

STATEMENT OF

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BEFORE THE

SUBCOMMITTEE ON PATENTS, COPYRIGHTS AND TRADEMARKS
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

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Mr. Chairman and Members of the Subcommittee:

I welcome this opportunity to testify on S. 1543, the "Process Patent Amendment of 1985". This bill would amend Title 35, United States Code, to extend the exclusive rights of the holder of a process patent to products made by the patented process. Unlike the laws of our major trading partners, U.S. patent law does not give the holder of a process patent the right to stop the importation, use or sale within the United States of a product made abroad by a process patented in the United States.

The Administration strongly supports S. 1543, which would significantly improve the patent law affecting process patents. Under United States law, a patent is infringed if the patented invention is made, used, or sold in the United States. Making, using, or selling the invention outside the United States does not constitute infringement, nor does the mere importation of the invention. Where the patented invention is a product, or tangible article, a foreign competitor cannot avoid liability to the patent holder by manufacturing the product overseas and importing it for the United States market since use or sale of the product in the United States would still constitute infringement, and the patent holder could obtain damages or an injunction based on this use or sale.

Where the patent claims only a process or method, however, only the use of the process in the United States constitutes infringement. Use of the process outside the United States will not infringe the U.S. patent, nor will use or sale of products made by the patented process. Thus, a U.S. manufacturer who uses the patented process would infringe, while a foreign manufacturer would not. When the chief commercial value of the process comes from the use or sale of the resulting product, sale of the foreign-made products may effectively destroy the value of the U.S. process patent and perhaps the patent holder's ability to recover an initial R&D investment.

This situation allows substantial problems to arise for process patent holders making products which are themselves unpatentable. A significant effort of the emerging biotechnology industry is directed toward new ways to produce naturally occurring substances such as insulin or interferon. Since naturally occurring substances are not patentable under the laws of the United States or most countries, failure to remedy this problem now plants the seeds for trade problems in yet another industry.

This leaves the owner of a United States process patent with very limited rights with respect to products made from the process. The only remedy available to a process patentee with respect to a product made by the process is under Sections 337 and 337a of the Tariff Act of 1930, as amended (19 USC 1337 and 1337a). Under Section 337, the patent owner may petition the International Trade Commission (ITC) to determine that the importation of the products of a patented process for use, sale or exchange constitutes an unfair practice in import trade and to exclude the product from entry. Although ITC procedures can be simpler and faster than litigation in United States district court, this remedy requires the patentee to establish that the product was made by a process patented in the United States and that the importation will damage an efficiently and effectively operated domestic industry, or prevent the establishment of such an industry, or will restrain or monopolize trade in the United States. If the International Trade

Commission finds a violation, it must publish its findings in the Federal Register and transmit a copy to the President, who can disapprove the determination at any time within a sixty-day period.

When the petitioner is successful, the ITC will exclude the goods from entry. If the goods have already entered the United States, the ITC can issue a cease and desist order against a particular firm. Cease and desist orders against individual firms may not be effective where importers of offending products can easily find alternative channels. Enforcement of exclusion orders by customs officials can also be difficult because of the problem of differentiating products made by the patented process from those produced by another process. If the importation is discovered after the goods have entered commerce, the process patent holder may be left with no remedy since the ITC does not have the authority to award damages. Although ITC proceedings are an important adjunct to enforcement of patent rights, they should not be the sole remedy available to process patent holders against competition from offshore manufacturers.

The only alternative available to a process patentee is to obtain and enforce patents in as many other countries as possible. This option is unrealistically expensive and largely ineffective because of the impossibility of obtaining adequate protection in all of the countries in which a process might be used. This consideration is

particularly important for small and medium-sized businesses who are not doing business abroad and are thus unlikely to seek patent protection for foreign markets. Even if a company is able to afford the legal expenses associated with securing patents around the world, however, patent protection is not available in all the countries in the world. In fact, some countries do not even have patent laws. Even for major markets, this is an expensive alternative. In addition to the substantial costs of securing patents, the patent holder must be prepared to enforce these rights vigorously in many foreign countries. This is realistic only for the largest firms.

Importation, use and sale in the United States of products produced by processes patented in this country severely diminishes the value of such patents. This practice must be effectively countered by changes in the patent laws to protect the legitimate interests of U.S. inventors. Expanding the scope of our laws in this fashion would bring them into conformity with the European Patent Convention and the national laws of many industrialized countries.

Mr. Chairman, I have appended to my testimony a chart which summarizes the protection offered to process patent holders in the Group B or developed market economy countries, along with some typical examples of foreign laws in this area. As you will see from the chart, most countries' patent laws are structured so that the direct product of a patented process is also included within the

scope of the patent. Nearly one-half of those countries make importation an infringement. S. 1543 is an important step toward providing U.S. industry the protection available to the industry of our trading partners.

Enforcing a patent against an infringer is a substantial undertaking. The patent holder must give notice to the infringer, either directly or by marking the patented product, and if the infringement continues, the patentee may sue for damages or an injunction in United States District Court.

In the case of a patented process which is carried out in the United States, discovery procedures are available to both foreign and domestic patentees to ascertain whether a product was made by the patented process. However, with respect to products made abroad by processes patented in the United States, the laws of most foreign countries do not provide these discovery procedures. This makes it extremely difficult for a U.S. patent holder to determine the process used to make the product outside the United States. The laws of approximately one-third of the Group B countries provide a presumption in favor of the process patentee in order to overcome that deficiency.

We believe that it would be highly desirable to establish a rebuttable presumption that a product which could have been made by patented process was in fact made by the patented process. This provision would greatly relieve the burden on domestic industry where a foreign manufacturer is not subject to service of process in

the United States and where probable infringers do not willingly cooperate with the patentee to assure that infringement has not occurred. The burden of overcoming this presumption should be on the defendant in an infringement suit, since an alleged infringer is in a much better position to establish that a questioned product was made by another process.

We recognize, however, that presumptions should not be casually established. To ensure that an unfair burden is not imposed on importers and distributors of noninfringing products, any provision dealing with this subject should, at a minimum, require the patentee to demonstrate, on the basis of available evidence, that a substantial likelihood exists that the product was produced by the patented process and, further, that a reasonable but unsuccessful effort was made to determine that the process was actually used in the production of the product. To establish a substantial likelihood, for example, a patentee might show that the patented process was the only known method, or the only commercially practical method, for producing the product, or that physical evidence, such as the exact chemical composition of the product, indicates the use of the patented process. A reasonable effort requirement could easily be satisfied in the United States through our discovery procedures. For a foreign manufacturer the patentee would have to take some reasonable step, such as writing to the manufacturer, to determine how the product was made and to have been

unsuccessful in this regard. The reasonableness of the effort would depend on the facts of the case but should generally avoid the need for such measures as letters rogatory or suits in a foreign country.

Absence of a provision of this nature seriously weakens the ability of owners of U.S. process patents to prove infringement.

Industrialized countries which are our major trading partners have recognized this difficulty, and many have included presumption provisions in their patent laws. Developing countries, on the other hand, are constantly urged by us to improve their laws to provide strong protection for industrial property. Failure to provide for a presumption in U.S. law, when it is amended to provide increased protection for process patents, could encourage developing countries to follow suit, thereby making it difficult for U.S. industry adequately to enforce process patents obtained in those countries.

We also suggest that the language used in S. 1543 should be amended to clarify that it applies only to products "directly" produced by the patented process. This would lay to rest arguments that, for example, a product made by several intermediate processes should be covered by this legislation, when only the first and possibly unimportant process, leading to an intermediate product, was patented. In our opinion, only those products should be covered which are directly made by the patented process. This is consistent with the laws of other countries on this subject, as well as with

the European Patent Convention. The legislative history of the bill should, however, reflect that the provisions of this legislation could not be circumvented by adding to the process immaterial steps which are, for example, chemically trivial to the process as a whole. Identical products made by other processes would not be affected by this Act, but a process would be judged by the usual principles of patent law in determining infringement.

Mr. Chairman, S. 1543 would strengthen the rights of U.S. process patent holders by providing the protection available under the laws of our trading partners. Our industry needs this protection. We urge the bill's enactment.

Process Patent Protection in Group B Countries

<u>Country</u>	<u>Process Patent protects its direct product</u>	<u>Importation constitutes infringement</u>	<u>Presumption in favor of process patentee</u>
Austria ¹	yes		yes ²
Belgium ¹	yes ^{3,4}	yes	
Canada	yes ^{3,4}		yes ^{2,4}
Cyprus ⁵	yes	yes	
Denmark	yes	yes	
Finland	yes	yes	
France ¹	yes	yes	
Federal Republic of Germany ¹	yes		yes ²
Great Britain ¹	yes	yes	
Greece	yes		yes ²
Holy See ⁶			
Iceland	yes	yes	
Ireland	unclear ^{3,7}		
Italy	yes		yes ²
Japan	yes	yes	yes
Liechtenstein ⁸	yes		yes
Luxembourg ^{1,9}	yes ⁴		
Monaco ⁶			
Netherlands ¹	yes		yes ²
New Zealand	yes ⁴		
Norway	yes	yes	
Portugal	yes	yes	
San Marino ¹⁰	yes		yes ²
South Africa	yes		yes
Spain	yes	yes ⁴	
Sweden ¹	yes	yes	yes ²
Switzerland ¹	yes		yes
Turkey ⁹			
United States of America			

- 1 EPC member.
- 2 Applies to new substances only.
- 3 No clear statutory provision.
- 4 Apparently applies in at least some situations.
- 5 Registration in Cyprus of a United Kingdom patent confers the same rights in Cyprus.
- 6 No patent law.
- 7 Claims are permitted, but legal issues are apparently unsettled.
- 8 Liechtenstein and Switzerland constitute a single territory for patent purposes.
- 9 No copy of the national law was available.
- 10 Industrial property rights acquired in Italy are valid in San Marino and vice versa.