicket of patents protecting them.[6]

Instead, skinny labels are used where the drug approval is based on usage for the expired patent applications only. IP protections are intended to work this way, when patents expire, they become publicly available. But skinny labels in the context of known generic bioequivalence to the pioneer drug, and state laws requiring generic preference can combine to encourage off label usage which may infringe secondary, still active, patents.

When secondary patents are considered burdens, this type usage wouldn't be problematic to the general public, but this usage can still be detrimental. If secondary patents aren't respected, then the incentive for subsequent improvements on existing drugs disappears. This is not an ideal

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[1] *See, e.g.*, King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 394 (3d Cir. 2015).
[2] Pub. L. No. 98-417, 98 Stat. 1585 (1984).
[3] *See* CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (1998).
[4] *See* Julian W. Marrs, *Forever Green? An Examination of Pharmaceutical Patent Extensions*, 18 OR. REV. INT'L L. 81, 83-89 (2008).
[5] *See, e.g.*, 35 U.S.C. §§ 311-319 (inter partes review); *id.* §§ 321-329 (post-grant review).
[6] Chris Ratcliffe, *Drugmakers Undercut Rivals With New Patent Tactic as Law Shifts*, BLOOMBERG LAW (Oct. 26, 2021), https://news.bloomberglaw.com/health-law-and-business/drugmakers-undercut-rivals-with-new-patent-tactic-as-law-shifts.

outcome because researching into additional drug uses for developed drugs is still a valid, valuable, and costly endeavor which should be pursued. And in the context of patentability, developing a new medical use for an existing pharmaceutical can be a novel ground for patentability[7].

While skinny labeling may provide a means to circumvent problematic secondary patents, it is still non-ideal because secondary patents can be societally valuable and alternatively because it makes challenging secondary patents a disfavored option. This combination contributes to problematic secondary patents remaining in force and discouraging potentially innovative secondary patents.

[7] *See, e.g.*, Christopher M. Holman, *In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination*, 50 IND. L. REV. 759, 760-61 (2017).