



A NEW REGIME FOR PROCESS PATENTS IN THE U.S.

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The Omnibus Trade and Competitive Act of 1988 created an important new avenue for enforcing process patents in the United States. Previously, it was not an infringement of a United States process patent to use the patented process in a foreign country (i.e., Taiwan, Mexico) and import the product so produced into the United States. The new law changes this. The law establishes liability as an infringer for the importer, seller, and user of goods manufactured using a patented process. The statute is not limited to goods manufactured outside the United States; it also covers domestically manufactured products. Thus new remedies are available for downstream purchasers of products manufactured by a patented process.

There are three substantive sections of the new process patent legislation:

1. 35 USC 271(g) defines infringement and exclusions;
2. 35 USC 287(b) imposes limitations on damages and other remedies; and
3. 35 USC 295 establishes a presumption of process patent infringement.

35 USC 271(g) gives process patent owners the right to exclude others from using or selling in the United States, or importing into the United States, products made by the patented process.

There are many limitations on this right. These include:

Exhaustion of Remedies -

1. There is an exhaustion of remedies clauses regarding suits against noncommercial users and retailers. Only if no adequate remedy can be obtained for importation or other use or sale, are there any remedies available to noncommercial users and retailers.

Subsequent Change -

2. There are no remedies for products materially changed by subsequential processes.

Trivial Component -

3. There are no remedies for products that are a trivial and nonessential component of another product.
- Pre-Notice Products -
4. There is an exemption for products in the possession of or in transit to a party at the time of notice of infringement. The party claiming the exemption has the burden of proof.

Notice -

5. There are significant notice provisions. Damages are available only from the date of notice of infringement. Notice must be actual knowledge or written notice "sufficient to persuade a reasonable person that it is likely" that the product was made by the patented process. Marking the patent number on the product produced by the process is insufficient notice. The written notice must specify the patent believed to be infringed and provide sufficient information to demonstrate the reasons for a good faith belief that the patented process was used. The filing of a lawsuit for infringement most likely will constitute a notice of infringement.

At the time of notice, if a party possesses an abnormally large inventory, actual knowledge of

infringement will be presumed. 35 U.S.C. Section 287(b)(5)(D). The legislative history guidelines indicate that a reasonable inventory is an 18- month inventory for retailers and a six-month inventory for others. The infringer will likely only be liable for the excess. Care should be taken, however, of massive overstocking.

Good Faith -

7. Mitigation of damages can be obtained by a defendant if the defendant can show good faith. One way to show good faith is to obtain a statement from the manufacturer or the supplier that the patented process is not being used. This can be done in response to a notice of infringement.

Another way to show good faith is to serve a request for disclosure on the patent owner. A request can be made to the patentee to list all process patents that could be infringed. This includes patents owned or licensed. If the request is directed to a licensee instead of a patentee, the licensee is required to respond to the request or notify the licensor of the request. The purpose of the request is to assist in avoiding infringement. The request cannot be a fishing expedition.

Only parties engaged in the sale of the same type of product as the patentee owners or parties who plan to engage in the sale of such products are eligible to make the request for disclosure. The request must be made before the first importation, use, or sale of the product. The request must include a representation by the requestor that it will promptly submit patents identified by the patent owner to the requestor's manufacturer or supplier.

The person sending the request shall pay the patentee a reasonable fee to cover the actual costs of complying with the request. This is subject to three limitations: (1) the actual cost of any activity undertaken to comply with the request; (2) the cost of a commercially available automated patent search; and (3) no greater than \$500. The provision applies separately to each product. Thus, if there is a request for disclosure for two products, two reimbursements are necessary.

The new law includes a provision that there is a presumption that a product is made by a patented process if the court finds:

1. that a substantial likelihood exists that the product was made by the patented process; and
2. the plaintiff made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine.

Many laws of foreign countries limit the application of this type of presumption to processes for making "new" products. The presumption in the U.S. statute is not limited to new products. This is because many valuable processes are for new ways of obtaining old products such as in biotechnology, where there are already viable processes for manufacturing naturally occurring substances.

The effective date of the statute is February 23, 1989. There is a Grandfather Clause for importers active in importing on January 1988. Specifically, there is an exemption for continued importation, sale and use of any 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 a 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 that date."

Thus patent owners have another valuable arrow in their quiver against competitors, and particularly off-shore manufacturers.

The patentee should:

1. Use the request for disclosure to obtain competitive business information;
2. Marked products or packaging with process patent numbers and/or extensive responses should be given to the request;
3. Give immediate comprehensive notice of infringement; and
4. File infringement suits early to improve notice.

D. Process Patents in Section 337.

1. Change in Regard to Process patents - Impetus

The second feature relating to process patents is the addition to the Tariff Act of the following: "It is prohibited to import or sell, after importation, articles that are made, produced, processed or mined under, or by means of, a process covered by the claims of a valid and enforceable United States Patent." (CB: What is the purpose of this new process provision? Tariff Act could also be used for this? There is a legislative history on this sub-section.)

The overall purpose of the change is to assist emerging United States industries, particularly, biotech, to compete in a marketplace against importing products manufactured using the genetic engineering process of the U.S. patent. Overall, the Tariff Act changes encountered no opposition; hence, there are few new limitations and qualifications on liability. In fact, the amendments are a decided broadening of the right of action before the ITC.

The legislative history indicates that this provision is a desire to protect American innovation.

2. Elimination of the Injury Test for Intellectual Property Infringement.

It is unnecessary for a complainant to show that the alleged infringement of a U.S. patent, copyright, trademark or mask work results in an injury to a domestic industry. Infringement is the injury.

The elimination of this requirement will result in the decrease of costs to prosecute a section 337 action, and, hence, a likely increase in actions before the ITC.

The Japanese have already noted that now, small companies are enabled to file complaints with the U.S. Government. Friction over patents with the United States and Japan could mount. Small businesses should be defined in terms of labor, time, as well as the financial resources they have committed to developing, patenting or licensing inventions. Likewise, smaller businesses should not be denied the right to seek relief merely because they have made smaller financial investments than large companies, in developing, exploiting an intellectual property right.

3. Domestic Industry Definition Broadened

In addition, the definition of "domestic industry" under the Trade Act is substantially relaxed in the above situations. There is no need to show "efficient and economic operation". It is sufficient that the industry "exists or is in the process of being established." Three situations indicate that the industry exists:

1. Where there is a significant investment in plant and equipment;
2. Where there is significant employment of labor or capital; or
3. Where there is substantial investment in the exploitation of the industry, including engineering, research, and development or licensing.

"Substantial investment should be judged in the light of the facts or circumstances of the particular person or entity seeking to enforce the exclusion order.

This definition does not exclude the ability of foreigners to bring action before the ITC. Foreigners can, in fact, patent and license U.S. patents as a basis to give them standing against other foreigners. This should be an incentive for foreigners to patent and license and litigate in the U.S.

4. Strengthening ITC Procedures and Sanctions.

Miscellaneous other changes to ITC, Section 337, actions have been enacted.

1. Consent orders and terminations of investigations on the basis of the settlement agreement can now be entered;
2. The cease and desist orders in addition to exclusion orders or temporary exclusion orders can be made. The penalties for violations of cease and desist orders are substantially increased: \$100,000 for each day of violation or twice the value of articles entered or sold;
3. Default judgments to obtain exclusion orders are possible where the complaint is filed and notice of investigation is served on the respondent and the respondent has failed to respond or answer. The Commission can enter a general or blanket exclusion order even if no person appears to contest the investigation so long as the violation is established by substantial, reliable and

- probative evidence.
4. The statutory deadline for granting or denying temporary relief is shortened to 90 days with extensions up to 150 days in more complicated investigations. The posting of a bond is a prerequisite and if the ITC ultimately determines non violation, the bond is forfeited to the U.S. Treasury.
 5. The ITC is authorized to impose sanctions for abuse of discovery or abuse of process under Section 337.
 6. Orders of seizure and forfeiture can be entered if:
 1. The importer or previous owner attempted to import the articles;
 2. The article was previously denied entry pursuant to an exclusion order; and
 3. Upon previous denial of entry, the Secretary of Treasury gave the owner or importer actual written notice of the exclusion order and that seizure or forfeiture would result from any further attempts to import the article.

This should act as deterrent to importers who knowingly attempt to circumvent a Section 337 exclusion order by "port shopping" or by the repeated attempts to enter goods or like goods subject to the order. The general exclusion order prohibits the importation of all infringing articles regardless of whether the importer of the articles was a respondent.

E. Likely Consequences of Process Patent Legislation Changes.

If a product change does not rise to the level of "materiality," liability is created for incorporating a product as a component of a larger item under the process patent infringement provisions. Section 337 benefits are also substantially enhanced.

Producers, both domestic and foreign, should apply for U.S. patents on every new process they can develop related to big ticket products. This will enable them to take advantage of opportunities for market control represented by the two new provisions.

Those who make substantial investments in research, in the creation of intellectual property, and, then, license their creations now have a remedy under the Section 337 reforms. Independent inventors and small businesses who otherwise lack the capacity to produce their product can now seek relief under Section 337. This should be an incentive to patent, license, and develop and exploit intellectual property rights.

Process patents have become increasingly important in the industrial, pharmaceutical, and chemical areas; and in biotech. For instance, the well-known example is Genentech's principal asset since 1976 of the process of making human insulin and growth hormone. In the biotech field, there is a need for process claims since products may often be unpatentable or cannot be accurately defined. Product protection should exist for first generation products: a purer product form should be patentable as in the case of prostaglandin of Bergstrom. Factor VIIIIC produced in a higher potency per unit was patentable.

In the semi-conductor industry, ITC cases have been brought successfully by U.S. semiconductor companies against foreign semi-conductor manufacturers. Importation through ITC action can be blocked. Through process patents importers of products made by infringing processes can be enjoined and be liable for damages.

F. Effective Procurement of Process Patents

It would seem to make sense to file many claims in process patents relating to different downstream steps to avoid questions of material change. Claims should be directed, even in dependent form, to final or end product claims as well as to intermediate products.

The trend in the use of process patent claims may have decreased as more countries permitted product protection for chemical compounds. However, the developing process patent law now dictates the need for process claims.

G. Conclusion

Process patent protection and amendment of the Tariff Act is a modernization of U.S. patent laws. The changes bring U.S. law closer to the European Patent Convention and the national laws of many industrialized countries in respect to process patent protection.

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