OFFICIAL TRANSCRIPT

PROCEEDINGS BEFORE

THE SUPREME COURT

OF THE

UNITED STATES

CAPTION: ELI LILLY AND COMPANY, Petitioner V.

MEDTRONIC, INC.

CASE NO: 89-243

PLACE: Washington, D.C.

DATE: February 26, 1990

PAGES: 1 - 45

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IN THE SUPREME COURT OF THE UNITED STATES

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ELI LILLY AND COMPANY, :

Petitioner :

v. : No. 89-243

MEDTRONIC, INC. :

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Washington, D.C.

Monday, February 26, 1990

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 1:45 p.m.

APPEARANCES:

TIMOTHY J. MALLOY, ESQ., Chicago, Illinois; on behalf of the Petitioner.

ARTHUR R. MILLER, ESQ., Cambridge, Massachusetts; on behalf of the Respondent.

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PROCEEDINGS

(1:45 p.m.)

CHIEF JUSTICE REHNQUIST: We'll hear argument now in Number 89-243, Eli Lilly and Company v. Medtronic, Inc.

ORAL ARGUMENT OF TIMOTHY J. MALLOY

ON BEHALF OF THE PETITIONER

MR. MALLOY: Thank you, Mr. Chief Justice, and may it please the Court:

We are here on certiorari to the United States Court of Appeals for the Federal Circuit.

This suit was filed in 1983 to stop Medtronic from infringement of two basic patents related to a medical device known as an automatic implantable defibrillator. Medtronic defended in part in the court below arguing that its infringing activities were exempt from the patent infringement laws based on a 1984 statute.

The question before this court is the interpretation of that statute, which is 35 U.S.C. Section 271(e)(1). That statute provides that it shall not be an act of infringement to manufacture, use or sell a patented invention solely for uses reasonably related to the development and submission of information under a Federal law regulating drugs.

I submit that there is only one proper

interpretation of that statute. It applies to drugs only, and has no application whatever to other nondrug products regulated under the Food, Drug and Cosmetic Act, namely, medical devices, color additives and food additives.

The statute refers on its face only to drugs. The statutory definition of drugs in the FDA Act excludes specifically devices. A century of FDA legislation has treated drugs differently from devices from 1906 until the present.

Now, Medtronic argues that the phrase "Federal law regulating drugs" -- and it takes that phrase out of context -- Medtronic, the respondent, argues that the phrase "Federal law regulating drugs" equals and means the entire Food, Drug and Cosmetic Act and even the nondrug products.

QUESTION: Well, the court though so too, didn't it?

MR. MALLOY: No, Your Honor. The court, I suggest -- well, the court of appeals did not analyze what the phrase Federal law regulating drugs meant. What the court did was go to one piece of the legislative history dealing with their analysis of what the Roche Bolar decision had done and look at that.

And, in fact, the court decision when it goes to the words of the statute simply leads off by saying we

conclude that this statute covers any patented invention so long as it's for the limited purposes enumerated. But it never discusses how -- what the meaning of the remaining phrase is and how does that fit into the statute.

And I suggest one of the errors of the court of appeals' opinion which Medtronic has failed to support is that it doesn't deal with the specific language of the statute.

QUESTION: Mr. Malloy, am I right the critical language of the statute is, "a Federal law which regulates the manufacture, use or sale of drugs"?

MR. MALLOY: No, Your Honor. I would suggest that the critical language starts with after "solely for use as reasonably related to," and then we focus, "the development and submission of information under a Federal law regulating drugs."

QUESTION: No, under -- well, but is the last language -- I

-- I just want to make sure I have the last part of the language correct.

MR. MALLOY: Oh, absolutely.

QUESTION: "Which regulates the manufacture, use or sale of drugs."

MR. MALLOY: Yes, Your Honor.

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QUESTION: Thank you.

MR. MALLOY: Now, if -- if Medtronic's construction is accepted, what we have then is the inclusion in the exemption by a matter of mere happenstance, a product is now included, even though not referred to, just because it happens to have been regulated under the Federal law, the FD&C Act that also regulates drugs.

Indeed, what we wind up with is the -- the absurd result, I suggest, that the law would mean the same, that the medical devices and color additives would be equally well included if the statute read "Federal law regulating color additives" or "Federal law regulating cosmetics" since these products, too, like drugs, are all regulated under the Food, Drug and Cosmetic Act.

QUESTION: Well, how do you -- how do you answer the argument, though, that the law -- the Federal Food and Drug Act, or whatever the -- the Federal Drug, Cosmetic and so forth -- is a law regulating the sale of drugs?

MR. MALLOY: Your Honor, it's a law regulating many products.

QUESTION: Right.

MR. MALLOY: Drugs are one, devices are another.

QUESTION: But is it not a law regulating the sale of drugs?

MR. MALLOY: Out of context I think it might be referred to as that, Your Honor.

QUESTION: Well --

MR. MALLOY: Within the context of the statute, especially where they have already referred to the entire act --

QUESTION: Your position is the Federal Food and Drug Act is not a law relating -- regulating the sale of drugs?

MR. MALLOY: Within the context of this statute, yes, Your Honor.

If I take the -- if I take the lines out of context and I say can I sit there and look at that phrase out of context, I would say yes, it is possible. But when we consider that we have the FDA Act itself defining drugs as "excluding devices" -- when we have the legislative history specifically stating that the only activity that is being exempted is drug testing activity and when we have the fact that other nondrug products, such as medical devices, color additives and food additives, are developed and submitted under different laws, different provisions of the Food, Drug and Cosmetic Act, then are drugs, then I say yes, Your Honor, it is not -- the Food, Drug and Cosmetic Act within the context of this statute and all of its provisions are not --

QUESTION: What it means, in other words, is the provisions of the law regulating drugs, which regulate drugs?

MR. MALLOY: I missed the question, but --

QUESTION: You're saying it should be -- it's meant to read "under any provision of the law regulating drugs, which provisions also regulate drugs."

MR. MALLOY: Well, I think that's what Medtronic is saying, which happened to regulate drugs or anything else. And what I am saying --

QUESTION: Anything else covered by the statute regulating drugs is their position.

MR. MALLOY: Yes. And -- and what I -- what I am --

QUESTION: And your position is covered by the portions of the statute regulating drugs that do regulate drugs? The portions that regulate drugs.

MR. MALLOY: What I'm saying is it -- it -- the law that regulates -- regulates for development and submission -- for example, in drugs, is Section 355 of the Food, Drug and Cosmetic Act. For devices it would be 360(e) and (j) and different provisions for the different nondrug products. And when they said Federal law regulating drugs, they literally meant drugs and they did not mean nondrug products such as devices.

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QUESTION: They did not mean law regulating drugs. They meant portion of law regulating drugs.

MR. MALLOY: Well, they didn't mean the entire Food, Drug and Cosmetic Act --

QUESTION: Right.

MR. MALLOY: -- since they've already referred to that just three lines above and had they intended to use that phrase, they would have.

Now, I would suggest with respect to the -- the absurd result that I think is caused by Medtronic's interpretation -- that is, the law would have meant the same thing under Medtronic's interpretation if it said Federal law regulating cosmetics or color additives -- that that alone suggests it's an unreasonable interpretation that Medtronic is suggesting.

Now, I believe that Congress would not have been so haphazard and so totally inconsistent with the term drugs as it's used throughout the Food, Drug and Cosmetic Act and that Congress was not so inconsistent.

QUESTION: Why is it that in answering the Chief Justice's first question you were insistent that the critical words of the statute include "solely for uses reasonably related to the development submission"? Would you tell us that?

MR. MALLOY: Yes. Because submissions are made

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under different sections of the law for different products that are regulated within the drug and device field. And submission for drugs is made under 355, submission for devices under 360(e) and (j), and so on. Color additives, I believe, under 348, and food additives under 376.

So, when Congress was talking about development and submission, that's what they were talking about. They didn't intend to refer to the entire act. Had they done so, they would have used the phrase, "the entire Food, Drug and Cosmetic Act" as they did a few lines above in the very same statute.

Now, the legislative history --

QUESTION: You're -- you're -- excuse me. Are you saying that under a Federal law means under -- under a Federal law requiring development and submission? So, you say it refers to the particular section of the law? Is that your position?

MR. MALLOY: It -- it does if that -- it can also refer to an act, Your Honor, if the act does nothing but regulate drugs and if all of its provisions are drug regulatory.

So, it -- it -- it may refer to a section in the case -- the section is a drug-only section, or it may refer to an act if it's a drug-only act, but it refers only to the provisions that do the regulation and require

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submission of -- of information under a drug law.

QUESTION: Is there a question of the Food -- Food and Drug Act that requires the development and submission of information only relating to drugs?

MR. MALLOY: Yes, and that's 355.

QUESTION: Then wouldn't the natural way to explain the position, say under Section 355 of the act, if it means what you say?

MR. MALLOY: Your Honor, they might have done that and -- and that's -- that's an alternative way they could have done it.

QUESTION: And that's the meaning you're -- you're saying that's what the statute really means?

MR. MALLOY: Well, I'm not limiting it to 355 because, of course, we have biological products -- I mean, human biological products that are regulated under a different section -- in fact, a different act, the Public Health Service Act.

QUESTION: Well, were they in it when it was first enacted?

MR. MALLOY: They were. Veterinary biologics were not, but human biologics were. All human drug products were included in the 1984 statute as enacted.

Now, legislative history is intended to resolve doubt, but not to create it. I'd suggest Medtronic has

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attempted to do just the opposite here. There are 13 separate references in the committee reports regarding Section 271(e)(1). Each and every one of them is drug in the drug context and drug specific.

The House report, in fact, specifically states that the only activity exempted is drug testing activity. In Medtronic's only quote from the legislative history, in their only quote, they omit the very phrases in the legislative history that specifically say the purpose is to exempt drug testing.

I suggest Congress meant what it said. Section 271(e)(1) is a narrow exemption. It's a drug-only statute, and it does not apply to infringing medical devices such as Medtronic's product in suit.

The -- the focus on the language which I've talked about, development and submission, we've talked about it applying to different sections of the Food, Drug and Cosmetic Act. I think it would be difficult for Congress to have selected a less appropriate word than drugs if it intended to include devices in light of the fact that the statute already defines drugs as excluding devices.

And it's unreasonable, I suggest, that Congress later in different reference to Federal law regulating drugs was intended to include the entire Food, Drug and

Cosmetic Act referred to just a few lines above.

In addition, other statutes also confirm and support that 271(e)(1) is a drug-only statute. For example, (e)(1) exempts drugs. Section (e)(2) applies certain patent owner protections with respect to that exemption.

In 1984 when Congress placed human drugs in the exemption of (e)(1), they also placed human drugs in the patent order protections of (e)(2). In 1988 when the laws were amended, Congress added animal drugs and veterinary biological products to the exemption of (e)(1). They also added them to the exemption to the patent owner protection of (e)(2). Indeed, the proposed Senate bill which sought to add medical devices to Section 271(e)(1) also added them to the patent owner protections of (e)(2).

I suggest it's indisputable, even by Medtronic, medical devices are not in Section (e)(2), and the reason is simple: Because Congress never put them in Section (e)(1).

In addition, the relationship of the patent extension law, Section 156, and the words of that statute to the words of (e)(1) are also relevant and also confirm that (e)(1), 271(e)(1), is a drug-only statute.

The words of 156, the patent extension, use the specific products: drugs, medical devices, food additives

and color additives. In sharp contrast, 271(e)(1) refers only to drugs. And this disparate inclusion and exclusion of these two statutes enacted at the same time in 1984 also confirms that 271(e)(1) is a drug-only statute.

And it's no wonder that Section 271(e)(1) is limited to drugs whereas Section 156 is a multi-product statute for extensions.

Section 156, the patent extension law, was in Congress or similar bills were before Congress for years and years before Section 271(e)(1) had ever been thought of. In 1980-81 there were extension bills that applied the extension in order to further patent rights to multi-product applications.

The quid pro quo for 156 as it was -- as it was shepherded through the House was not (e)(1). It was the speedy new procedures for generic drugs, which we call ANDA or abbreviated new drug applications. And that was the tradeoff that Congress entered into, and that tradeoff had been effected in 19 -- late '83 or early '84. And then along came the Roche Bolar decision of the Federal circuit which said specifically that generic -- that the use of a generic drug for a bioequivalency test in order to get approval was a patent infringement.

And it was then that the generic drug companies said if we're to get the benefit of these speedy -- new

speedy drug laws called ANDA, we need to get a concomitant exemption. And it was with that thought in mind that Section (e)(1) came into effect in order to further the abbreviated new drug applications, again confirming it's a drug --

QUESTION: Well, does that apply also to the veterinary biological products?

MR. MALLOY: Veterinary biological products were added in 1988.

QUESTION: Well, it's there, though.

MR. MALLOY: Yes, it is. And veterinary biological products as well as animal drugs were both added to the statute, and there are, I believe, Your Honor, that there -- there is a -- the application now applies to a speedy procedure for animal drugs, and it applies to veterinary biological products across the board.

I am not sure, Your Honor, whether there is any speedy procedure for veterinary biological products. I believe that there is none, but I'm not sure of that fact.

QUESTION: But 271(e)(1) has that -- those words in it, does it not?

MR. MALLOY: 271(e)(1) in 1984 specifically excluded animal drugs and veterinary biological products from its application and then in 1988 both of those

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things, except when they were manufactured through a genetic engineering process, were both put into the exemption so now animal drugs, veterinary biological products and human drugs, all drug products, I suggest, all of those things are in the exemption of Section (e)(1), yes, Your Honor.

QUESTION: And for the same reason?

MR. MALLOY: I can't be certain whether the '88 amendments were for the same -- were across the board for the same reasons or not because, as I say, I think there is a speedy provision for animal drugs for --

QUESTION: Well, what was the -- what was the claimed infringement here?

MR. MALLOY: Here it was a medical device called an automatic implantable defibrillator.

QUESTION: Yes, but what were they using it for?

MR. MALLOY: They were using it -- they were implanting it in patients on a long-term, permanent basis, selling it for from $17,000 to $20,000 per unit and using it for its normal intended purpose to --

QUESTION: Well, I thought that if it's -- if it's -- if it was used solely -- in order to -- not to be an infringement, it would have to be used solely for uses reasonably related to the development of information that had to be filed?

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MR. MALLOY: That's correct, Justice White, and we would suggest that they aren't in the statute in any event because their uses were so far beyond the solely for clause.

QUESTION: Well, that may be -- that may be so, but -- but you -- you -- the argument you're making that even if it was for the purpose stated in this exemption section, that would still be an infringement?

MR. MALLOY: Let me see if I understand the question. What I am saying is that the statute doesn't apply to medical devices.

QUESTION: Right.

MR. MALLOY: They are a medical device, and so they're not -- no matter how narrowly they conform to the FDA solely for -- if they're doing nothing but testing for FDA purposes, they're not within that exemption because they are a medical device rather than a drug.

QUESTION: I understand -- I understand that. But if they were using this device for the -- for the purpose that would give them an exemption, you still that it's an infringement?

MR. MALLOY: I -- I'm not -- I'm pausing because I'm not sure I understand Your Honor's question.

When you say for the purposes of the statute, I say they can't use it for the purposes of the statute.

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But maybe if I said -- if the device were a drug and then if they solely used that -- let's say if FDA had said this device is a drug for whatever reason and then they limited their uses to the -- solely to uses that were related to submission and FDA information, then they would not any longer be an infringement because (e)(1) says we're going to make an exception regarding certain activities from Section 271(a). Section 271(a) is a very broad statute --

QUESTION: Yes.

MR. MALLOY: -- that says any manufacture, use or sale by whoever of a patented invention constitutes an infringement.

I hope I've answered that question. I'm not -- I'm not sure.

QUESTION: May I ask you one question Justice White's question prompted.

Are veterinary biological products regulated under the Federal Food, Drug and Cosmetic Act?

MR. MALLOY: They are not, Your Honor. They are regulated under a different department, as a matter of fact, the Department of Agriculture, and under an act called the Virus, Serum and Toxin Act.

QUESTION: I see.

MR. MALLOY: And I think that's a further

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support that when Congress wants to talk about -- if they want to include an entire act, they refer to it. In fact, they had referred to both the FD&C Act and the Virus, Serum and Toxin Act in that --

QUESTION: They don't in this -- in this statute. They jut refer to -- they -- they describe it by the fact that it's the Federal law regulating veterinary biological products. They don't use the name of the statute, do they?

MR. MALLOY: That's -- yes, because that's the only thing it regulates.

QUESTION: Yeah. I see.

QUESTION: You said, Mr. Malloy, that in -- in '84 271(e)(1) excluded human drug and veterinary biological products. How did it exclude them? Did it explicitly state that it excluded them or did --

MR. MALLOY: Yes, it did. It was in a parenthetical clause, and it started -- the statute read, "It shall not be an active infringement to manufacture, use or sell a patented invention (except for, et cetera, et cetera) solely for uses." And that's how it excluded them.

And then in '88 --

QUESTION: Well, but -- but -- but -- but then it went on the way it is now, solely for use as reasonable

related to the development under the Federal law which regulates the manufacture, use or sale of drugs did it say?

MR. MALLOY: Correct.

QUESTION: Of drugs. But then -- but under your theory they wouldn't have been included under that anyway, and there wouldn't have been a need to exclude them in the parenthetical.

MR. MALLOY: By "they" you mean the veterinary? Both were included, Your Honor, because the term drugs is a broad -- is defined in the statute and includes not only human drugs but also animal drugs.

QUESTION: And also --

MR. MALLOY: And also veterinary biological products.

QUESTION: Okay.

MR. MALLOY: There was an Eighth Circuit en banc decision which actually met that point and decided -- on Grand Laboratories, I believe -- that veterinary biologics were a drug within the meaning of that statute.

Medtronic has attempted -- I should suggest there is a very good reason, although you don't find these words in the legislative history, why drugs were appropriate to distinguish from devices with respect to the exemption, and that's because of the real world

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differences of testing a drug, a bioequivalency test versus a medical device.

In a bioequivalency test, quite often, the drugs are administered free to nonpatient volunteers on a short-term basis. No "customers," quote, no patients are used. It's not -- it's not a long-term thing.

In this case, to be quite specific, we have four competitors who may seek to implant as many as 200 units at $20,000 per unit, which constitutes a -- $16 millon of infringement, all in the name of experimentation. I suggest that's inappropriate and Congress never intended to include that kind of activity specifically where they said they were concerned about the constitutional issue of taking; that they were worried that this 271(e)(1) would take patent owners' rights where a patent owner had already surrendered before the statute a full disclosure of the invention in exchange for this specific period of time. And Congress said -- the legislative history said we're concerned about it, but it's appropriate to -- to ignore it because the bioequivalency testing of a drug is de minimis, it's very small activity.

In no way -- in no way is this kind of activity --

QUESTION: Well, you're -- you're -- you're saying what this exemption doesn't -- doesn't cover, but

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give me an example of something that is -- give me an example of the use of a patented invention that is exempt under this section.

MR. MALLOY: Yes, Your Honor. If I -- I'll use it in a drug, because that's what I say it applies to, and that's what Congress said it did.

In a drug -- if I -- the patent has two years to run. It's a --

QUESTION: What patent, a drug patent?

MR. MALLOY: -- a drug patent. It has two years to run, and I'm a generic drug company, and I want to make sure that on the day the patent expires, I can start selling my generic drug. But the problem is I need an approval from the FDA to do that.

So, to get the approval, I have to take the drug and administer it to a small, select number of voluntary patients to see whether the drug is infused at the same rate of absorption and with the same effectiveness as the patented drug.

QUESTION: So, you say the patented invention that -- that won't be infringed under this section is a patent on a drug, is that all?

MR. MALLOY: Correct, Your Honor.

QUESTION: Is that all?

MR. MALLOY: Yes, Your Honor.

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Now --

QUESTION: And it isn't -- and it isn't -- it isn't that -- that the information that you have to furnish is -- must be for the development of a drug?

MR. MALLOY: Well, if -- if you -- what you were doing was not in order to -- solely for the purposes of developing and submitting the information for the FDA, then even your testing would be -- would not be -- even your drug testing would not be exempt under (e)(1). It's got to be solely for the purposes reasonably related to development and submission. Otherwise, even the bioequivalency test --

QUESTION: The development and submission of information about what?

MR. MALLOY: Under a Federal law that regulates manufacture, use or sale of drugs.

So, in other words, under the drug statutes.

QUESTION: It would have to be -- your information would have to be relevant to the development of a drug?

MR. MALLOY: That's correct, Your Honor.

Now --

QUESTION: Well, I thought by your hypothesis you weren't -- they weren't developing any new drug. They were just going to copy the other drug as soon as the

patent expired.

MR. MALLOY: Your Honor, this statute you want applies to both -- it says development and submission of information, and if I -- if I misspoke when Your Honor asked me the prior question -- I may have misspoken -- what -- what I meant was development and submission of information, and the bioequivalency person must -- must do that, must develop -- both develop and submit information.

But I should say this statute on its face does apply to more than simply a bioequivalency type of test drug. It applies to development of a new drug as well, although I have yet to see a specific example or any pragmatic example of when that occurs, when a new pioneer drug might infringe the pioneer patent of an earlier pioneer drug. It would be rare, a very rare instance indeed, I think.

Now, Medtronics attempted to explain the absolute void in the legislative history of 271(e)(1) by stating in its brief that the void is equally applicable, not only to (e)(1), but that there is also an equal void with respect to legislative history of medical devices in 156. In fact, Medtronic's brief states, "The legislative history of 156 is as devoid of mention of devices as is that of Section 271(e)(1)."

That statement is pure, unadulterated fiction.

There are six separate references in the legislative history of Section 156, each recognizing that 156 is a medical device, drug, color additive and food additive extension. There are no separate references, no references whatsoever, in 271(e)(1) commenting on anything other than drug products.

Medtronic, as I've said, doesn't attempt to justify the reasoning of the Federal Circuit opinion. I suggest it's because it's not supportable. Instead, they raise a new defense called experimental use. That defense has been waived. It was never raised below. It was never raised in the appellate court. It wasn't even raised in our petition for cert.

There are also policy issues that Medtronic raises, but I suggest that the policy issues should not be allowed to be twisted to favor copiers over inventors. Our Constitution favors invention, not copyists, and the patent in this suit, the 757 patent, is a perfect example of the benefits of Federal policy. It's saved thousands of lives, and it's brought a completely new therapy to our field.

Finally, Your Honors, should this court reverse as we have requested -- time is running out on this patent. The lawsuit is seven years old. Medtronic has been allowed to infringe for six of those seven years.

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The patent expires in just eight months. I request that this Court order the immediate reinstitution of the injunction in place. Six years of willful infringement is enough.

QUESTION: Thank you, Mr. Malloy.

Mr. Miller.

ORAL ARGUMENT OF ARTHUR R. MILLER

ON BEHALF OF THE RESPONDENT

MR. MILLER: Mr. Chief Justice, members of the Court, may it please the Court:

If the Court will bear with me, I would like to attempt on Medtronic's behalf to pursue its plain meaning argument with regard to 271(e)(1). The statute says, "It shall not be an act of infringement to make, use or sell a patented invention." Those words, "patented invention" were clearly elided by Mr. Malloy in his argument.

"Patented invention" are words used earlier in that same section, in 271(a), the basic infringement provision in the Patent Act. The words "patented invention" mean every patented invention.

What this statute says is that it is not an infringement to use any patented invention for uses reasonably related to the development and submission of information under a Federal law which regulates drugs. Those are the words Congress chose to write.

Clearly, the Lilly device is a patented invention. There's no debate on that. It requires no discussion.

QUESTION: Is that an expansive term in -- in -- in your belief, a Federal law that regulates drugs so that if a future law is enacted that regulates drugs, it would also fall within this?

MR. MILLER: Absolutely, Justice.

QUESTION: So, if Congress made the mistake of having a law that has drugs and also supersonic missiles in the same law, then any patents on supersonic missiles would also come under this exception?

MR. MILLER: If it met the qualification at the end --

QUESTION: Right.

MR. MILLER: -- of the section.

QUESTION: And that doesn't make a whole lot of sense.

MR. MILLER: The reason it does make sense is what Congress was trying to legislate here was the intersection between patent law and drug regulation and device regulation and additive regulation.

Discontinuities had grown up, time alterations had grown up since the beginning of the regulation of these devices. The mandatory testing requirements of the

FDA caused a long period of time to expire during the patent of a drug, a device or an additive.

Congress was trying to correct that situation and simultaneously correct the situation at the back end of the patent, which required the next comer to the marketplace to engage in its own FDA-mandated testing.

So, you had a foreshortening of the patent at the front because of FDA-mandated testing, you had an elongation at the back because of FDA testing. So the words "patented invention" are designed to embrace all of the patented items that are impacted by FDA-mandated testing.

A Federal law which regulates drugs is a Federal law which regulates drug. The FDCA, the Food, Drug and Cosmetic Act, is plainly a Federal law which regulates drugs.

Now, if I stopped right here, the plain meaning of the statute is obvious. If you've got a patented invention, whatever it may be, device or drug, and if you are testing it under a Federal law which regulates drugs, your testing is exempt. It is not an infringing act. That is the plain meaning of this statute.

Now, Lilly argues on the basis of a statute that Congress did not write. Lilly's argument requires the transformation of one or more words. Lilly argues that

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the statute only applies to drugs. The statute does not say it applies only to drugs.

QUESTION: Excuse me. The patent -- the invention has to be a drug patent, is that --

MR. MILLER: That is Lilly's position. The words "patented invention" used through in 271(a) and in 101 certainly are not limited to drugs.

If Congress wanted to limit this exemption to drugs it would have said make, use or sell a drug or a drug patent or a drug-related patent or a human drug patent. Why would it have used the embracive words "patented invention"?

One of Lilly's responses is that that last word at the end of the sentence, "drugs," modifies patented invention. That is syntactically impossible. Drug modifies Federal law under any standard of construction.

QUESTION: Was the -- was it determined in the case that the use made of this patented invention satisfied the last part of this exemption?

MR. MILLER: That issue is technically still open because the legal question of whether this statute applied to devices has preempted that.

QUESTION: Well, that -- you mean if we agreed with you the issue is still open as to whether or not six years of this testing was for the purpose indicated by the

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exclusion?

MR. MILLER: If you decide, as Medtronics contends, that this statute applies to devices, it is still open for the district court to inquire as to whether the particular implants achieved by Medtronic were for the use specified in the statute. That issue has -- there is nothing final on that question yet.

Now --

QUESTION: Mr. Miller, what about Subsection 2, (e)(2)? It seems to me this is sort of a bad-faith exception to the -- to (1). And it seems -- it seems to me that that bad-faith exception -- that is to say you're submitting the information, you're developing and submitting information, but your real purpose is -- is -- is to develop the product and sell it before the patent expires. You're a bad actor.

I don't see why that exception wouldn't have been extended to everything that (e)(1) covers, and it seems very strange for that exception in (e)(2) to cover only -- only exactly what Mr. Malloy contends (e)(1) covers exclusively, namely drugs and -- and veterinary biological products.

MR. MILLER: Several points, Your Honor.

If you look at (e)(2), it shows you exactly how Congress could write and did write a provision that only

applies to drugs. It says drug. It says Food, Drug and Cosmetic Act. It even defines drug.

If (e)(1) applied only to drugs, this is the way Congress would have written (e)(1) with words relating to drugs, with cross-references -- note the cross-reference in (e)(2) to 505 of the FDCA, a specific cross-reference to a particular provision. (e)(2) demonstrates that (e)(1) with its reference --

QUESTION: Right.

MR. MILLER: -- to patented invention. (e)(1) with its sort of broad encompassing of all Federal laws relating to drugs is a much broader provision than the very narrow exception to the exception which lies in (e)(2).

Now, why you ask?

QUESTION: You're finally coming to answer my question, having made the point you wanted to make.

(Laughter.)

MR. MILLER: We'll fight for any advantage, Justice.

(e)(2) is unique to drugs. As -- as Mr. Malloy said, the genesis of this '84 statute lies in a fight between the generic drug industry and the so-called pioneer drug industry.

The generic drug industry was given the so-

called ANDAs, these abbreviated new drug applications which would enable them to get to market faster. The pioneer drug industry, however, wanted some procedural safeguards against too rapid an ANDA, one that cleared the FDA before the patent expired. So (e)(2) and (e)(4) are concessions to the pioneers to provide them with a notice and litigation opportunity in case they got snookered.

That's totally irrelevant to the device industry. The device industry does not have that dichotomy between pioneers and generics.

QUESTION: Yeah, but it isn't -- it isn't only devices that we're talking about that are covered by (1) but not covered by (2).

MR. MILLER: Others.

QUESTION: There are -- there are other elements that are brought in by your broad interpretation of (1) to include everything under the -- under the Food, Drug and Cosmetic Act.

MR. MILLER: The only things that are included as a practical matter are drugs, devices, additives, because the second defect with petitioner's argument as to why they used drugs in (e)(1) is that drugs is the perfect descriptor.

The word "drugs" in the context of this statute meant in 1984 two acts: the Federal Food, Drug and

Cosmetic Act and the Public Health Service Act. Those are the only two acts that deal with the submission of test data regarding patented inventions. And they only deal with drugs, devices and additives.

The word drugs embraces those two like a glove. There is no device statute, and there is no additive statute. Basically there's the FDCA, which everybody calls the drug statute, and the Public Health Service Act.

Now, Mr. Malloy twice and in footnote 2 of his reply brief, makes this very catchy argument that gee, Congress could have used the word additive rather than drug, trying to suggest how stupid that construction is.

No, Congress could not have used the word additive or cosmetic or device. It could only have used the word drug to achieve its purpose because only the word drug embraces both the FDCA and the Public Health Service Act.

If you used additive, cosmetic or device, the statute would have a shortfall. So drug is the perfect descriptor.

QUESTION: Can I be sure I understand your answer to my question?

You -- you say that there is nothing that comes within the exemption of (e)(1), and that would have been subject to these expedited approval procedures which

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(e)(2) is directed to. There's nothing except the things that are in fact covered by (e)(2). There's --

MR. MILLER: That is correct.

QUESTION: There's no gap?

MR. MILLER: To my understanding, Justice Scalia, there is no gap. The words work.

The problem with the petitioner's argument is that you have to interpolate words that are not in the statute. You've somehow got to interpolate that patented invention means drug-related invention. You cannot do that.

You've got to interpolate the words under the information submission procedures of a law relating to drugs. Those words are not there.

QUESTION: Or you could just interpret Federal law to mean a Federal statute, not the whole Food, Drug and Cosmetic Act, just as, you know, it wouldn't be all of Title 35, just the -- the one law.

MR. MILLER: The one itty, bitty subsection. The problem with that, Justice Scalia is that when you go through the FDCA you discover that devices and drugs are intermingled.

If you take a look at 331, which we believe is the core regulatory provision, you find that drugs and devices are tied like knots. And if Congress wanted to

achieve that result, it would have been so easy for it to insert the words under the drug submission provisions of a Federal law relating to drugs.

The point is those words are not there.

QUESTION: It would have been very easy to say which regulate -- instead of under a Federal law which regulates the manufacture, use or sale of drugs you could have said under the -- under the Food, Drug and Cosmetic Act and the second act that you're concerned about. If you want to talk about being easy, wouldn't that have been a lot easier than this, which will pick up my -- my hypothetical statute about missiles?

MR. MILLER: Your hypothetical statute about missiles can be handled exactly the way the Congress handled the addition of animal drugs and veterinary biological products in 1988. That is, by adding them to 156, the extension provision, and then tucking them into 271(e)(1).

Now, that's worth a bit of note. When Congress did that in '88, notice veterinary biological products are regulated by the Toxin -- Toxin, Serum Act -- the Virus, Toxic Serum Act.

Congress didn't say the Virus, Toxin Serum Act in 1988. It says a Federal law which regulates veterinary biological products. Notice in '84 they used drugs as a

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generic descriptor. In '88 they used veterinary biological products as a generic descriptor not identifying the statutes by name.

I can't put my mind into the mind of the people who drafted that but it is plausible to say -- it is plausible to say that they were using the more generalized language simply because Congress might then enact another drug law or another veterinary biological products law. And 271(e)(1) would then act as a receptor.

Now, let -- let me broaden this a little bit and get -- get back from the words. Let's look at the context of the statute. I think it is exceedingly important to look at the context.

The '84 statute was a very important statute. If you look at the legislative history it was designed to achieve three objectives. One, the drug companies who were before Congress at that time were claiming loss of patent because of the elongated testing required by the FDA. So, Congress wanted to stimulate innovation.

Congress also made it clear it wanted to promote competition in the medical field on expiration of the patent, and Congress also made it clear that it wanted to restore some definiteness about patent expiration.

The problem with the testing was you never knew when it would end, and if you couldn't -- if you couldn't

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start, you were just left in limbo. What Congress did in '84 was say okay, all of you medical people, all of you drug people, all of you device people, all of you additive people, you're going to get an extension, and an elaborate scheme was established in 156 to give them the extension. Then Congress said, but that's it. That's it.

Congress quite clearly said there shall be no other direct or indirect extension of patent. That's what 271 was all about. Congress said you people -- and it named them all in 156 -- you get an extension, but you competitors, you can test during the patent period so that when this extended patent ends, you're prepared to compete, to enter the marketplace to bring these health products to test --

QUESTION: May they test just during the extension period or previously?

MR. MILLER: No, Chief Justice. The statute allows the testing -- and that's all it is, just testing -- to occur during the patent period. So it's theoretically possible that somebody might start testing in the first year, but won't be able to commercialize it until 17 plus extension.

Now, it's important to understand that the patent term is 17 years, the theoretical potential extension is five years. That's 22 years. And in 271

Congress said that's it, because we're going to allow people to test so after 22 years they can get to market and bring the drugs and devices and the additives to people.

And right in that legislative history is the clearest possible statement. There shall be no other direct or indirect extensions, clear reference to the fact that we're giving you something at the front end. We are in effect recognizing in 271(e)(1) a free to use, a freedom to use solely for testing, not for marketing.

QUESTION: Why does (inaudible) say testing?

MR. MILLER: Submission and development means --

QUESTION: Of information.

MR. MILLER: Yes, yes. That's the compliance with, the compliance with the FDA mandates which includes as in this case, Justice White, clinical tests. You cannot get a pacemaker onto the market until you've gone through FDA clinical testing.

You see, what we have here is an absolutely fortuitous patent extension created by the dictates of FDA-mandated testing that's an artificial barrier to market entry and -- and we believe the Congress said as to all three categories, we're going to give you the extension, but this artificial barrier simply must come

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down so we can get definiteness of patent term and we can get marketplace competition.

QUESTION: Why did Congress decide to give them the extension?

MR. MILLER: Because there was a -- a demonstration before Congress that the FDA-mandated testing was in effect cutting into the patent monopoly.

QUESTION: At the front end?

MR. MILLER: That's right.

QUESTION: In the beginning -- in the beginning of the patent.

MR. MILLER: Yes, yes, yes.

Now, the we believe absurdity of the Lilly position is that if 271(e)(1) does not permit device companies to test as drug companies can test, in effect the whole scheme of the 1984 act is destroyed. It leads to the absurd result that device companies are given double extensions. They can dip into the 156 extension and then say 271(e)(1), as Lilly is saying this case doesn't apply to you, Medtronics, which means that theoretically a device company would get 17 years plus five years plus two, four, six additional years, while the next comer would be testing if you exclude device companies from 271(e)(1).

It simply makes no sense from a policy

perspective. It makes no sense in terms of what Congress was trying to accomplish in '84. I submit to you that is exactly why 271(e)(1), its plain language, says patented invention for uses under a Federal law which regulates drugs embraces devices as well as drugs.

There are numerous other arguments. Mr. Malloy has said well, the reason Congress has distinguished between devices and drugs is because devices are tested differently. Medtronic charged $17,000 for its pacemaker implants. Drugs you don't charge.

The truth of the matter is that Medtronic's charges of $17,000 is authorized by the FDA. The FDA has in its regulations made a policy decision that device manufacturers can charge because of the cost of the devices, the cost of the devices; that if device manufacturers could not recoup a little of their investment, small device companies simply could not test. They simply could not afford.

The truth of the matter is that although $17,000 per device sounds like a lot of money, it is a small fraction first of the research development and manufacturing costs of Medtronics. These clinical trials are staggeringly expensive. Many of the implants are not charged. They are not charged in part because some of them go into animals, and it's hard to make Fido pay.

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Some of them are used for ladder tests, which are just dropping tests, and some of them simply are not collected.

There is no real distinction between drugs and devices. The few devices that must be tested -- less than 10 percent of all devices are tested. Only the highly risky devices. Nobody tests bedpans and scalpels. The only devices that are tested are things like prosthetic devices, artificial valves, pacemakers.

The number of devices that will fall under 271(e)(1) is relatively small, and any notion that there is a significant marketplace difference between drugs, which are typically run over 1,000 or 2,000 people and devices which are typically run over 50 or 100 people, that distinction does not wash. There's no evidence of it before Congress. Congress never tried to draw a distinction based on devices versus drugs.

QUESTION: Mr. Miller, can I come back to (e)(2)? I'm really hung up on (e)(2). I'm sorry.

The response that -- that petitioner's reply brief makes to what -- to what you said about (e)(2) is that while there are no abbreviated applications for -- for medical devices, there -- it is the case that they do not all require full pre-market clinical trials prior to marketing so that they are subject to the kinds of abuses that -- that (e)(2) seems to be directed at.

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I -- I -- I just find it very strange that -- I mean, that's such a -- that's such a bad-faith provision in (e)(2). You would think that you'd be sure to cover everybody who's trying to get out of -- out of (e)(1) in that provision. And if I have any doubt that there's something left out, which it seems to me there is, I wonder what (e)(1) means.

MR. MILLER: All generic drugs must go through bioequivalency testing. That can be a significant test on a lot of people and take a lot of time. 271(e)(2) is designed to protect the pioneer against the generic who's going to do that bioequivalency testing and try to slip through that ANDA and get approval before patent expiration.

Other than the handful of highly risky, highly intrusive devices like the pacemaker that we're talking about today, none of the other devices get tested. FDA has no resources, there's no ability to test the rest. All that happens, unlike the generics which are tested, is that the device manufacturer files a notice of substantial equivalence with the FDA and goes to market. There is no context comparable to the (e)(2)/(e)(4) -- situation in the device field. There is no testing as there is testing for generics. There's no ANDA.

Either you fall into the so-called Class III,

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like the pacemaker, where you go through clinical tests of enormous duration where there's no risk of an abbreviated pre-market approval, or you just go to market after you've filed your notice.

So there's -- there just is nothing comparable between the non-Class III device companies and the generic drug companies.

QUESTION: Can you go to market after filing notice, you wouldn't come under (e)(1) anyway because there's -- because there's nothing related to the development and submission of information, is that you're point?

MR. MILLER: That is right. If you -- if you have gone to market, you will be sued for infringement, and that -- that -- in other words, there is no need to protect the device company as there is a need to protect the pioneer against the sleazy generic.

QUESTION: Thank you, Mr. Miller.

Mr. Malloy, you have two minutes remaining.

REBUTTAL ARGUMENT OF TIMOTHY J. MALLOY

ON BEHALF OF THE PETITIONER

MR. MALLOY: The term drugs embraces like glove the term devices -- the term drugs embraces the term devices like a glove only with a crowbar and a hammer.

The statute specifically defines drugs as

excluding devices. We've heard that the theme of Congress, the theme of this was 156 tradeoff versus medical device technology coming in. Congress didn't use the term medical device technology. Congress 13 separate times used the term drugs or drug bioequivalency testing.

So I suggest that what we've heard about the theme of Congress in the tradeoff is totally incorrect.

With respect to the use of the term patented invention, if Congress used the term drug patent, then -- then processes or methods regarding drugs might not have been included as well. So it was easier to use the very terms they did, "development and submission under a Federal law regulating manufacture, use or sale of drugs" to be drug specific. Only -- only in our wildest dreams would Congress have used a -- one term which defined as excluding another for the purpose of including the other.

Now, regarding the (e)(1) and (e)(2) dichotomy, there are two reasons. First, if drugs -- if devices aren't in (e)(2), then a medical device company can come in and get approval two years before the patent expires, knowing that preliminary injunctions are rarely granted and no suit can be filed during that period. The suit's filed with two years left to run natural delays occur like the ones Medtronic caused in this lawsuit, and what we wind up with is no effective protection, no injunction.

That's what (e)(2) is there for. It was to stop people from going and getting approval ahead of time in an improper way.

And it would be a bizarre and unfair concoction to have medical devices construed into (e)(1) where it's not there and also not be in Section (e)(2). For all the reasons I've explained earlier, I think it's most urgent that we request that Medtronic's delay be stopped and that if this decision is reversed --

QUESTION: Your time has expired, Mr. Malloy.

MR. MALLOY: Thank you.

CHIEF JUSTICE REHNQUIST: The case is submitted.

(Whereupon, at 2:45 p.m., the case in the above-entitled matter was submitted.)

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No. 89-243 - ELI LILLY AND COMPANY, Petitioner V. MEDTRONIC, INC.

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BY Judy Freilicher

(REPORTER)