



United States Court of Appeals, Federal Circuit.
 ROCHE PRODUCTS, INC. Appellant,
 v.
 BOLAR PHARMACEUTICAL CO., INC., Appellee.

Appeal No. 84-560.
 April 23, 1984.

Before MARKEY, Chief Judge, NICHOLS, Senior
 Circuit Judge, and KASHIWA, Circuit Judge.

NICHOLS, Senior Circuit Judge.

This is an appeal from a judgment entered on October 14, 1983, in which the United States District Court 572 F.Supp. 255 for the Eastern District of New York held United States Patent No. 3,299,053 not infringed and denied relief. *We reverse and remand.*

I

At stake in this case is the length of time a pharmaceutical company which has a patent on the active ingredient in a drug can have exclusive access to the American market for that drug. Plaintiff-appellant Roche Products, Inc. (Roche), a large research-oriented pharmaceutical company, wanted the United States district court to enjoin Bolar Pharmaceutical Co., Inc. (Bolar), a manufacturer of generic drugs, from taking, during the life of a patent, the statutory and regulatory steps necessary to market, after the patent expired, a drug equivalent to a patented brand name drug. Roche argued that the *use* of a patented drug for federally mandated premarketing tests is a *use* in violation of the patent laws.

In early 1983, Bolar became interested in marketing, after the '053 patent expired, a generic drug equivalent to Dalmane. Because a generic drug's commercial success is related to how quickly it is brought on the market after a patent expires, and because approval for an equivalent of an established drug can take more than 2 years, Bolar, not waiting for the '053 patent to expire, immediately began its effort to obtain federal approval to market its generic version

of Dalmane. In mid-1983, Bolar obtained from a foreign manufacturer 5 kilograms of flurazepam hcl to form into "dosage form capsules, to obtain stability data, dissolution rates, bioequivalency studies, and blood serum studies" necessary for a New Drug Application to the United States Food and Drug Administration (FDA).

The district court held that Bolar's use of the patented compound for federally mandated testing was not infringement of the patent in suit because Bolar's use was *de minimis* and experimental.

III

A

When Congress enacted the current revision of the Patent Laws of the United States, the Patent Act of 1952, ch. 950, 66 Stat. 792 (codified at 35 U.S.C.), a statutory definition of patent infringement existed for the first time since section 5 of the Patent Act of 1793 was repealed in 1836. Title 35 U.S.C. § 271(a) incorporates the disjunctive language of the statutory patent grant which gives a patentee the "right to exclude others from making, using, or selling" a patented invention, 35 U.S.C. § 154. Congress states in section 271(a):

[W]hoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent.

It is beyond argument that performance of only *one* of the three enumerated activities is patent infringement. It is well-established, in particular, that the *use* of a patented invention, without either manufacture or sale, is actionable. Thus, the patentee does not need to have *any* evidence of damage or lost sales to bring an infringement action.

Section 271(a) prohibits, on its face, any and all uses of a patented invention. Because Congress has never defined use, its meaning has become a matter of judicial interpretation. Although few cases discuss the question of whether a particular use constitutes an infringing use of a patented invention, they nevertheless convincingly lead to the conclusion that the word

“use” in section 271(a) has never been taken to its utmost possible scope.

Bolar argues that its intended use of flurazepam hcl is excepted from the use prohibition. It claims two grounds for exception: the first ground is based on a liberal interpretation of the traditional experimental use exception; the second ground is that public policy favors generic drugs and thus mandates the creation of a new exception in order to allow FDA required drug testing. We discuss these arguments *seriatim*.

B

The so-called experimental use defense to liability for infringement generally is recognized as originating in an opinion written by Supreme Court Justice Story while on circuit in Massachusetts. In 1813, Justice Story sought to justify a trial judge's instruction to a jury that an infringer must have an intent to use a patented invention for profit, stating:

[I]t could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.

Despite skepticism, Justice Story's seminal statement evolved until, by 1861, the law was “well-settled 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.” Professor Robinson firmly entrenched the experimental use exception into the patent law when he wrote his famous treatise, W. Robinson, *The Law of Patents for Useful Inventions* § 898 (1890):

§ 898. No Act an Infringement unless it Affects the Pecuniary Interests of the Owner of the Patented Invention.

[T]he interest to be promoted by the wrongful employment of the invention must be hostile to the interest of the patentee. The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others. These, though not always taking the shape of money, are of a pecuniary character, and their value is capable of estimation like other property. Hence acts of infringement must attack

the right of the patentee to these emoluments, and either turn them aside into other channels or prevent them from accruing in favor of any one. An unauthorized sale of the invention is always such an act. But the manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. *Thus where it 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 experimenter, or if the experiments are conducted with a view to the adaptation of the invention to the experimenter's business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent. In reference to such employments of a patented invention the law is diligent to protect the patentee, and even experimental uses will be sometimes enjoined though no injury may have resulted admitting of positive redress. [Emphasis supplied, footnotes omitted.]

Despite Bolar's argument that its tests are “true scientific inquiries” to which a literal interpretation of the experimental use exception logically should extend, we hold the experimental use exception to be truly narrow, and we will not expand it under the present circumstances. Bolar's argument that the experimental use rule deserves a broad construction is not justified.

Pitcairn, the most persuasive of the Court of Claims cases concerning the experimental use defense, sets forth the law which must control the disposition of this case: “[t]ests, demonstrations, and experiments * * * [which] are in keeping with the legitimate business of the * * * [alleged infringer]” are infringements for which “[e]xperimental use is not a defense.” *heir own intrinsic persuasiveness.*

Bolar's intended “experimental” use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar's intended use of flurazepam hcl to derive FDA required test data is thus an infringement of the '053 patent. Bolar may intend to perform “experiments,” but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experi-

mentor's business is a violation of the rights of the patentee to exclude others from using his patented invention. It is obvious here that it is a misnomer to call the intended use *de minimis*. It is no trifle in its economic effect on the parties even if the quantity used is small. It is no dilettante affair such as Justice Story envisioned. We cannot 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.

C

Bolar argues that even if no *established* doctrine exists with which it can escape liability for patent infringement, public policy requires that we create a new exception to the use prohibition.

*****[argument deleted]

It is the role of Congress to maximize public welfare through legislation. 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. *See* H.R. 3605, 98th Cong., 1st Sess. (1983) ("Drug Price Competition Act of 1983") (amending 21 U.S.C. § 355(b) to allow faster marketing of new generic drugs equivalent to approved new drugs); S. 1306, 98th Cong., 1st Sess. (1983) ("Patent Term Restoration Act of 1983") (amending 35 U.S.C. § 155 to add to the patent grant a period of time equivalent to that lost due to regulatory delay), Cong.Rec.S. 6863 (daily ed. May 17, 1983), 26 Pat. Trademark & Copyright J. (BNA) 87-88 (May 26, 1983). No matter how persuasive the policy arguments are for or against these proposed bills, this court is not the proper forum in which to debate them. Where Congress has the clear power to enact legislation, our role is only to interpret and apply that legislation. "[I]t is not our job to apply laws that have not yet been written." We will not rewrite the patent laws here.

IV

Section 283, by its terms, clearly makes the issuance of an injunction discretionary: the court "*may grant*" relief "*in accordance with the principles of equity*." The trial court thus has considerable discretion in determining whether the facts of a situation require it to issue an injunction. The scope of relief, therefore, is not for us to decide at the first instance,

nor is this the time or place for a discourse on the "principles of equity."

Whether an injunction should issue in *this* case, and of what form it should take, certainly depends on the equities of the case. Bolar, Roche, and *amici* Pharmaceutical Manufacturers Association and Generic Pharmaceutical Industry Association, each detail the "catastrophic" effect our decision for either party will have on the American public health system. It is true that it "is a principle of general application that courts, and especially courts of equity, may appropriately withhold their aid where the plaintiff is using the right asserted contrary to the public interest," Since "the standards of the public interest, not the requirements of private litigation, measure the propriety and need for injunctive relief in these cases," we remand this case to the district court for further proceedings to consider what this interest is and what measures it calls for.

[argument deleted]

The application of historic equity principles to the case at bar is in the first instance for the district court.

V

Conclusion

The decision of the district court holding the '053 patent not infringed is reversed. The case is remanded with instructions to fashion an appropriate remedy.

REVERSED AND REMANDED.

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