Syllabus

# ELI LILLY & CO. *v.* MEDTRONIC, INC.

## CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 89–243. Argued February 26, 1990—Decided June 18, 1990

Claiming infringement of two of its patents, petitioner Eli Lilly's predecessor-in-interest filed suit to enjoin respondent Medtronic's testing and marketing of a medical device. Medtronic defended on the ground that its activities were undertaken to develop and submit to the Government information necessary to obtain premarketing approval for the device under § 515 of the Federal Food, Drug, and Cosmetic Act (FDCA) and were therefore exempt from a finding of infringement under 35 U. S. C. § 271(e)(1), which authorizes the manufacture, use, or sale of a patented device "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 District Court concluded that § 271(e)(1) does not apply to medical devices and, after a jury trial, entered judgment on verdicts for Eli Lilly. The Court of Appeals reversed on the ground that, under § 271(e)(1), Medtronic's activities could not constitute infringement if they were related to obtaining regulatory approval under the FDCA, and remanded for the District Court to determine whether that condition had been met.

*Held:* Section 271(e)(1) exempts from infringement the use of patented inventions reasonably related to the development and submission of information needed to obtain marketing approval of medical devices under the FDCA. Pp. 665–679.

(a) The statutory phrase of § 271(e)(1), "a Federal law which regulates the manufacture, use, or sale of drugs," is ambiguous. It is somewhat more naturally read (as Medtronic asserts) to refer to the entirety of any Act, including the FDCA, at least some of whose provisions regulate drugs, rather than (as Eli Lilly contends) to only those individual provisions of federal law that regulate drugs. However, the text, by itself, is imprecise and not plainly comprehensible on either view. Pp. 665–669.

(b) Taken as a whole, the structure of the 1984 Act that established § 271(e)(1) supports Medtronic's interpretation. The 1984 Act was designed to remedy two unintended distortions of the standard 17-year 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. Section 202 of the Act addressed the latter distortion by creating § 271(e)(1), while § 201 of the Act sought to eliminate the former distortion by creating 35 U. S. C. § 156, which sets forth a patent-term extension for inventions subject to a lengthy regulatory approval process. Eli Lilly's interpretation of § 271(e)(1) would allow the patentee of a medical device or other FDCA-regulated nondrug product to obtain the advantage of § 201's patent-term extension without suffering the disadvantage of § 202's noninfringement provision. It is implausible that Congress, being demonstrably aware of the *dual* distorting effects of regulatory approval requirements, should choose to address both distortions only for drug products, and for other products named in § 201 should enact provisions which not only leave in place an anticompetitive restriction at the end of the monopoly term but simultaneously expand the term itself, thereby not only failing to eliminate but positively aggravating distortion of the 17-year patent protection. Moreover, the fact that § 202 expressly excepts from its infringement exemption "a new animal drug or veterinary biological product"—each of which is subject to premarketing licensing and approval under, respectively, the FDCA and another "Federal law which regulates the manufacture, use, or sale of drugs," and neither of which was included in § 201's patent-term extension provision—indicates that §§ 201 and 202 are meant generally to be complementary. Interpreting § 271(e)(1) as the Court of Appeals did appears to create a perfect "product" fit between the two sections. Pp. 669–674.

(c) Sections 271(e)(2) and 271(e)(4), which establish and provide remedies for a certain type of patent infringement only with respect to drug products, do not suggest that § 271(e)(1) applies only to drug products as well. The former sections have a technical purpose relating to the new abbreviated regulatory approval procedures established by the 1984 Act, which happened to apply only to drug products. Pp. 675–678.

872 F. 2d 402, affirmed and remanded.

SCALIA, J., delivered the opinion of the Court, in which REHNQUIST, C. J., and BRENNAN, MARSHALL, BLACKMUN, and STEVENS, JJ., joined. KENNEDY, J., filed a dissenting opinion, in which WHITE, J., joined, *post*, p. 679. O'CONNOR, J., took no part in the consideration or decision of the case.

*Timothy J. Malloy* argued the cause for petitioner. With him on the briefs were *Gregory J. Vogler*, *Lawrence M. Jarvis*, and *Edward P. Gray*.

*Arthur R. Miller* argued the cause for respondent. With him on the brief were *Ronald E. Lund*, *John F. Lynch*, and *W. Bryan Farney*.*

JUSTICE SCALIA delivered the opinion of the Court.

This case presents the question whether 35 U. S. C. § 271(e)(1) (1982 ed., Supp II) renders activities that would otherwise constitute patent infringement noninfringing if they are undertaken for the purpose of developing and submitting to the Food and Drug Administration (FDA) information necessary to obtain marketing approval for a medical

---

*Briefs of *amici curiae* urging reversal were filed for the Industrial Biotechnology Association by *Stephan E. Lawton;* for Intellectual Property Owners, Inc., by *Donald W. Banner* and *Herbert C. Wamsley;* for Neuromedical Technologies, Inc., by *John R. Feather;* for Procter & Gamble Co. by *Ronald L. Hemingway* and *Richard C. Witte;* and for Zimmer, Inc., by *Donald O. Beers*, *Barbara J. Delaney*, *Timothy Wendt*, and *Paul David Schoenle*.

Briefs of *amici curiae* urging affirmance were filed for the Commonwealth of Pennsylvania et al. by the Attorneys General for their respective States as follows: *Ernest D. Preate, Jr.*, of Pennsylvania, *Mary Sue Terry* of Virginia, *Don Siegelman* of Alabama, *John Steven Clark* of Arkansas, *Charles M. Oberly III* of Delaware, *Warren Price III* of Hawaii, *Neil F. Hartigan* of Illinois, *William J. Guste, Jr.*, of Louisiana, *Frank J. Kelley* of Michigan, *Brian McKay* of Nevada, *Lacy H. Thornburg* of North Carolina, *James E. O'Neil* of Rhode Island, *T. Travis Medlock* of South Carolina, *Roger A. Tellinghuisen* of South Dakota, *R. Paul Van Dam* of Utah, *Jeffrey L. Amestoy* of Vermont, *Kenneth O. Eikenberry* of Washington, *Roger W. Tompkins II* of West Virginia, and *Hubert H. Humphrey III* of Minnesota; for the American Association of Retired Persons by *Jamie S. Gorelick* and *Jonathan B. Sallet;* for Carbon Implants Inc. by *Michael M. Phillips;* for Cook Group Inc. by *Charles R. Reeves;* for Intermedics, Inc., by *John R. Merkling;* for Teletronics, Inc., by *Michael I. Rackman* and *William C. Nealon;* for the University of Minnesota et al. by *William P. Donahue;* for Ventritex, Inc., by *George H. Gerstman;* and for Dr. Gust H. Bardy by *David L. Garrison*.

Briefs of *amici curiae* were filed for Paralyzed Veterans of America by *Charles L. Gholz*, *Jeffrey H. Kaufman*, and *Robert L. Nelson;* for Pfizer Hospital Products Group, Inc., by *Rudolf E. Hutz;* and for Dr. Denton Cooley by *Margaret E. Anderson*.

device under § 515 of the Federal Food, Drug, and Cosmetic Act (FDCA), 90 Stat. 552, 21 U. S. C. § 360e.

## I

In 1983, pursuant to 28 U. S. C. § 1338(a), the predecessor-in-interest of petitioner Eli Lilly & Co. filed an action against respondent Medtronic, Inc., in the United States District Court for the Eastern District of Pennsylvania to enjoin respondent's testing and marketing of an implantable cardiac defibrillator, a medical device used in the treatment of heart patients. Petitioner claimed that respondent's actions infringed its exclusive rights under United States Patent No. Re 27,757 and United States Patent No. 3,942,536. Respondent sought to defend against the suit on the ground that its activities were "reasonably related to the development and submission of information under" the FDCA, and thus exempt from a finding of infringement under 35 U. S. C. § 271(e)(1) (1982 ed., Supp. II). The District Court rejected this argument, concluding that the exemption does not apply to the development and submission of information relating to medical devices. Following a jury trial, the jury returned a verdict for petitioner on infringement of the first patent, and the court directed a verdict for petitioner on infringement of the second patent. The court entered judgment for petitioner and issued a permanent injunction against infringement of both patents.

On appeal, the Court of Appeals for the Federal Circuit reversed, holding that by virtue of § 271(e)(1) respondent'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. It remanded for the District Court to determine whether in fact that condition had been met. 872 F. 2d 402 (1989). We granted certiorari. 493 U. S. 889 (1989).

## II

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (1984 Act), 98 Stat. 1585, which amended the FDCA and the patent laws in several important respects. The issue in this case concerns the proper interpretation of a portion of § 202 of the 1984 Act, codified at 35 U. S. C. § 271(e)(1). That paragraph, as originally enacted, provided:

> "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, 1913)) 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." 35 U. S. C. § 271(e)(1) (1982 ed., Supp. II).[1]

The parties dispute whether this provision exempts from infringement the use of patented inventions to develop and submit information for marketing approval of medical devices under the FDCA.

### A

The phrase "patented invention" in § 271(e)(1) is defined to include all inventions, not drug-related inventions alone. See 35 U. S. C. § 100(a) ("When used in this title unless the context otherwise indicates . . . [t]he term 'invention' means invention or discovery"). The core of the present controversy is that petitioner interprets the statutory phrase, "a Federal law which regulates the manufacture, use, or sale of drugs," to refer only to those individual provisions of federal law that regulate drugs, whereas respondent interprets it to refer to the entirety of any Act (including, of course, the

---

[1] Unless otherwise specified, references to sections of the United States Code are to those sections as they existed upon the effective date of the 1984 Act.

FDCA) at least some of whose provisions regulate drugs. If petitioner is correct, only such provisions of the FDCA as § 505, 52 Stat. 1052, as amended, 21 U. S. C. § 355, governing premarket approval of new drugs, are covered by § 271 (e)(1), and respondent's submission of information under 21 U. S. C. § 360e, governing premarket approval of medical devices, would not be a noninfringing use.

On the basis of the words alone, respondent's interpretation seems preferable. The phrase "a Federal law" can be used to refer to an isolated statutory section—one might say, for example, that the judicial review provision of the Administrative Procedure Act, 5 U. S. C. § 706, is "a Federal law." The phrase is also used, however, to refer to an entire Act. The Constitution, for example, provides that "Every Bill which shall have passed the House of Representatives and the Senate, shall, before it become *a law*, be presented to the President of the United States." U. S. Const., Art. I, § 7, cl. 2 (emphasis added). And the United States Code provides that "[w]henever a bill . . . becomes *a law* or takes effect, it shall forthwith be received by the Archivist of the United States from the President." 1 U. S. C. § 106a (emphasis added). This latter usage, which is probably the more common one, seems also the more natural in the present context. If § 271(e)(1) referred to "a Federal law which *pertains to* the manufacture, use, or sale of drugs" it might be more reasonable to think that an individual provision was referred to. But the phrase "a Federal law which *regulates* the manufacture, use, or sale of drugs" more naturally summons up the image of an entire statutory scheme of regulation. The portion of § 271(e)(1) that immediately precedes the words "a Federal law" likewise seems more compatible with reference to an entire Act. It refers to "the development and submission of information *under* a Federal law" (emphasis added). It would be more common, if a single section rather than an entire scheme were referred to, to speak

of "the development and submission of information *pursuant to* a Federal law," or perhaps "*in compliance with* a Federal law." Taking the action "under a Federal law" suggests taking it in furtherance of or compliance with a comprehensive scheme of regulation. Finally, and perhaps most persuasively, the fact that § 202 of the 1984 Act (which established § 271(e)(1)) used the word "law" in its broader sense is strongly suggested by the fact that the immediately preceding—and, as we shall see, closely related—section of the 1984 Act, when it meant to refer to a particular provision of law rather than an entire Act, referred to "the first permitted commercial marketing or use of the product under *the provision of* law." § 201, 98 Stat. 1598, 35 U. S. C. § 156(a)(5)(A) (emphasis added).

The centrally important distinction in this legislation (from the standpoint of the commercial interests affected) is not between applications for drug approval and applications for device approval, but between patents relating to drugs and patents relating to devices. If only the former patents were meant to be included, there were available such infinitely more clear and simple ways of expressing that intent that it is hard to believe the convoluted manner petitioner suggests was employed would have been selected. The provision might have read, for example, "It shall not be an act of infringement to make, use, or sell a patented drug invention . . . solely for uses reasonably related to the development and submission of information required, as a condition of manufacture, use, or sale, by Federal law." Petitioner contends that the terms "patented drug," or "drug invention" (or, presumably, "patented drug invention") would have been "potentially unclear" as to whether they covered only patents for drug products, or patents for drug composition and drug use as well. Brief for Petitioner 22. If that had been the concern, however, surely it would have been clearer and more natural to expand the phrase constituting the object of the sentence to "patented invention for drug product, drug

composition, or drug use" than to bring in such a limitation indirectly by merely limiting the laws under which the information is submitted to drug regulation laws.

On the other side of the ledger, however, one must admit that while the provision more naturally means what respondent suggests, it is somewhat difficult to understand why anyone would *want* it to mean that. Why should the touchstone of noninfringement be whether the use is related to the development and submission of information under a provision that happens to be included within an Act that, *in any of its provisions*, not necessarily the one at issue, regulates drugs? The first response is that this was a shorthand reference to the pertinent provisions Congress was aware of, all of which happened to be included in Acts that regulated drugs. But since it is conceded that all those pertinent provisions were contained within only two Acts (the FDCA and the Public Health Service Act (PHS Act), 58 Stat. 682, as amended, 42 U. S. C. §201 *et seq.*), that is not much of a time-saving shorthand. The only rejoinder can be that Congress anticipated future regulatory-submission requirements that it would want to be covered, which might not be included in the FDCA or the PHS Act but would surely (or probably) be included in another law that regulates drugs. That is not terribly convincing. On the other hand, this same awkwardness, in miniature, also inheres in petitioner's interpretation, unless one gives "under a Federal law" a meaning it simply will not bear. That is to say, if one interprets the phrase to refer to only a single *section* or even *subsection* of federal law, it is hard to understand why the fact that that section or subsection happens to regulate drugs should bring within §271(e)(1) other products that it also regulates; and it does not seem within the range of permissible meaning to interpret "a Federal law" to mean only isolated portions of a single section or subsection. The answer to this, presumably, is that Congress would not expect two products to be dealt with

in the same section or subsection—but that also is not terribly convincing.

As far as the text is concerned, therefore, we conclude that we have before us a provision that somewhat more naturally reads as the Court of Appeals determined, but that is not plainly comprehensible on anyone's view. Both parties seek to enlist legislative history in support of their interpretation, but that sheds no clear light.[2] We think the Court of Appeals' interpretation is confirmed, however, by the structure of the 1984 Act taken as a whole.

B

Under federal law, a patent "grant[s] to the patentee, his heirs or assigns, for the term of seventeen years, . . . the right to exclude others from making, using, or selling the invention throughout the United States." 35 U. S. C. § 154. Except as otherwise provided, "whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." § 271(a). The parties agree that the 1984 Act was designed to respond to two unintended distortions of the 17-year patent term produced by the requirement that certain products must receive premarket regulatory approval. First, the holder of a patent relating to such products would as a practical matter not be able to reap any financial rewards during the early years of the term. When an inventor makes a potentially useful discovery, he ordinarily protects it by applying for a patent at once. Thus, if the discovery relates to a product that cannot be marketed without substantial testing and regulatory approval, the "clock" on

[2] Petitioner's principal argument is that the legislative history of § 202 mentions only drugs—which is quite different, of course, from its saying (as it does not) that only drugs are included. "It is not the law that a statute can have no effects which are not explicitly mentioned in its legislative history . . . ." *Pittston Coal Group* v. *Sebben*, 488 U. S. 105, 115 (1988). As respondent notes, even the legislative history of § 201—whose text explicitly includes devices—contains only scant references to devices.

his patent term will be running even though he is not yet able to derive any profit from the invention.

The second distortion occurred at the other end of the patent term. In 1984, the Court of Appeals for the Federal Circuit decided that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement, see § 271(a), even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval. See *Roche Products, Inc.* v. *Bolar Pharmaceutical Co.*, 733 F. 2d 858, cert. denied, 469 U. S. 856 (1984).[3] Since that activity could not be commenced by those who planned to compete with the patentee until expiration of the entire patent term, the patentee's *de facto* monopoly would continue for an often substantial period until regulatory approval was obtained. In other words, the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term.

The 1984 Act sought to eliminate this distortion from both ends of the patent period. Section 201 of the Act established a patent-term extension for patents relating to certain products that were subject to lengthy regulatory delays and could not be marketed prior to regulatory approval. The eligible products were described as follows:

> "(1) The term 'product' means:
> "(A) A human drug product.

---

[3] Petitioner suggests that it was "the 1984 *Roche* decision which prompted enactment of [§ 202]," Brief for Petitioner 20, n. 13, which should therefore be regarded as quite independent of the simultaneously enacted patent-term extension of § 201. Undoubtedly the decision in *Roche* prompted the *proposal* of § 202; but whether that alone accounted for its *enactment* is quite a different question. It seems probable that Congress—for the reasons we discuss in text—would have regarded § 201 and § 202 as related parts of a single legislative package, as we do.

"(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

"(2) The term 'human drug product' means the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient." 35 U. S. C. § 156(f).

Section 201 provides that patents relating to these products can be extended up to five years if, *inter alia*, the product was "subject to a regulatory review period before its commercial marketing or use," and "the permission for the commercial marketing or use of the product after such regulatory review period [was] the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred." 35 U. S. C. § 156(a).

The distortion at the other end of the patent period was addressed by § 202 of the Act. That added to the provision prohibiting patent infringement, 35 U. S. C. § 271, the paragraph at issue here, establishing that "[i]t shall not be an act of infringement to make, use, or sell 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." § 271(e)(1). This allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval.

Under respondent's interpretation, there may be some relatively rare situations in which a patentee will obtain the advantage of the § 201 extension but not suffer the disadvantage of the § 202 noninfringement provision, and others in

which he will suffer the disadvantage without the benefit.[4] Under petitioner's interpretation, however, that sort of disequilibrium becomes the general rule for patents relating to all products (other than drugs) named in § 201 and subject to premarket approval under the FDCA. Not only medical devices, but also food additives and color additives, since they are specifically named in § 201, see 35 U. S. C. § 156(f), receive the patent-term extension; but since the specific provisions requiring regulatory approval for them, though included in the FDCA, are not provisions requiring regulatory approval for drugs, they are (on petitioner's view) not subject to the noninfringement provision of § 271(e)(1). It seems most implausible to us that Congress, being demonstrably aware of the *dual* distorting effects of regulatory approval requirements in this entire area—dual distorting effects that were roughly offsetting, the disadvantage at the beginning of the term producing a more or less corresponding advantage at the end of the term—should choose to address both those distortions only for drug products; and for other products named in § 201 should enact provisions which not only leave in place an anticompetitive restriction at the end of the monopoly term but simultaneously expand the monopoly term itself, thereby not only failing to eliminate but positively ag-

[4] We cannot readily imagine such situations (and petitioner has not described any), except where there is good enough reason for the difference. Petitioner states that disequilibrium of this sort will often occur because the § 271(e)(1) noninfringement provision applies "whether the patent term is extended or not," and even with respect to "patents which cannot qualify for a term extension." Reply Brief for Petitioner 11. But if the patent term is not extended only because the patentee does not apply, he surely has no cause for complaint. And the major reason relevant patents will not qualify for the term extension is that they pertain to "follow-on" drug products rather than "pioneer" drug products, see §§ 156(a)(5)(A), 156 (f)(2); *Fisons plc* v. *Quigg*, 876 F. 2d 99 (CA Fed. 1989). For these, however, the abbreviated regulatory approval procedures established by Title I of the 1984 Act, 98 Stat. 1585, see 21 U. S. C. §§ 355(b)(2), (j), eliminate substantial regulatory delay at the outset of the patent term and thus eliminate the justification for the § 156 extension.

gravating distortion of the 17-year patent protection. It would take strong evidence to persuade us that this is what Congress wrought, and there is no such evidence here.[5]

Apart from the reason of the matter, there are textual indications that §§ 201 and 202 are meant generally to be complementary. That explains, for example, § 202's exception for "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, 1913)." 35 U. S. C. § 271(e)(1). Although new animal drugs and veterinary biological products are subject to premarket regulatory licensing and approval under the FDCA, see 21 U. S. C. § 360b (new animal drugs), and the Act of March 4, 1913, see 21 U. S. C. §§ 151, 154 (veterinary biological products)—each "a Federal law which regulates the manufacture, use, or sale of drugs"—neither product was included in the patent-term extension provision of § 201. They therefore were excepted from § 202 as well. Interpreting § 271(e)(1) as the Court of Appeals did

---

[5] Petitioner argues that there was good reason for Congress to establish an infringement exemption with respect to drugs but not devices, since testing of the latter does much greater economic harm to the patentee. Devices, petitioner contends, are much more expensive than drugs ($17,000 apiece for respondent's allegedly infringing defibrillators); and many have only a small number of potential customers, who will purchase only a single device each, so that depleting the market through testing may do substantial harm. Brief for Petitioner 30–31. These concerns, however, apply with respect to certain drugs as well. According to one source, a year's dosage of Cyclosporine (used to suppress rejection of new organs) costs from $5,000 to $7,000; of AZT (used to treat AIDS) $8,000; of Monoclate (used to speed blood clotting in hemophiliacs) $25,000; and of Growth Hormone (used to treat dwarfism) $8,000 to $30,000. A. Pollack, The Troubling Cost of Drugs That Offer Hope, N. Y. Times, Feb. 9, 1988, p. A1, col. 3. Another new drug, Tissue Plasminogen Activator, used in the treatment of heart attacks to dissolve blood clots, costs $2,200 per dose and is prescribed for only a single dose. *Ibid.* Moreover, even if the factors petitioner mentions could explain the omission from § 271(e)(1) of medical devices, they could not explain the omission of food additives and color additives.

here appears to create a perfect "product" fit between the two sections. All of the products eligible for a patent term extension under § 201 are subject to § 202, since all of them—medical devices, food additives, color additives, new drugs, antibiotic drugs, and human biological products—are subject to premarket approval under various provisions of the FDCA, see 21 U. S. C. § 360e (medical devices); § 348 (food additives); § 376 (color additives); § 355 (new drugs); § 357 (antibiotic drugs), or under the PHS Act, see 42 U. S. C. § 262 (human biological products). And the products subject to premarket approval under the FDCA and the Act of March 4, 1913, that are *not* made eligible for a patent term extension under § 201—new animal drugs and veterinary biological products—are excluded from § 202 as well.[6]

---

[6] It is true that § 202, if interpreted to apply to all products regulated by the FDCA and other drug-regulating statutes, has a product coverage that includes other products, in addition to new animal drugs and veterinary biological products, not numbered among the specifically named products in § 201—for example, food, infant formulas, cosmetics, pesticides, and vitamins. But for the § 202 exemption to be applicable, the patent use must be "reasonably related to the development and submission of information under" the relevant law. New animal drugs and veterinary biological products appear to be the only additional products covered by drug-regulating statutes for which the requirement of premarket approval—and hence the need for "development and submission of information"—existed. With respect to food, infant formulas, cosmetics, and pesticides, for example, the FDCA merely established generally applicable standards that had to be met. See, *e. g.*, 21 U. S. C. § 341 (food); § 350a (infant formula); § 361 (cosmetics); § 346a (pesticides); cf. § 350 (vitamins).

It must be acknowledged that the seemingly complete product correlation between § 201 and § 202 was destroyed in 1986, when, without adding "new infant formula" to the defined products eligible for the patent-term extension under § 156, Congress established a premarket approval requirement for that product, and thus automatically rendered it eligible for the § 271(e)(1) exemption from patent infringement. See Pub. L. 99–570, § 4014(a)(7), 100 Stat. 3207–116, codified at 21 U. S. C. § 350a(d). That subsequent enactment does not change our view of what the statute means. That isolated indication of lack of correlation between § 156 and § 271(e)(1) is in any event contradicted by the 1988 amendment that added

## III

According to petitioner, "[t]he argument for a broad construction of Section 271(e)(1) is refuted by the companion Sections (e)(2) and (e)(4)." Brief for Petitioner 17. The latter provide:

> "(2) It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.
>
> . . . . . .
>
> "(4) For an act of infringement described in paragraph (2)—
>
> "(A) the court shall order the effective date of any approval of the drug involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
>
> "(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, or sale of an approved drug, and
>
> "(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, or sale of an approved drug.
>
> "The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph

---

most new animal drugs and veterinary biological products to § 156 and simultaneously deleted from § 271(e)(1) the infringement exception for those products. See Generic Animal Drug and Patent Term Restoration Act, 102 Stat. 3971, 3984–3989.

(2), except that a court may award attorney fees under section 285." 35 U. S. C. §§ 271(e)(2), (4).

Petitioner points out that the protections afforded by these provisions are conferred exclusively on the holders of drug patents. They would, petitioner contends, have been conferred upon the holders of other patents if Congress had intended the infringement exemption of § 271(e)(1) to apply to them as well.

That is not so. The function of the paragraphs in question is to define a new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications. As an additional means of eliminating the *de facto* extension at the end of the patent term in the case of drugs, and to enable new drugs to be marketed more cheaply and quickly, § 101 of the 1984 Act amended § 505 of the FDCA, 21 U. S. C. § 355, to authorize abbreviated new drug applications (ANDA's), which would substantially shorten the time and effort needed to obtain marketing approval. An ANDA may be filed for a generic drug that is the same as a so-called "pioneer drug" previously approved, see § 355(j)(2)(A), or that differs from the pioneer drug in specified ways, see § 355(j)(2)(C). The ANDA applicant can substitute bioequivalence data for the extensive animal and human studies of safety and effectiveness that must accompany a full new drug application. Compare § 355(j)(2)(A)(iv) with § 355(b)(1). In addition, § 103 of the 1984 Act amended § 505(b) of the FDCA, § 355(b), to permit submission of a so-called paper new drug application (paper NDA), an application that relies on published literature to satisfy the requirement of animal and human studies demonstrating safety and effectiveness. See § 355(b)(2). Like ANDA's, paper NDA's permit an applicant seeking approval of a generic drug to avoid the costly and time-consuming studies required for a pioneer drug.

These abbreviated drug-application provisions incorporated an important new mechanism designed to guard against

infringement of patents relating to pioneer drugs. Pioneer drug applicants are required to file with the FDA the number and expiration date of any patent which claims the drug that is the subject of the application, or a method of using such drug. See § 355(b)(1). ANDA's and paper NDA's are required to contain one of four certifications with respect to each patent named in the pioneer drug application: (1) "that such patent information has not been filed," (2) "that such patent has expired," (3) "the date on which such patent will expire," or (4) "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." §§ 355(b)(2)(A), 355(j)(2)(A)(vii).

This certification is significant, in that it determines the date on which approval of an ANDA or paper NDA can be made effective, and hence the date on which commercial marketing may commence. If the applicant makes either the first or second certification, approval can be made effective immediately. See §§ 355(c)(3)(A), 355(j)(4)(B)(i). If the applicant makes the third certification, approval of the application can be made effective as of the date the patent expires. See §§ 355(c)(3)(B), 355(j)(4)(B)(ii). If the applicant makes the fourth certification, however, the effective date must depend on the outcome of further events triggered by the Act. An applicant who makes the fourth certification is required to give notice to the holder of the patent alleged to be invalid or not infringed, stating that an application has been filed seeking approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent, and 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. See §§ 355(b)(3)(B), 355(j)(2)(B)(ii). Approval of an ANDA or paper NDA containing the fourth 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. See §§ 355(c)(3)(C), 355(j)(4)(B)(iii).

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. And that was precisely the disability that the new 35 U. S. C. § 271(e)(1) imposed with regard to use of his patented invention only for the purpose of obtaining premarketing approval. Thus, an act of infringement had to be created for these ANDA and paper NDA proceedings. That is what is achieved by § 271(e)(2)—the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent. Not only is the defined act of infringement artificial, so are the specified consequences, as set forth in subsection (e)(4). Monetary damages are permitted only if there has been "commercial manufacture, use, or sale." § 271(e)(4)(C). Quite obviously, the purpose of subsections (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA 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.[7]

[7] Although petitioner has not challenged § 271(e)(1) on constitutional grounds, it argues that we should adopt its construction because of the "serious constitutional question under the takings clause of the Fifth Amendment . . . [that would arise] if the statute is interpreted to authorize the infringing use of medical devices." Brief for Petitioner 31. We do not see how this consideration makes any difference. Even if the competitive injury caused by the noninfringement provision is *de minimis* with respect to most drugs, surely it is substantial with respect to some of them—so the

* * *

No interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship. To construe it as the Court of Appeals decided, one must posit a good deal of legislative imprecision; but to construe it as petitioner would, one must posit that and an implausible substantive intent as well.

The judgment of the Court of Appeals is affirmed, and the case is remanded for further proceedings consistent with this opinion.

*So ordered.*

JUSTICE O'CONNOR took no part in the consideration or decision of this case.

JUSTICE KENNEDY, with whom JUSTICE WHITE joins, dissenting.

Petitioner contends that respondent infringed its patents by testing and marketing a medical device known as a cardiac defibrillator. The Court holds that 35 U. S. C. § 271(e)(1) (1982 ed., Supp. II), a provision of the patent law, may give respondent a defense to this charge. It rules, in particular, that § 271(e)(1) will excuse respondent if it acted for the sole purpose of developing information necessary to obtain marketing approval for the device under § 515 of the Federal Food, Drug, and Cosmetic Act (FDCA), 90 Stat. 552, 21 U. S. C. § 360e. I dissent because I find the Court's decision contrary to the most plausible reading of the statutory language.

The applicable version of § 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, 1913)) solely for uses reasonably related

---

"serious constitutional question" (if it is that) is not avoided by petitioner's construction either.

> to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U. S. C. § 271(e)(1) (1982 ed., Supp. II).

The Court says that Congress used the phrase "a Federal law which regulates the manufacture, use, or sale of drugs" to refer to the entirety of any Act, at least some portion of which regulates drugs. The FDCA fits this description. As a result, even though respondent sought marketing approval under the FDCA for a medical device instead of a drug, the Court concludes that § 271(e)(1) may serve as a defense to patent infringement. I disagree.

Section 271(e)(1), in my view, does not privilege the testing of medical devices such as the cardiac defibrillator. When § 271(e)(1) speaks of a law which regulates drugs, I think that it does not refer to particular enactments or implicate the regulation of anything other than drugs. It addresses the legal regulation of drugs as opposed to other products. Thus, while the section would permit a manufacturer to use a drug for the purpose of obtaining marketing approval under the FDCA, it does not authorize a manufacturer to use or sell other products that, by coincidence, the FDCA also happens to regulate. Respondent, in consequence, has no defense under § 271(e)(1).

The Court asserts that Congress could have specified this result in a clearer manner. See *ante*, at 667–668. That is all too true. But we do not tell Congress how to express its intent. Instead, we discern its intent by assuming that Congress employs words and phrases in accordance with their ordinary usage. In this case, even if Congress could have clarified § 271(e)(1), the Court ascribes a most unusual meaning to the existing language. Numerous statutory provisions and court decisions, from a variety of jurisdictions, use words almost identical to those of § 271(e)(1), and they never mean what the Court says they mean here.

For instance, in delineating the scope of pre-emption by the Employee Retirement Income Security Act of 1974 (ERISA), Congress stated that "nothing in this title shall be construed to exempt or relieve any person from *any law of any State which regulates insurance, banking, or securities.*" 88 Stat. 897, 29 U. S. C. § 1144(b)(2)(A) (emphasis added). Interpreting this language as the Court interprets § 271(e)(1) would imply that Congress intended to give the States a free hand to enact any law that conflicts with ERISA so long as some portion of the state enactment regulates insurance, banking, or securities. No one would contend for this result. The Texas Legislature, in a like manner, has said that "a person shall pay $1 as a court cost on conviction of any criminal offense . . . except that a conviction arising under *any law that regulates pedestrians or the parking of motor vehicles* is not included." Tex. Govt. Code Ann. § 56.001(b) (Supp. 1990) (emphasis added). I do not think that Texas intended by this language to exclude all convictions that might arise under an Act, such as a traffic code, that regulates speeding in addition to pedestrians and parking. And, when the Missouri Legislature specified that "[n]o governmental subdivision or agency may enact or enforce *a law that regulates or makes any conduct in the area [of gambling] an offense*," Mo. Rev. Stat. § 572.100 (1986) (emphasis added), I doubt that it meant to invalidate local enactments in their entirety whenever some portion of them regulates gambling. Countless other examples confound the Court's method of reading the operative language in this case. See, *e. g.*, N. C. Gen. Stat. § 42–37.1 (1984) (prohibiting retaliatory eviction by landlords for complaints about violations of any *"[s]tate or federal law that regulates premises used for dwelling purposes"*) (emphasis added); *Cochran* v. *Peeler*, 209 Miss. 394, 408, 47 So. 2d 806, 809 (1950) ("[T]he violation of *a law which regulates human conduct in the operation of vehicles on the roads* becomes, by legislative fiat, negligence") (emphasis added); *Local 456 Int'l Brotherhood of Teamsters* v. *Cort-*

*landt*, 68 Misc. 2d 645, 653, 327 N. Y. S. 2d 143, 153 (1971) ("[U]nder the home rule power to enact local laws, a town may enact *a law which regulates the powers, duties, qualifications, [etc.] of its officers and employees*") (emphasis added); see also U. S. Const., Amdt. 14, § 1 ("No State shall make or enforce *any law which shall abridge the privileges or immunities of citizens of the United States*") (emphasis added). Unless we assume that these examples do not reflect ordinary usage, which I see no basis for doing, we cannot hold that § 271(e)(1) refers to the entirety of the FDCA or any other Act which regulates drugs. Instead, I would conclude, the section refers only to the actual regulation of drugs and does not exempt the testing of a medical device from patent infringement.

Congress did not act in an irrational manner when it drew a distinction between drugs and medical devices. True, like medical devices, some drugs have a very high cost. See *ante*, at 673, n. 5. Testing a patented medical device, however, often will have greater effects on the patent holder's rights than comparable testing of a patented drug. As petitioner has asserted, manufacturers may test generic versions of patented drugs, but not devices, under abbreviated procedures. See 21 U. S. C. § 355(j). These procedures, in general, do not affect the market in a substantial manner because manufacturers may test the drugs on a small number of subjects, who may include healthy persons who otherwise would not buy the drug. See § 355(j)(7)(B) (stating the requirements of a showing of the "bioequivalence" of drugs). By contrast, as in this case, manufacturers test and market medical devices in clinical trials on patients who would have purchased the device from the patent holder. See App. 39–42; see also 21 CFR § 812.7(b) (1989) (permitting manufacturers to recover their costs in clinical trials). Although the Court gives examples of high cost drug dosages, it does not demonstrate that the testing of these drugs detracts from a patent holder's sales. Congress could have determined that the dif-

ferences in testing or some other difference between drugs and devices justified excluding the latter from the ambit of § 271(e)(1). See 879 F. 2d 849, 850, n. 4 (CA Fed. 1989) (Newman, J., dissenting from the denial of rehearing en banc). For these reasons, I dissent.

## Reporter's Note

The next page is purposely numbered 901. The numbers between 683 and 901 were intentionally omitted, in order to make it possible to publish the orders with *permanent* page numbers, thus making the official citations available upon publication of the preliminary prints of the United States Reports.