

LEXSEE 733 F2D 858

**ROCHE PRODUCTS, INC. Appellant, v. BOLAR PHARMACEUTICAL CO., INC.,
Appellee**

Appeal No. 84-560

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

733 F.2d 858; 1984 U.S. App. LEXIS 15006; 221 U.S.P.Q. (BNA) 937

April 23, 1984, Decided

PRIOR HISTORY: [**1]

Appealed from: United States District Court for the
Eastern District of New York.

DISPOSITION:

Reversed and Remanded.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff appealed from a judgment of the United States District Court for the Eastern District of New York, which held that plaintiff's pharmaceutical patent was not infringed by defendant.

OVERVIEW: Plaintiff pharmaceutical company sued defendant, a manufacturer of generic drugs, for patent infringement. Plaintiff sought to enjoin defendant from taking, during the life of a patent, the statutory and regulatory steps necessary to market, after the patent expired, a drug equivalent to the patented drug. The trial court held that plaintiff's patent was not infringed by such action. On appeal, the court reversed since the court could not construe the experimental use rule so broadly to allow a violation of patent law in the guise of scientific inquiry when that inquiry had definite, cognizable, and not insubstantial commercial purposes. The court remanded since the application of historic equity principles was in the first instance for the trial court.

OUTCOME: The court reversed the trial court's finding that plaintiff's pharmaceutical patent was not infringed, because the court could not construe the experimental use rule so broadly to allow a violation of patent law in the guise of scientific inquiry when that inquiry had cognizable commercial purposes.

LexisNexis(R) Headnotes

Patent Law > Infringement Actions > Infringing Acts > Sale
Patent Law > Infringement Actions > Infringing Acts > Use
Patent Law > Infringement Actions > Exclusive Rights > General Overview
[HN1] See 35 U.S.C.S. § 271(a).

Patent Law > Infringement Actions > Infringing Acts > Use
Patent Law > Infringement Actions > Infringing Acts > Sale
Patent Law > Remedies > Damages > Patentholder Losses
[HN2] It is beyond argument that performance of only one of the three enumerated activities in 35 U.S.C.S. § 271(a) 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.

Patent Law > Infringement Actions > Exclusive Rights > General Overview

[HN3] 35 U.S.C.S. § 271(a) prohibits, on its face, any and all uses of a patented invention.

Governments > Legislation > Interpretation

[HN4] It is true that the words used, even in their literal sense, are the primary, and ordinarily the most reliable, source of interpreting the meaning of any writing: be it a statute, a contract, or anything else. But it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning.

Patent Law > Infringement Actions > Exclusive Rights > General Overview

[HN5] The word "use" in 35 U.S.C.S. § 271(a) has never been taken to its utmost possible scope.

Patent Law > Infringement Actions > Defenses > Experimental Use & Testing***Patent Law > Statutory Bars > Experimental Use > General Overview***

[HN6] The law is 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.

Patent Law > Statutory Bars > Experimental Use > General Overview

[HN7] In the patent infringement context, the experimental use exception is truly narrow.

Patent Law > Statutory Bars > Experimental Use > General Overview

[HN8] Tests, demonstrations, and experiments which are in keeping with the legitimate business of the alleged infringer are infringements for which experimental use is not a defense.

Patent Law > Infringement Actions > Exclusive Rights > General Overview***Patent Law > Statutory Bars > Experimental Use > General Overview***

[HN9] The experimental use rule cannot be interpreted 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.

Governments > Legislation > Interpretation***Governments > Legislation > Suspension, Expiration & Repeal***

[HN10] Simply because a later enacted statute affects in some way an earlier enacted statute is poor reason to ask courts to rewrite the earlier statute. Repeals by implication are not favored. Thus, 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. There is no affirmative obligation on Congress to explain why it deems a particular enactment wise or necessary, or to demonstrate that it is aware of the consequences of its action. Rather, laws are presumed to be passed with deliberation, and with full knowledge of all existing ones on the same subject.

Governments > Legislation > Interpretation

[HN11] It is the role of Congress to maximize public welfare through legislation.

Governments > Legislation > Interpretation

[HN12] Where Congress has the clear power to enact legislation, the court's role is only to interpret and apply that legislation. It is not the court's job to apply laws that have not yet been written.

Patent Law > Remedies > Equitable Relief > Injunctions

[HN13] See 35 U.S.C.S. § 283.

Patent Law > Remedies > Equitable Relief > Injunctions

[HN14] 35 U.S.C.S. § 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 the appellate court to decide at the first instance.

Patent Law > Remedies > Equitable Relief > Injunctions

[HN15] 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. The standards of the public interest, not the requirements of private litigation, measure the propriety and need for injunctive relief in these cases.

Patent Law > Remedies > Equitable Relief > Injunctions

[HN16] An appeal to the equity jurisdiction conferred on federal district courts is an appeal to the sound discretion which guides the determinations of courts of equity. The historic injunctive process was designed to deter, not to punish. The essence of equity jurisdiction has been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it. The qualities of mercy and practicality have made equity the instrument for nice adjustment and reconciliation between the public interest and private needs as well as between competing private claims. Such a major departure from that long tradition should not be lightly implied.

COUNSEL:

John C. Vassil, of New York, New York, argued, for Appellant. With him on the brief were Stephen R. Smith, J. Robert Dailey, Janet Dore, Ralph N. Del Deo and Ann G. McCormick.

Robert V. Marrow, of New York, New York, argued, for Appellee. With him on the brief were Leo Salon, Joel Salon, David L. Shandalow and Jacques Catafago.

Peter Barton Hutt and Bruce J. Brennan, of Washington, District of Columbia, were on the brief for Pharmaceutical Manufacturers Association, Amicus Curiae.

Alfred B. Engelberg, Morton Amstar and Anthony F. LoCicero, of New York, New York, were on the brief for Pharmaceutical Industry Association as Amicus Curiae.

JUDGES:

Markey, Chief Judge, Nichols, Senior Circuit Judge, and Kashiwa, Circuit Judge.

OPINIONBY:

NICHOLS

OPINION:

[*860] 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 [**2] 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.

Roche was the assignee of the rights in U.S. Patent No. 3,299,053 (the '053 patent), which expired on January 17, 1984. The '053 patent, which issued on January 17, 1967, is entitled "Novel 1 and/or 4-substituted alkyl

5-aromatic-3H-1,4-benzodiazepines and benzodiazepine-2-ones." One of the chemical compounds claimed in the '053 patent is flurazepam hydrochloride (flurazepam hcl), the active ingredient in Roche's successful brand name prescription sleeping pill "Dalmane."

In early [**3] 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).

On July 28, 1983, Roche filed a complaint in the United States District Court for the District of New Jersey against three parties: Bolar, Bolar's principal officer, and the importer of the infringing flurazepam hcl. Only Bolar remains a party defendant. Roche sought to enjoin Bolar from using flurazepam hcl for any purpose whatsoever during the life of the '053 patent. When Bolar stated during discovery, on [**4] August 30, 1983, that it intended immediately to begin testing its generic drug for FDA approval, Roche moved for and was granted a Temporary Restraining Order, on September 2, 1983.

On September 26, 1983, Bolar was granted a change of venue and the case was transferred to the United States District Court for the Eastern District of New York. That court consolidated Roche's motion for a preliminary injunction with the trial on the merits pursuant to *Fed. R. Civ. P. 65(a)(2)* (both parties had stipulated to all the pertinent facts so no testimony was necessary) and on October 11, 1983, issued a Memorandum and Order denying Roche's application for a permanent injunction. The court held that Bolar's use of the patented compound for federally mandated [**861] testing was not infringement of the patent in suit because Bolar's use was *de minimis* and experimental. The court entered judgment for Bolar on October 14, 1983, and Roche filed its notice of appeal that same day.

II

The district court correctly recognized that the issue in this case is narrow: does the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during [**5] the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable? The

district court held that it does not. This was an error of law.

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):

[HN1] Whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent.

[HN2] 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. *See Aro Manufacturing [**6] Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 484, 12 L. Ed. 2d 457, 84 S. Ct. 1526, 141 U.S.P.Q. (BNA) 681, 685 (1964); *Coakwell v. United States*, 178 Ct. Cl. 654, 372 F.2d 508, 510, 153 U.S.P.Q. (BNA) 307, 308 (1967). Thus, the patentee does not need to have *any* evidence of damage or lost sales to bring an infringement action.

Section 271(a) [HN3] prohibits, on its face, any and all uses of a patented invention. Of course, as Judge Learned Hand observed in *Cabell v. Markham*, 148 F.2d 737, 739 (2d Cir.), *aff'd*, 326 U.S. 404, 66 S. Ct. 193, 90 L. Ed. 165 (1945):

[HN4] It is true that the words used, even in their literal sense, are the primary, and ordinarily the most reliable, source of interpreting the meaning of any writing: be it a statute, a contract, or anything else. But it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning.

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Because Congress has never defined use, its meaning has become a matter of judicial interpretation. [**7] 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 [HN5] the word "use" in section 271(a) has never been taken to its utmost possible scope. See, e.g., *Pitcairn v. United States*, 212 Ct. Cl. 168, 547 F.2d 1106, 192 U.S.P.Q. (BNA) 612 (1976), cert. denied, 434 U.S. 1051, 54 L. Ed. 2d 804, 98 S. Ct. 903 (1978) (experimental use may be a defense to infringement); *United States v. Univis Lens Co.*, 316 U.S. 241, 86 L. Ed. 1408, 62 S. Ct. 1088 (1942) ("An incident to the purchase of any article, whether patented or unpatented, is the right to use and sell it, * * *." *Id.* at 249); *General Electric Co. v. United States*, 215 Ct. Cl. 636, 572 F.2d 745, 198 U.S.P.Q. (BNA) 65 (1978) ("It can be properly assumed that as part of the bargain the seller of a device incorporating a patented combination * * * authorizes the buyer to continue to use the device so long as the latter can and does use the elements he purchased from the patentee or licensor." *Id.* at 784-85, 198 U.S.P.Q. (BNA) at 98).

[*862] Bolar argues that its intended use of flurazepam [**8] 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 *Whittemore v. Cutter*, 1 Gall. 429, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600), 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:

It 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, see, e.g., *Byam v. Bullard*, 1 Curt. 100, 4 F. Cas. 934 (C.C.D. Mass. 1852) (No. [**9] 2,262) (opinion by Justice Curtis), Justice Story's seminal

statement evolved until, by 1861, [HN6] 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." *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279). (For a detailed history and analysis of the experimental use exception, see Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. Pat. Off. Soc'y 357 (1957).) 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.

The 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 [**10] 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 [**11] 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.]

The Court of Claims, whose precedents bind us, on several occasions has considered the defense of experimental use. [**863] See *Ordnance Engineering Corp. v. United States*, 84 Ct. Cl. 1, 32 U.S.P.Q. (BNA) 614 (1936), cert. denied, 302 U.S. 708, 37 U.S.P.Q. (BNA) 842, 82 L. Ed. 547, 58 S. Ct. 28 (1937); *Chesterfield v. United States*, 141 Ct. Cl. 838, 159 F. Supp. 371, 116 U.S.P.Q. (BNA) 445 (1958); *Douglas v. United States*, 181 U.S.P.Q. (BNA) 170 (Ct. Cl. Tr. Div. 1974), aff'd, 206 Ct. Cl. 96, 510 F.2d 364, 184 U.S.P.Q. (BNA) 613, cert. denied, 423 U.S. 825, 46 L. Ed. 2d 41, 96 S. Ct. 40 (1975); *Pitcairn v. United States*, 212 Ct. Cl. 168, 547 F.2d 1106, 192 U.S.P.Q. (BNA) 612 (1976), cert. denied, 434 U.S. 1051, 54 L. Ed. 2d 804, 98 S. Ct. 903 (1978). Bolar concedes, as it must, that its intended use of flurazepam hcl does not fall within the "traditional limits" of the experimental use exception as established in these cases or those of other circuits. [**12] Its concession here is fatal. Despite Bolar's argument that its tests are "true scientific inquiries" to which a literal interpretation of the experimental use exception logically should extend, [HN7] 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: [HN8] "tests, demonstrations, and experiments * * * [which] are in keeping with the legitimate business of the * * * [alleged infringer]" are infringements for which "experimental use is not a defense." 547 F.2d at 1125-1126, 192 U.S.P.Q. (BNA) at 625. We have carefully reviewed each of the other Court of Claims cases, and although they contain some loose language on which Bolar relies, they are unpersuasive. The *Ordnance Engineering* case provides no guidance concerning the boundaries of an appropriately applied experimental use rule other than flatly stating that a device must have been "built for experimental [**13] purposes." In *Chesterfield*, the court's flat declaration that "experimental use does not infringe" is pure *obiter dictum*. See *Pitcairn*, 547 F.2d at 1125, 192 U.S.P.Q. (BNA) at 625. *Douglas* has no precedential value here since the Court of Claims never affirmed the part of the trial judge's opinion dealing with experimental use; moreover, Trial Judge Cooper's

well-reasoned analysis of the experimental use rule concluded that no case had permitted a pattern of systematic exploitation of a patented invention for the purpose of furthering the legitimate business interests of the infringer. The authority of Trial Judge Cooper's views rests on his reputation as a fine patent lawyer, and on their 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 adaption of the patented invention to the experimenter's business is a violation of [**14] 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. [HN9] 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. Parties and *amici* seem to think, in particular, that we must resolve a conflict between the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § § 301-392 (1982), and the Patent Act of 1952, or at least the Acts' respective policies and purposes. We decline [**864] the opportunity here, however, to engage in legislative activity proper only for the Congress.

The new drug approval procedure which existed between 1938 and 1962 was relatively [**15] innocuous and had little impact on the development of pioneer prescription new drugs. Section 505 of the FDCA, ch. 675, 52 Stat. 1052 (1938), required the manufacturer of a pioneer new drug to submit to the FDA a New Drug Application (NDA) containing information concerning the safety of the drug. If the FDA did not disapprove the new drug within 60 days after it received the NDA, marketing could begin.

The provisions of the Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, caused a substantial increase in the time required for development and approval of a pioneer new drug. Beginning in 1962, the amended Section 505 (codified at 21 U.S.C. § 355 (1982)) required an NDA to contain proof of efficacy (effective-

ness) as well as safety, and required the FDA affirmatively to approve the NDA rather than just to permit marketing by inaction. A recent study indicated that it now can take on average from 7 to 10 years for a pharmaceutical company to satisfy the current regulatory requirements. National Academy of Engineering, *The Competitive Status of the U.S. Pharmaceutical Industry* 79-80 (1983).

Because most FDA-required testing is done after a patent issues, the remaining [**16] effective life of patent protection assertedly may be as low as 7 years. *Id.*, citing Statement of William M. Wardell to the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, U.S. House of Representatives, Feb. 14, 1982, at 14. 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 argues that the patent laws are intended to grant to inventors only a limited 17-year 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 contends, 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. Because the FDCA affected prevailing [**17] law, namely the Patent Act, Bolar argues that we should apply the patent laws to drugs differently.

[HN10] Simply because a later enacted statute affects in some way an earlier enacted statute is poor reason to ask us to rewrite the earlier statute. Repeals by implication are not favored. *See, e.g., Mercantile National Bank v. Langdeau*, 371 U.S. 555, 565, 9 L. Ed. 2d 523, 83 S. Ct. 520 (1963). Thus, "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." *Morton v. Mancari*, 417 U.S. 535, 551, 41 L. Ed. 2d 290, 94 S. Ct. 2474 (1974). There is no affirmative obligation on Congress to explain why it deems a particular enactment wise or necessary, or to demonstrate that it is aware of the consequences of its action. *See Harrison v. PPG Industries, Inc.*, 446 U.S. 578, 592, 64 L. Ed. 2d 525, 100 S. Ct. 1889 (1979). Rather, because "laws are presumed to be passed with deliberation, and with full knowledge of all existing ones on the same subject," T. Sedgwick, *The Interpretation and [**18] Construction of Statutory and Constitutional Law* 106 (2d ed. 1874), we must presume

Congress was aware that the FDCA would affect the earning potentiality of a drug patent, and chose to permit it. Although arguably Title 21 and Title 35 are not laws on the "same subject," we note that during Congress' deliberations on the 1962 amendments to the FDCA, it considered [**865] the relationship and interaction of the patent laws with the drug laws. *See* S. Rep. No. 1744, 87th Cong., 2d Sess., reprinted in 1962 U.S. Code Cong. & Ad. News 2884, 2911-2915.

[HN11] 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. [**19] 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. [HN12] Where Congress has the clear power to enact legislation, our role is only to interpret and apply that legislation. "It is not our job to apply laws that have not yet been written." *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 456, 78 L. Ed. 2d 574, 104 S. Ct. 774, 796, 220 U.S.P.Q. (BNA) 665, 684, 52 U.S.L.W. 4090, 4100 (1984). We will not rewrite the patent laws here.

IV

The district court refused to grant a permanent injunction against Bolar because it believed the law did not require that it find infringement of the '053 patent. Since we hold that there is infringement, Roche is entitled to a remedy. We are not in a position, however, to decide the form of that remedy.

Roche requested us, at first, to remand this case to the district court with instructions to enter a permanent injunction against infringement by Bolar. After the main briefs were filed, but before oral argument, the '053 patent expired. [**20] This case is not moot, however, because although the initially requested order no longer is necessary, other remedies can be fashioned to give Roche relief against Bolar's past infringement. Roche requests, for example, an order to confiscate and destroy the data which Bolar has generated during its infringing activity, citing, *Pfizer, Inc. v. International Rectifier Corp.*, 217 U.S.P.Q. (BNA) 157 (C.D. Cal. 1982) (granting an in-

junction of that nature to remedy infringement done in contempt of a court order).

Statute provides the basis for Roche's request for injunctive relief, 35 U.S.C. § 283:

[HN13] The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

Section 283, [HN14] 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 [**21] 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 [HN15] 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," *Morton Salt Co. v. Suppiger Co.*, 314 U.S. 488, 492, 86 L. Ed. 363, 62 S. Ct. 402 (1941), *reh'g denied*, 315 U.S. 826, 86 L. Ed. 1222, 62 S. Ct. 620 (1942). Since "the standards of [**866] the public interest, not the requirements of private litigation, measure the propriety and need for injunctive relief in these cases," *Hecht Co. v. Bowles*, 321 U.S. 321, 331, 88 L. Ed. 754, 64 S. Ct. 587 (1944), *rev'g Brown v. Hecht Co.*, 78 U.S. App. D.C. 98, 137 F.2d 689 (D.C. [**22] Cir. 1943), we remand this case to the district court for further proceedings to consider what this interest is and what measures it calls for.

There are other aspects here that might make a tribunal reluctant to select, within the scope of its discretion, relief along the harsher side of the possible scale. The case clearly was regarded by both sides as a test. The good faith with which Bolar acted is undisputed, at least before us. Bolar says it did nothing clandestine, but notified Roche what it was going to do at all times before doing it, so Roche could act promptly to defend what it believed to be its rights. The case may be unlike *Pfizer*,

Inc., *supra*, in that Bolar scrupulously obeyed all court orders while they were in effect, or so it says, whereas in *Pfizer, Inc.*, the infringer acted in defiance of court decrees. The destruction of material in *Pfizer, Inc.*, was ordered after everything milder had proved useless. If other measures can be made sufficient, one might well be reluctant to order destruction of the records of research and tests that may embody information that would contribute to the health and happiness of the human race. All this is, of course, [**23] for the district judge to consider so far as he finds the factual predicates established.

The actual infringing acts are said to have all occurred in the relatively brief period between vacation of the lower court's restraining order and the expiration of the patent. Counsel for Roche was candid in explaining that he pushed so hard for the harsh relief he did because he thought any money damages would have to be nominal. The correctness of this belief has not been briefed or argued, and we hesitate to state a firm position, but tentatively, at least, we are skeptical. It is clear that the economic injury to Roche is, or is threatened to be, substantial, even though the amount of material used in the tests was small. If the patent law precludes substantial damages, there exists a strange gap in the panoply (in its proper meaning, a suit of armor) of protection the patent statutes place around an aggrieved and injured patentee. The district judge, before getting into the issue of equitable relief, must determine if he can deal with the case by adequate money damages. If he can, the predicate for equitable relief of a harsh, or even a mild, character is gone.

Counsel are equally [**24] mistaken in their apparent belief that once infringement is established and adjudicated, an injunction must follow. In *Hecht Co. v. Bowles*, *supra*, the statute, unlike the one we have here, was seemingly mandatory by its language that once a violation was shown, an injunction *must* follow, and the D.C. Circuit had so held. But the circumstances made an injunction somewhat repugnant. *Hecht Co.*, an unquestionably legitimate and long-established District of Columbia retailer, had got tangled up in the price control regulations of World War II, and its employees had in good faith unwittingly committed some violations. The situation was ironic in that the *Hecht Co.* had been a leader in extending the patriotic cooperation of the retail trade in application of the unpopular but necessary retail price controls, and had itself offered its own operation for study as illustrating the problems and how they could be solved.

After discovering some loopholes in the statute, in light of the legislative history, Justice Douglas continued at 329:

We are dealing here with the requirements of equity practice with a background of several hundred years of history. Only the other day [**25] we stated that [HN16] "An appeal to the equity jurisdiction conferred on federal district courts is an appeal to the sound discretion which guides the determinations of courts of equity." *Meredith v. Winter Haven*, 320 U.S. 228, 235 [88 L. Ed. 9, 64 S. Ct. 7]. The historic injunctive process was designed to deter, not to punish. The essence [**867] of equity jurisdiction has been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it. The qualities of mercy and practicality have made equity the instrument for nice adjustment and reconciliation between the public interest and private needs as well as between competing private claims. We do not believe that such a major departure from that long tradition as is here proposed should be lightly implied.

While two justices declined to join in the opinion, none expressed themselves in favor of affirming the D.C. Circuit. In short, if Congress wants the federal courts to issue injunctions without regard to historic equity principles, it is going to have to say so in explicit and even shameless language rarely if ever [**26] to be expected from a body itself made up very largely of American lawyers, having, probably, as much respect for traditional equity principles as do the courts. If an injunction was not mandatory in *Hecht Co. v. Bowles*, the more permissive statutory language here makes it *a fortiori* that an injunction is not mandatory now.

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. Each party to bear its own costs.

REVERSED AND REMANDED.