May 8, 1985

REPLIES TO ARGUMENTS RAISED BY GENERIC DRUG INDUSTRY CONCERNING PROCESS PATENT LEGISLATION

(The arguments set forth below are the ones raised by Alfred B. Engleberg in testimony before the Senate Judiciary Subcommittee on Patents, Copyrights, & Trademarks on April 3, 1984, plus others that the generic drug companies have raised more recently in oral discussions.)

1. THE LEGISLATION WOULD BE COSTLY TO THE GENERIC DRUG INDUSTRY, REQUIRING THE INDUSTRY TO RAISE PRICES OF GENERIC DRUGS.

ANSWER: Ninety-nine percent of generic drugs sold in this country are made from material imported from abroad, according to Generic Pharmaceutical Industry Association president William Haddad, quoted in the New York Times last year. It is unlikely, however, that many of these drugs are being manufactured by processes patented in the U.S. Research-based drug companies in the U.S. feel that most of their important patents are product patents, not process patents.

Even if the generic industry had to pay a reasonable royalty on some process patents, it seems doubtful that there would be any measurable effect on the prices of generic drugs. The generic industry representatives vacillate on whether they or their suppliers in fact are using processes covered by patents. It is important for Congress to schedule hearings at an early date to elicit more information on this.

The bill would affect only materials imported after the date of enactment, so the generic companies would not be liable for any damages for materials imported before the date of enactment. It is true that the legislation would block the generic companies from taking a free ride on the R&D expenditures of biotechnology companies in the future, but this is only fair.

2. THE LEGISLATION WOULD BE UNFAIR BECAUSE THE UNITED STATES PATENT LAW DOES NOT INCLUDE A REQUIREMENT FOR THE PATENT OWNER TO "WORK" THE INVENTION.

ANSWER: First, working requirements (requirements for the patent owners to grant licenses unless the owner is manufacturing the invention in this country) are irrelevant to the issue. Working requirements are not a part of American patent law for any type of a patent, including a product patent. No one questions the fairness of enforcing U.S. product patents

against products manufactured abroad which are brought into this country.

Second, although it is true that a number of foreign countries have working requirements in their statutes, in practice these provisions are virtually never used. A study by the United Nations Conference on Trade and Development reported "very few instances in any country of implementation of compulsory license provisions".

3. IF THE LEGISLATION IS ENACTED WITHOUT IMPOSING ANY WORKING REQUIREMENT ON OWNERS OF U.S. PROCESS PATENTS, THE PATENT OWNERS WILL DO THEIR MANUFACTURING ABROAD, CAUSING A LOSS OF JOBS IN AMERICA.

ANSWER: The legislation will preserve jobs in America, not cause loss of jobs. The United States does not prohibit U.S. companies from manufacturing abroad, but more often than not companies which perform research and development in the United States and obtain patents here will do their manufacturing here, provided they are given adequate legal protection against unfair competition and piracy by foreign competitors who have not invested in research and development. Many factors operate to encourage U.S. patent owners to manufacture in the U.S., including proximity to the large U.S. market.

Under current law, in cases where only a process patent exists, importers can buy a product from a foreign manufacturer who utilized the U.S. patented process outside this country, thereby causing a job loss here.

4. FOREIGN MANUFACTURERS OF GENERIC DRUG MATERIALS WOULD NOT DISCLOSE THEIR MANUFACTURING PROCESSES, WHICH WOULD MEAN THAT DOMESTIC "USERS" AND "SELLERS" (I.E., U.S. GENERIC DRUG COMPANIES AND THEIR CUSTOMERS) WOULD BE FOUND LIABLE.

ANSWER: U.S. courts have effective procedures for protecting trade secrets. Courts can issue protective orders and conduct in camera proceedings. Domestic manufacturers disclose manufacturing processes in confidential court proceedings frequently. Contrary to the assertion of the generic drug companies, United States courts have a good track record of preserving the confidential nature of trade secrets.

Moreover, U.S. generic drug companies can insist, as a requirement for buying from a foreign manufacturer, that a process be used that does not infringe a U.S. patent. It is a rare case where alternative and economical processes are not available. Foreign manufacturers who are using noninfringing processes will prove this to prospective U.S. purchasers when necessary to obtain sales, or they will give warranties to U.S. purchases.

5. THE USE OF PRESUMPTIONS IN THE PROPOSED LEGISLATION WOULD CREATE AN UNFAIR SITUATION FOR IMPORTERS, USERS, AND SELLERS OF GENERIC DRUG PRODUCTS.

ANSWER: The proposed legislation requires infringers other than manufacturers to be on notice of the infringement before there is any liability. Moreover, there would be no presumption that an imported product had been made by a U.S. process patent until the patent owner had shown a substantial likelihood that the product was being produced by the patented process. This is the same kind of presumption already applied in ITC proceedings.

6. THE REMEDY FOR PROCESS PATENT OWNERS AGAINST IMPORTATION IN PROCEEDINGS AT THE U.S. INTERNATIONAL TRADE COMMISSION IS ADEQUATE.

ANSWER: The ITC remedy is inadequate to protect patent owners from offshore manufacturing for a number of reasons: (1) monetary damages, which can run to tens or hundreds of millions of dollars for patent infringement awards in federal courts, are unavailable in ITC proceedings; (2) ITC proceedings are more expensive and more uncertain for patent owners than litigation in federal district courts, because of the need not only to prove patent infringement but also to prove an "effect or tendency... to destroy or substantially injure an industry, efficiently and economically operated, in the United States..."; (3) temporary exclusion orders are almost impossible to obtain from the ITC; and (4) attorney fees are not available in ITC proceedings; (5) the ITC and the President of the United States apply "public interest" and "foreign policy" tests which should be irrelevant to deciding whether intellectual property rights are infringed.

7. THE LEGISLATION IS UNFAIR BECAUSE IT WOULD MAKE FOREIGN ACTS THE BASIS FOR A CHARGE OF PATENT INFRINGEMENT WITHOUT MAKING EARLIER FOREIGN ACTS A BASIS TO HAVE THE U.S. PATENT CONSIDERED TO BE INVALID.

ANSWER: First, the proposed legislation does not make the foreign act of manufacturing an act of infringement. The act of infringement in the proposed legislation is the importation into or use or sale within the United States. Second, virtually all earlier foreign acts by someone other than the U.S. patent owner -- including earlier publication or patenting anywhere in the world -- can be used to invalidate the U.S. patent. The same earlier foreign acts are available to invalidate U.S. process patents that are available to invalidate U.S. product patents.

8. THE LEGISLATION IS INCONSISTENT WITH DEALS WHICH WERE STRUCK WHEN THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT WAS PASSED LAST YEAR.

ANSWER: No one from the research-based drug companies who worked on the Drug Price Competition and Patent Term Restoration

Act last year has any recollection of process patent legislation even being mentioned during the extensive deliberations on that act.

There is no inconsistency with the Drug Price Competition and Patent Term Restoration Act. That legislation clearly provided for extension of process patents under certain circumstances. All this new legislation would do is to attribute product protection to the product of a patented process, as in other industrialized countries, in order to give meaning to the process patent. Otherwise, the process patent is easily circumvented.

9. THE PROCESS PATENT LEGISLATION WOULD NEUTRALIZE THE EFFECTS OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT BY DELAYING THE MARKETING OF OFF-PATENT GENERIC DRUG PRODUCTS.

ANSWER: This is not correct. A separate patent exists on a manufacturing process for a drug only when that process is a separate invention from the drug product. Chemical compounds, including drugs, can be made by a variety of processes. Generic drug manufacturers and their suppliers can use an unpatented process to manufacture the drug as soon as the product patent expires. At least one process for manufacturing the drug has to be known in order to obtain a product patent. The generic company and foreign manufacturers are free to use that process as soon as the product patent expires.

A subsequent patent on another process for manufacturing the drug cannot be obtained unless that process meets the statutory requirements for patentability -- a new, useful, and nonobvious process. The argument about "evergreening" of drug product protection by obtaining subsequent process patents is specious.

10. THE LEGISLATION IS SIMILAR TO BILLS WHICH WERE PROPOSED IN 1967 AND 1968 AND DEFEATED.

ANSWER: This is misleading. Although there was some testimony in opposition to certain bills in 1967 and 68 which included process patent provisions, the process patent measure had been recommended in 1966 by the President's Commission on the Patent System and probably would have been enacted if it had not been in an omnibus patent law reform bill which contained other, more controversial provisions.