**Eli Lilly & Co. v. Medtronic, Inc. - 496 U.S. 661 (1990)**

**(United States Supreme Court, June 18, 1990)**

Prepared by UNCTAD's Intellectual Property Unit

**Summary**

The Supreme Court held that the scope of the regulatory review exemption covers the use of patented inventions reasonably related to the development and submission of information needed to obtain marketing approval of medical devices under the Federal Food, Drug, and Cosmetic Act.

## The facts

In 1983, Eli Lilly filed an action against Medtronic in the United States District Court for the Eastern District of Pennsylvania claiming that Medtonic's testing and marketing of an implantable cardiac defibrillator (a medical device used in the treatment of heart patients) infringes its two related patents (United States Patent No. Re 27,757 and No. 3,942,536). Medtronic argued that its activities were "reasonably related to the development and submission of information under" the Federal Food, Drug, and Cosmetic Act (FDCA), and thus exempt from a finding of infringement under Section 271(e)(1) of the Drug Price Competition and Patent Term Restoration Act of 1984, which provides that:

> "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) … 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" (the 'regulatory review exemption' or 'the exemption' hereinafter).

The District Court rejected Medtronic's argument, concluding that the exemption does not apply to the development and submission of information relating to medical devices, thus Medtronic's activities infringe Eli Lilly's patents. The Court of Appeals reversed, holding that Medtronic's activities could not constitute infringement if they had been undertaken to develop information reasonably related to the development and submission of information necessary to obtain regulatory approval under the FDCA. On further appeal, the Supreme Court agreed to hear the case.

## The legal issues

The regulatory review exemption provides safe harbor from patent infringement claims for acts related to the development and submission of information required under a Federal law that regulates the manufacture, use, or sale of drugs. The main legal question in this case was whether the exemption covers medical devices or is limited to drugs.

The Supreme Court admitted that the statutory phrase "a Federal law which regulates the manufacture, use, or sale of drugs," is ambiguous. It held that, taking the action "under a

Federal law" suggests taking it in furtherance of or compliance with a comprehensive scheme of regulation rather than to refer to a particular provision of law. The 1984 Act was designed to remedy two unintended distortions of the standard patent term produced by the requirement that certain products receive premarket regulatory approval:

> (1) the patentee would, as a practical matter, not be able to reap any financial rewards during the early years of the term while he was engaged in seeking approval; and
>
> (2) the end of the term would be effectively extended until approval was obtained for competing inventions, since competitors could not initiate the regulatory process until the term's expiration.

To address the first distortion, the Act established a patent-term extension for patents relating to certain products (both drugs and devices) that were subject to lengthy regulatory delays and could not be marketed prior to regulatory approval. To address the second distortion, the Act adopted the regulatory review exemption, allowing competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval. Eli Lilly's argument would allow the patentee of a medical device or other FDCA-regulated nondrug product, such as food additives and color additives, to obtain the advantage of patent-term extension without suffering the disadvantage of the regulatory exemption. It is implausible that Congress, being demonstrably aware of the *dual* distorting effects of regulatory approval requirements (see (1) and (2), above), should choose to address both distortions only for drug products. As further evidence, the Act when excluding new animal drugs and veterinary biological products that are subject to FDCA premarketing approval, did so both for the patent term extension and regulatory review exemption.

There is, however, a specific section in the Act that provides for abbreviated new drug applications (ANDAs) and remedies for a certain type of patent infringement only with respect to drug products. Eli Lily relied on the ANDA section to suggest that the regulatory review exemption applies only to drugs. According to the Supreme Court, however, the section does not suggest that the ANDAs procedure is evidence that the regulatory review exception is applicable only to drugs.

ANDAs are required to provide certifications with respect to each patent named in the pioneer drug application that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. An applicant who makes such certification is required to give notice to the holder of the patent alleged to be invalid or not infringed, setting forth a detailed statement of the factual and legal basis for the applicant's opinion that the patent is not valid or will not be infringed. Approval of an ANDA containing such certification may become effective immediately only if the patent owner has not initiated a lawsuit for infringement within 45 days of receiving notice of the certification. If the owner brings such a suit, then approval may not be made effective until the court rules that the patent is not infringed or until the expiration of (in general) 30 months, whichever first occurs. This scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement. Thus, an act of infringement had to be created for these ANDA proceedings. Quite obviously, the

purpose is to enable the judicial adjudication upon which the ANDA schemes depend. It is wholly to be expected, therefore, that these provisions would apply only to applications under the sections establishing those schemes – which (entirely incidentally, for present purposes) happen to be sections that relate only to drugs, and not to other products.

The judgment of the Court of Appeals is affirmed.

**Points of Significance**

In 2005, in a separate proceeding, the Supreme court has affirmed that the regulatory review exception applies to pre-clinical trials, in as far as the trials are reasonably related to the development and submission of data required under Federal laws (See *Merck KGaA v. Integra Lifesciences I, Ltd., et al.*, 545 U.S. 193 (2005)[1]). The case at hand, taken together with the decision in *Merck KGaA v. Integra Lifesciences I,* broadens the application of the regulatory review exemption.

**Key words**: regulatory review exception, medical devices, patent term extension, abbreviated new drug applications (ANDA).

**Available at**: https://www.law.cornell.edu/supct/html/89-243.ZO.html

[1] See the summary of that decision in this database.