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The Process Patents Amendments Act: The Labyrinth

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INTRODUCTION

The Process Patent Amendments Act of 19881 ("Act") has its genesis in a desire to improve United States commercial competitiveness and to place process and product patents on an equal footing.2 To accomplish this purpose, the Act creates a cause of action for the importation into the United States or the sale or use within the United States of products made by a patented process and applies regardless of the location where the process is practiced (i.e. in the United States or in a foreign location).

This complex Act presents numerous questions and issues, yet provides little guidance for one who attempts to interpret its provisions. For example, are the procedures and remedies different when the process is practiced in the U.S. rather than in a foreign country? Does the Act create a cause of action against purchasers of products made by the process? Under what circumstances is notice of infringement required? When notice is required, to whom


2. Only time will tell whether the Act will achieve this limited purpose or elevate process patents above product patents. After all, the owner of a process patent not only enjoys a presumption of validity, but in proper circumstances, a presumption of infringement as well.
must notice be sent, and what should the notice contain? What is the extent and applicability of the Grandfather Clause? Does the Act apply to methods of use as well as processes of manufacture? Following a brief discussion of the history of the Act, this Article discusses these questions and possible resolutions. Upon examination, it will be seen that the Act may result in use more widespread than Congress intended.

I. THE STATE OF THE LAW

A. The Law Prior to February 23, 1989, Relating to Products of Patented Processes and Why a Change in the Law Was Needed

Initially, it may be helpful to discuss what exactly process patents are and their importance with respect to the commercial competitiveness of the United States. Section 101 of the Patent Act of 1952 states the following: "Whoever invents or discovers any new and useful process . . . may obtain a patent therefor, subject to the conditions and requirements of this title."3 Section 100(b) defines the term "process" as a "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."4

Basically, there are two types of process patents: (1) methods of use; and (2) processes of manufacture. One may obtain patent protection on a method of using a particular product to achieve a particular result. For example, a method of using a quality control apparatus to detect defects in a polymeric substance is a method of use. It is important to note, however, that the Act does not apply to process patents that do not produce products (i.e. methods of use), since previously existing patent laws prohibited the unauthorized use of such patents.5 On the other hand, one may obtain patent protection on a process of manufacturing a particular prod-

uct, for instance, a process of manufacturing a polymeric substance. This is the type of process patent to which Congress expected the Act to apply.

As one could imagine, process patents that produce products have enormous economic reward and commercial value in various disciplines, such as the biotechnology, bioengineering, semiconductor fabrication, fiber optics manufacture and pharmaceutical industries. However, prior to the Act, the sale or use of products in the United States made from a patented process practiced in a foreign country did not constitute infringement under the United States patent laws. The only protection patent process holders had was the right to exclude others from using the patented process. Therefore, one could manufacture a product in a foreign country using a process that was only patented in the United States and thereafter import and sell that product in the United States without legal repercussions.

Clearly, the importation, use and sale in the United States of products made from processes patented in the United States drastically diminished the commercial value of such patents and exercised an injustice on owners of United States process patents. The Act sought to remedy this injustice by giving United States patent process owners the right to exclude others from importing, selling, or using in the United States, products resulting from the patented process. The rationale for including products obtained from a patented process in the scope of the protection afforded by the process patent is the same as that adopted by the European Patent Convention, the Community Patent Convention, and the World Intellectual Property Organization (WIPO). This rationale was articulated in a memorandum prepared by the International Bureau

6. Koratron Co. v. Lion Uniform, Inc., 449 F.2d 337, 338 (9th Cir. 1971) ("It is settled that the sale of a product made from a process does not infringe a patent on that process."); American Graphophone Co. v. Gimbel Bros., 234 F. 361, 368 (S.D.N.Y. 1916) ("[A] process patent is not infringed by selling the product, and the vendee of a product which has been made in infringement of a patented process cannot be held liable to the patentee, or in any extent to be an infringer."). aff'd, 240 F. 974 (2d Cir. 1917).
8. Id.
The extension (to the product of the process) seems to be an exception to the principle that the protection conferred by a patent or another title of protection for an invention is defined by the object of the invention. In the case of a process invention, a strict application of the said principle would mean that the owner of a process patent could only exclude others from using the patented process. The legal provisions which extend process protection to products obtained by the patented process are based on practical economic considerations. A process which leads to a specific product presents an economic value only through the product. However, it is not always possible to obtain a patent for the product; for example, the product may not be new or may—although new—lack inventive step. The invention of a new and inventive process for the production of such a product which is not patentable constitutes an important technological advance but the reward granted through a process patent is not important because—without an extension to the product—the process patent would be difficult to enforce (since infringement of the process is difficult to prove) and could even be circumvented by use of the process in another country where the process is protected. In order to make patent protection of a process meaningful, it is therefore necessary to consider the patented process and the resulting product as a whole, with the consequence that process protection is automatically extended to the resulting product even if the said product has not been claimed.

With the creation of the Act, United States patent laws were brought into significant conformity with those of the European Patent Convention and other industrialized countries. The intent of Congress was to elevate the rights of process patent owners to

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9. *Id.* at 30-31 (citation omitted).
10. However, patent protection offered under United States law is somewhat different from that which is provided under the European patent law system. A discussion of these differences is beyond the scope of this Article.
such an extent as to put process patent owners on equal footing with product patent owners. Furthermore, Congress wished to balance the interests of patent owners against the interests of importers, sellers, and end users of products made from patented processes who will unlikely be able to determine if the product was made from a patented process.\textsuperscript{11}

However, has Congress achieved its goal? Has seeking this conformity caused the pendulum to swing too far in favor of process patent owners? Are the legitimate interests of end users of products made from patented processes adequately protected?

\textbf{B. Method of Use vs. Process to Make}

Although numerous patent practitioners employ the terms "method" and "process" in an interchangeable fashion, there is indeed a distinction, as discussed above, between methods of use and processes to make. Nowhere does this distinction appear to be more important than when dealing with the Act, which does not offer protection for methods of use.

Under § 271(g), "[w]hoever without authority imports into the United States or sells or uses within the United States a product which is \textit{made by} a process patented in the United States shall be liable as an infringer . . . .\textsuperscript{12} Section 271(g) and the legislative history make clear that the Act is only intended to offer protection to those processes that produce products. However, what about methods of use that may be incorporated into processes to make? Does the degree of protection depend upon the drafting skills of the patent practitioner?

These questions can best be analyzed in the context of two hypothetical situations: first, reacting elements A and B to manufacture widgets, which is a \textit{known} prior art process; and second, reacting elements A and B to manufacture widgets which is a \textit{novel} process. Inventor X develops a quality control mechanism, Q, which detects defects in widgets. Inventor X comes to you, a pat-

\textsuperscript{11} See S. REP. NO. 83, supra note 5, at 40.
\textsuperscript{12} 35 U.S.C. § 271(g) (emphasis added).
A claim for manufacturing widgets may read as follows:

1. A process for manufacturing widgets, comprising the steps of:
   reacting a mixture of elements A and B at an elevated temperature of 70°C to 140°C in an inert atmosphere.

A claim for detecting defects in widgets may read as follows:

2. A method of detecting defects in widgets, comprising the steps of:
   exposing the surface of widgets to apparatus Q.

Claim 1, assuming the process is novel, would result in products that would be protected by the Act. However—it follows from the terms of the Act—the products of claim 2 that, standing alone, are subjected to the quality control mechanism, would not be worthy of such protection.

Now assume that claim 1 was known in the art. What if the patent practitioner were to combine claims 1 and 2 to read as follows?

3. A process for manufacturing widgets comprising the steps of:
   reacting a mixture of elements A and B at an elevated temperature of 70°C to 140°C in an inert atmosphere to produce widgets; and
   thereafter exposing the surface of said widgets to apparatus Q.

The Act would seem to accord protection to products made by claim 3 because the claimed process is producing a product and thus within § 271(g)—even though the first step is known. Thus, the questions are presented: If a method of use for quality control is tagged to an unpatentable process to make, can it result in a patentable process? Does such a result not put the public at the mercy of the drafting skills and savvy of the patent practitioner? Is this exalting form over substance?

Assuming it is fair to allow one to convert a quality control
method that detects defects to a finished "product" of a process to manufacture, one must then ask whether it makes a difference if this quality control method is introduced before achieving the end product. That is, to what extent is process control the equivalent of a process to make? For example, assume the prior art discloses that a polymer composition could be molded at a temperature in the range of 100°C to 110°C, and if the temperature went above 110°C, the polymer would decompose. Assume further that in molding parts from the plastic, the reject ratio was high because the mold heated up during use, and it was difficult to time the opening of the mold before exceeding 110°C. Assume that the invention consists of placing a thermocoupler in the mold and connecting it to a microprocessor that automatically opens the mold so that 110°C is not exceeded. Is this a method to use equipment or a process to make? It is in the nature of a method to use a mold. It is also in the nature of a quality control method applied to a molding method midstream rather than post-completion. Thus, in this situation a piece of apparatus (i.e. quality control measure), which does not change the known parameters of the process but applies them more efficiently, may be claimed in a process patent such that a process to make a product is set forth rather than a control method. With that in mind, will the courts look beyond the plain language of the preamble to the claim? Is the draftsman wise to discard the word "method" from his vocabulary and describe the invention as a "process"?

II. INFRINGEMENT UNDER 35 U.S.C. § 271(g)

The basic infringement provisions are set forth in 35 U.S.C. § 271(g), which reads as follows:

Whoever without authority imports into the United States or sells or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless
there is no adequate remedy under this title for infringement on account of the importation or other use or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes; or
(2) it becomes a trivial and nonessential component of another product.13

The exceptions set out represent compromises reached during the lengthy legislative debate that led to the present Act; however, Congress offered little guidance on the meaning of these exceptions. We will explore these exceptions in detail.

A. Products Exempted

Under 35 U.S.C. § 271(g), a product may not be considered made from a patented process if certain modifications have been made to that product. Congress recognized that in certain situations products created from patented processes may be altered to such an extent as to preclude a finding of infringement.14

In many foreign countries, where the patent laws extend protection to products resulting from patented processes, infringement occurs only if the product is made “directly” from the process.15

15. Id. at 49.

Many foreign patent statutes extending process protection to the product resulting from the process include the limitation that the patented product be made “directly” from the process. They use the word “directly” to exclude as an infringement the importation, use or sale of a product which is materially changed from the product resulting from the patented process by subsequent steps or processes.

Id.

Further, article 64(2) of the European Patent Convention states, “[i]f the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.” EUROPEAN PATENT CONVENTION: CONVENTION ON THE GRANT OF EUROPEAN PATENTS art. 64(2) (Kurt Haertel ed., Volker Vossius trans., 1973).
Although Congress agreed “that once a product has been materially changed . . . subsequent purchasers, users and sellers should no longer be liable for process patent infringement,” it rejected the “directly” language as too restrictive:

[T]he Committee decided against including the word “directly” in the statute out of concern that the word “directly” might have been construed too broadly and possibly exempt too many products that have been altered in insignificant ways after manufacture by the patented process. These products ought to be treated as infringing under the bill.

As a result, Congress adopted a disjunctive two-part test by which exemption from infringement is determined. Under this test, “[a] product which is made by a patented process will . . . not be considered to be so made after—(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product.”

1. “Materially changed”

Congress originally proposed a two-pronged test to define “ma-

17. Id. “Industry advocates” were concerned that the term “directly” might be interpreted too narrowly, such that it would “exclude products that had been altered in trivial ways after the stage of manufacture where the patented process was used.” On the other hand, certain members of the Committee exhorted that by including the “directly” language, uniformity would be promoted in that United States law would “conform to the norm of industrialized nations” and patent process protection would not become too broad. The final language adopted was a compromise between both parties. Id. at 46.
18. 35 U.S.C. § 271(g). According to the legislative history:
    The Committee expects the courts to exercise careful judgement [sic] in distinguishing those products that are too far removed from the patented process, and those that have been changed only in insignificant ways. The Committee believes that the courts will be in a better position to settle such issues without the standard of “directly” constraining their judgment.
19. 35 U.S.C. § 271(g) (emphasis added). It was thought that the “trivial and nonessential” language would “further assist” the courts in their attempt to distinguish products that are too far removed from the patented process. S. Rep. No. 83, supra note 5, at 50.
A product that is made by a patented process is *not* materially changed:

1. If it would not be possible or commercially viable to make [a] product *but for* the use of the patented process.

2. If the additional processing steps . . . do not change the physical or chemical properties of the product in a manner which changes the *basic utility* of the product by the patented process.21

The legislative history suggests that “[i]n judging commercial viability, the courts shall use a flexible standard which is appropriate to the competitive circumstances.”22 In this regard, the Senate Report offers a number of examples to “help provide additional resources to the courts.” A chemical example is provided as follows:

[1.] If the patented process produces chemical X, any person importing, using or selling chemical X is liable for infringement.

[2.] If new entity, chemical Y, is produced from chemical X as the result of a material change, the court must also consider the other phase of the test before deciding if Y is infringing or non-infringing: [sic]

[3.] If the only way to have arrived at Y is to have used the patented process at some step, e.g., producing X as an intermediate, Y is infringing.

[4.] If there is more than one way to have arrived a [sic]

20. S. REP. NO. 83, supra note 5, at 50-52.
21. *Id.* at 50 (emphasis added).

However, a change in the physical or chemical properties of a product, even though minor, may be “material” if the change relates to a physical or chemical property which is an important feature of the product produced by the patented process. Usually, a change in the physical form of a product (e.g. the granules to powder, solid to liquid) or minor chemical conversion, (e.g., conversion to a salt, base, acid, hydrate, ester, or addition or removal of a protection group) would not be a “material” change.

*Id.*

22. *Id.*
Y, but the patented process is the only commercially viable way to have done so, Y is infringing.

[5.] If there are commercially viable non-infringing processes to have arrived at X, the connection between the patented process for producing chemical X and the ultimate product, chemical Y, is broken, and Y would be a non-infringing product having satisfied both phases of the test.23

Of particular interest is an example given in the Senate Report relating to a “metal strip”:

A metal strip with certain unique properties is produced by a U.S. patented process. A foreign competitor makes the strip using the process, then turns the strip into a core, puts the core in a transformer and imports the transformer into the United States. Even if there were other commercially or economically viable non-infringing processes for making the strip, this is still a clearcut case of infringement of the process patent that this Act is intended to prevent because the subsequent changes would not be considered material.24

If the “metal strip” example is compared to the chemical example above, wherein the evidence of a commercially viable alternative precluded a finding of infringement, one must ask how the results reached in the two examples can be reconciled. That is, the chemical product would be exempt from infringement if there are viable alternative commercial means of producing the chemical. In contrast, the metal strip is not exempt from infringement even though there are viable alternative commercial means of processing the strip.

The only difference, it would appear, is that the chemical product has taken on a “new utility,” whereas the metal strip has maintained its original “basic utility.” One may argue, therefore, that commercially viable alternatives are not a consideration with respect to whether or not a product made from a patented process has

24. S. REP. NO. 83, supra note 5, at 50 (emphasis added).
retained its "basic utility." Thus, for a product made from a patented process to be exempt from infringement, it must satisfy both aspects of the "materially changed" test. That is, to be exempt there must exist a commercially viable noninfringing alternative process that changes the "basic utility" of the product.

One must question whether this makes sense. Is it not unduly burdensome and contrary to logical thought to require a competitor both to formulate a commercially viable noninfringing alternative process and to produce a product that does not have the same basic utility as the product made from a patented process? Assuming the end product of the patented process is marketable and desirable, why would a competitor with a commercially viable alternative process seek to produce a product whose basic utility diverges from the basic utility of the product made from the patented process?

2. "Trivial and nonessential"

The second part of the two-part disjunctive test adopted by Congress would exclude products made from patented processes if such products were a "trivial and nonessential component of another product." However, how does one determine if a product is "trivial and nonessential"?

The examples in the legislative history are not very helpful. The Senate Report states:

In the semiconductor industry, a manufacturer may have a process patent for forming a semiconductor structure in a semiconductor substrate. Subsequent processing to complete and finish the component does not materially change the semiconductor substrate in which the semiconductor structure formed. In addition, a court could determine that

25. The House version of the bill adopted the phrase "minor and nonessential," however the House acceded to the Senate version of "trivial and nonessential." It appears that the Senate version provides the process patent owner greater protection than the House version, in that many products may be considered to be "minor" but not "trivial." For example a screw or a nut used on an aircraft may be considered to be a "minor" component of the aircraft but not a "trivial" component, because the screw or nut—although minor—performs the essential function of holding the aircraft together.
the cost of a semiconductor component was trivial in relation to the cost of the whole product, but if that same component is essential to the intended function of the whole product then it would be covered by this title.26

The semiconductor example provided in the Senate Report suggests that the monetary value of the component should not be the standard by which we judge the essentialness of the component. Certainly, one can imagine a situation in which a component made from a patented process is relatively inexpensive when compared to the cost of a product of which it is a part. Nevertheless, the component may be vital with respect to the operability of the product.27

Another inappropriate standard would be a test based on functionality. Every component of a product would be essential in the sense that it provided some function, although relatively minor when compared to the functions other components perform. Therefore, the “trivial and nonessential” exception would be rendered meaningless if the standard were merely based on the functional quality of a particular component.

A somewhat more viable and equitable standard may be that which is suggested by Professor Dratler.28 That is, “[w]here components are made using a patented process, determining whether they are ‘trivial and nonessential’ in a particular product should require analyzing their advantages in that product relative to commercially available substitutes.”29 Thus, if there are no commercially available substitutes that would provide an equally satisfactory component, the product made from a patented process would then appear to be an essential component. An equally satisfactory component is one that, when compared to a product made from a patented process, is of similar cost and offers similar advantages.

27. For example, a spark plug with respect to an automobile or a reed with respect to a clarinet.
29. Id.
However, this "commercially available substitutes" test of the "trivial and nonessential" provision of § 271(g) appears to be the same as the "but for" test employed in the "materially changed" aspect of § 271(g). If this were the case, one could conclude that if a product is held not "materially changed by a subsequent process" (i.e. no commercially available substitutes), then the infringing product is not "trivial and nonessential." On the other hand, a product which satisfies the "but for" test of "materially changed" would also be "trivial and nonessential" due to the existence of "commercially viable substitutes." Nevertheless, the product may infringe if it has retained "the basic utility of the product [made] by the patented process," despite the existence of commercial available substitutes.

As a result, the "materially changed" test of § 271(g) would render the "trivial and nonessential" test moot if it were limited to a "commercially viable substitutes" analysis. One must ask then, when or in what circumstances is a product which is not "materially changed" a "trivial and nonessential" component? In light of the fact that the legislative history justifiably frowns upon purely financial analysis, perhaps the approach for "trivial and nonessential" becomes very similar to the evaluations of "materially changed."

For example, if a method to make a core for a spark plug were the subject matter to be analyzed (i.e. the product made from a patented process), the first step would be to examine the product (i.e. the sparkplug). The analysis would be to determine whether subsequent steps in the process to finalize the spark plug materially changed it.

In contrast, the second step encompassing the "trivial and nonessential" test can be applied on two levels. First, is the patented process used to make the internal core material of the sparkplugs? If not, is that internal core material trivial and nonessential to the spark plug? On the other hand, suppose that the spark plug is incorporated into an automobile. Is the spark plug a trivial and nonessential part of the automobile? Clearly, any number of spark

30. See supra notes 22-26 and accompanying text.
plugs could perform the function and the spark plug is an insignificant portion of the cost of the automobile, but could the section analysis achieve a just result? The problem appears to be in ascertaining what exactly the relevant "product" is.

It appears that a purpose of the "trivial and nonessential" provision may be to grant some latitude to a manufacturer who buys a large number of goods to select minor components without being unduly burdened in determining if they are made by a noninfringing process. With this in mind, the standard for contributory infringement may offer some guidance.

A contributory infringer is one who sells a component of a patented invention or a material or apparatus for use in a patented process which constitutes a material part of the invention, knowing the item is adapted for infringement and that the article is not a staple item of commerce. Thus, the focus is on whether the process produces a part or material which has unique properties.

Does the "trivial and nonessential" test really accomplish the purposes of the Act? It is not hard to propose a set of facts where inequitable results would occur. For example, if a domestic automobile manufacturer imported spark plugs made by an infringing process, he could be liable for infringement, even though they are "nonessential" to operation of his domestically made car. In contrast, a foreign car company using the same spark plugs could import complete automobiles and not infringe because the spark plug is a "trivial and nonessential" item of the large product (i.e. the automobile).

The legislative history suggests that the patent owner could still sue the importer of the automobile and obtain some damage relief based on an apportionment of the contribution of the infringing part

Whoever sells a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

Id.
to the value of the product. The legislative history further suggests that injunctive relief might not be appropriate under these circumstances. Thus, Congress seems to be suggesting that if the component was of minor value to the overall product, an injunction would not be appropriate. Does this mean Congress then endorses courts' ability to issue compulsory licenses for future imports in this situation? Or would the patentee be required to file suit repeatedly for future infringements? Suppose the court does not issue injunctive relief. Can the patentee claim willful infringement for further importations? Congress's suggestion is troublesome in that it seems to endorse a compulsory license for domestic importers of large products in relation to minor components, whereas U.S. manufacturers would not be able to use the same components. All in all, the legislative history concerning trivial and nonessential components provides conflicting guidance to courts and presents the possibility that the statutory language may be construed to be essentially meaningless.

B. The Meaning of "Imports" in Light of Bristol-Myers

Section 271(g) of Title 35 impacts "[w]hoever without authority imports into the United States ... a product." At what point is a product considered to be imported into the United States? The Act itself does not define the term "import."

However, in *Bristol-Myers Co. v. Erbamont Inc.*, the United States District Court for the District of Delaware offered some guidance with respect to the meaning of "import." In *Bristol-Myers*, the accused infringer, Bristol-Myers, arranged for a Japanese supplier to ship a large quantity of the drug doxorubicin into the United States. The drug was alleged to be made by a process covered by plaintiff's patent. The shipment arrived at a Puerto Rico trade zone on February 16, 1989, one week prior to the effective date of 35 U.S.C. § 271(g). The drug remained in the custody of the United States Customs Service until May 1, 1989. In the

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interim, on April 13, 1989, Bristol-Myers received FDA approval to distribute the drug.

Erbamont sought to establish that the mere arrival of the drug in Puerto Rico was not "importation" under the Act and thus that the drug was not imported before the effective date of the Act. Erbamont argued that a product is not imported until it has lawfully cleared customs and entered into United States commerce. Further, Erbamont asserted that the presence of the drug in the United States was conditional on FDA approval, and it asserted that importation of the drug was not complete until approval was received; otherwise Bristol-Myers had the contractual right to return the goods. The district court rejected these arguments:

"The terms "importation" and "import" in § 271(g) (and the term "imported" in § 9006 of the Act) are to have their plain ordinary meaning of bringing goods into the United States from another country. This term does not depend on or require an analysis of the intent of the person in bringing the goods into the United States. Furthermore, it is not necessary that the goods in issue have passed through U.S. Customs to be imported under § 271(g) and § 9006 of the Act. Therefore, the term "import" in § 271(g) has no special meaning, but simply denotes the bringing of goods from a foreign country into the United States.

Though physical presence in the U.S. and its territories appears to be sufficient, what about the case where goods are delivered into, or are in transit through, the U.S. foreign trade zones? In the context of trademark law, the court in Ocean Garden Inc. v. Marktrade Co. addressed the issue of "whether Congress has the power to regulate commerce within United States foreign trade zones, or whether it has precluded the reach of the Lanham Act into such zones by withdrawing from them Congress' relevant regulatory powers." The United States Court of Appeals for the

34. Id. at 1044.
35. Id.
36. 953 F.2d 500 (9th Cir. 1991).
37. Id. at 504.
Ninth Circuit held that Congress did not withdraw its power, but rather retained its authority. It referred to 19 U.S.C. § 81c, which states: "Foreign and domestic merchandise of every description, except such as is prohibited by law, may, without being subject to the custom laws of the United States . . . be brought into [foreign trade zones]." The court went on to analyze the Code of Federal Regulations, which provide that "[d]istrict directors shall not admit prohibited merchandise."

Prohibited merchandise is defined as "merchandise the importation of which is prohibited by law on grounds of public policy or morals, or any merchandise which is excluded from a zone by order of the Board." The court also referenced 19 C.F.R. § 133.21(a), which reads "[a]rticles of foreign or domestic manufacture bearing a mark or name copying or simulating a recorded trademark or trade name shall be denied entry and are subject to forfeiture as prohibited importations."

Therefore, the court concluded that: "It is reasonable to infer that merchandise that infringes trademarks under section 133.21(a) would be another example of prohibited merchandise under section 146.31." The court also stated: "Given this fact, entry of infringing goods into a foreign trade zone is a sufficient act in commerce to trigger subject matter jurisdiction in federal courts under the Lanham Act, which, by definition, can only be brought to vindicate marks that enjoy protection in the United States by virtue of proper registration."

One can conclude from the holding in *Ocean Garden* that if the existence of goods in a foreign trade zone can serve as the basis for subject matter jurisdiction under the Lanham Act, then by analogy, the same can serve as the basis for jurisdiction under 35

38. *Id.* at 505.
41. *Id.* § 146.1(b)(13). The Board consists of the Secretary of Commerce, the Secretary of the Treasury, and the Secretary of the Army.
42. Trademarks, Trade Names, and Copyrights, 19 C.F.R. § 133.21(a) (1992).
43. 953 F.2d at 505.
44. *Id.*
C. Liability of Noncommercial Users and Retail Sales

The statute provides that no remedy may be granted for non-commercial use or retail sale.\(^{45}\) However, this exemption is conditioned upon the existence of an adequate remedy elsewhere. What is retail sale? Is it limited to sales to individuals? Does it include the retail sales of products to "commercial" customers? One definition of "retail" is "the sale of goods to ultimate consumers, usually in small quantities."\(^{46}\) Another definition is, the sale of commodities or goods in small quantities.\(^{47}\) "Retailing" has also been defined as "the activities involved in the selling of goods to ultimate consumers for personal or household consumption."\(^{48}\)

The legislative history is clear that sale of drugs to individual consumers is considered sale to a "noncommercial user"\(^{49}\) and therefore retailing. Thus, a drug store is protected, provided it does not also import. One point for clarification is the definition of retail sale and whether it is dependent on noncommercial use. Is retail sale limited to sales to noncommercial consumers? Is there any reason that sales to a corporate end user should not also be considered retail? Should a large drug store chain be entitled to avoid liability for sales of drugs to customers while a seller of industrial saw blades would be liable even though the blades were only used by timber mills? The two examples below would give the following results:

1. The drug
   a. Drug store retailer: No liability if not the im-

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45. 35 U.S.C. § 271(g).
47. THE RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE UNABRIDGED 1642 (2d ed. 1987).
49. S. REP. No. 83, supra note 5, at 48. "Finally, there is no intent whatsoever for the innocent consumer to even be subject to suit." Id. at 52.
porter or manufacturer or controlled by either.

b. Individual consumer: No liability because of noncommercial use.

2. The saw blades
   a. Industrial saw blade supplier: No liability if not the importer or manufacturer or controlled by either.
   b. Mill user: Liability as a commercial user.

3. Either drug or saw blade

Liability would exist for the manufacturers and importers in each case. The patentee could proceed against the retailer only if he has no other adequate remedy.

Who has the burden to establish the lack of adequate remedy? Is the exhaustion of remedies an element the patentee must prove, or is it the burden of the retail seller or noncommercial user? It seems that it should be an element the patentee must bear once the retailer has established retail sales. The legislative history demonstrates this provision was in response to a concern to balance the rights of the patentee against the "innocent" infringer. Also, it serves to force the patentee to go to a defendant closer to the source of the infringing process. Is the provision a restriction on recovery of damages? It appears that the provision is a restriction designed to focus on the real parties in interest.\(^5\)

It is interesting to note that the statute does not provide for recovery based on retail sales activities unless there is no other adequate remedy. The plain language of the statute appears to indicate that the exemption applies to the individual acts of sale, rather than to individual defendants. Therefore, a combined retailer/distributor is protected, insofar as the sales are retail.

Clearly, Congress did not intend for the patentee to be able to obtain profits generated down the distribution line by retail sellers. After all, the patent monopoly must extinguish someplace. As the courts have held, once a patentee collects damages from a manu-

manufacturer, it cannot also collect damages from customers, and while some caselaw has recognized that a claim would exist against the customer who was an original defendant, any recovery against such customer should be minimal. Congress must have known that any patentee who produced a product and retailed it would be able to claim lost profits, which included retail mark-up. Thus, the mere fact that the patentee cannot recover damages for retail sales does not constitute "no adequate remedy," thereby allowing him to proceed against the retailer.

There are only two situations in which the "no adequate remedy" rule seems to apply. First, where the importer is insolvent or unable to respond to the damages. In that instance, perhaps the retailer would be or could be liable. The other instance is injunctive relief. Consider the saw blade example above. Where a retailer sells to an individual end user who is a commercial user, an injunction prohibiting the individual user who is a defendant may not be adequate. The sale of the blades to others would result in infringement as well. Therefore, injunctive relief against the retailer to prohibit sales to commercial users would be appropriate to prevent infringement by others not party to the action, but a damage award would be inappropriate.

If the Act was intended to place apparatus patents and process patents on an equal footing, then the provision exempting retail sales is contrary to that intent. After all, the retailer seller of a patented apparatus would be an infringer. A significant difference at the retail level between apparatus and process patents is that if one sells a patented apparatus, by access to the product he theoretically has all the information needed to determine infringement. In

51. Wagner Sign Serv. v. Midwest News Reel Theatres, 119 F.2d 929, 930 (7th Cir. 1941) ("[I]t is the generally accepted doctrine that where a patentee has been fully compensated by an infringing manufacturer for the manufacture and sale of the infringing device, the patentee has no recourse against a customer of such infringing manufacturer who is solely a user of such device.").

52. Stickle v. Heublein, Inc., 716 F.2d 1550, 1562 (Fed. Cir. 1983) ("Once full recovery is obtained from one infringer with respect to a particular infringing device, at most nominal additional damages may be awarded against another with respect to the same device.").
contrast, the retailer of a product made by a patented process typically is several levels removed from the manufacturer and has no information as to the process employed to make the product.

III. PRESUMPTION THAT PRODUCT IS MADE FROM PATENTED PROCESS

The Act provides for presumption of infringement in 35 U.S.C. § 295, which states:

§ 295. Presumption: Product made by patented process

In actions alleging infringement of a process patent based on the importation, sale, or use of a product which is made from a process patented in the United States, if the court finds—

(1) that a substantial likelihood exists that the product was made by the patented process, and

(2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine,

the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.53

A first item of note is that while the presumption is not explicitly referencing practice of the process by a domestic manufacturer, the reference to sale would include U.S. manufacturers. Obviously, at some point, the U.S. manufacturer will sell the product. However, the legislative history tends to support an argument that this provision does not apply to domestic manufacturers, which states:

The Committee notes that the rebuttable presumption would be inapplicable if the defendant has used the process

53. 35 U.S.C. § 295 (1988). "This presumption addresses the great difficulties a patentee may have in proving that the patented process was used in the manufacture of the product in question where the manufacturer is not subject to the service of process in the United States." S. REP. NO. 83, supra note 5, at 57.
in the United States, or has derived the products directly or indirectly from a manufacturer who used the process in the United States. In these circumstances, the discovery provisions of the Federal Rules of Civil Procedure and the equitable powers of Federal courts should be sufficient to allow the plaintiff to ascertain what process was employed.\(^5^4\)

Thus, a nonmanufacturing user or seller from a domestic manufacturer may have less exposure than one who purchases from a foreign manufacturer. However, the statutory language is such that courts may not recognize any distinction based on location of manufacture. Thus, a potentially significant change is that the domestic manufacturer may suffer a presumption of infringement for an item made by a patented process but never be subject to such a presumption for a patented product.\(^5^5\)

The presumption requires two elements of proof. These elements were incorporated into § 295 "[t]o minimize the risk of aggressive litigation intended to discourage firms from carrying competing products."\(^5^6\) Congress was well aware of the difficulties this provision could create. The presumption addresses the great difficulty a patentee may have in proving that a patented process practiced overseas infringes. Congress recognized that while the defendant might not necessarily have in its possession the means necessary to rebut the presumption, it was in a far better position than the patentee to obtain them. The purchasers had the right of indemnification.\(^5^7\) The two elements which seek to offer some protection to the defendant are discussed below.

A. "Substantial Likelihood"

The Act provides little guidance as to what is meant by "substantial likelihood" that the product was made by the patented process. The first question is how to establish a substantial likelihood. Does "substantial likelihood" require the same standard of proof

\(^{54}\) S. Rep. No. 83, supra note 5, at 58.

\(^{55}\) Thus, in doing clearance studies one must consider the processes as well.

\(^{56}\) S. Rep. No. 83, supra note 5, at 57.

\(^{57}\) Id.
one would need to demonstrate to achieve a preliminary injunction in an apparatus case, i.e. substantial likelihood of infringement? Can the substantial likelihood test be met by a reasonable belief in conjunction with the absence of denial from the infringer? The legislative history states:

Exactly how much evidence will be needed in particular situations to satisfy the "substantial likelihood" condition will depend on the circumstances. However, the patentee's burden would be less than that of proving successfully at trial by a fair preponderance of the evidence that a product in question was in fact made by the patented process but would be more than a slight possibility that the product was so made. 8

Although Congress intended the patentee's burden of proof to be something less than a "fair preponderance of the evidence," exactly how much less is uncertain. One suggestion by Congress was that evidence of substantial likelihood could include chemical analysis of the product which had indications or "marks" in the product itself from the process. Another suggestion was the use of expert testimony regarding known methods of production and the costs that would justify sale of the product at the prices being charged. 9

B. A "Reasonable But Unsuccessful Effort"

The second prong that the patentee must satisfy to achieve the presumption is that a reasonable but unsuccessful effort was made to determine the process actually used. 61 If the patentee has a reasonable belief that the process used by the accused manufacturer infringes, the patentee may send a notice to the accused infringer, but such notice must state some reasonable basis for the belief of

58. Id.
59. Id.
60. The legislative history states "[t]he reasonableness of the effort would include the use of discovery procedures under the Federal Rules of Civil Procedure or other good-faith methods, such as requesting the information from the manufacturer, if not subject to U.S. jurisdiction." S. Rep. No. 83, supra note 5, at 58.
61. 35 U.S.C. § 295(2)
infringement. Thus, this provision would seem to require that the notice must (1) contain a reasonable basis for the belief that the patented process is being used, and (2) must be sent to an appropriate party. Therefore, the presumption will likely be applied where efforts were made to deal with the manufacturer, or if unknown, to deal with the party in the chain of distribution closest to the manufacturer. The legislative history would seem to support such a conclusion:

While the defendant may not necessarily have in its possession the means necessary to rebut the presumption, it is likely to be in a far better position than the patentee to obtain them. Importers, for example, because of their relationships with foreign manufacturers, may be able to exert pressure on such manufacturers to produce the necessary information. Users and sellers who purchase possibly infringing articles from importers may be able to exert similar pressure on those importers, who would in turn influence foreign manufacturers.

These provisions probably could not be satisfied merely by stating a suspicion that the product infringes, but rather there must be some real basis. Otherwise, a patentee could send numerous notices without any basis for infringement whatsoever. No party should be put to the expense of responding to a bald allegation at the risk of presumption of infringement. The recipient, however, is faced with difficult choices on how to respond to a notice where he has difficulty in determining whether there is any reasonable basis or belief for the charge.

Furthermore, in the instance where there is some reasonable basis for the patentee's suspicion of infringement, how is the accused infringer to avoid the presumption? For example, suppose the accused infringer has a trade secret process which does not infringe, but which leaves a telltale element that is a signature of the infringing process. While the Act provides that a patentee need not disclose his trade secrets when sending a notice, no such recip-

local protection is provided for the purported infringer. Thus, the alleged infringer is in the unenviable position of deciding whether to reveal a trade secret or to ignore the notice.

It would seem that such an accused infringer has several options, among which would include a response to the patentee that its process is a trade secret and not infringing, along with some type of offer to permit review under a confidentiality agreement. This, of course, highlights the inherent problems. Who would be allowed to review the information? Obviously, the accused infringer would not want its competitor to have the confidential information. Further, to what extent would the alleged infringer be entitled to enforce such an agreement, and more importantly, how would it ever be aware of a violation of the agreement?

Suppose the information is disclosed in confidence with the restriction that it is not to be used. However, suppose the patentee then broke the confidence and used the process of the previously alleged infringer. Assume that the patented process and the trade secret process both leave a telltale chemical at about the same level. Thus, the accused infringer with the trade secret process could not rely on just the sale of the product in order to prove a theft of the secret or even bring a suit in the first place. Perhaps the offer should include a willingness to disclose a trade secret with an obligation that the patentee will not use it, and further with a right in the accused infringer to make inspections of the patentee's plant and records to assure no breach in the future. If the patentee objects to such a proposal, has his effort been reasonable?

On the other hand, could the accused infringer respond merely with a request that the patentee demonstrate to him that there is no other process known to the patentee which results in the trace telltale element? Suppose a patentee fails to respond with such proof, but later after filing suit, uses such proof to support a showing of substantial likelihood and utilizes the alleged infringer's failure to explain his process as further evidence. It would appear that the alleged infringing manufacturer would have a better bargaining position to achieve a confidentiality agreement which would allow him the right to monitor the patentee prior to filing suit than simply asking the patentee for further evidence, although the inquiry may
be the same.

Consider these two scenarios. First, in response to the patentee’s notice the accused infringer contends that his process is a trade secret which is not infringing and requests the patentee to enter into a confidentiality agreement whereby the accused infringer discloses his process and the patentee grants the accused infringer the right to monitor the patentee’s process in the future. However, the patentee subsequently refuses to do so and then sues. To what extent has the patentee complied with the requirements of making a reasonable attempt to determine the process utilized? Courts will have to resolve these issues, but equity would seem to favor some recognition of the need to protect the accused infringer’s information.

In the second scenario, the accused infringer responds, asking the patentee for his evidence that there is no other suitable or commercially viable process. The patentee refuses to provide the information and files suit. At trial, the patentee presents such information. The accused infringer is not the manufacturer and does not possess that knowledge. Is it fair to allow the patentee to withhold such information and force the accused to rely on cooperation of a supplier who may be far removed?

As will be discussed below in the notice section, in considering the applicability of the presumption it seems that the following factors should be considered:

1. The extent to which the patentee’s belief is based on scientific evidence;
2. The extent to which the patentee’s case is based on circumstantial evidence, i.e. cost or purchase of raw materials;
3. The extent to which the patentee had attempted to direct notice to the manufacturer or the person known to the patentee closest to the manufacturer;
4. Whether the party accused of infringing the patented process practices the process in the United States;
5. The response of the infringer—if a manufacturer, to what extent he was willing to provide process informa-
tion; if a nonmanufacturer, to what extent he attempted to achieve information from the manufacturer; and
6. The extent to which the patentee was forthright with the nonmanufacturing defendant in providing information.

IV. NOTIFICATION OF INFRINGEMENT: WHERE TO BEGIN?

A. Notice Is Actual Knowledge—Written Notification

The Act contains some stringent and complex notice provisions that were intended to prevent abusive and coercive allegations of infringement against recipients of a product made by a patented process.\textsuperscript{63} Obviously, the threat of an infringement suit, coupled with the threat of presumed infringement, is a substantial coercive tool the patentee can direct against a nonmanufacturing recipient. Thus, notice of infringement must be sent to certain classes of defendants to balance the interests of the parties. The notice provisions are set forth in 35 U.S.C. § 287.

1. Who must receive notice?

Under the Act, notice must be sent to the nonmanufacturing recipient or user of the product, but it is not required to be sent to the manufacturing defendant.\textsuperscript{64} Notice to the nonmanufacturing recipient must be sufficient to give a reasonable basis for a claim of infringement.\textsuperscript{65}

a. Notice to the nonmanufacturing recipient

The Act provides that in the absence of notice, there can be no remedy against a nonmanufacturer, and until notice is given, no cause of action accrues against the nonmanufacturer. These notice provisions reflect the sensitivity of Congress to the plight of innocent purchasers of goods under the Act. In relevant part, the new

\textsuperscript{63} 35 U.S.C. § 287.

\textsuperscript{64} Id. § 287(b).

\textsuperscript{65} Although no notice is required to the manufacturer under the Act, this is not a departure from existing caselaw.
statute provides:

Section 287. Limitations on damages and other remedies; marking and notice

* * *

(b)(2) No remedies for infringement under section 271(g) of this title shall be available with respect to any product in the possession of, or in transit to, the person subject to liability under such section before that person had notice of infringement with respect to that product. The person subject to liability shall bear the burden of proving any such possession or transit.

* * *

(5)(A) For purposes of this subsection, notice of infringement means actual knowledge, or receipt by a person of a written notification, or a combination thereof, of information sufficient to persuade a reasonable person that it is likely that a product was made by a process patented in the United States.

(B) A written notification from the patent holder charging a person with infringement shall specify the patented process alleged to have been used and the reasons for a good faith belief that such process was used. The patent holder shall include in the notification such information as is reasonably necessary to explain fairly the patent holder's belief, except that the patent holder is not required to disclose any trade secret information.

(C) A person who receives a written notification described in subparagraph (B) . . . shall be deemed to have notice of infringement with respect to any patent referred to in such written notification or response unless that person, absent mitigating circumstances—

(i) promptly transmits the written notification or response to the manufacturer or, if the manufacturer is not known, to the supplier, of the product purchased or to be purchased by that person; and
(ii) receives a written statement from the manufacturer or supplier which on its face sets forth a well grounded factual basis for a belief that the identified patents are not infringed.\textsuperscript{66}

A party is required to receive notice of infringement unless he falls within one of the categories of § 287(b)(1). This section provides:

(b)(1) An infringer under section 271(g) shall be subject to all the provisions of this title relating to damages and injunctions except to the extent those remedies are modified by this subsection or section 9006 of the Process Patent Amendments Act of 1988. The modifications of remedies provided in this subsection shall not be available to any person who—

(A) practiced the patented process;

(B) owns or controls, or is owned or controlled by, the person who practiced the patented process; or

(C) had knowledge before the infringement that a patented process was used to make the product the importation, use, or sale of which constitutes the infringement.\textsuperscript{67}

The "notice of infringement" can be satisfied under 35 U.S.C. § 287(b)(5)(A) by either (1) actual knowledge of information sufficient to persuade a reasonable person that it is likely that a product is made by a patented process in the United States, or (ii) receipt of a "written notification" of such information, or (iii) the combination of actual knowledge and written notification of such information. Since actions against nonmanufacturers require notice, one must recognize the problems with establishing such notice. How does a plaintiff patentee satisfy Rule 11 and yet employ some of these provisions?\textsuperscript{68} That is, how does the patentee prove actual knowledge? There will probably be a few cases where the patentee

\textsuperscript{66} 35 U.S.C. § 287.
\textsuperscript{67} 35 U.S.C. § 287(b)(1).
\textsuperscript{68} See Fed. R. Civ. P. 11 (providing that no attorney or party shall sign legal papers unless the facts contained therein are accurate to the best of the signer's knowledge, information, and belief).
learns that the defendant has actual knowledge. However, the actual knowledge provision may find application in pushing back the date of notice to increase damage exposure. Can actual knowledge be used in a circumstance where a suit is based on defective written notice but where discovery has progressed far enough to establish actual notice prior to the defective notice of infringement?

Where there is a lack of "actual knowledge," the defendant must receive the statutorily required "notice of infringement" in the form of "written notification" as that term is used in 35 U.S.C. § 287(b)(5)(B). Such written notification must specify the patented process alleged to have been infringed and the reasons for a good faith belief that such process was used, and must include "such information as is reasonably necessary to explain fairly the patent holder's belief."70

How much information is needed in the notice of infringement? The statute says the patentee does not have to disclose trade secrets. Does this provision offer an election such that the patentee can elect not to disclose trade secret information and forego notice, or does it mean that the patentee, who has such trade secret information, has no obligation to convey all the information it has which would establish reasonable belief of infringement? Both would seem appropriate. The notice is destroyed where the purchaser receives back from the manufacturer a statement as to why there is no infringement. However, note that there is no requirement that the response be sent on to the patentee. One rationale for extinguishing notice is that the nonmanufacturing recipient is then merely put in the middle of a factual contest between the two parties in interest. Professor Chisum has opined:

Section 287(b) contemplates a "stalemate" when there is a difference of opinion as to whether or not the product in question is made by a process covered by a United States patent. . . . For example, in the "notice of infringement"

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69. 35 U.S.C. § 287(b)(5)(A). The Act assumes the manufacturer has actual knowledge and imputes such knowledge to a purchaser who is owned or controlled by the supplier.

protocol, assume (1) a process patent owner sends to a major importer/retailer an adequate written notification of infringement as to a product; (2) the importer/retailer forwards the notification to the manufacturer of the product; and (3) the manufacturer provides to the importer/retailer a written statement that sets forth "on its face" a "well grounded factual basis for a belief that the identified patents are not infringed." The importer/retailer is not under "notice of infringement," at least not by virtue of the patentee's notice of infringement.71

Suppose further that the response from the manufacturer is that they have filed a declaratory judgment action against the patentee. Would this extinguish a reasonable notice of infringement?

B. Ramifications of Lack of Notice

Failure to provide adequate notice results in a loss of right against the recipient. Thus, in order to proceed against a party who neither practices the invention nor is controlled by the party practicing the invention, adequate notice is required. This raises an interesting jurisdictional point. Suppose that notice is sent which is considered by the recipient to be inadequate. The patentee believes notice is sufficient and later files suit. To what extent can the suit be supported by later events? Suppose the court agrees that the notice was not adequate. Can the patentee, by deposing the producer or other discovery, later claim notice has been made adequate? If so, does the court have jurisdiction or must the case be refiled? There will undoubtedly be some very interesting jurisdictional battles similar to those in declaratory judgment actions.

V. ACTIONS TO BE TAKEN IN RESPONSE TO A NOTICE

Taking appropriate action upon receipt of a notice is important in receiving the benefits of the Act if one is a nonmanufacturer. Interesting issues arise regarding notice. For example, the language

71. 4 DONALD S. CHISUM, PATENTS § 16.02[6], at 16-56 (1992).
of the Act encourages a recipient of notice to contact its supplier or manufacturer; however, the Act provides no guidance concerning the use or disposition of any response received from the manufacturer. The actions to take upon receipt of notice are different, depending on whether one is the manufacturer, distributor or retailer. It is important to act upon the patentee’s notice in order to have the opportunity to defeat the presumption of infringement. Again, this area raises a number of significant issues to be addressed below.

A. Effect on the Recipient of Notice of Infringement

Notice to the nonmanufacturer who is not owned or controlled by the manufacturer or is without actual knowledge is a requirement for recovery.72 Additionally, an effective notice of infringement would seem to result in the presumption that the product is made by the patented process under 35 U.S.C. § 295. Recall, § 295 provides for such a presumption if the court finds that: (1) there is a substantial likelihood that the product is made by the patented process, and (2) the claimant has made a reasonable but unsuccessful effort to determine the process actually used in production of the product. If these two elements are established, then the burden of proof shifts to the party asserting that the product was not made in an infringing manner.

The first question is whether the notice of infringement in itself is sufficient to establish that a substantial likelihood exists that the product is made by the patented process. Note that this language is different from that in the notice, which requires only sufficient information to persuade a reasonable person that it is likely the process is infringing. These two provisions are not co-extensive, and it appears that the duty placed upon the court is to determine whether the reasonable basis for believing there is infringement rises to the level of substantial likelihood. The second prong of the test, whether the claimant has made a reasonable effort, is only

briefly discussed in the legislative history and suggests that the patentee should attempt to contact the manufacturer directly. Since the Act's central purpose is to obtain information from the actual manufacturer, such a reasonable effort should include at least a contact with the offending manufacturer.

B. Ramifications of Lack of Response

Failing to respond to an adequate notice results logically in a probability that the time for damages will begin either (1) upon receipt of the adequate notice, (2) after a reasonable time to evaluate the notice, or (3) after a reasonable period has passed without response from the manufacturer to an inquiry from the nonmanufacturer. Also, a response can contain information which removes or negates the notice. Thus, failing to respond may increase the time period over which damages are recoverable. Also, the Act specifically directs the court to consider the good faith of each party, and lack of a response may result in a balance of the equities tipping in favor of the plaintiff. The Act is vague as to when infringement begins as a result of receipt of notice, and the patent bar will have to await judicial clarification.

VI. THE "GRANDFATHER" CLAUSE

The effective date of the Act is six months after its date of enactment and applies only with respect to products made or imported after the effective date. The Act was passed on August 23, 1988, and became effective February 23, 1989. The Act also contains a Grandfather Clause in § 9006(b) of P.L. 100-418, which provides as follows:

(b) Exceptions—The amendments made by this sub-

75. 35 U.S.C. § 287(b)(5)(C).
76. Id. § 287(b)(3)(A).
title shall not abridge or affect the right of any person or any successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on January 1, 1988, or for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investments made or business commenced in the United States before such date. This subsection shall not apply to any person or any successor in business of such person using, selling, or importing a product produced by a patented process that is the subject of a process patent enforcement action commenced before January 1, 1987, before the International Trade Commission, that is pending or in which an order has been entered. 78

It should be noted that the language of the Grandfather Clause is substantially identical to that of the second sentence of the second paragraph of 35 U.S.C. § 252 relating to equitable intervening rights arising from reissue or reexamination. The second paragraph of 35 U.S.C. § 252 provides:

No reissued patent shall abridge or affect the right of any person or his successors in business who made, purchased or used prior to the grant of a reissue anything patented by the reissue patent, to continue the use of, or to sell to others to be used or sold, the specific thing so made, purchased or used, unless the making, using or selling of such thing infringes a valid claim of the reissued patent which was in the original patent. The court before which such matter is in question may provide for the continued manufacture, use or sale of the thing made, purchased or used as specified, or for the manufacture, use or sale of which substantial preparation was made before the grant of the reissue, and it may also provide for the continued practice of any process patented by the reissue, practiced, or for the practice of which substantial preparation was made,

78. Id. § 9006, 102 Stat. at 1563.
prior to the grant of the reissue, to the extent and under such terms as the court deems equitable for the protection of investments made or business commenced before the grant of the reissue.\footnote{35 \textit{U.S.C.} § 252 (1988).}

The first consideration is to whom the Grandfather Clause offers protection. Does it protect the foreign manufacturer, the importer, or the retailer? The Grandfather Clause does not protect the foreign manufacturer unless the manufacturer is also the importer and seller in the United States—by the explicit terms of the Grandfather Clause, it is limited to actions in the United States. At least one court has interpreted that the Grandfather Clause does not offer protection to foreign manufacturers.\footnote{See \textit{Allegheny Ludlum Corp. v. Nippon Steel Corp.}, 765 F. Supp. 224, 226 (E.D. Pa. 1991); \textit{see also Shamrock Technologies, Inc. v. Precision Micron Powders, Inc.}, 20 U.S.P.Q.2d 1797 (E.D.N.Y. 1991).} In \textit{Allegheny Ludlum Corp. v. Nippon Steel Corp.}, the court stated:

\begin{quote}
[I]n the Senate Report regarding the Act, the Senate Committee stated, “The primary target of the U.S. process patentholder will naturally be the manufacturer, who is practicing the process and importing the resulting goods in the United States. . . . In any case, the Committee does not expect or intend the bill to be used to sue purchasers of the product, when the infringing manufacturer can be sued instead.” S. Rep. No. 100-83, at 39, 47. Clearly, then, the first portion of the Grandfather Clause was only to apply to persons in the United States who are not allegedly infringing manufacturers.\footnote{765 F. Supp. at 226.}
\end{quote}

Thus, the Grandfather Clause clearly does not protect the foreign manufacturer.

The next question is whether it protects a United States manufacturer. The answer to this question should also be “no.” Basically, the Grandfather Clause has one major restriction, to the extent its protection would be “equitable.” How can a U.S. manufacturer who has been infringing the process directly under § 271(a)
prior to the enactment of the Act claim an entitlement to any equity? One such situation where there may be a possible claim by the domestic manufacturer is where the Act changes the forum in which he is subject to suit. Prior to the Act, some courts had held that infringement of the process patent occurred where the manufacturing takes place. Further discussion on this point is beyond the scope of this Article, and we leave it to the reader to consider whether this Grandfather Clause can equitably be invoked to prevent jurisdiction over the manufacturer in a forum other than where he practices the process (should such a manufacturer be able to escape the jurisdiction of other forums where he resides and in which he has sold the product produced by the patented process).

The Grandfather Clause clearly applies to distributors. However, is any protection really afforded? How can a distributor have a substantial investment or have made substantial preparation? His cost would be the cost of inventory, distribution control, maybe repackaging, sales force, etc. If the courts apply the same standards that are applied in 35 U.S.C. § 252 to intervening rights resulting from broadened claims in reissue patents, then the Grandfather Clause does not offer much comfort. Among the often-recited remedies available under § 252 are that the court may permit unconditional continuation of the business, permit business to continue at the same level, or permit continuation of business until investment is recouped. In many instances, a distributor will quickly recoup the cost associated with adding a product. Then does equity say he is out of business?

Does it make a difference whether this is his sole product or a major source of his revenue? What about an instance where at the time of passage of the Act the product was a relatively small percentage of the manufacturer's revenue but has grown to a substantial percentage at the time suit was filed? In the case of the reissue patent, one takes a snapshot at the time of the reissue. Here, however, the situation is slightly different—the snapshot is taken at the

82. See United States v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1127 (D.C. Cir. 1981); Koratron Co. v. Lion Uniform, Inc., 449 F.2d 337, 338 (9th Cir. 1971).
date specified in the Grandfather Clause which is different from the effective date of the Act. No real explanation for this divergence is presented, but the divergence could support arguments that the Grandfather Clause is to be more liberally construed and precedent from reissue cases is not to be strictly followed. In any event, the Grandfather Clause offers little solace when one considers the poor showing intervening rights have been accorded under § 252.

The Grandfather Clause provisions would also apply to a retailer; however, a retailer already enjoys protection from liability. This is an additional protection for those retailers who are also distributors.

VII. WILLFUL INFRINGEMENT

One question under the Act is whether the nonmanufacturer can be charged with willful infringement. In the very beginning of the Act, it is noted that good faith is relevant in determining even basic infringement by a nonmanufacturing seller or user. The person who buys a patented product and resells it is liable for infringement without regard to his knowledge of the infringement. By contrast, the same person selling a product made by a patented process must have notice that the product is so made. Thus, even before infringement can be found, the party must be shown to have some information which would at least demonstrate or support a reasonable belief that the product was made by the patented product.

Does this mean that the party receiving notice is ipso facto a willful infringer? Obviously, in many situations the party receiving the notice will not have the means by which to make a determination as to whether the process used infringes. Many times they will have no more than the allegations of the patentee in contrast to denials by the manufacturer. Indeed, the manufacturer could be less than forthcoming with the truth with respect to the process. Thus, the receiver of the notice faces a number of difficulties not faced by most alleged infringers: He will likely not have access to the details of the process or to persons knowledgeable in the art,

and he will lack resources to devote to such questions. At this stage, one must assume that there is the potential for some recovery for willful infringement. The attorney’s dilemma is how to advise a client when the supplier refuses to provide information and the client is thus denied the necessary information to make a reasonable determination as to infringement (and many times as to validity). Courts will have to determine if the guidelines for willful infringement are different for purchasers than for practitioners of the process.

CONCLUSION

The Process Patent Amendments Act has not been brought to bear in many cases to date. Congress had sufficient concerns about the Act and as a result conducted a review of the Act five years after its enactment. However, it is quite likely that the implications and problems of the Act will not come to light until much later. The Act may provide an impetus for the development of two bodies of law: one for process patents and the other for non-process patents. Further, the principles could be different for manufacturers and nonmanufacturers. Such a result would be contrary to the intended purpose of the Act. Significant uncertainties exist in the interpretation and application of the Act offering attorneys the challenge of formulating arguments which further the aims of Congress.