Roche Products Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 04/23/1984)

(United States Court of Appeals for the Federal Circuit, 23 April 1984)

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Summary

The Court of Appeals for the Federal Circuit (CAFC) ruled that the experimental use exception in US patent law is truly narrow. Where the subject matter of a patent is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind. But if the products of the experiment are sold, or used for the convenience of the experimentor, or if the experiments are conducted with a view to the adaptation of the invention to the experimentor's business, the acts of making or of use are patent infringements. This decision was taken prior to the introduction into US law of a new regulatory review exception under the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act").

Facts

Roche Products, Inc. (Roche) – a large research-oriented pharmaceutical company – was the assignee of the rights in a U.S. patent issued on January 17, 1967 that expired on January 17, 1984. The patent claimed flurazepam hydrochloride – the active ingredient in Roche's successful brand name prescription sleeping pill "Dalmane."

In early 1983, Bolar Pharmaceutical Inc – a manufacturer of generic drugs – became interested in marketing, after the patent expired, a generic drug equivalent of Dalmane. Bolar, not waiting for the patent to expire, decided to immediately begin its effort to obtain marketing approval for its generic Dalmane. The decision of Bolar was due to the fact that a generic drug's commercial success is related to how quickly it is brought on the market after a patent expires, and because its marketing approval from the United States Food and Drug Administration (FDA) can take more than 2 years. In order to submit its request for approval of the generic version of the drug, in mid-1983 Bolar obtained from a foreign manufacturer 5 kilograms of the active ingredient to develop the capsule dosage form of the drug, to obtain stability data, dissolution rates, bio-equivalency studies, and blood serum studies necessary for a New Drug Application (NDA) to the FDA.

Upon the complaint of Roche, on October 11, 1983, the United States District Court for the Eastern District of New York held that Bolar's use of the patented active ingredient for federally mandated testing was not infringement of the patent in suit because Bolar's use was *de minimis* and experimental. Roche filed its notice of appeal to the CAFC on the same day.

Legal Issues

According to the CAFC, the issue is narrow: does the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, may constitute patent infringement? Bolar claimed two grounds for exception justifying its use of the patented compound: the experimental use exception and the ground that public policy favors generic drugs and thus mandates the creation of a new exception in order to allow FDA required drug testing during the life of a patent. The CAFC rejected both grounds.

Experimental use defense

The CAFC argued that by 1861 the so-called experimental use defense was well-settled in that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is not an infringement of the rights of the patentee.

Along these lines, the CAFC elaborated that the interest of the patentee, though not always taking the shape of money, is of a pecuniary character. Where the subject matter of a patent is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind. But if the products of the experiment are sold, or used for the convenience of the experimentor, or if the experiments are conducted with a view to the adaptation of the invention to the experimentor's business, the acts of making or of use are patent infringements.

Bolar conceded that its intended use of the active ingredients did not fall within the "traditional limits" of the experimental use exception. Instead, it argued the experimental use rule deserved a broad construction.

The CAFC held that the experimental use exception is truly narrow, and that it will not expand it under the present circumstances. Bolar's intended "experimental" use was solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar's intended use of the active ingredient to derive FDA required test data was thus an infringement of the patent. The CAFC refused to construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of "scientific inquiry," when that inquiry has definite, cognizable, and not insubstantial commercial purposes. The CAFC further concluded that it is a misnomer to call Bolar's intended use as *de minimis*. The use is no trifle in its economic effect even if the quantity used is small.

Public policy justification for a new exception

Bolar argued that even if no established doctrine exists with which it can escape liability for patent infringement, public policy requires that the CAFC create a new exception to

the prohibition of use of a patent. Along those lines the CAFC must resolve a conflict between the Federal Food, Drug, and Cosmetic Act (FDCA), as amended in 1962 and the Patent Act of 1952, or at least the Acts' respective policies and purposes.

The amendment of the FDCA caused a substantial increase in the time required for development and approval of a pioneer new drug by requiring NDA to contain proof of efficacy (effectiveness) and safety. No drug can be marketed except with the FDA's affirmative approval. Since the amendment, it can take on average from 7 to 10 years for a pharmaceutical company to satisfy the current regulatory requirements. The remaining effective life of patent protection may be as low as 7 years. Litigation such as this is one example of how research-oriented pharmaceutical companies have sought to regain some of the earning time lost to regulatory entanglements. They gain for themselves, it is asserted, a *de facto* monopoly of upwards of 2 years by enjoining FDA-required testing of a generic drug until the patent on the drug's active ingredient expires.

Bolar argued that the patent laws are intended to grant to inventors only a time-limited property right to their inventions so that the public can enjoy the benefits of competition as soon as possible, consistent with the need to encourage invention. The FDCA, Bolar contended, was only intended to assure safe and effective drugs for the public, and not to extend a pharmaceutical company's monopoly for an indefinite and substantial period of time while the FDA considers whether to grant a pre-marketing clearance to a generic competitor.

According to the CAFC, courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective. The CAFC noted that Congress is well aware of the economic and societal problems which the parties debate here, and has before it legislation with respect to these issues: "Drug Price Competition Act of 1983"–to allow faster marketing of new generic drugs equivalent to approved drugs; and "Patent Term Restoration Act of 1983" – to add to the patent grant a period of time equivalent to that lost due to regulatory delay. No matter how persuasive the policy arguments are for or against these proposed bills, the CAFC stated that it is not the proper forum in which to debate them. Where Congress has the clear power to enact legislation, the role of courts is only to interpret and apply that legislation.

Accordingly, the decision of the district court holding the patent not infringed was reversed. The CAFC remanded the case with instructions to fashion an appropriate remedy, including injunction, requested by Roche.

Points of significance

In 1984 the United States Congress enacted the Drug Price Competition and Patent Term Restoration Act (also know as "Hatch-Waxman Act"). The Act basically provides a new exception to patent rights as suggested by Bolar in the case at hand. This new "Bolar" exception (in technical terms "regulatory review exception") provides that:

> It shall not be 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.

The Act also provided for, among others:

- An extension of patent terms for not more than 5 years or for a total of 14 years from the date of the drug approval to compensate for delay in the marketing authorisation of the originator's drug;
- Exclusive rights in data submitted to the FDA by originators of new drugs and
- The requirement for NDA applicants to notify a patent that claims a drug or method of using a drug and with respect to which a claim of infringement can reasonably be asserted (patent linkage).

In 2000, the WTO panel in *Canada-Patent Protection of Pharmaceutical Products* upheld the Canadian regulatory review exception.[1]

Key words: experimental use, Bolar exception, New Drug Application, generic drug. $

Available at: http://biotech.law.lsu.edu/cases/IP/patent/roche_v_bolar.htm

[1] See the summary in this database.