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A Survey of 35 U.S.C. § 271(e)(1) as Interpreted by the Courts: The Infringement Exemption Created by the 1984 Patent Term Restoration Act

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**A SURVEY OF 35 U.S.C. § 271(e)(1) AS INTERPRETED
BY THE COURTS: THE INFRINGEMENT EXEMPTION
CREATED BY THE 1984 PATENT TERM
RESTORATION ACT***

Samuel M. Kais†

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I. INTRODUCTION

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act (PTR Act).¹ The purpose of this Act was to encourage expenditure in the areas of pharmaceutical inventions while simultaneously ensuring greater competition in these fields immediately after relevant patents expire.² By rectifying distortions in the patent system created by the Food and Drug Administration's (FDA's) regulatory approval process, Congress struck a balance between the interests of pharmaceutical companies and competing "generic" manufacturers. The result was an exemption to patent infringement codified as § 271(e)(1) of the Patent Statute. This section provides:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) 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.³

The language of this exemption lends itself to interpretation towards which the courts have provided limited clarification. Many questions have arisen with regards to eligibility, scope, disqualifying activity, and procedural administration. It is crucial that these questions be answered. Misinterpretation of this legislation can cost a company license fees, business opportunities, unnecessary litigation expenses, and most importantly its patent protection.

This writing will explore the scope of § 271(e)(1) as interpreted by courts and the resulting effect upon corporate business and patent practices.

1. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. The PTR Act is also referred to as the Waxman-Hatch exemption.

2. Amy Stark, *The Exemption from Patent Infringement and Declaratory Judgments: Misinterpretation of Legislative Intent?*, 31 SAN DIEGO L. REV. 1057, 1059 (1994).

3. 35 U.S.C. § 271(e)(1) (1988).

II. BACKGROUND

The 1984 Act was motivated by two distortions that were occurring to the standard 17-year patent term. Both of these distortions were created by the long and arduous FDA approval required prior to the marketing of any pharmaceutical products.⁴

The first distortion was occurring because patentees complying with the FDA requirements were being robbed of their full patent term. While patentees were tied up in the regulatory process, the clock was ticking on their patents. As a result they were deprived of valuable sales time from the front end of their patent terms.⁵

The second distortion came from the fact that once the original patents expired, the lack of FDA approval precluded competitors from entering the marketplace. Since regulatory approval inherently entails the limited making, use, and sale of infringing products, "generic" drug manufacturers had to wait until patents expired before seeking FDA approval. In effect, this inadvertently gave patentees term extensions while their competitors were engaged in the long regulatory process.⁶

To restore to patentees the time lost from their patents, the PTR established a patent-term extension for products that are subject to lengthy pre-market regulatory delays.⁷ Codified as 35 U.S.C. § 156, this section provides that patents relating to eligible products can be extended up to five years if, *inter alia*, the product was "subject to a regulatory review period before its commercial marketing or use," and "the permission for the commercial marketing or use of the product after such regulatory review period was the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred."⁸

4. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 662 (1990).

5. *Id.*

6. *Id.*

7. 35 U.S.C. § 156(f) (1988) defines eligible products:

(1) The term "product" means:

(A) A human drug product.

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

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

8. 35 U.S.C. § 156(a) (1988).

In conjunction with § 156, the PTR addressed the distortion at the back end of the patent period by providing for an exemption to patent infringement.⁹ Codified as 35 U.S.C. § 271(e)(1), this exemption allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval. It is this exemption that has created so much confusion.

III. SCOPE OF § 271(e)(1)

The first point of confusion that has arisen with this exemption is to what products does this law apply? In 1990, the Supreme Court clarified this issue by stating that § 271(e)(1) not only covers drugs but also medical devices and food and color additives.¹⁰

The controversy behind the scope of this exemption was based on the fact that as drafted, § 271(e)(1) appears to be limited exclusively to drugs.¹¹ However, in *Eli Lilly & Co. v. Medtronic, Inc.*, the Federal Circuit held that the § 271(e)(1) exemption was not strictly limited to drugs but also extends to medical devices that are subject to FDA approval.¹² In the process of affirming this decision the Supreme Court broadened the scope of § 271(e)(1) even further.¹³

The logic behind *Eli Lilly* was stated by Justice Scalia who wrote that "the phrase 'patented invention' in § 271(e)(1) is defined to include all inventions, not drug-related inventions alone."¹⁴ This is because § 271(e)(1) must be interpreted in light of § 156. Since § 156 covers human drug products, medical devices, and food and color additives, so must § 271(e)(1).

It was intended by Congress that §§ 156 and 271(e)(1) work together in alleviating the dual patent term distortions. For this reason, they must be interpreted relative to each other rather than as independent provisions.¹⁵ This is reflected by Justice Scalia in *Eli Lilly*:

[I]t seems most implausible to us that Congress, being demonstrably aware of the dual distorting effects of regulatory approval requirements in this entire area . . . should choose to address both those distortions only for drug products; and for other products named in §201 (35 USC §156) should enact provisions which not

9. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 662 (1990).

10. *Id.* at 662.

11. 35 U.S.C. § 271(e)(1) (1988).

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

13. *Eli Lilly*, 496 U.S. at 662.

14. *Id.* at 665.

15. *Id.* at 666-69.

only leave in place an anticompetitive restriction at the end of the monopoly term but simultaneously expand the monopoly term itself, thereby not only failing to eliminate but positively aggravating distortion of the 17-year patent protection.¹⁶

As a result of this logic, the § 271(e)(1) exemption has been found to apply not only to drugs, but also to medical devices, food additives, color additives, and human biological products.

IV. ELIGIBILITY UNDER § 271(e)(1)

Section 271(e)(1) focuses only on acts of infringement as defined in § 271(a), i.e., the accused act(s) must constitute making, using, selling, or offering to sell an infringing device.¹⁷ If the accused activity falls outside of these categories, it is a noninfringing act and the exemption is not relevant.¹⁸ As a condition to eligibility, the accused activity must be *solely for uses reasonably related to gaining FDA approval*.¹⁹ Based on deviations from these concepts, patentees have been quick to charge that accused infringers should be disqualified from the exemption. The courts have responded by holding that an accused infringer is not disqualified from this exemption for intent to commercialize prior to patent expiration, collateral uses of data submitted to the FDA, foreign activity, or demonstrations of infringing devices at trade shows.

A. *Infringer's Intent To Commercialize Prior To Patent Expiration*

In *Intermedics v. Ventritex*,²⁰ it was argued that Congress intended § 271(e)(1) to apply only when the allegedly infringing manufacturer is preparing to commercialize after expiration of the patent-in-suit.²¹ The district court did not approve of this limitation and held that a proper § 271(e)(1) analysis objectively and exclusively focuses on potentially infringing "acts" themselves, not the "intent" or "purposes" behind these acts.²²

The *Intermedics* court reached its ruling because it felt that the

16. *Id.* at 672.

17. 35 U.S.C. § 271(a) (1988).

18. *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1278 (N.D. Cal. 1991), *aff'd* 26 U.S.P.Q.2d (BNA) 1524 (Fed. Cir. 1993) (unpublished), *cert. denied* 115 S Ct. 205 (1994).

19. *Id.* at 1277-78.

20. 775 F. Supp. 1269.

21. *Id.*

22. *Id.* at 1274.

application of section 271(e)(1) should be kept simple and the addition of an "intent" element would inevitably convolute the issue. In expressing this concern, it stated:

[W]e are troubled by the prospect of having to search for [intent] 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 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 To apply such test it would be necessary to make guesses about *when* FDA approval was likely to be forthcoming. Yet the process of securing FDA approval for a new medical product can be tortuously extended and riddled with unpredictability.²³

The Federal Circuit affirmed this view on appeal and in further support of it held that from a direct reading of the PTR Act, "[t]here is no suggestion that a producer may only rely on the exemption if it does not intend to commercialize the product before expiration of the patents, . . . reliance on § 271(e)(1) is not precluded by manifestation of an intent to commercialize upon FDA approval."²⁴

The courts have therefore concluded that "the law is not concerned . . . with motives, purposes, or ulterior designs. Instead, the law is concerned only with actual uses."²⁵

B. Public Dissemination of Clinical Data: Promotional and Fundraising Uses

Noninfringing collateral uses of clinical data generated primarily for FDA approval do not affect the application of § 271(e)(1). A company therefore does not lose this exemption by disseminating its clinical data for uses other than submission to the FDA.²⁶ These collateral uses include business activities such as raising capital and establishing mechanisms for product distribution.

In *Intermedics*, the district court emphasized that § 271(e)(1) is not relevant to activities, commercial or otherwise, that are not in-

23. *Id.*

24. *Intermedics Inc. v. Ventritex Co. Inc.*, 26 U.S.P.Q.2d (BNA) 1524, 1528 (Fed. Cir. 1993) (unpublished).

25. *Intermedics*, 775 F. Supp. at 1285.

26. *Id.* at 1278.

fringing under § 271(a).²⁷ As stated above infringing activity must constitute making, using, selling, or offering to sell an infringing device.²⁸ Since dissemination of FDA data does not literally fall into one of these categories, the Federal Circuit has held that there is no infringement when disclosure is made for fundraising and other business purposes.²⁹ Such purposes include “presenting clinical trial data at professional conferences, reporting clinical trial progress to investors, analysts and journalists, and describing clinical trial results in private fundraising memoranda.”³⁰

Congress’s intent in enacting this exemption was “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.”³¹ Meaningful sales require more than just FDA approval; to be successful, competitors need to engage in promotional activities to raise funds for developing and testing their products. When Congress drafted § 271(e)(1), it had this in mind. The Federal Circuit reflected this sentiment in *Telectronics Pacing Systems v. Ventritex*.³² In its opinion, the court stated that:

[I]t would strain credulity to imagine that Congress was indifferent to the economics of developing and marketing drugs and medical devices when it enacted § 271(e)(1), . . . if Congress intended to make that more difficult, if not impossible, by preventing competitors from using in an admittedly non-infringing manner, the derived test data for fund raising and other business purposes, it would have made that intent clear.³³

Collateral business uses of FDA clinical data have therefore been held to be irrelevant in a proper § 271(e)(1) analysis. As long as the data is primarily generated for regulatory approval, subsequent

27. *Id.* at 1281.

28. 35 U.S.C. § 271(a) (1988).

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

30. *Id.*

31. *Intermedics*, 775 F. Supp. at 1279.

32. *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992). In this case, defendant used the clinical data submitted to the FDA for promotional purposes. Some of Ventritex’s clinical investigators submitted an abstract to the American College of Cardiology and presented results of the clinical trials at medical conferences. Furthermore, in a fund raising effort, Ventritex’s CEO described the on-going clinical trial to investors, analysts, and journalists. He also distributed a handout which stated “Early clinical results are quite promising.”

33. *Telectronics*, 982 F.2d at 1524.

uses of it for business purposes will not destroy the § 271(e)(1) exemption. In the minds of the Federal Circuit, Congress did not intend to repeal the exemption in the event that data obtained during clinical trials is publicly disclosed for promotional and business purposes.³⁴

C. *Demonstrations of Infringing Devices at Trade Shows*

Because of the commercial nature of trade shows, the presence of infringing devices exempted under § 271(e)(1) is a troublesome matter. The courts, however, have held that so long as the trade show displays are reasonably related to obtaining information for FDA approval, and they are not done to advance actual sales of the products, they do not disrupt the infringement exemption.

In *Telectronics*, the court legitimized the trade show displays by finding that demonstrations of infringing devices "constitute an exempted use reasonably related to FDA approval."³⁵ An important consideration with FDA clinical trials is the need to obtain clinical investigators who in turn can generate data to be submitted to the FDA. "[B]ecause device sponsors are responsible for selecting qualified investigators and providing them with the necessary information to conduct clinical testing," the court recognized the necessity for such demonstrations and displays.³⁶ Demonstrations at trade shows are therefore deemed to be reasonably related to the development of information for FDA approval. As such, it is an exempted activity under § 271(e)(1).

Subsequent to its decision in *Telectronics*, the Federal Circuit affirmed *Intermedics* in an unpublished opinion.³⁷ In doing so, it endorsed trade show displays and demonstrations from a different angle. The district court held that "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."³⁸ "[M]ere demonstration or display of an accused product, even in an obviously commercial atmosphere, does not constitute an infringing use under § 271(a)."³⁹ The Federal Circuit was more than willing to agree in stating that "assuming these nonsale

34. *Id.* at 1523.

35. *Telectronics*, 982 F.2d at 1523.

36. *Id.*

37. *Intermedics*, 26 U.S.P.Q.2d (BNA) 1524.

38. *Intermedics*, 775 F. Supp. at 1286.

39. *Id.*

demonstrations at medical conferences constitute an infringing use, we have previously held they are an exempt use that is reasonably related to procuring FDA approval of the device."⁴⁰

After *Intermedics*, the Federal Circuit affirmed a similar case in an unpublished opinion called *Chartex International v. M.D. Personal Products*.⁴¹ The *Chartex* decision cites *Telectronics* and holds that trade show displays to obtain necessary information for clinical testing are exempted activity under § 271(e)(1). This is because they are reasonably related to obtaining information for FDA approval.⁴² The general rule is therefore reiterated in that the use of clinical data for more than FDA approval does not revoke the infringement exemption.

D. Foreign Uses

The question of whether § 271(e)(1) applies to foreign-related activities is a matter that is currently unresolved due to the lack of any precedential Federal Circuit review. District courts appear unsettled as to how narrowly or broadly to construe § 271(e)(1).

In *Scripps Clinic & Research Foundation v. Baxter Travenol Laboratories, Inc.*,⁴³ a district court in Delaware heard a case where the defendant had submitted the data it generated not only to the FDA, but also to equivalent agencies in foreign countries.⁴⁴ The court sought to determine whether Baxter's activities were "solely for purposes reasonably related to" FDA approval of Factor VIII:C. There were, however, unanswered factual questions as to "what data was sent to the European agencies, what data developed in Europe was given to the FDA, and what tests were required by FDA regulations."⁴⁵ Because of these factual questions, the court was unable to resolve the foreign activity issue.⁴⁶

In *Intermedics*, the district court of northern California held that "defendants' use of clinical data to support foreign import applications and defendants' publication of articles describing features of the

40. *Intermedics*, 26 U.S.P.Q.2d at 1524.

41. *Chartex Int'l PLC. v. M.D. Personal Prod. Corp.*, 5 F.3d 1505, 1993 WL 306169 (Fed. Cir. 1993) (unpublished).

42. *Chartex*, 1993 WL 306169 at *3.

43. *Scripps Clinic & Research Found. v. Baxter Travenol Labs., Inc.*, 7 U.S.P.Q.2d (BNA) 1562 (D. Del. 1988).

44. *Id.* at 1564.

45. *Id.* at 1565.

46. *Id.*

[product] are not otherwise infringing acts under § 271(a).⁴⁷ In this case, testing activities conducted in Germany were found to be reasonably related to generating data for submission to the FDA. In this jurisdiction, it appears that the submission of foreign-generated clinical data is exempted so long as the procedures used in compiling the data comply with FDA requirements.⁴⁸

In *Ortho Pharmaceutical Corp. v. Smith*,⁴⁹ the court out of the eastern district of Pennsylvania held that uses of a patented invention not "solely for purposes reasonably related to the development and submission of information under Federal Law which regulates the manufacture, use or sale of drugs" is an act of infringement.⁵⁰ The court noted that § 271(e)(1) does not permit other uses, such as obtaining foreign premarketing approval and any promotional or commercial use in the U.S. or abroad.⁵¹ The court enjoined Ortho from transmitting to any foreign affiliate or third party any data based on the manufacture, use or sale of norgestimate. It examined Johnson & Johnson's and Ortho's use of domestically made norgestimate, and concluded that this use was not protected under § 271(e)(1).⁵² It appears that the injunction was intentionally worded to cover even the dissemination of data which had to be developed anyway to satisfy FDA.

In *NeoRx Corp. v. Immunomedics, Inc.*,⁵³ a district court out of New Jersey emphasized once again that § 271(e)(1) only requires that the making, using, or selling of the patented invention be solely for uses reasonably related to FDA approval.⁵⁴ It held that the commercial motivation of trying to obtain foreign regulatory approval does not necessarily deprive defendant of the § 271(e)(1) exemption.⁵⁵ Submitting data to foreign regulatory agencies is not a per se infringing act. However, using the data to serve multiple purposes unrelated to meeting FDA requirements will put the defendant beyond the protection of § 271(e)(1).⁵⁶

In *Chartex v. Int'l PLC v. M.D. Personal Prod. Corp.*, the court

47. *Intermedics, Inc. v. Ventritex, Inc.* 775 F. Supp. 1269, 1281 (N.D. Cal. 1991).

48. *Id.* at 1284.

49. *Ortho Pharm. Corp. v. Smith*, 18 U.S.P.Q.2d (BNA) 1977 (E.D. Pa. 1990).

50. *Id.* at 1992.

51. *Id.*

52. *Id.*

53. *NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202 (D. N.J. 1994)

54. *Id.* at 207.

55. *Id.* at 206.

56. *Id.* at 207.

of the northern district of California held that "making arrangements to have a device manufactured overseas or making arrangements to have it imported into a foreign country is not an infringing 'making,' 'using,' or 'selling' of the invention within the United States."⁵⁷ Therefore, the defendant's overseas business arrangements did not constitute infringement.⁵⁸

Aside from affirming the district court decision in *Intermedics*, the Federal Circuit has not yet resolved the issue of whether foreign uses of the data submitted for FDA approval is within the scope of protection under § 271(e)(1). The focus of the courts' inquiry, however, seems to be whether the foreign use was "solely" for and "reasonably related" to obtaining FDA approval.

V. DECLARATORY JUDGMENT IN LIGHT OF § 271(e)(1)

As currently applied by the courts, § 271(e)(1) has also changed the role played by declaratory judgments in patent law. Patentees who wish to take action against those protected by this exemption now face an exposure to a declaratory judgment of invalidity. This threat to patent owners has essentially put teeth into the exemption.

Declaratory actions provide a method whereby the respective rights of both patent owners and alleged infringers can be established.⁵⁹ Such relief can afford parties a quick, practical, and inexpensive means for resolving their conflicts.⁶⁰ A court, however, is not justified in hearing such an action unless the party seeking it can show a "true and actual controversy."⁶¹ If the plaintiff is a potential infringer, there are two elements necessary to demonstrate the required showing: (1) the defendant's conduct must have given the plaintiff a reasonable apprehension of a charge of infringement, and (2) the plaintiff must be engaged in infringing acts or have the ability and intention to engage in such acts.⁶² If the plaintiff is the patent holder, a "true and actual" controversy can be found if the defendant is engaged in infringing activity and apparently refuses to alter the activity despite acts by the patent owner sufficient to create a reason-

57. *Chartex Int'l PLC v. M.D. Personal Prod. Corp.* 5 F.3d 1505, 1993 WL 306169, *3 (Fed. Cir. 1993) (unpublished).

58. *Id.*

59. *See, e.g., Lang v. Pacific Marine and Supply Co.*, 895 F.2d 761 (Fed. Cir. 1990).

60. *See, e.g., Smith v. Transit Casualty Co.*, 281 F. Supp. 661, 670 (Fed. Cir. 1968).

61. 28 U.S.C. § 2201 (1988). *See also Maryland Casualty Co. v. Pacific Coal and Oil Co.*, 312 U.S. 270, 272 (1941).

62. *See, e.g., Arrowhead Indus. Water, Inc. v. Ecolchem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988).

able apprehension that a suit will be forthcoming.⁶³ In either case, the party seeking declaratory relief generally has to demonstrate immediacy before a court has jurisdiction to hear its complaint.⁶⁴

The Federal Circuit has recently reconciled these tests with the § 271(e)(1) exemption.⁶⁵ In both *Intermedics* and *Telectronics*, patentees' declaratory judgment actions were denied because of an insufficient case of controversy.⁶⁶ The logic behind these rulings was that if the infringing activity was to be specifically allowed under the § 271(e)(1) exemption, it would be inconsistent to apply a declaratory action aimed at prohibiting it. "To permit Ventritex to be protected from direct suit of infringement and yet allow the same activities to be subject to suit in a declaratory judgment action would be nonsensical."⁶⁷ Accordingly, the court in *Intermedics* denied the patentee's request for declaratory judgment despite the fact that the defendant admitted its intent to market its infringing device as soon as it received FDA approval (a nonexempted activity).⁶⁸ As a result, the door has been closed on the use of declaratory actions by patentees with regards to § 271(e)(1).

Section 271(e)(1) has also been used by the courts to define the declaratory relief available to potential infringers.⁶⁹ In *Farmaceutisk*, a patent action was brought by a patentee against an infringer whose activity was protected under § 271(e)(1). The defendant counter-claimed with declaratory actions for both noninfringement and patent invalidity. Since the defendant's activity was clearly exempted, both the plaintiff's suit and the defendant's declaratory action for noninfringement were thrown out.⁷⁰ Of critical importance, however, was the fact that the court allowed the defendant's declaratory action for patent validity. The court's reasoning was based on the following policy reasons:

[P]ermitting new drug manufacturers, at their choosing and subject to court discretion, to test validity of a patent-in-issue early on in

63. See, e.g., *Lang*, 895 F.2d at 764.

64. See, e.g., *Farmaceutisk Laboratorium Ferring v. Solvay Pharms., Inc.*, 25 U.S.P.Q.2d (BNA) 1344, 1349 (N.D. Ga. 1992).

65. *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269 (N.D. Cal. 1991), *aff'd* 26 U.S.P.Q.2d (BNA) 1524 (Fed. Cir. 1993) (unpublished), *cert. denied* 115 S. Ct. 205 (1994); *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992).

66. *Intermedics*, 26 U.S.P.Q.2d at 1527, *Telectronics*, 982 F.2d at 1526.

67. *Intermedics*, 26 U.S.P.Q.2d at 1528.

68. *Intermedics*, 775 F. Supp. at 1275.

69. *Farmaceutisk*, 25 U.S.P.Q.2d at 1344.

70. *Id.* at 1351-52.

the development process best serves the competing interests of protecting valid patents, protecting new drug manufacturers during the testing process, and moving alternative drugs into the market.⁷¹

The functional effect of this ruling is the expansion of benefits provided to infringers who are protected by § 271(e)(1). Patent holders now must seriously contemplate the strategic implications of attacking potentially exempted activity. Bringing an infringement suit provides the defendant with a *prima facie* "true and actual controversy" that he might not otherwise have been able to demonstrate. As a result, this conduct would likely give the defendant the grounds upon which he could seek declaratory relief. Patent owners who bring suit attacking a potentially exempted activity under § 271(e)(1) should therefore be wary of bringing such a suit. They just may be exposing their patents to declaratory rulings of invalidity.

VI. CONCLUSION

Section 271(e)(1) is intended to remedy the distortion of the patent term produced by the requirement that certain products must receive premarket regulatory approval. This enables competitors to effectively enter the market on the day the relevant patent(s) expire. As it currently stands, § 271(e)(1) is not limited to drugs but extends to other products that are subject to FDA approval. Intent and collateral uses of FDA clinical data and infringing devices apparently do not disqualify infringers from the exemption. In light of this, patentees should be wary of bringing infringement suits against those eligible for § 271(e)(1). Such conduct may just expose them to declaratory judgments of invalidity.

On a final note, it is important to address the fact that there is very limited precedence dealing with this exemption. The Federal Circuit has yet to completely clarify the precise scope and application of § 271(e)(1). Until such precedential opinions are issued, those dealing with § 271(e)(1) should proceed with caution.

71. *Id.*

