

KEYNOTE ADDRESS:

**EXPERIMENTAL USE EXCEPTION:
THE FEDERAL CIRCUIT'S INTERPRETATION
OF 35 U.S.C. SECTION 271(e)**

Judge Randall Rader*

Today we have a very daunting task. We need to discuss Title 2 of the Drug Price Competition and Patent Term Restoration Act of 1984.¹ That lengthy title is usually shortened to the Hatch-Waxman Act. The Hatch-Waxman Act is actually a remedy for a collision between the Food and Drug Administration's ("FDA") regulatory process and the incentives of the Patent Act. As legal scholars, you are probably thinking "Judge Rader, it cannot be true that Congress would have in place a magnificent system of incentives for invention, for over two hundred years, and then enact another regulatory scheme that would conflict with it and undercut it; then, because of the conflict and collision between these two important acts, they would have to enact still a third provision to ameliorate the damage they have done by creating the collision." Certainly Congress would not engage in such an unreasonable change of events. Unfortunately, that is precisely what happened. The 1984 Act was meant to remedy the collision that occurred between the FDA regulatory regime and the incentives of the Patent Act.

The Food and Drug Act often delays, for more than seven years, the regulatory process. So, even though a patent owner has filed early to obtain a patent, they then have their financial reward postponed for a lengthy period of time, five to seven years. These are years they lose out of their period of exclusive right.

Not only did the collision of these two acts affect the front of the patent term, but for a different group of individuals – the public, and particularly generic drug manufacturers – it deferred the end of the patent term. You would expect that one would be able to create generic drugs and reap the benefits of the expiration of the patent. Unfortunately, the generic drug producer could not do so because any activity to prove that their drug was worthy of FDA approval, such as the experimentation required to prove that the drug was safe and effective, would not be able to commence until the end of the patent period. This is

Edited for publication by Kraig Hill, Toshiko Takenaka and/or Kevin Takeuchi, CASRIP.

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* United States Court of Appeals for the Federal Circuit, Washington D.C. This document is a verbatim transcript of the remarks presented by Judge Rader on July 20, 2001 at the High Technology Protection Summit at the University of Washington School of Law. Judge Rader's remarks were given without formal written materials.

¹ Pub. L. No. 98-417, 1984 Stat. 1538 (codified as amended in scattered sections of 21 & 35 U.S.C.).

because in 1984, the Federal Circuit, in *Roche v. Bolar*,² stated that experiments even if only for the purpose of obtaining FDA approval were still infringing uses. The Federal Circuit said experimenting before the end of the patent term was infringing use. Therefore, a generic drug producer could only start experiments after the patent expired. It would take several years of experimenting and submitting data to the FDA before a generic drug producer could begin to reap any financial rewards from the expiration of the patent.

The 1984 Act was a remedy for these problems. First it gave a term restoration to patent owners for the time they lost at the front end of the patent term. Second, it allowed a generic producer of drugs, upon expiration of a patent, to file an Abbreviated New Drug Application, an “ANDA.” This ANDA allows a generic producer to simply show that they have a bioequivalent, or the same as the patented invention, and then they can gain very quick FDA approval and proceed to the marketplace without much delay. But you would say, “They would still not be able to make it on the day of expiration because that would require them to experiment before the expiration of the patent and that would be an infringement.” They have to experiment, at least, to show that they have a bioequivalent. This is where Section 271(e)³ comes in.

Section 271(e) states that it is not infringement to make, use, sell, offer to sell, or import a patented invention, as long as this activity is done 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. In other words, it is not infringement, as long as the activity is solely for uses reasonably related to acquiring information for the FDA.

The 1984 Act specifically uses the words “for a Federal law which regulates drugs.” Interpreting these words was the first and one of the most important Federal Circuit cases under 271(e). The question arose, “does a medical device fit under the 1984 Act?” The language of the statute says, “a Federal law regulating drugs.” It does not say anything about medical devices. The Food and Drug Act, however, covers both medical devices and drugs.

So, does the language “a Federal law which regulates drugs” mean *anything* covered by the FDA Act, including medical devices, or does it mean “only drugs,” as stated in the statute? In the 1989 opinion, *Eli Lilly v. Medtronic*,⁴ Judge Helen Nee, my late colleague, offered an opinion in which she said, “it is the law that counts.” She said, “The last clause describes the type of law, not the type of patented invention; therefore, medical devices also fit underneath the 1984 Act.” Accordingly, one could experiment on medical devices before the patent expired, as long as one was doing it for FDA approval.

That issue went to the United States Supreme Court.⁵ In a six-to-two opinion, the Supreme Court affirmed the Federal Circuit. Judge Stevens, writing for the Court, held that “medical devices also fall within the 1984 Act and can be experimented on before the expiration of the patent.” Note however, that Justice Kennedy, says in his dissent, “FDA

² *Roche Prod. Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984).

³ 35 U.S.C. §271(e).

⁴ *Eli Lilly and Co. v. Medtronic, Inc.*, 872 F.2d 402 (Fed. Cir. 1989).

⁵ *Eli Lilly and Co. v. Medtronic, Inc.*, 493 U.S. 889 (1989).

patented medical devices would often have greater effects on the patent holder's rights, than comparable testing would have on drugs." According to Justice Kennedy, the difference between drugs and medical devices is a very significant difference that probably should warrant different treatment under the 1984 Act. I will come back to this point in just a moment.

Probably the most important question is: what is the scope of this experimental use exception? What kind of activities can you undertake in the name of experimentation and still escape the consequences of infringement? Remember, you can make, sell, manufacture, use, offer to sell or import, and it is not infringement if it solely for uses reasonably related to FDA approval.

The key case in this area is *Intermedics v. Ventritex*.⁶ Interestingly, this is not a Federal Circuit case. It is a district court case, out of the Northern District of California. It is perhaps the only instance where a district court case has remained more important than the Federal Circuit's pronouncement. This is mostly due to the nature of the case and because it was the early test case in this area. It was approved and affirmed by the Federal Circuit but in a non-precedential opinion. Accordingly, we will discuss the district court opinion. This case involves a medical device, an implantable defibrillator called the "Cadence," which is a pacemaker for cardiac patients. Of course, FDA approval is needed to market this device. The device must be shown to be safe and effective; therefore, clinical testing on human beings is required to show that the device is safe and effective like the patented defibrillator, which was owned by Ventritex.

Let us revisit Justice Kennedy's dissent point for a minute. He said there is something different about medical devices such that they should be treated differently than drugs. What was he talking about? Think for a minute about the nature of experimentation with a big medical device like this defibrillator. How many hospitals are there in the United States that conduct tests and actually implant these devices? There is going to be a limited number of these hospitals. Probably the leading hospitals in the country; there are probably hospitals that are affiliated with universities or medical schools doing such testing and research as well. Suppose there are thirty hospitals in the nation that are conducting the testing and actual implanting of artificial hearts or pacemakers. If a manufacturer asks just ten of these hospitals to perform clinical testing then it has already captured one-third of the market. Moreover, it has captured the market during the period of experimentation. Once the period of experimentation is over they already have those hospitals accustomed to using their product. Therefore, they are going to keep that one-third of the market once the experimentation has ended. Afterward, they can move on to the rest of the market.

From the patent owners' standpoint, they are losing their market before the patent even expires. The competitor is hiding behind 271(e), the permissive 1984 Act provision, to cut into their market while the patent is still valid and enforceable. Therefore, patent owners are very worried about 271(e). They want to limit this experimentation as much as possible.

⁶ *Intermedics, Inc. v. Ventritex, Inc.*, 152 F.R.D. 188 (N.D. Cal. 1991), *aff'd.*, 991 F.2d 808 (Fed. Cir. 1993) (non-precedential decision).

In this case of *Intermedics v. Ventritex*, the patent owner challenged five different things that Intermedics had done in exceeding the protection against infringement given by the 1984 Act. Specifically, they argued that Intermedics manufactured several hundred Cadence devices. Isn't that far too many for the purpose of experimenting for FDA approval? The District Court said the use just has to be reasonably related to the acquisition of information for the FDA. They are not sure how much information the FDA is going to need; so if they need to put out 100 or 200 or many hundred devices among these hospitals it is still reasonably related to FDA approval. Therefore, hundreds of manufactured devices were within the Section 271 exception to infringement and Intermedics was free to do it.

The second point raised was the selling of the Cadence device to hospitals. They are experimenting and should not be selling or making money during this time, right? It does not matter, they are still generating information. A more important point was that they continued to sell the Cadence devices after they had already submitted their information to the FDA for approval. Can they do that? The answer from the court was yes, Intermedics can continue to sell devices after submitting information to the FDA. The experimentation was not over because the FDA could reject the application for insufficient information. So they may continue to sell even after submitting information to the FDA.

Third, Intermedics was selling these cadences to international distributors with commercial clauses in the sales contract saying that "you have to supply us with market share information and you must encourage the distributor to promote the cadence." Isn't this commercial activity, not experimentation? The court stated that although there was some commercial activity, it does not negate the fact that they are still experimenting and the data that they are acquiring is going to be submitted to the FDA, even if it is from Germany, which was the fourth point.

The fifth point was the interesting one: the trade show. What is the reasonable relationship to FDA experimentation in delivering the Cadence device at a medical trade show? Medical trade shows are for marketing products, as well as convincing doctors and hospitals to use them. What was that? Convince hospitals to use it? Now we have our hook. We can say, "we are actually just recruiting hospitals to serve as clinical testing sites. We go to these trade show fairs to meet hospital administrators and encourage them to perform clinical tests for us for the FDA."

There was, however, a little problem in the Intermedics case. Intermedics continued to recruit – they continued to go to trade shows – beyond the time when they had recruited all the necessary hospitals for their clinical testing. Why did they continue to recruit when they already had a full array of hospitals to perform tests? This issue put the District Court in a tough spot. To escape, the District Court pulled the little rabbit out of the hat, and said such action was *de minimis*. Although over-reaching, and maybe Intermedics should not have done this, it was such a minor infringement that the District Court decided not to call it an infringement. Once again, Intermedics use was permissible.

There are two strains of experimental use dogma in patent law. First, there is the strain of experimental use dogma created by the 1984 Act that we have been discussing. If you are experimenting for the FDA you are excused from infringement. Second, there is a much older doctrine of experimental use, which at its roots is something like fair use in copyright law, that says, "if you were just experimenting and just doing a little bit of it,

then it will not be deemed infringement because it was *de minimis* and was for the good purpose of scientific exploration.” This is a very old doctrine, with cases that hinted at it a hundred years ago. All of a sudden, in *Intermedics*, the District Court pulled that doctrine up and applied it, stating that this was a minimal infringement.

However, isn't a little infringement still infringement? In fact, there was a Federal Circuit case just last year called *Embrex v. Service Engineering*.⁷ In that case, the infringing party raised the defense of *de minimis* experimental use. “We just did it a little bit, therefore, we should not be punished for it.” The Court found that even though there was only a little bit of use, it had a commercial purpose and if you have a commercial purpose, you lose. A concurring opinion stated that this Court has not tolerated the notion that a little infringement, *de minimis* infringement, is acceptable infringement or not infringement at all. The statute states directly that any unauthorized use of a patented invention is infringement. With regards to the experimental use excuse, neither the statute nor any precedent gives any reason to excuse infringement because it was committed with a particular intent or purpose, such as scientific experimentation or out of curiosity. Rather the Supreme Court and the Federal Circuit have reiterated that intent is irrelevant in infringement.

Does the *de minimis* infringement excuse still survive? Perhaps on the books. In reality, if there is a commercial taint at all, and it is hard to imagine a case without such a commercial taint, it would never be called *de minimis*. Nonetheless, *Intermedics v. Ventritex* was affirmed by the Federal Circuit.

Once again, in another case, *Telectronics v. Ventritex*,⁸ notice that the same patent is at stake, involving cardiac defibrillators. Ventritex again was losing their market share to this type of experimentation from another, who saw Intermedics was getting away with it and decided to do the same thing. Ventritex sued them and the whole case came down to one thing again: trade shows. What do trade shows have to do with experimenting for the FDA? Well, once again, the defendant argued that they were recruiting hospitals. The Federal Circuit upheld that argument finding that it was reasonably related to FDA experimentation to have a trade show presentation.

In conclusion, “reasonably related to gathering information for the FDA” is quite broad language that generic drug or medical device manufacturers can hide behind to do many things that would otherwise constitute infringement before the expiration of the patent. I do not want to leave the impression that the 1984 Act leaves the patentee without any recourse. Indeed, it also benefits the patentee, beyond just patent term restoration, which we discussed earlier. For example, if a patent is not expired, then someone who wants to file an ANDA with the FDA will have to certify: (1) that they will not market or commercially exploit the product before the expiration of the patent, (2) that the patent is invalid, or (3) that their ANDA drug will not infringe.

If they certify that either the patent is invalid or they are not going to infringe, then the patentee has forty-five days to file suit. Once suit has been filed the District Court

⁷ *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343 (Fed. Cir. 2000).

⁸ *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992).

determines whether there is infringement by the ANDA drug or whether the original patent is invalid. This lawsuit will suspend all FDA approval until the patent expires, the court determines the validity or the infringement issue, or seven months from certification.

The patentee is not bad off under the 1984 Act. Although there is a broad experimentation exception, if the ANDA drug tries the market before patent expiration, a very powerful artificial infringement section kicks in to give the patentee protection for the full term and perhaps even beyond the term. As such, the Act has operated to ease the collision between the FDA regulations and the Patent Act – that unthinkable circumstance that we did not think could happen in the first place anyway.

Thank you very much.

Toshiko Takenaka: The rest of the world is expanding or clarifying the experimental use exception by using loose statutory language to limit the enforcement against experimental uses, instead of fortifying the language of their statutes such as we are doing with section 271(e) in this country. They use general provisions to cover clinical testing as well as other activities done by universities. It is essential for universities to conduct research. Some of the information in the specifications may not be sufficient to enable someone skilled in the art to practice the invention; therefore, it is necessary to conduct experiments to prove the information in the specifications is correct. You stated that intent is irrelevant for infringement or the determination of infringement. That seems to create a significant gap between the United States and the rest of the world, even though we are following the same language of WIPO and TRIPS.

Judge Rader: I understand your question as asking, “Can universities experiment to verify what the invention actually says it accomplishes without infringing?” Well, that experimentation would be a use of the patented invention and it may even be a making of the patented invention, which in the United States is infringement. The way the system deals with this is through either a liberal licensing policy or permission from the patentee. Usually a university can quite liberally use an invention as long as it gives notice to the patent owner and guarantees that no commercial activity is involved. In some instances, the patentee may ask for a tiny royalty. In other instances, permission simply will be given.

As a matter of enforcement administration, the concern I have with the European Patent system is that anyone could say, “I am just experimenting to verify the results of this patent and I am going to produce 100 tons of this drug because I am just not sure that it will work in those big amounts.” At what point do the courts decide experimenting has become commercial? It is all based on an intent theory, which is very hard to administer.

I think that the better way to proceed is with a system that acknowledges it as patent infringement and then places the patent owner in the controlling position of deciding how much experimentation to allow before considering it a commercial threat. This system has worked quite well in the United States. The hospitals and experimenting universities do not complain that they are restrained because the system does acknowledge in its enforcement a liberal use meaning, so long as there is no commercial exploitation. I hate to inject the court into that, which I am afraid could happen now with the broad language of the Japanese and European experimental use cases. That would be my concern.

Robert Blackburn: One concern that people have is a patent that defines the scope of the claims in terms of experimentation or an experiment, such as in the biotech industry: “a probe which hybridizes at a certain stringency.” It would appear that it is a legitimate objective of the patent system to allow people who are trying to avoid patents, such as by designing around them, the possibility of accidentally infringing and then entitling them to adjust their conditions in such an event. Many of us view such events as non-infringing but maybe we should be looking at what our damages would be if, in fact, it were technically an infringement.

Judge Rader: I think you put your finger right on it. Even if it were an infringement to have accidentally produced one ounce of an infringing material in an effort to design around or for some other purpose, the enforcement of that patent would produce damages of a couple pennies. It would not even pay to hire an attorney to write a complaint, let alone bring a case. So the nature of the enforcement process is going to discourage unreasonable enforcement.

Here, I think there is an advantage in having the patentee in control of deciding when enforcement ought to occur. If there is experimentation that is going to lead to very broad commercial applications that will endanger your marketplace considerably, maybe you would even sue with damages of a nickel involved. That is a hard hypothetical to imagine.

But you are right, the key is that the low damages will make enforcement in this area quite reasonable. Indeed, it has seemed to work that way for years here in the U.S.

Robert Blackburn: This conference got me to reread *Roche v. Bolar*.⁹ At the end of the decision there is a very interesting discussion on damages. The author of the opinion pointed out that counsel at oral argument had really wanted to get an injunction because they assumed that the damages would be *de minimis*. The court’s response was: “this has significant commercial impact on your operations; therefore, do not assume damages will be *de minimis* merely because only a kilogram of infringing drug was at issue.”

In this era of research tool patents, where the only way to come up with a competing technology is to use the tool, even *de minimis* use of the tool would have a commercial impact that could be quite significant. I wonder whether or not we can rely on damages being *de minimis* while attempting to design around a patent – or will that still constitute infringement?

Judge Rader: Well our damages theory is that “but for” infringement where would you have been? Even if the infringement does not lead to some considerable commercial impact, perhaps there are broader damages if an infringer has gained a commercial advantage. The court has never had a case like that, so all we are talking about is hypotheticals. In terms of the real world, no one has ever brought a case saying, “yes, they only produced one gram of the infringing drug, but by doing so they were able to produce 150 tons of non-infringing drug and we want damages on all of that.” That case has never been brought

⁹ *Supra*, note 2.

before the court. It is a hypothetical case, and I cannot tell you exactly what would happen. It seems to me that at least one thing is sure, which you pointed out: there should be an injunction against any further infringement. This damage theory is an interesting one. We will have to wait and see how that case turns out.

Bill Christiansen: How do you anticipate 271(e)(1) protection covering a client's use of research tools? Say certain discovery reagents are necessary to produce a drug that is going to trial. Later, when the drug goes on the market, the company that owned the research tools might say, "Hey, you were testing to get to market and the actual drug you created was protected, but the tool was not protected." This is where I am seeing a lot of concern, at least in the biotech industry, and I am amazed that this has not come before the court because it is a big concern. I think the reason we have not seen this come up is that, much of the time, no one knows that this testing is going on, and it is difficult to determine that it has happened until way down the pipeline. So maybe we will start seeing some of this, now that some drugs are being produced by these methods.

Judge Rader: The key to your question, as you realize, is that it has not been to the Federal Circuit yet. The question he asked is, "What if, a year or two into the patent term, someone starts to replicate, make and use the patented invention; then toward the end of the patent term they are going to submit this information to the FDA; is what they are doing now reasonably related to what we will be submitting to the FDA sixteen years from now?"

That is going to be an interesting case. You can see that the argument on one side is, "with so much time remaining, how can there be a reasonable relationship between clinical testing and what you are doing now?" What is being done now is merely preparation for commercial exploitation, right? On the other hand, the argument will be, "how will we ever get to clinical testing if we cannot now begin to detect what kind of product we will produce that will be a bioequivalent, which can then be the subject of an ANDA filing? We need to start at some point, why is there a time limit? There is no time limit in 271(e)."

Those are the arguments. I am sure that there will be excellent counsel, like the last questioner, who will present that argument to my colleagues and myself. I wonder how it will end.