775 F.Supp. 1269
United States District Court,
N.D. California.

INTERMEDICS, INC., a Texas corporation, Plaintiff,
v.
VENTRITEX, INC., a California corporation; Michael Sweeney, an individual; and Benjamin Pless, an individual, Defendants.

No. C 90 20233 JW (WDB).
|
Sept. 13, 1991.

Synopsis
Patent holder brought action against competitor and related parties, alleging they were liable for patent infringement, misappropriation of trade secrets, and other unfair business practices in connection with development of implantable defibrillator. On motions for summary judgment, the District Court, Wayne D. Brazil, United States Magistrate Judge, held that: (1) alleged infringing uses of accused device came within clinical trial exemption to patent infringement, as use was reasonably related to development and submission of information to Food and Drug Administration (FDA) in order to obtain approval for device, and (2) determination that exemption was applicable precluded granting declaratory relief regarding whether accused device infringed patent holder's rights.

Summary judgment entered in part.

See also 775 F.Supp. 1258.

West Headnotes (15)

[1] Patents
Safe harbor for drug development
Patents
Defenses
Patents
Health Care and Medical Products

It is not necessary to establish intent to commercialize accused device only after expiration of patent-in-suit for clinical trial exemption to patent infringement, exempting use or sale of patented invention solely for uses reasonably related to development and submission of information under federal law regulating manufacture, use, or sale of drugs, to be applicable. 35 U.S.C.A. § 271(e)(1).

4 Cases that cite this headnote

[2] Patents
Safe harbor for drug development
Patents
Defenses
Patents
Medical devices and appliances

Alleged infringers' indication that they intended to market accused implantable defibrillator upon securing Food and Drug Administration (FDA) approval, even if it was before patent expired, did not render unavailable clinical trial exemption to patent infringement, for uses reasonably related to development and submission of information under federal law regulating manufacture, use, or sale of drugs. 35 U.S.C.A. § 271(e)(1).

4 Cases that cite this headnote

[3] Patents
Safe harbor for drug development
Patents
Defenses
Patents
Drugs and medicines

Clinical trial exemption to patent infringement, for uses reasonably related to development and submission of information under federal law regulating manufacture, use, or sale of drugs, reduced scope of rights of patent holders in two significant respects: first, it permitted potential competitors, during life of patent, to engage in acts that otherwise clearly would constitute acts of infringement, as long as those acts generated data Food and Drug Administration (FDA) would use in deciding whether to approve product for commercial marketplace, thereby

depriving patent holders of sales that might well be significant, and second, it enabled competitors' large scale entry into commercial marketplace as soon as relevant patents expired. 35 U.S.C.A. § 271(e)(1).

1 Cases that cite this headnote

[4] **Patents**

Intent or Purpose, and Knowledge

Inquiry in determining whether otherwise infringing conduct comes within clinical trial exemption to patent infringement, for uses reasonably related to development and submission of information under federal law regulating manufacture, use, or sale of drugs, focuses only on acts by alleged infringer that would be deemed "infringing" but for exemption and in which alleged infringer actually engaged; with respect to those actual acts, it is not asked what underlying motives might have inspired them or what indirect, ripple effects they might bring, but rather it is simply asked whether actual uses are solely reasonably related to development and submission of information to the Food and Drug Administration (FDA). 35 U.S.C.A. § 271(e)(1).

1 Cases that cite this headnote

[5] **Patents**

Safe harbor for drug development

Patents

Defenses

Requirement that infringing uses of patented device be "reasonably related" to development and submission of information to the Food and Drug Administration (FDA) to come within clinical trial exemption to infringement did not place alleged infringer outside exemption simply because it turned out, after the fact, that some of its otherwise infringing "uses" either failed to generate information in which FDA was interested or generated more information than turned out to be necessary to secure FDA approval; instead it should be asked whether it would have been objectively reasonable for party in alleged infringer's situation to believe that there was decent prospects that "use" in question would contribute (relatively directly) to generation of kinds of information that was likely to be relevant in processes by which FDA would decide whether to approve product. 35 U.S.C.A. § 271(e)(1).

14 Cases that cite this headnote

[6] **Patents**

In general; products and devices

In ruling on motion for summary judgment on defense that alleged patent infringement comes within clinical trial exemption, it must be determined first if there are genuine factual issues regarding whether alleged infringer's uses are infringing, and second if there is genuine factual dispute about whether any of alleged infringer's otherwise infringing and nondeminimus uses are not reasonably related to securing approval of Food and Drug Administration (FDA). Fed.Rules Civ.Proc.Rule 56, 28 U.S.C.A.; 35 U.S.C.A. § 271(e)(1).

2 Cases that cite this headnote

[7] **Patents**

Medical devices and appliances

Alleged infringer's use of clinical data regarding accused implantable defibrillator to provide potential investors with information about status and testing of device and to support foreign import applications, and publication of articles describing features of device, were not infringing acts and, therefore, those acts were irrelevant to determination of whether alleged infringing acts came within clinical trial exemption, for uses reasonably related to development and submission of information under federal law regulating manufacture, use, or sale of drugs. 35 U.S.C.A. § 271(e)(1).

1 Cases that cite this headnote

[8] **Patents**

Safe harbor for drug development

Patents

Defenses

Patents

Medical devices and appliances

Alleged infringer's manufacture of patented implantable defibrillator did not, by itself, deprive alleged infringer of clinical trial exemption, for uses reasonably related to development and submission of information under federal law regulating manufacture, use, or sale of drugs, where it was undisputed that most devices were used to generate data for Food and Drug Administration (FDA). 35 U.S.C.A. § 271(e)(1).

3 Cases that cite this headnote

[9] **Patents**

Safe harbor for drug development

Patents

Defenses

Patents

Medical devices and appliances

Alleged infringer's continuing sales of accused implantable defibrillators to clinical investigators after submitting its application for premarket approval to the Food and Drug Administration (FDA) did not deprive alleged infringer of clinical trial exemption, so long as it was objectively reasonable for company in alleged infringer's position to believe that continuing clinical trials would, relatively directly, contribute to generation of kind of data relevant to FDA's inquiry. 35 U.S.C.A. § 271(e)(1).

5 Cases that cite this headnote

[10] **Patents**

In general; products and devices

Patent holder failed to establish genuine issue of material fact as to whether alleged infringer's sale of accused implantable defibrillators to individual distributors was not reasonably related to obtain Food and Drug Administration (FDA) approval, such that those sales would not come within clinical trial exemption, though some distribution agreements described "market share criteria" and encouraged distributor to promote device, where patent holder failed to controvert alleged infringer's evidence that market share language was inadvertently included "boilerplate" language that was since changed to clarify that there could be no general commercial sales or promotion of device until after FDA approval was obtained, and that distributors performed limited function of clearing devices through customs so that they could be delivered to clinical sites overseas. Fed.Rules Civ.Proc.Rule 56, 28 U.S.C.A.; 35 U.S.C.A. § 271(e)(1).

6 Cases that cite this headnote

[11] **Patents**

In general; products and devices

Patent holder failed to establish genuine issue of material fact as to whether alleged infringer's testing of accused implantable defibrillator in Germany was unrelated to securing Food and Drug Administration (FDA) approval, such that testing would not come within clinical trial exemption, where patent holder failed to controvert alleged infringer's evidence that clinical investigator in Germany was one of the preeminent figures in world in field, that every single defibrillator that was sold and sent to Germany was used for implantation by clinical investigator, and that all data generated in those clinical trials in fact was submitted only to FDA. Fed.Rules Civ.Proc.Rule 56, 28 U.S.C.A.; 35 U.S.C.A. § 271(e)(1).

[12] **Patents**

Safe harbor for drug development

Patents

Defenses

Patents

Medical devices and appliances

Foreign testing of accused implantable defibrillator required to obtain safety certification, which was necessary in order to obtain import approval to conduct clinical tests, was itself reasonably related to generation of clinical data for Food and Drug Administration (FDA), and thus came within clinical trial exemption to patent infringement, though results

of certification testing was never submitted to FDA. 35 U.S.C.A. § 271(e)(1).

1 Cases that cite this headnote

[13] Patents

Safe harbor for drug development

Mere demonstration or display of accused device, even in obviously commercial atmosphere, is not otherwise infringing act that would have to be examined to determine whether it came within clinical trial exemption, for uses reasonably related to development and submission of information under federal law regulating manufacture, use, or sale of drugs, unless totality of circumstances also reveals concurrent sales-oriented activity which results in, or at least substantially advances, actual sale of accused device. 35 U.S.C.A. § 271(a), (e)(1).

14 Cases that cite this headnote

[14] Patents

In general; products and devices

Patent holder failed to create genuine issue of material fact as to whether alleged infringer's demonstration of accused implantable defibrillator at various medical conferences was infringing use, was entirely unrelated to generating data for submission to Food and Drug Administration (FDA), and could not be considered de minimus to extent it was not so related, such that clinical trial exemption would not apply, where patent holder failed to identify any sales or act of solicitation of sales at such conferences, failed to controvert alleged infringer's evidence that conferences were principal means by which to identify potential clinical investigators, and failed to show that alleged infringer's failure to screen all persons to whom device was demonstrated encroached in any significant way on patent holder's interest. Fed.Rules Civ.Proc.Rule 56, 28 U.S.C.A.; 35 U.S.C.A. § 271(a), (e)(1).

5 Cases that cite this headnote

[15] Declaratory Judgment

Infringement of patents

Determination that alleged uses of accused implantable defibrillator came within clinical trial exemption to patent infringement, for uses reasonably related to development and submission of information under federal law regulating manufacture, use, or sale of drugs, precluded granting declaratory relief regarding whether accused device, as currently configured, infringed patent holder's rights; it was not clear that there would ever be case or controversy arising under federal patent law, and exercise of jurisdiction over request for declaratory relief would undermine purpose of Congress in enacting exemption. 35 U.S.C.A. § 271(e)(1).

2 Cases that cite this headnote

Attorneys and Law Firms

***1272** Jeffrey Olson, Robert Lyon and Robert Laurenson of Lyon and Lyon, Los Angeles, Cal., for plaintiff.

Denis Salmon and Madison Jellins of Brobeck, Phleger & Harrison, Palo Alto, Cal., and George Gerstman of Gerstman and Ellis, Chicago, Ill., for defendants.

ORDER AND OPINION RE MOTIONS FOR SUMMARY JUDGMENT CONCERNING DEFENDANTS' ENTITLEMENT TO 271(E)(1) DEFENSE

WAYNE D. BRAZIL, United States Magistrate Judge.

Plaintiff's second amended complaint alleges that defendants are liable for patent infringement, misappropriation of trade secrets, and a variety of other unfair business practices in connection with defendants' development of the Cadence, an implantable defibrillator.

Both parties have filed motions [1] concerning defendants' entitlement to assert the affirmative defense provided for at 35 U.S.C. § 271(e)(1). Having considered the parties' written and oral submissions, the court hereby enters the following ORDERS:

I. INTRODUCTION.

35 U.S.C. § 271(e)(1) provides: "It shall not be an act of patent 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." The U.S. Supreme Court has held that the clinical trial exemption in § 271(e)(1) also applies to medical devices which are subject to FDA approval. *Eli Lilly and Co. v. Medtronic, Inc.,* 496 U.S. 661, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990).

§ 271(e)(1), enacted under the Drug Price Competition and Patent term restoration Act of 1984, overruled the Federal Circuit's 1984 decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.,* 733 F.2d 858 (Fed.Cir.1984). The defendant in *Roche* had obtained from a foreign manufacturer a generic drug covered by a domestic patent in order to conduct bioequivalency tests necessary for FDA approval. The Federal Circuit held this use to be infringing, despite the fact that it was limited to "testing and investigation" strictly related to FDA approval. *Id.* at 861.

The 1984 Act, enacted after the *Roche* decision, established a streamlined procedure for FDA approval of generic drugs to hasten their introduction into the market place. Specifically, the Act was designed to respond to two unintended distortions of the 17–year patent term produced by the requirement that certain products receive pre-market regulatory approval.

First, as a practical matter, the holder of a patent related to a device or drug that is subject to regulatory approval could not reap financial rewards during the early term of a patent because the patented product was kept out of the market place until substantial testing and regulatory approval was completed. Section 201 of the 1984 Act sought to eliminate this distortion by establishing a patent term extension for patents related to certain products that were subject to lengthy regulatory delays and that could not be marketed prior to regulatory approval. *Eli Lilly,* 110 S.Ct. at 2688.

The second distortion addressed by the 1984 Act occurred at the other end of the patent term. Section 271(e)(1), enacted as section 202 of the 1984 Act, responded to congressional concern that under *Roche* the arrival of generics on the market place would be unduly delayed if the bioequivalency testing required by the FDA could not begin until expiration of the patent. Since, under *Roche,* testing which made ***1273** use of a patented product could not begin until after expiration of the competitor's patent term, the patentee's monopoly would continue, often for a substantial period of time, until the competitor obtained regulatory approval. In order to eliminate this distortion Congress passed § 202 (271(e)(1)), which allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities reasonably related to obtaining regulatory approval. *Id.* at 2689; *See,* H.R.Rep. No. 98–857, 98th Cong., 2d Sess., reprinted in 1984 U.S.Code Cong. & Ad.News (hereafter "legislative history at ——") 2647, 2678–79, 2692–93.

The motions pending before the court raise difficult questions about the scope and applicability of the § 271(e)(1) clinical trial exemption. Plaintiff's first motion for summary judgment requires the court to consider whether the § 271(e)(1) exemption would be lost on a showing that defendants intend to commercialize their product *before the expiration* of the allegedly infringed patents. Defendants' motion to dismiss and plaintiff's accompanying cross-motion for summary judgment raise directly the issue of whether defendants' otherwise infringing activities have been "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" as required by § 271(e)(1).

II. PLAINTIFF'S FIRST MOTION FOR SUMMARY JUDGMENT REGARDING DEFENDANTS' ENTITLEMENT TO ASSERT § 271(e)(1) DEFENSE.

Plaintiff contends that § 271(e)(1) does *not* exempt the making, selling, or using of an infringing device in connection with supplying data to the FDA if the manufacturer *intends* to commercialize the device *before* the expiration of the allegedly infringed patents. Rather, plaintiff argues that Congress intended the statute to apply only when the allegedly infringing manufacturer is preparing to commercialize the device *after* expiration of the patent-in-suit.

In support of this interpretation, plaintiff presents two related arguments. The first focuses on alleged differences between the "purposes" for which defendants seek to utilize the exemption provided by § 271(e)(1) and the purposes for which Congress passed this statute. Plaintiff's second argument focuses on the possible effects of granting the § 271(e)(1) exemption to a defendant who intends to market its device before the expiration of the allegedly infringed patents.

[1] In support of its first line of argument, plaintiff correctly notes that a reason Congress passed § 271(e)(1) was to prevent a patent holder from obtaining the *de facto* extension of its patent-monopoly which could otherwise occur if

the alleged infringing manufacturer had to wait until the expiration of the patents-in-issue to start the investigations necessary to secure FDA approval. Plaintiff argues that, given this purpose, the only type of permissible use anticipated by Congress must be that use which results in the alleged infringer entering the market place *after* the patent-in-issue has expired.

One difficulty (not the most serious) with plaintiff's argument is that it builds from a particular characterization of Congress' purpose in enacting the exemption that we believe is misfocused. Congress' primary concern in enacting § 271(e)(1) was not with the *de facto* length of patent holders' rights; rather, it's primary concern was to create a legal environment that would enable new, medically beneficial, cost-competitive products to reach the general marketplace in meaningful volume just as soon as the undistorted operation of the patent laws would permit (i.e., as soon as the 17–year life of relevant patents expired). [2]

***1274** This characterization of Congress' primary purpose seems to us to lend support to a conclusion directly contrary to plaintiff's position: instead of suggesting that Congress wanted the courts to ensure that the exemption was available only to those parties who would enter the general marketplace after the relevant patents expired, this characterization suggests that Congress wanted the courts to ensure that the new statutory protection was afforded to every party who might be in a position to enter the general marketplace when the relevant patents expired. The emphasis, in other words, should be on the positive, not the negative. And it would be inconsistent with the positive goal of maximizing post-patent availability of lower priced new products to artificially limit the exemption only to those parties who would (or could) not enter the marketplace until after the patents expired.

There are additional, arguably more telling difficulties with plaintiff's position. We note first that Congress explicitly rejected an effort by Representative Moorehead to limit the availability of the exemption to the last year of the term of any relevant patent. (See Legislative History at 2692). Thus, it is clear that the issue of limiting the availability of the exemption was squarely considered by the legislative Branch. Yet that branch did not even remotely intimate in the statute that it enacted that it wanted any such limitation imposed. This fact should make the judiciary extremely reluctant to superimpose a substantial reduction in the scope of the statute that has no basis in statutory language.

We also have grave concerns about the feasibility of judicial implementation of the limitation that plaintiff would have us read into the statute. Plaintiff has urged the we put the "intent" of the party that claims to be engaged in activity protected by the exemption at the center of the judicial inquiry.

We are not sure what "intent" means here. One possibility is that plaintiff is suggesting that the ultimate target of the inquiry should be a subjective state of mind. If so, we are troubled by the prospect of having to search for such a thing in a corporate body or other business organization. Even with respect to natural persons, ascertaining subjective intent can be an elusive and labor intensive exercise. It also is the kind of exercise that almost always would have to be undertaken through a trial; disposing of issues of subjective intent by way of summary judgment is extremely difficult.

We also fail to understand why the subjective state of mind of a party should be significant in this setting. Surely Congress was not concerned about clearing certain "unacceptable" thoughts or hopes or visions out of certain persons' minds.

Nor does the concept of "intent" become substantially more attractive in this setting if it is "objectively" addressed. There would remain serious difficulties even if the test were something like the following: "Is it more probable than not that a rational person who had engaged in the conduct proved by plaintiff would intend to enter the marketplace before the expiration of plaintiff's patent rights?" To apply any such test it would be necessary to make ***1275** guesses about *when* FDA approval was likely to be forthcoming. Yet the process of securing FDA approval for a new medical product can be torturously extended and riddled with unpredictabilities. (See, Gibbs declaration accompanying defendants' opposition to plaintiff's first motion for summary judgment at 4–14).

[2] For reasons set forth in the discussion of plaintiff's alternative motion for summary judgment, we also reject plaintiff's second argument that because defendants have indicated that they intend to market the Cadence as soon as they secure FDA approval, even if it is before plaintiff's patent expires, defendants' clinical testing cannot, by definition, be "solely for uses reasonably related" to developing and submitting data to the FDA. As we explain in the next section, the availability of the exemption turns on actual uses, not on the "purposes" of the party doing the using.

Nor are we persuaded that the limitation that plaintiff wants us to read into the statute is necessary to avoid incursions on

the economic interests of patent holders that would be larger than Congress intended to allow when it enacted the § 271(e)(1) exemption. The simple response to this line of argument is that the courts will vigorously protect patent holders from any "uses" of patented material that are outside the umbrella of the exemption. The courts stand ready to issue injunctions and to order payment of full damages for all conduct by defendants that Congress elected *not* to protect. Thus, it simply is not necessary to read into the statute that additional, artificial, and conceptually elusive limitation urged by plaintiff.

Finally, plaintiff has suggested that construing § 271(e)(1) to include defendants who may intend to market their allegedly infringing devices before the patents-in-issue expire places the constitutionality of the statute in jeopardy because it permits an improper "taking" without just compensation. Congress extensively considered whether the interferences with a patent holder's rights contemplated by the statute would amount to an unconstitutional taking. The committee assigned to consider this question determined that the law did not amount to an unconstitutional taking. (See, Legislative History at 2711–2714). Subsequently, the *Supreme Court* considered whether the inclusion of medical devices along with drugs within the scope of the statute would create a taking. The Court concluded that it would not, noting along the way that the competitive injury resulting from the exemption statute would be *de minimis* in some cases *although "surely it is substantial in others." Eli Lilly and Co. v. Medtronic, Inc.,* 110 S.Ct. 2683, 2692, n. 5, 2693, n. 7.

We are not persuaded that by allowing defendants the protections of the statute we place its constitutionality in any greater jeopardy than before. Because courts remain ready to vigorously protect patent holders from any conduct by the defendants that is *not* covered by the statute and thus, will maintain the patent holders' rights to exclude others (including defendants) from the general commercial marketplace, the harms that a patent holder may suffer because of a competitors' use of § 271(e)(1) are substantially the same regardless of when the defendant hopes to conclude testing.

For all of the above reasons, Plaintiff's first motion for summary judgment is DENIED.

III. DEFENDANTS' MOTION TO DISMISS AND PLAINTIFF'S CROSS–MOTION FOR SUMMARY JUDGMENT RE DEFENDANTS' ENTITLEMENT TO § 271(e)(1) DEFENSE.

Defendants have moved this court for an order dismissing the complaint, or, in the alterative, for entry of summary judgment, on the ground that defendants are immunized from suit by 35 U.S.C. § 271(e)(1). [3]

***1276** A. INTRODUCTION

§ 271(e)(1) exempts from claims of patent infringement otherwise infringing activity that is "solely for uses reasonably related" to obtaining FDA approval. Defendants' implantable defibrillator, the Cadence, is a Class III device which must be approved by the FDA before it can be commercially distributed.

Section 515(a) of the Food, Drug and Cosmetic Act (21 U.S.C. § 360e(a)) requires that an application for a pre-market approval (PMA) be filed and granted by the FDA for all Class III devices. To make the necessary showing of safety and efficacy, a manufacturer of a Class III device typically conducts a clinical investigation of the device, during the course of which the device is implanted in human subjects by investigators at various institutions. The investigators will then, on behalf of the manufacturer, monitor the patients and gather data, which in turn is submitted to the FDA as part of the PMA application.

In order to be able to conduct the clinical investigation, the manufacturer is required to apply for and obtain an investigational device exemption (IDE) from the FDA. Upon the FDA's approval of the IDE application, the manufacturer may proceed with the clinical investigation and eventually submit its application for a PMA. After receiving a PMA the manufacturer is authorized by the FDA to commercially distribute the device. Pursuant to an IDE granted by the FDA, defendants are currently engaged in clinical trials of the Cadence. The data gathered in these trials has been prepared for submission to the FDA.

Defendants argue that because the Cadence is currently involved in the clinical trials described above they are exempt from claims of patent infringement under § 271(e)(1). Plaintiff argues that defendants also have engaged in a variety of activities unrelated to obtaining FDA approval. According to plaintiff, these activities demonstrate that defendants' allegedly infringing use of the Cadence is not "solely for uses reasonably related" to FDA approval.

B. THE OPERATION OF § 271(e)(1)

1. History and Purposes of § 271(e)(1)

[3] To reason reliably about the issues raised by these motions, we must recall the history and purposes of this statutory provision. Congress enacted § 271(e)(1) in 1984 in order to reverse the opinion of the United States Court of Appeals for the Federal Circuit in *Roche Products, Inc. v. Bolar Pharmaceutical Co.,* 733 F.2d 858 (Fed.Cir.1984). The *Roche* court had ruled that the experimental use exception was not broad enough to protect manufacturers of generic drugs while they were conducting the extensive field tests of their products that were necessary to generate the data that the FDA required before granting permission to market the drugs commercially. After the opinion in *Roche* issued, generic drug interests lobbied Congress vigorously for a statutory amendment that would grant such protection. In the legislative battles that ensued, it was clear that a principal purpose of the generic drug interests was to position themselves to be able to market their products on a massive commercial scale just as soon as the patent rights expired on the drugs which the generics incorporated. *Eli Lilly and Co. v. Medtronic, Inc.,* 872 F.2d 402, 404–405 (Fed.Cir.1989).

We believe that when it responded positively to the lobbying of the generic drug manufacturers by enacting § 271(e)(1), Congress made a fully self-conscious choice between two directly competing interests: continuing full protection of the rights of patent holders, on the one hand, and, on the other, assuring access by the public to medically beneficial new products at truly competitive market prices (i.e., lower prices) immediately after the expiration of the terms of relevant patents. In essence, Congress elevated the health care interests ***1277** of the public above the pecuniary interests of the patent holders.

In making this election, Congress reduced the scope of the rights of patent holders in two significant respects. First, it permitted potential competitors, during the life of the patent, to engage in acts that otherwise clearly would constitute acts of infringement, as long as those acts generated data the FDA would use in deciding whether to approve a product for the commercial marketplace. Since Congress knew that the FDA sometimes required data based on considerable use of a product, Congress knew that creating this protection would deprive patent holders of sales that might well be significant, even though Congress apparently expected the patent holders in most instances to retain the lion's share of the relevant markets.

The second negative impact on the interests of patent holders that Congress effected through the adoption of § 271(e)(1) was arguably even more significant. Under the scenarios that would have obtained under *Roche,* a competitor could not have begun generating data for the FDA until after expiration of the patent. Because generating the data required by the FDA, and processing an application to market a new product through the FDA bureaucracy, predictably took considerable time, the practical effect of *Roche,* was to add several years of life to patents by making it impossible for competitors to be ready to enter the commercial marketplace in any significant measure for several years after the formal expiration of the patent holder's rights. Congress knew that enacting § 271(e)(1) would dramatically change this situation. We believe that in enacting this exemption Congress clearly decided that it wanted potential competitors to be able to ready themselves, fully, during the life of the patent, to enter the commercial marketplace in a large scale way as soon as the relevant patents expired. Only by permitting this preparation to enter the market meaningfully could Congress achieve its goal of assuring the public prompt access to new medical products at the lowest commercially feasible prices.

Understanding the hard choices that Congress made and the policy objectives it sought to achieve when it enacted § 271(e)(1) helps inform our interpretation and application of this exemption.

2. Interpreting § 271(e)(1) in Context of this Litigation

In relevant part, § 271(e)(1) declares that:

> It 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 or veterinary biological products.

In *Eli Lilly and Co. v. Medtronic, Inc.,* 496 U.S. 661, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990), the Supreme Court held that this statutory exemption is available not only to drug and veterinary products, but also to medical devices (like those in issue here) that cannot be marketed without FDA approval

under § 515 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360e.

[4] Through § 271(e)(1), Congress changed the status in law only of acts which, but for this exemption, would constitute acts of infringement. Thus the only kinds of acts to which this legislation applies are acts which would constitute acts of infringement. When trying to determine whether a party is protected by this exemption, the *target of a court's inquiry* is on *those acts of manufacture, use, or sale* of a patented invention *that would constitute acts of infringement* but for this exemption. It is these kinds of acts, only, that must be "solely for uses reasonably related" to generating data for submission to the FDA. It is these kinds of acts whose "uses" are in issue, and the exemption is lost only if the court concludes that acts of these kinds have been undertaken for "uses" that are outside those permitted under the statute. In other words, by enacting this exemption, congress has said to the public: "You may commit acts of *infringement* only so long as *those* acts are solely for uses reasonably ***1278** related to gaining FDA approval to market your product. If you engage in infringing activities for other uses, the exemption will not protect you. But if you engage in *non-infringing* acts for other uses, you do not lose the benefits of this statutory amendment."

Despite intimations to the contrary in some of plaintiff's earlier papers, the inquiry is *not* generally whether the allegedly infringing party has engaged in conduct that shows that it has purposes beyond generating and presenting data to the FDA. Congress obviously knew that companies that were trying to position themselves to enter the commercial market in a significant way immediately after a patent expired would engage in a range of business activities (like raising capital, establishing mechanisms for product distribution, etc.) for uses other than simply generating data for the FDA. Congress was concerned about those activities only to the extent that, but for § 271(e)(1), they would constitute acts of infringement. Thus, the exemption Congress provided is not lost simply as a result of a showing that the defendant has engaged in *non*-infringing acts whose "uses" fall outside those permitted by the statute.

Do activities that would not constitute infringements have any possible relevance to a court's determination of whether a party is protected by this statutory exemption? Plaintiff has argued that we should take a full look at a wide range of non-infringing acts by defendants in order to determine what the real *purposes* were of those activities by defendants that would constitute infringements but for § 271(e)(1). Plaintiff insists that the character of the non-infringing activities shows that defendants have engaged in the allegedly infringing acts of making, using, and selling its product not solely for purposes reasonably related to generating data for the FDA, but also, clearly, for independent commercial purposes.

When we first began considering this matter we were inclined to accept the proposition, at least in the abstract, that it would be appropriate to examine a defendant's non-infringing activities to see if they shed light on the purposes underlying his related infringing activities. On further reflection, however, we feel considerable reluctance to endorse this line of reasoning. That reluctance is informed by several considerations. First, we feel that it is significant that when Congress chose the words in which to articulate the conditions under which the exemption would attach it did *not* use the word "*purposes* " at all, *but, instead,* settled on the word "*uses.*" It is plaintiff, not Congress, that has insisted that the word "purposes" is fungible in this context with the word "uses." We are not at all sure, however, that Congress intended any such fungibility. The relevant phraseology is "solely for uses reasonably related," not "solely for purposes reasonably related." Obviously Congress is familiar with the word "purposes." If Congress had wanted courts to focus on "purposes" it probably would have selected that word instead of the substantially more awkward word "uses" (the awkwardness is compounded in this context, where "uses" appears earlier in the same sentence, as a verb instead of a noun, in the listing of categories of conduct that can constitute infringement). Given the obviousness of the alternative, we think that the selection by Congress of the word "uses" at this critical juncture in the exemption supports two related inferences: (1) that Congress intended the "test" for determining whether the exemption has been lost to be "objective" rather than "subjective" (focusing on conduct rather than motive or ultimate aim) and (2) that Congress wanted the courts, in applying this statute, to focus on *conduct ("uses") that actually has occurred* (as opposed to uses to which a party might put its product in the future)[4] *and that would constitute infringement* but for the exemption.

***1279** These inferences are supported by additional considerations. The inference that Congress intended the test to be objective is consistent with trends generally in the law away from use of subjective tests, in part because of the difficulties of proof they present. Congress generally has elected to regulate behavior and to eschew efforts to regulate hearts or states of mind. If the test were subjective, plaintiffs

would virtually never be able to dispose of the exemption issue by motion, forcing resolution of this question by trial. Moreover, adoption of a subjective test might enable some defendants to protect themselves in a much wider range of circumstances than Congress intended by persuading the fact-finder that they actually felt that their infringing conduct was solely for uses reasonably related to the FDA, even though much of that conduct would not in fact generate anything in which the FDA would have the slightest interest. Thus a subjective test would threaten both the judiciary's capacity to manage the litigation of such matters and Congress' ability to achieve the ends it sought through the statute.

Strong textual support for the view that Congress intended the test to be objective derives from the legislators' selection of the phrase "reasonably related" to modify the word "uses." "Reasonably related" is language that clearly has become associated with objective standards.

Our reluctance to conclude that Congress intended the courts, when construing this section of the statute, to ascribe much (or any) significance either to the indirect (ripple) effects of a defendant's otherwise infringing activities, or to inferences about "purposes" that might be drawn from focusing on collateral (i.e., non-infringing) conduct is reinforced by two factors. First, as we noted above, Congress clearly intended, by enacting this exemption, to create a legal environment in which the potential competitors of patent holders would be free, through non-infringing activities like raising capital, to position themselves to enter the market in a commercially significant way just as soon as the relevant patents expired. And at least with respect to products like those in issue here, products that are extremely sophisticated, that will carry a large price tag if they reach the retail stage, and that are very expensive to develop, potential competitors foreseeably must engage in considerable "business" development and promotion activity just to meet the FDA's requirements, let alone to be in a position to market their products meaningfully when the various legal barriers have been overcome. Collateral (i.e., non-infringing) activities undertaken by an entity that is trying to prepare itself to enter a competitive commercial marketplace and to survive there will virtually always be inspired, at least in substantial measure, by "business purposes," rather than simply by a desire to generate data for the FDA. Since virtually all collateral activities will have business purposes, to permit finders of fact to infer that infringing uses have business purposes from the fact that non-infringing uses have business purposes would be to invite wholesale loss of the exemption and, with that, frustration of Congress' objective in enacting it. In other words, permitting courts (finders of fact) to draw inferences about the "purposes" of infringing acts by examining the purposes of non-infringing acts builds into the analysis a virtual certainty that the conclusion will be reached that the infringing "uses" have been inspired by commercial purposes.

Moreover, we are confident that Congress understood that in the real world of high-tech medicine, at least, it is "business purposes" that inspire the kinds of infringing activities that the exemption clearly covers. Congress could not have intended the exemption to apply only to those whose purposes were purely scientific, or to those who were motivated simply by a driving curiosity. The common law already provided shelter for persons so motivated. See *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed.Cir.1984). Rather, Congress surely knew, when it enacted § 271(e)(1), that pursuit of commercial gain ultimately underlies, legitimately, the entire range of activities predictably undertaken by companies in positions ***1280** like defendants' in this case. We see no reason to conclude that Congress intended to prohibit all product development and testing work (potentially infringing conduct) which was inspired, in part, by a hope that it would someday lead to profitable sales. Again, if a party were to lose the exemption every time a business purpose was detectable in its otherwise infringing activities, the exemption would virtually never be available and thus would fail to achieve Congress' objective.

For all these reasons, Congress sensibly chose words in the exemption that would lead courts to focus not on "purposes" or motives, but on "uses," and not on collateral activities, but only on the kinds of conduct which, absent the exemption, would constitute infringement. In the context of this understanding, we have struggled with the question of what analytical significance, if any, to ascribe to the "effects" of the otherwise infringing "uses" by defendant of the patented material. Because we believe that Congress contemplated a strictly objective test (to determine whether the exemption attaches), and because we believe that Congress did not intend the availability of the exemption to turn on findings about a party's "purposes" or "motives," we believe that we should consider "effects" only to the extent that doing so is helpful in identifying what the actual uses have been, and not, obviously, to shed light on the designs or ambitions or goals ("purposes") that might have underlay those uses. Moreover, since what we are examining is actual, otherwise infringing uses, not purposes and not collateral activity, we conclude that the only kinds of "effects" to which

it might be appropriate to ascribe appreciable significance in this analysis are those that are immediate and direct. We will concern ourselves little, if at all, with effects that are indirect, or in which the causal chain has several links. We will ignore altogether effects that are speculative or remote.

Thus, our inquiry is relatively straightforward. We focus only on those acts by Ventritex which would be deemed "infringing" but for § 271(e)(1) and in which Ventritex actually has engaged (as opposed to the acts in which the company might engage in the future). With respect to those actual acts, we do not ask what underlying motives might have inspired them or what indirect, ripple effects (e.g., long range consequential benefits) they might bring. Instead, we simply ask: are these actual uses "solely ... reasonably related to the development and submission of information" to the FDA. If so, the exemption protects Ventritex. But if there are any actual, non-*de minimis* uses that are not reasonably related to generating data for the FDA, the exemption will not protect Ventritex.

[5] We infer that the phrase "reasonably related" (to development of information for the FDA) as used in § 271(e)(1) reflects Congress' acknowledgement that it will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will take to win that agency's approval. Thus, Congress used this phrase to communicate its intention that the courts give parties some latitude in making judgments about the nature and extent of the otherwise infringing activities they would engage in as they sought to develop information to satisfy the FDA. Contrary to the suggestion seemingly made by plaintiff, we do not believe that Congress intended a party to lose the exemption simply because it turns out, after the fact, that some of that party's otherwise infringing "uses" either failed to generate information in which the FDA was interested or generated more information than turned out to be necessary to secure FDA approval. Instead, with respect to this aspect of the test we should ask: would it have been reasonable, objectively, for a party in defendant's situation to believe that there was a decent prospect that the "use" in question would contribute (relatively directly) to the generation of kinds of information that was likely to be relevant in the processes by which the FDA would decide whether to approve the product? If the answer is yes, it should not matter that other reasonable persons might have concluded that FDA approval could be ***1281** secured even without the information in question.

3. Standards Applicable to Ruling on These Motions

[6] As we noted in the introduction, we are treating the parties' cross motions as motions for partial summary judgment. Thus, we apply standards developed under Federal Rule of Civil Procedure 56. In so doing we resolve all reasonable doubts about whether any material issue can be viewed as genuinely in dispute in favor of the party against whom the motion is made.

In the specific setting of the motions directed toward the availability of the exemption under § 271(e)(1), we first ask: Absent the exemption, which alleged uses by Ventritex would be deemed "infringing"? In connection with this first inquiry, we ascertain whether there are genuine disputes about whether in fact Ventritex engaged in any of the uses that we believe, as a matter of law, could constitute "infringements" but for the exemption. If there are genuine disputes about whether Ventritex engaged in any such uses, we will assume, for purposes of ruling on these motions, that Ventritex in fact engaged in those uses.

Our next task will be to determine whether there is a genuine factual dispute about whether any of Ventritex's otherwise infringing and non-*de minimis* uses of its product are not reasonably related to securing FDA approval. If any such factual matters are genuinely in dispute, we may not grant summary judgment in defendant's favor.

C. APPLICATION

In earlier papers plaintiff identified a number of activities which it claims constitute uses of the Cadence that are not reasonably related to generating data for the FDA. These activities include:

1. Using data gathered from the testing of the Cadence to obtain import approval from foreign governments;

2. Authorizing the publication of articles describing features of the Cadence;

3. Relying on the Cadence to assist efforts to raise capital for Ventritex Corp., Inc.;

4. Demonstrating the Cadence at various scientific meetings/trade shows;

5. Obtaining foreign patent rights on the Cadence.

Most of these activities, however, would not constitute acts of patent infringement under § 271(a). Because we have determined that our inquiry should be confined to "uses" that would be infringing but for the exemption, these collateral, non-infringing, activities are not relevant.

[7] For example, as a start up company, Ventritex had to raise millions of dollars to finance the development and testing of the Cadence. To raise the funds, and to comply with securities laws, Ventritex provided potential investors with information about the status and testing of the Cadence. Plaintiff contends that this activity establishes that the Cadence was not used solely for the generation of data for the FDA.

However, the use of clinical *data,* in a prospectus or otherwise, is not an infringing act under § 271(a). *Eli Lilly and Co. v. Medtronic, Inc.,* 915 F.2d 670, 673 (Fed.Cir.1990). Moreover, the fact that this non-infringing activity reveals a commercial "purpose" unrelated to obtaining FDA approval cannot provide a basis for denial of the exemption. Raising capital is a necessary and legitimate business activity. As we noted, we are confident that Congress understood that long-range business purposes (i.e., pursuit, eventually, of profit) would underlie the activities of companies legitimately protected by § 271(e)(1).

Similarly, defendants' use of clinical data to support foreign import applications and defendants' publication of articles describing features of the Cadence are not otherwise infringing acts under § 271(a). And, like raising capital, these activities are important means for Ventritex to position itself to enter the marketplace if the Cadence ever receives FDA approval. The fact that these non-infringing activities evidence a business "purpose" or motive that is unrelated to obtaining FDA approval has no bearing on our resolution of this matter.

***1282** After explaining (earlier in the pretrial period) our interpretation of the operation of § 271(e)(1) to the parties, the court ordered plaintiff to identify those activities of the defendants that plaintiff believes, but for operation of the statute, *would* constitute acts of infringement under § 271(a).

Plaintiff identified five such activities:

1. Manufacture of several hundred Cadences;

2. Sales of the Cadence to hospitals in the U.S.;

3. Sales of the Cadence to international distributors;

4. Testing of the Cadence (particularly certain testing done in Germany);

5. Demonstrations of the Cadence at "trade shows".

[8] 1. *Manufacture of the Cadences.* There are no disputed facts regarding the actual manufacture of the Cadence. In the setting we confront here, where it is undisputed that most of the Cadences have been used to generate data for the FDA, the fact of manufacture, by itself, does not deprive defendants of the statutory exemption. In the paragraphs that follow we consider each of the other alleged uses by defendants, determining, one at a time, whether a rational trier of fact could conclude that one or more was not reasonably related to securing FDA approval.

[9] 2. *Sales of the Cadence to U.S. Hospitals.* It is undisputed that every single Cadence sold to a U.S. hospital has been used only in clinical trials. Plaintiff has not offered any evidence that a single Cadence has been sold to a hospital for any use other than clinical testing of the device.

Plaintiff emphasizes, however, that Ventritex has continued to sell Cadences to clinical investigators even after submitting its application for pre-market approval (PMA) to the FDA. Plaintiff claims that the filing of this application establishes that Ventritex has accumulated enough data for the FDA to determine whether it will approve the Cadence for general commercial marketing. Thus, according to plaintiff, additional sales to clinical investigators are unnecessary and cannot be solely for uses reasonably related to obtaining FDA approval.

In opposition, defendants have presented evidence that despite the considerable efforts companies put into their PMA applications, a substantial percentage of PMA's are not accepted for filing by the FDA and are, instead, returned to the company for more testing. (See, Gibbs declaration at 5–6). Moreover, even after being accepted for filing, a substantial number of applications for pre-market approval are provisionally rejected because the FDA concludes that the manufacturer has not submitted sufficient information of one sort or another. *Id.* For all of these reasons, defendants argue that it is prudent for a company seeking FDA approval to continue conducting clinical trials of the device even after it initially files its application for a PMA.

Plaintiff has not presented any evidence to contradict defendants' assertion that it is reasonable to continue to

generate clinical data after submitting an initial PMA application. As we noted earlier, congress' decision to include the phrase "reasonably related" reflects an intention that a manufacturer not be denied the protections afforded by the statute simply because it turns out, after the fact, that some of the manufacturer's testing activities generated information which the FDA did not end up needing or relying on. Rather, the question is whether it would be objectively reasonable for a company in Ventritex's position to believe that continuing the clinical trials would, relatively directly, contribute to the generation of the kind of data relevant to the FDA's inquiry. We find that a reasonable trier of fact would be constrained to conclude that Ventritex's continuing sales of Cadences to clinical investigators were reasonably related to obtaining FDA approval.

[10] 3. *Sales of the Cadence to International Distributors.* It is undisputed that defendants have sold Cadences, pursuant to distribution agreements, to individual distributors. Because some of these distribution agreements described "market share criteria" and encouraged the distributor ***1283** to promote the Cadence, plaintiff argues that these sales are not solely for uses reasonably related to obtaining FDA approval.

Defendants have adduced competent evidence that the market share language was inadvertently included "boilerplate" language that has since been changed to clarify that there may be no general commercial sales (i.e., other than to a duly selected test site facility) or promotion of the Cadence until after FDA approval is obtained. Much more importantly, defendants' evidence establishes that these overseas distributors perform the limited function of clearing the devices through customs so that they may be delivered to the clinical sites overseas. (See, Fisher declaration at 1). Defendants submissions show that every Cadence sold to a distributor has been subsequently resold to an FDA approved clinical investigator. *Id.*

Plaintiff has failed to present any evidence to suggest that these distributors functioned in any capacity other than as middle-persons between Ventritex and its foreign clinical investigators. Plaintiffs have not identified a single sale of a Cadence to a distributor that did not result in the immediate resale to a clinical investigator. Because there is no genuine dispute about the role which these distributors played, and because that role was directly related to the development of information to be submitted to the FDA, we find that a reasonable trier of fact could conclude only that Ventritex's use of these distributors was reasonably related to obtaining FDA approval.

4. *Testing of the Cadence in Germany*

[11] In addition to domestic testing of the Cadence, which indisputably is related to securing FDA approval, plaintiff contends that Ventritex decided to conduct clinical tests of the Cadence in Germany because Ventritex had formed a plan to commercially market the Cadence in Germany and believed that the German government would not permit such marketing unless the product had been tested clinically within Germany. This line of argument, however, appears to proceed from the incorrect assumption that the outcome of § 271(e)(1) analysis turns on a party's "purposes" or ultimate objectives, rather than its actual uses of the product in question. The focus of our inquiry at this point must be on evidence of actual uses. We ask, more specifically, whether plaintiff can point to evidence that would support an inference that Ventritex has in fact actually used the Cadence in Germany to secure permission from governmental authorities there to market the product commercially.

In support of its position, plaintiff refers to the deposition of Earl Canty, Ventritex's Vice–President for Regulatory Affairs:

> Q. What are the requirements for shipping generally into West Germany once PMA approval is received in the U.S.?
>
> A. We would file to have approval to generally import the device into West Germany.
>
> Q. At any point in time has the West German government advised you or do you anticipate being advised by the West German government that a clinical site must be selected in West Germany prior to general commercial distribution into the country?
>
> A. Yes.
>
> Q. Which one is it? Do you anticipate or has it already occurred?
>
> A. It has occurred.
>
> Q. What have they specifically said about that?
>
> A. That clinical studies will take place at the site that we have designated at this point, the site that we have identified and are having discussions with.

Plaintiff also claims that using an overseas investigator is considerably more expensive than conducting clinical trials domestically and that a reasonable company in Ventritex's position would not have gone to the greater expense of using a foreign investigator unless the company also intended to obtain foreign approval to commercially distribute the device.

Having considered the evidence in the light most favorable to the plaintiff, we conclude, for reasons we explain below, that a reasonable trier of fact could only ***1284** conclude that defendants testing activities in Germany were reasonably related to generating data for submission to the FDA.

It does not follow from the undisputed fact that it was not *necessary* to conduct clinical trials in Germany to obtain FDA approval that such trials were not *reasonably related* to obtaining FDA approval. The FDA permits the submission of foreign-generated clinical data so long as the procedures used in compiling the data comply with FDA requirements. (See, Gibbs declaration at 18–19). Moreover, although foreign testing may be more expensive than domestic testing, it would be both reasonable and responsible for a manufacturer conducting clinical trials to utilize the most experienced and well respected investigators available, even if some of them practice overseas. *Id.* Defendants have adduced uncontradicted evidence that the clinical investigator that they selected in Germany is one of the preeminent figures in the world in this field. *Id.* A reasonable trier of fact could only conclude that it was reasonable for defendants to determine that Dr. Klein's clinical tests would contribute to the generation of the kind of data that the FDA would consider in deciding whether to grant pre-market approval.

More importantly, it is undisputed that every single defibrillator that was sold and sent to Germany was used for implantation by a clinical investigator and that all data generated in those clinical trials in fact has been submitted *only* to the FDA. (See, Klein declaration at 2). Plaintiff has not presented any evidence that defendants have submitted test data to or in fact sought approval from any regulatory agency other than the FDA.

Plaintiff has suggested that defendants delayed their initial PMA application to the FDA until after some of the German data could be assembled as an after-the-fact rationalization for testing that defendants really conducted for the purpose of obtaining, eventually, German regulatory approval. Plaintiff has presented no evidence, however, that would support an inference that such considerations played any role in the timing of defendants' application for a PMA. Much more importantly, this line of argument by plaintiff misses the analytical point. As explained at some length in an earlier section of this opinion, the law is not concerned in this setting with motives, purposes, or ulterior designs. Instead, the law is concerned only with actual uses. And the only actual uses in Germany about which we have been presented with any evidence clearly are reasonably related to securing FDA approval of the Cadence. To repeat, there is no evidence that Ventritex has actually submitted any data from the clinical trials in Germany to any German authorities or that Ventritex has used clinical data generated from the testing of the Cadence in Germany to support an application for approval to commercially market the Cadence in that country.

5. TUV Testing of the Cadence Programmer

[12] In order to conduct tests at a clinical site in Germany, Ventritex was required by German authorities to submit the Cadence to a German company, TUV Rheinland, to test the safety of the electrical systems in the "programmer" used in connection with the Cadence.

Plaintiff contends that the testing conducted by the TUV agency, the results of which were never submitted to the FDA, constitutes an otherwise infringing use of the Cadence which was not reasonably related to obtaining FDA approval.

There are two fundamental difficulties with plaintiff's position. First, plaintiff has pointed to no evidence that TUV tested the Cadence itself. Instead, the uncontradicted evidence shows that TUV tested only the programmer and that the purpose of this testing was only to assure the electrical safety of the programmer to its operators. (See, Canty declaration [filed July 2, 1991] at 6). It also is undisputed that the programmer is a computer which is used to establish various operating parameters for the implanted device. It is a separate device which transmits information to, and receives information from, the defibrillator. ***1285** (See, Fisher declaration [filed July 2, 1991] at 7–8).

Second, because safety certification from TUV was necessary in order to obtain import approval *to conduct clinical tests,* the TUV tests necessary to obtain that certification would have to be considered reasonably related to the generation of data for submission to the FDA. Thus, even if the testing had been of the Cadence itself, and not merely of the programmer, such testing would have to be characterized as reasonably related to the generation of clinical data for the FDA.

On this record, a reasonable trier of fact could reach only one conclusion: the fact that the TUV test data was not submitted to the FDA does not suggest that the *Cadence* was used in a manner not reasonably related to obtaining FDA approval.

6. *Demonstrations of the Cadence at scientific trade shows*
Finally, plaintiff alleges that (1) defendants' demonstrated the Cadence at various scientific trade shows, (2) that these uses would constitute acts of infringement but for the exemption, and (3) that these uses of the Cadence were not reasonably related to obtaining FDA approval.

[13] Plaintiff's argument presupposes that demonstrating the cadence at trade shows is an otherwise infringing act under § 271(a). Although defendants appear to concede this point for the purpose of these motions, we are not convinced that these demonstrations constitute acts of infringement under § 271(a).

All of the cases which plaintiff cites in support of the assertion that trade show demonstrations can constitute acts of infringement under § 271(a), *U.S Environmental Products, Inc. v. Infilco Degremont, Inc.,* 611 F.Supp. 371, 374 (N.D.Ill.1985); and *Knapp–Monarch Co. v. Casco Products Corp.,* 342 F.2d 622, 626 (7th Cir.1965). Cf. *Neff Instrument Corp. v. Cohu Electronics, Inc.,* 269 F.2d 668, 673 (9th Cir.1959), were concerned with defining "acts of infringement" in the context of deciding whether *venue* was proper. Venue in patent cases is proper "where the defendant has committed acts of infringement and has a regular and established place of business." 28 U.S.C. § 1400(b).

These cases hold that, in some circumstances, advertising demonstrations may constitute acts of infringement sufficient to establish *venue* under 28 U.S.C. § 1400(b). It is well established, and these cases recognize, that "the test for establishing patent venue is less strict than the standard required to establish patent infringement, for otherwise a disposition of the venue question would also amount to a disposition on the merits whenever venue is tested." *Celotex Corp. v. V.E Power Door Corp.,* 204 U.S.P.Q. 636, 638 (E.D.N.Y.1979). "Thus, the fact that the advertising demonstrations can support patent venue does not imply that such demonstrations in themselves constitute direct infringement." *Id.*

Unfortunately, there is very little case law which directly addresses the issue of whether trade show demonstrations comprise § 271(a) acts of infringement. The *Celotex* case held that a single demonstration of an allegedly infringing product, which did not lead to a sale of the product, did not constitute a direct infringement of plaintiff's patent. *Id.* The court relied, in part, on the holding in *Kaz Manufacturing Co., Inc. v. Chesebrough–Ponds, Inc.,* 317 F.2d 679 (2d Cir.1963), that the use of a patented product for the purpose of advertising defendant's product is not a § 271(a) act of infringement.

Brennan v. Mr. Hanger, Inc., 479 F.Supp 1215 (S.D.N.Y.1979) also held that the mere display of an allegedly infringing product does not constitute an "infringing use" under § 271(a). Both the *Celotex* and *Brennan* courts relied, in part, on the fact that the demonstration activity complained of did not culminate in a sale of the accused product.

Similarly, even those cases which apply the less strict standard for "acts of infringement" applicable to *venue* disputes have generally required not only demonstration of the accused device, but also some other activity *culminating in a sale* ***1286** of that device as a prerequisite to formally resolving the venue issue.

For example, in *U.S. Environmental Products, Inc. v. Infilco Degremont, Inc.,* 611 F.Supp. 371 (N.D.Ill.1985), the court held that demonstration of an accused device *plus* the simultaneous solicitation of purchase orders for the accused device amounted to a sufficient degree of *selling* activity to establish venue. *Id.* at 611 F.Supp at 373. The court, noting that mere solicitation does not constitute an act of infringement even for venue purposes, stated that "the totality of the circumstances must be considered ... when deciding whether a defendant is selling its product in this district or merely soliciting." *Id.* Thus, two separate findings were crucial to the venue decision: (1) that defendant demonstrated the product in order to consummate a sale *and* (2) that defendant executed a sales contract in the district. *Id.* [5]

From these cases and others, e.g., *Marlatt v. Mergenthaler Linotype Co.,* 70 F.Supp. 426 (D.C.Cal.1947); *Patent Tube Corporation v. Bristol–Myers Co.,* 25 F.Supp. 776 (S.D.N.Y.1938); *Ferguson v. Ford Motor Co.,* 77 F.Supp. 425 (S.D.N.Y.1948); *Knapp–Monarch Co. v. Casco Products Corp.,* 342 F.2d 622 (7th Cir.1965); *Andco Environmental Processes, Inc. v. Niagara Environmental Associates, Inc.,* 204 U.S.P.Q. 652, 654 (W.D.N.Y.1979), we conclude that even under the less strict test of infringement applied to venue disputes, demonstration of an accused device does not constitute an act of infringement unless the "totality of the circumstances" also reveals concurrent "sales oriented"

activity which results in, or at least substantially advances, an actual sale of the accused device. We conclude that the mere demonstration or display of an accused product, even in a obviously commercial atmosphere, does not constitute an infringing use under § 271(a).

[14] Defendants do not deny demonstrating the Cadence at various medical conferences. However, despite the allegedly commercial character of these conferences, there is no evidence that Ventritex sold a single Cadence as a result of any of these demonstrations. On the contrary, Ventritex displayed signs at the exhibits indicating that the Cadence was an "investigational device" and, thus, not available for general commercial sale. (See, Canty declaration at 2).

Nor has plaintiff offered any evidence that defendants solicited sales agreements in connection with its demonstrations of the Cadence. At most, these demonstrations "advertised" the existence and features of the cadence to potential customers. Moreover, major contingencies would have to be overcome before any such potential customers might actually consummate a purchase. Most obviously, the FDA would have to issue its approval of the device for general commercial marketing. Such approval is in no sense a foregone conclusion. And how long it might take the FDA to make its determination was (and is) quite unpredictable. Considering the totality of the circumstances surrounding the demonstrations and displays of the Cadence, and given plaintiff's failure to identify any ***1287** sales or active solicitation of sales at these conferences, we find that defendants' demonstrations and displays of the Cadence do not constitute § 271(a) acts of infringement and, therefore, cannot provide a basis for a finding that defendants are not entitled to the statutory protections afforded by § 271(e)(1).

Even if it were held by some other court that defendants' demonstrations of the Cadence constituted acts of infringement under § 271(a), we would hold that a reasonable trier of fact would be compelled to conclude that defendants' activities at the trade shows did not breach the limitations Congress imposed in § 271(e)(1).

Plaintiff claims that defendants demonstrated the Cadence at various medical conferences, at least in part, to generate commercial interest in the device. Thus, plaintiff alleges that defendants have engaged in an actual, non-*de minimis,* use of the Cadence that is not reasonably related to obtaining FDA approval. Defendants, on the other hand, claim that they attended the trade shows and demonstrated the Cadence to identify potential clinical investigators and that that activity was clearly reasonably related to obtaining FDA approval.

In deciding whether defendants' activities at the trade shows offend the limiting provisions of § 271(e)(1), we will address three separate issues. First, we will consider whether a reasonable trier of fact would be compelled to conclude that at least some of Ventritex's demonstration activities were reasonably related to generating data for submission to the FDA. Second, we will consider whether, in addition, a reasonable trier of fact could find that some of Ventritex's demonstration activity was not reasonably related to obtaining FDA approval. Third, if such a finding could reasonably be made, we will consider whether the evidence compels the conclusion that any such activities that might not have been "reasonably related" were in fact *de minimis.*

A reasonable trier of fact would be compelled to conclude that at least some of Ventritex's demonstration activity was reasonably related to identifying potential clinical investigators and, therefore, to generating data for submission to the FDA. A manufacturer such as Ventritex relies on professional contacts within the medical community to locate investigators. (See, Fisher declaration at 2). It is undisputed that these conferences, which are attended by many of the doctors who are qualified to act as investigators, provide a prime opportunity for a manufacturer of a medical device to cultivate business contacts within the relevant medical community and to educate potential investigators about an investigational device like the Cadence. *Id.* Defendants' evidence shows that these conferences are, in fact, a principal means by which they identify potential clinical investigators. *Id.* Because the evidence is uncontradicted that the visibility achieved by attending these conferences and educating the medical community about the Cadence facilitates the process of locating qualified investigators, we find, as a matter of law, that it was reasonable for defendants to believe that demonstration of the Cadence at the trade shows would contribute, ultimately, to the generation of data for submission to the FDA.

Although plaintiff does not dispute that the demonstrations were, in part, reasonably related to obtaining FDA approval, plaintiff argues that defendants made an additional (perhaps secondary) use of the Cadence at these conferences that was not reasonably related to generating data for the FDA and, instead, was solely related to increasing market awareness of the Cadence.

In support of this contention plaintiff points to evidence that defendants (1) continued to demonstrate the Cadence, both domestically and in Germany, after defendants had all of the investigators they needed and (2) at least on some occasions during the trade shows, failed to pre-qualify individuals as potential investigators before demonstrating the Cadence to them.

While defendants contest at least some aspects of these factual allegations, we hold that, on the record thus far developed, a reasonable trier of fact could conclude ***1288** that each of these two factual assertions is accurate. We also hold that a reasonable trier of fact could conclude that these constitute additional "uses" (i.e., in addition to helping identify potential clinical investigators) that were not reasonably related to securing FDA approval to commercially market the Cadence.

Thus we turn to the last of the three issues in this setting: would a reasonable trier of fact be constrained to conclude that these additional trade show uses were *de minimis?* The phrase *de minimis* is not self-defining in the abstract or out of context. To give it meaning, we must look to the policies and interests that Congress sought to advance and balance when it enacted the statutory scheme which we are interpreting and applying here. We attempt to do this in some of the paragraphs that follow.

An important piece of the reasoning that supports our finding that these additional uses would have to be considered *de minimis* is our prior determination that a reasonable trier of fact would be compelled to conclude that defendants' demonstration activity was, at least in very substantial part, reasonably related to generating data for FDA approval.

Turning first to the "additional use" that consisted of continuing to demonstrate the Cadence after defendants allegedly had a sufficient list of potential investigators, we point out that the magnitude of this use is readily exaggerated. On the record presented to us, a reasonable trier of fact could not conclude that this use was large or significant. This follows because defendants have presented evidence that would compel the conclusion that it was reasonable, even after they had a long list of potential investigators, for them to continue to attempt to identify additional, highly qualified physicians who might serve as clinical investigators. Defendants have never been in a position where they could know with certainty that the FDA would not demand additional data from them. Given that indisputable fact, and the unforseeability of how much more data the FDA might want, and from what kinds of settings, it clearly was reasonable for Ventritex to seek to add highly qualified potential investigators to its lists. Since the trier of fact would be constrained to find that some of this particular "additional use" was reasonably related to securing FDA approval of the Cadence, it would not be reasonable, given the volume of such "extra" demonstration activity evidenced in the record before us, to conclude that whatever additional "unrelated" use remained was legally significant.

At this juncture we turn to consider the potential magnitude of the second of the allegedly unrelated uses: defendants' alleged failure to pre-qualify individuals as potential investigators before demonstrating the Cadence to them.

On the record presented to us, we find, as a matter of law, that Ventritex' failure to determine that all of the people to whom it demonstrated the Cadence at medical trade shows were qualified to serve as potential investigators does not significantly threaten the interests that the limiting provisions of § 271(e)(1) seek to protect and, therefore, must be deemed *de minimis.*

Congress was fully aware that by enacting § 271(e)(1) it was reducing some of the economic rights previously held by patent holders. In order to contain the impact of the exemption, Congress limited the statute's applicability to those manufacturers engaged in activities reasonably related to obtaining FDA approval, thereby preserving the patent holders' right to exclude others (including a manufacturer conducting clinical trials) from the general commercial market place during the life of the patent.

No reasonable trier of fact could conclude that the activity we are considering here, i.e., failing to screen all persons to whom defendants demonstrated the Cadence, encroached in any significant way on the patent-holder's interest in preserving its exclusive access to the general commercial market for these kinds of devices. First, we note that there is no evidence whatsoever that defendants solicited any orders for or otherwise attempted to make sales of the Cadence at any of the trade ***1289** shows. And, as we pointed out earlier, defendants posted signs at their booths at the trade shows, as required by the FDA, clearly indicating that the Cadence was an "investigational device" and not currently available for general commercial sales. Moreover, there is no evidence that these demonstrations led to a single sale of the Cadence. Thus, what is left as the subject of plaintiff's complaint here is the allegation that the trade show activity generated general

commercial interest in defendants' product. While this might be true, the gap between this possibility and actual harm to an interest protected by plaintiff's patent is far to wide to justify a finding that the demonstration activity should cost defendants the benefits of § 271(e)(1). It goes without saying that the FDA must approve the Cadence before it can be sold commercially. Neither we, nor a jury, have any way of knowing when, or if, such approval might be forthcoming. The approval process could take years. During that period, any residual effects of the defendants' demonstration activities presumably would be diluted to the point of imperceptibility. Moreover, with the passage of time before FDA approval, it becomes increasingly probable that persons whose interest in a product like the Cadence might have been stimulated by the trade show demonstrations would turn to suppliers other than defendants (perhaps even plaintiff). Finally, we note that the evidence does not make clear the extent of the shortfall in defendant's screening processes. There is evidence that defendant did some screening. How often defendants failed to screen just is not clear. Given all of these considerations, a jury could return a finding about whether, or to what extent, this conduct by defendants caused harm to any of plaintiff's protected interests *only* on the basis of speculation. In other words, any harm occasioned by the conduct at issue here is far too remote and speculative to be legally significant.

We emphasize, again, that if Ventritex begins selling the Cadence commercially at some time in the future, or actually engages in non-*de-minimis* uses that are not reasonably related to securing FDA approval of the Cadence, plaintiff can revive its patent infringement claims and have the issue of infringement decided on the merits. If plaintiff were to prevail in such litigation, the courts would award it full damages.

D. CONCLUSION RE DEFENDANTS' INVOCATION OF THE § 271(e)(1) DEFENSE

For the reasons set forth in detail above, we hold that there are genuine disputes as to none of the facts that are material to a determination that defendants are entitled to the protections of § 271(e)(1), and that defendants have shown that, as a matter of law, they are entitled to summary judgment on the basis of this statutory exemption to plaintiffs patent infringement claims (Counts I–VII). We therefore GRANT defendants' motion for summary judgment on these first seven counts and ORDER immediate entry of judgment thereon.

IV. DEFENDANTS' MOTION TO DISMISS THE DECLARATORY RELIEF CLAIMS (COUNTS VIII AND IX).

[15] In opposition to a motion pressed by defendants, plaintiff argues that the court should retain jurisdiction over plaintiffs claims for declaratory relief even if the court grants defendants' motions for protection from the infringement claims under § 271(e)(1). For the reasons we set forth here, the court declines plaintiff's invitation.

First, it is not at all clear that we will ever have a case and controversy between these litigants that arises under federal patent law. Given our ruling above on the § 271(e)(1) exemption, a case and controversy could arise only if either defendants departed substantially in the future from their past course of conduct or the FDA granted pre-market approval of the Cadence and defendants began attempting to sell it in the general commercial market. We have no basis for concluding that defendants will depart substantially (or at all) from their past course of conduct unless ***1290** and until the FDA approves the Cadence for sale in the general market. And we have no way of knowing whether the FDA will ever grant that approval. We can only speculate about how long it might take the FDA to make a determination in response to defendants' application. To expect such a determination much sooner than about a year from now appears to be unrealistic, and there is a very real prospect that the determination will not be forthcoming for a considerably longer period than that. (See, Fischer decl. at 5). Moreover, the FDA could require defendants to make changes in the Cadence as a condition to approval. If so, the content of the dispute between these parties could change. Finally, we repeat a point we made earlier: because defendants' current activities are protected by § 271(e)(1), plaintiff is not suffering, at this juncture, any legally cognizable harm as a result of defendants' conduct. Under these conditions, there is no compelling reason to assert jurisdiction to determine whether defendants' product, as currently configured, infringes plaintiff's patent rights.

A second kind of consideration reinforces our decision to dismiss the declaratory relief claims at this juncture. We are concerned that if we exercise jurisdiction over declaratory relief actions in a setting like this, where we have held that defendants are entitled to protection from suit for infringement under § 271(e)(1), we will be undermining one of Congress' purposes in enacting this exemption. It appears to us that Congress intended this exemption to offer a "safe haven" to companies who confined their conduct to the boundaries set forth in the statute. The purpose of

the safe haven is to permit these companies to develop and test their new products so that they can be positioned to enter the general market at the end of the lives of relevant patents. At least for relatively small start-up companies like Ventritex, where much of the business and technical work essential to survival is done by a small group of people, the promise by Congress of a safe haven could prove to be completely illusory if the courts permitted competitors to proceed full bore with expensive, resource-draining, and personnel-distracting litigation in the form of actions for declaratory relief. It makes little sense, and thus we assume would be inconsistent with Congress' intent, to protect companies like Ventritex from suit for actual patent infringement but leave them fully exposed to declaratory relief actions whose gravamen and burdens are much the same. While the considerations discussed in the preceding paragraph are sufficient to support our decision not to exercise jurisdiction at this time over plaintiff's declaratory relief counts, the fact that these additional policy considerations cut in the same direction intensifies our resolve.

For all the reasons discussed in this section, we hereby GRANT defendants' motion to dismiss plaintiff's declaratory relief claims (Counts VIII and IX). Those Counts are ORDERED dismissed.

V. DEFENDANTS' MOTION TO DISMISS THE REMAINING STATE LAW CLAIMS (COUNTS X–XIX).

Defendants earlier moved this court to dismiss plaintiff's state law claims asserted in Counts X–XVII of plaintiff's original complaint. Defendants contended that, since the sole basis of subject matter jurisdiction over these claims was pendency to the federal question claims in Counts I–IX, the court should dismiss the state law claims if it grants defendants' motion to dismiss the federal law claims in counts I–IX.

However, plaintiff has since amended its complaint. The second amended complaint now alleges a separate basis for jurisdiction under 28 U.S.C. § 1332(a) (diversity). Plaintiff also has added two new counts, including an additional federal claim (Count XVIII—Correction of Inventorship) that is not disposed of by our ruling on the applicability of the 271(e)(1) defense. Thus, we hereby DENY defendants' motion to dismiss plaintiff's state law claims.

VI. CONCLUSION.

Given the dispositive effect of the 271(e)(1) defense on Counts I–IX of plaintiff's ***1291** second amended complaint, this court finds that there is no just reason for delaying final judgement on those counts, despite the remaining federal law count and the state law counts. Thus, we ORDER entry of summary judgment on Counts I–IX.

IT IS SO ORDERED.

All Citations

775 F.Supp. 1269, 20 U.S.P.Q.2d 1422

Footnotes

1 Plaintiff filed a motion for summary judgment regarding defendants entitlement to assert the § 271(e)(1) defense. Defendants then filed a motion to dismiss, pursuant to Federal Rule of Civil Procedure 12(b)(6), on the grounds that plaintiff's patent infringement claims are precluded by defendants' entitlement to the § 271(e)(1) defense. Plaintiffs filed an opposing brief styled as an opposition to defendants' motion and second, cross-motion, for summary judgment.

2 Plaintiff cites language from the statute's legislative history in support of its characterization of Congress' purpose in enacting § 271(e)(1). Specifically, plaintiff cites language which refers to an “infringing” manufacturer entering the commercial market only after the patent-in-suit expires. However, all of the examples of permissible use presented in the legislative history of § 271(e)(1) were articulated before the U.S. Supreme Court's determination in *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990) that § 271(e)(1) covered medical devices as well as drugs.

Thus, the legislative history speaks almost exclusively in terms of a *generic drug* manufacturer using a patented *drug* product, during the life of the patent, so that it may establish the bioequivalency of a generic drug substitute as part of the FDA approval process. (Legislative History at 2689–2692). Because the bioequivalency process applied to generic drugs necessarily involves the use of another patented drug, the legislative history invariably speaks of the “infringing” manufacturer entering the market place after the patent-in-issue has expired. However, while medical devices are also subject to FDA pre-approval testing, such testing does not necessarily involve comparison of an unpatented device with its patented prototype, as is the case with bioequivalency testing of generic drugs. *Eli Lilly and Co. v. Medtronic, Inc.*,

5 U.S.P.Q.2d 1760, 1762, n. 9, 1987 WL 26676 (E.D.Pa.1987). Such a manufacturer, though subject to FDA approval and theoretically engaged in activities "solely for uses reasonably related" to such approval, may not believe that it is infringing, and therefore may have no reason to wait until the expiration of the allegedly infringed patent to begin commercial marketing.

3 Although defendants' originally styled their motion as a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the court notified the parties that it would decide these motions under the summary judgment standard articulated in Federal Rule of Civil Procedure 56. Our decision to convert defendants' 12(b)(6) motion to a motion for summary judgment was compelled, in part, by both parties' presentation of extensive material outside of the pleadings. *Mack v. South Bay Beer Distributors, Inc.,* 798 F.2d 1279, 1282 (9th Cir.1986).

4 As the Court of Appeals for the Federal Circuit noted in its most recent opinion in *Eli Lilly and Co. v. Medtronic, Inc.,* 915 F.2d 670, 673 (Fed.Cir.1990), "[a] threat of sale does not constitute an act of infringement."

5 In *Union Asbestos & Rubber Company v. Evans Products Company,* 328 F.2d 949 (7th Cir.1964) the Court of Appeals held that systematic and continuous solicitation *plus* demonstration may be sufficient to establish *venue.* Significantly, the court also noted that "the demonstrations are proper proof of 'sale' and not proper proof of 'use' because in them the accused article was not used for the purpose for which it was intended. Its intended use was to divide freight cars, not for demonstration to intended customers. We believe it is illogical to lay venue on 'use' where proof is to be of a 'sale' and we prefer not to nourish that procedure." *Id.* at 951.

While we certainly would be reluctant to resolve this matter solely on the basis of this authority, we believe that the court's reasoning is sound. § 271(a) defines infringing acts in terms of "making", "selling" or "using." Common sense suggests that demonstration activity should be considered as evidence of an infringing "sale" and not as evidence of an infringing "use." Thus, accepting the premise that demonstration activity can properly be evidence only of infringing "sales," and not "infringing uses," plaintiff's failure to present evidence that the demonstrations led to any sales of the Cadence strongly suggests that the defendants' demonstration activity does *not* constitute an act of infringement under § 271(a).

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