Patents on New Drugs and Inducing Infringement

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In the recent case of *Warner-Lambert v. Apotex*, the Federal Circuit was faced with interesting patent infringement questions involving elements of an expired patent on an approved drug, an expired patent on an FDA approved use of a drug, an ANDA filing, a (patented) off-label use of the approved drug, and whether one induces another to infringe by selling a product that likely will be used in an infringing manner. This case could be relevant for any drugs that have multiple patented uses with patents that expire at different times.

Background on the Hatch-Waxman Act

The history of the Hatch-Waxman Act (The Drug Price Competition and Patent Term Restoration Act of 1984) is the story of competing interests of drug development pharmaceutical companies and the generic drug industry. The Hatch-Waxman Act was designed to reconcile two seemingly contradictory policy goals:

- to encourage and reward innovation to drug-developing pharmaceutical companies, and
- to facilitate competition from the generic drug industry.

The Act recognized the balancing of interests between the patent owners of a drug patent to obtain partial restoration for time lost on the patent term due to regulatory delays in the FDA and the interests of the generic drug companies to conduct pre-market testing in support of a generic copy of a brand name drug before the patent expired on the drug.

To balance these competing interests, the Hatch-Waxman Act included:

- a process to extend the term of a patent to compensate for the length of time it took a New Drug Application (NDA) to gain approval from the FDA, and
- the creation of an Abbreviated New Drug Application (ANDA) process for generic drug developers to obtain FDA approval of a generic copy of an approved drug by showing bioequivalence—an ANDA did not require preclinical and clinical data to establish safety and effectiveness, but could rely on the data developed from the NDA.

The *Roche Products* case prompted the Hatch-Waxman Act when the Federal Circuit decided in 1984 that a generic drug company infringed a patent, even if the company's use of the patented drug was only for the purpose of beginning bioequivalency testing on the drug. In response, the Hatch-Waxman Act provided a safe harbor: under the Act, it is not an act of infringement to "make, use, offer to sell, or sell within the United States or import into the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."

In addition to exempting these development efforts, the Hatch-Waxman Act allows a generic drug company to file an ANDA to obtain marketing approval on the approved drug before the patent expires. If a generic drug company chooses this route, the Hatch-Waxman Act states that it is an act of infringement to submit an ANDA for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product "claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

Patented and Non-Patented Uses

Warner-Lambert's patent on the drug at issue, Neurontin® (gabapentin) had expired, but it still had patent protection for the FDA-approved use of gabapentin to treat epilepsy. Apotex filed an ANDA seeking approval to market a generic copy of gabapentin when Warner-Lambert's patent on a

method of treating epilepsy with gabapentin expired. Warner-Lambert asserted that Apotex's submission nonetheless constituted an infringement —because of another patent it owned—on using gabapentin for treating neurodegenerative diseases. As proof of infringement, Warner-Lambert provided evidence that a majority of the sales of gabapentin were for off-label uses, including the treatment of neurodegenerative diseases.

The Federal Circuit interpreted the Hatch-Waxman Act as requiring that either the *drug itself* or the *use for which approval is sought* must be claimed in a non-expired patent for the ANDA filing to be an act of infringement. Thus, the Federal Circuit held that it is not an act of infringement to submit an ANDA when both the patent on the drug and the patent on the approved use have expired, even when there is an active patent covering a non-approved use of the drug. Further, the Federal Circuit pointed out that if Warner-Lambert's point of view were to be followed, then the original new drug developer could prolong its exclusivity over a drug simply by filing new patent applications claiming narrower methods of use not covered by the original NDA, and not approved by the FDA. This interpretation would run counter to Congress' stated intention of expediting generic drug developers' entry into the market by passing the Hatch-Waxman Act.

Apotex's ANDA certified that its labeling would not include any indication claimed by the non-expired patent, but the Federal Circuit stated that this certification was not even required because the ANDA was not seeking approval for that particular use.

This decision by the Federal Circuit may have far-reaching consequences, since it is possible that no infringement by Apotex would have been found even if Warner-Lambert had obtained FDA approval for the use claimed in the non-expired patent, so long as Apotex's ANDA did not seek approval for the use claimed in that patent.

Inducement to Infringe

Warner-Lambert had an alterative theory that Apotex would induce

infringement of its non-expired patent by its submission of the ANDA, primarily because of the evidence of off-label use of gabapentin for the patented use for treating neurodegenerative diseases.

The Federal Circuit stated that it was reiterating its standard that one must have the specific intent and action to induce infringement, and that mere knowledge of possible infringement by others does not amount to infringement. Simply filing an ANDA for approval to make and sell a drug labeled with a previously approved and off-patent use cannot reasonably be interpreted as an act of infringement (inducement or otherwise), since the ANDA does not induce anyone to perform the unapproved acts needed to infringe.

Such an act to induce infringement can only be determined when and if that occurs (i.e., after the generic drug is approved and enters the market). For example, Apotex could induce infringement if its representatives were encouraging doctors to prescribe for the still-patented use.

Thus, the Federal Circuit held that in the situation in which a product has substantial noninfringing uses (e.g., an FDA-approved, off-patent use), intent to induce infringement cannot be inferred even when there is actual knowledge that some users of the product may be infringing the patent.

A patentee of a drug could, in theory, sue doctors who prescribe a competitor's drug for the patented use, or could even sue patients for infringing use of the drug if they used the competitor's drug for the patented use. A patentee pharmaceutical company might be reluctant to take such steps.

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