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BATTLE BETWEEN BIG PHARMA AND GENERICS

There is a movement afoot to reform the system enacted to address patent disputes between pioneer drug developers and their generic drug competitors. When this system, referred to as the Hatch-Waxman Act, was passed in 1984, it was intended to balance the competing interests of pioneer pharmaceutical manufacturers and the generic drug industry. Critics of the amendments say they have set the stage for near-obligatory litigation between pioneer pharmaceutical companies and generic drug companies before the launch of nearly every new generic drug. With the huge growth in the generic drug industry, the result is an intensely competitive pharmaceutical market where life and death battles are fought in the courts. Certain reforms will more equitably balance the policies of the patent system, and assist in delivering cheaper drugs.

AUTOMATIC ACTION

Generic manufacturers can bypass much of the FDA approval process for a new drug by filing an abbreviated new drug application (ANDA). Under patent law, however, the very act of submitting an ANDA can automatically create a cause of action for infringement. Once an infringement suit is filed, the generic drug company automatically is stayed from marketing the generic product for at least 30 months.

The voices for reform see the automatic stay as an opportunity for abuse because it provides an incentive for pioneers to sue, even if the suit is groundless, or of doubtful merit. While the lawsuit is pending, pioneer drug companies maintain exclusivity in the market, and the generic is kept out of the market. Consequently, the FTC and state attorneys general are investigating and pursuing allegations of antitrust violations stemming from efforts perceived to unfairly prevent generic products from entering the market.

SUPPORT FOR REFORM

Recently, support for reform has gained a substantial boost from an influential coalition of businesses and special interest groups known as Business for Affordable Medicine (BAM). The corporate members in BAM include companies such as General Motors, Wal-Mart, Georgia Pacific Corp., and Verizon Communications, who argue that the automatic stay costs millions of dollars annually in continued payments for brand-name prescription drug coverage for employees.

There is no dispute that the Hatch-Waxman Act has increased litigation. Since 1984, the number of patent infringement cases between pioneer and generic manufacturers has increased dramatically. For the first 10 years, just 30 cases were decided. In 2001 alone 32 cases were decided, and in just the first five months of 2002, there have already been 17 cases decided. The numbers in the Court of Appeals for the Federal Circuit are similar — two in the first 10 years; 14 in the next five; seven in 2001 alone; and three already decided in 2002.

An overall analysis from 1984 to 2002 shows a distinct trend in appellate decisions rendered on patent infringement suits involving generics and big pharmaceuticals. From 1989 to 1996, the Federal Circuit found in favor of the pioneer manufacturers in the first six cases decided on appeal. Since 2001, however, the numbers are nearly the opposite. The Federal Circuit has found clearly for the generic drug companies in seven of the 10 cases decided on appeal from 2001 until the present, and only once for the pioneer drug companies. Two cases were returned to the district courts for further review.

Considering the tremendous resources expended and the substantial risks borne to bring every successful new drug to market, it is understandable that pioneer drug makers seek to extend their effective patent terms by any means available. In some cases, pioneer-drug companies have received only a few years of exclusivity before generic drug manufacturers were eligible to enter the market, despite the current system for providing patent-term extensions. Nonetheless, critics claim these circumstances do not justify allegedly frivolous lawsuits, brought merely to invoke the automatic 30-month stay.

FINDING AN EQUITABLE SOLUTION

One solution, supported by the critics, is to make litigation under Hatch-Waxman more like regular patent infringement cases: repeal the 30-month automatic stay, and force the pioneer maker to prove the case for an injunction to prevent the generic from entering the market. If the automatic stay is eliminated, the incentive for de facto litigation would be removed.

To address the concern of short periods of exclusivity, a special status may be provided for pioneer drugs, in which the patent term begins counting from the date of FDA approval. The term could be a minimum of somewhere between seven to 12 years, or some other reasonable number of years that reflects the average effective life of patents in other fields. This appears to be an equitable solution for all parties.

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