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NONINFRINGEMENT SALES OF INFRINGING MEDICAL DEVICE *LILLY v. MEDTRONICS*

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Certain sales of medical devices, which would otherwise infringe an existing patent are, according to the Supreme Court, not infringing sales. *Eli Lilly and Company v. Medtronic, Inc.*, Case No. 89-243, (Sup. Ct.) June 18, 1990. The decision could have a far-reaching effect on manufacturers who produce products subject to review by the FDA prior to the issuance of a right to market. Based on this decision a medical product manufacturer can now start evaluation of devices solely for the purpose of FDA approval before a patent covering the product expires. This could move product introductions forward by three to five years.

BACKGROUND

In 1984, the Federal Circuit heard the case of *Roche Products, Inc. v. Bolar Pharmaceutical*. (733 F.2d 858, 221 USPQ 937). An action for patent infringement had been brought against Bolar, a generic drug manufacturer, for conducting testing required by the FDA to gain approval for marketing. This testing took place before the expiration of Roche's patent. Bolar argued that a prohibition of this testing until the expiration of the Roche patent would result in a de facto extension of the patent grant as it would take several years to obtain the FDA approval to market. The court ruled that the complained of experimental testing was a patent infringement under 35 U.S.C. 271(a). The court also indicated that Congress could best decide on how to best balance the interests of the patent holder and the consuming public.

Partly in response to *Roche v. Bolar* Congress, in 1984, enacted the Drug Price Competition and Patent Term Restoration Act (PTR Act) (98 Stat. 1535). Title I of the PTR Act established an expedited procedure for approval of generic equivalents of previously approved drugs (ANDA). Title II amended the patent laws by the addition of Section 156 which established guidelines for the extension of the term of patents covering medical devices, food additives, color additives and drugs which are subject to FDA regulatory delays. Title II also amended the patent laws by adding Section 271(e)(1) which is at issue in *Lilly v. Medtronics*.

35 U.S.C. 271(e)(1) states:

"It shall not be an act of infringement to make, use or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug and Cosmetic Act and the Act of March 4, 1912)) 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."

CASE HISTORY

Eli Lilly is the owner of U.S. Patent No. 3,942,536, issued March 9, 1976 and Reissue Patent 27,757, initially issued October 26, 1971, covering automatic implantable cardioverter defibrillators and catheter electrodes. Lilly applied for and received a two-year extension of Reissue Patent 27,757 under Section 156(b) so that its expiration date was changed from October 26, 1988 to October 26, 1990. Medtronics was charged with manufacturing and clinically testing several products allegedly within the scope of the Lilly patents. In the lower court, Medtronics brought a motion which the district court treated as a motion for summary judgment, claiming statutory non-infringement under 35 U.S.C. 271(e)(1) and (e)(3) on the basis that those statutes extend to medical devices tested under an FDA-approved Investigational Device Exemption. The lower court denied the motion and an order was entered precluding Medtronics from presenting any evidence at trial concerning this defense.

Eli Lilly v. Medtronic, Inc., 5 USPQ 2d 1760 (E.D.Pa. 1987). Judge Ditter found that the statute at issue applied only to drugs.

The United States Court of Appeals for the Federal Circuit reversed and remanded. *Eli Lilly and Company v. Medtronic, Inc.*, 10 USPQ 2d 1304 (March 29, 1989). The court found that the Roche holding, even though it addressed a drug product was not so limited.

Specifically, the court (in Roche) decided that the unlicensed use of a patented invention for testing and investigation, even though strictly related to obtaining FDA approval for a substitute, was an infringement under 35 U.S.C. 271(a). The clear intent of Congress was to create an FDA experimental use exception for use which Roche had held would constitute infringement under Section 271(a). *Id.* at 1306.

In support of this conclusion, the Appeals Court further stated:

No persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation. *Id.* at 1307.

The Supreme Court, in a decision rendered by Justice Scalia (6 to 2, Justice O'Connor abstaining) corrected two unintended distortions of the 17-year patent term which resulted from the government regulatory pre-market approval process. First of all, the owner of a patent would spend the early years of the 17-year patent protection gaining approval to market, thus, losing valuable sales and profits. Secondly, a de facto extension of the patent term existed as a competitor could not start the manufacturing or use of products for the FDA approval process until expiration of the patent. This could add at least three years competition-free years after the patent expires. It seemed implausible that Congress, being aware of the dual distortion, would choose to address the problem for drugs only and would, by granting devices a patent term extension without the FDA testing exclusions, give manufacturers of medical devices a monopoly far in excess of the 17-year patent grant. To balance the equities the court ruled that "patented inventions" covers all inventions and the phrase "a Federal law which regulates the manufacture, use, or sale of drugs" is a reference to the entire statutory scheme of regulation and not just the drug portions of that statute.

The case has been remanded to the trial court to determine if the allegedly infringing Medtronic manufacture, use and sales were "solely for uses reasonably related to the development and submission of information" to the FDA

DISCUSSION

The decision, while clarifying an issue of considerable concern to device manufacturers, still leaves open an issue. Section 271(e)(1), as interpreted by the court, does not restrict the timing of the FDA testing. Device manufacturers can charge customers for products during the clinical testing phase (21 CFR 812.7(b)) as long as that charge is not greater than that "necessary to recover costs of manufacture, research, development and handling." This can be quite lucrative for a so-called "generic device" manufacturer as he could sell a product and recover all his research and development investment without fear of infringing a patent. Nothing in the law would restrict those sales to the end of the patent term. Theoretically, the IDE could be abandoned upon completion of the clinical testing phase and a new IDE submitted for a modified product further extending the term of sales of competitive, noninfringing, but "patented" products. 35 U.S.C. 271(e)(2) makes it an act of infringement to submit an application under Section 505j of the Federal Food, Drug and Cosmetic Act (an abbreviated new drug application) for a drug claimed in a patent if the intent is to commercialize the drug prior to the expiration of the patent. There is no parallel restriction on devices; however, devices also do not have an abbreviated approval process similar to the ANDA. This issue is already under investigation. The FDA has announced it may withdraw an IDE approval or disallow data in support of an IDE if there is inappropriate commercialization of investigational devices. There is even a suggestion of an attempt to revoke Section 812.7(b).

CONCLUSION

Manufacture, use and sale of medical devices solely for uses reasonably related to the FDA approval process is not a patent infringement. Presently, there is no restriction as to when in the patent life this use can occur. There now exists a unique opportunity for a device manufacturer to sell products covered by a competitors patent.

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