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6.901 – Inventions and Patents

6.901 Final Project – Congress Committee
Prescription Drug Re-Importation:
Transitioning from the 108th to 109th Congress

Due to their patents, American companies maintain the exclusive right to sell and distribute a wide array of valuable pharmaceuticals. This is a significant power that, in our opinion, should be limited so that American society receives the benefits it deserves. This project will reflect on what happened in the 108th Congress and determine the roadblocks that prevented much of the proposed legislation from succeeding. We will then assess what needs to change - or what has already changed - to allow legislation to be more successful in the 109th Congress. Once we know the problems, we hope to propose potential compromise solutions to allow American citizens to have greater accessibility to potentially life-saving drugs.

Before partaking in our analysis, however, it is necessary to understand why drug importation has become such a large issue within the U.S. Congress, and there are multiple reasons for this. The first reason is price insulation. When a doctor prescribes a drug to a patient, the doctor generally has no idea of the relative prices of the drugs that *could have been* prescribed. Because doctors don't consider prices, the drug companies know they can charge more. In addition, since most Americans have HMO insurance plans, customers have no incentive to shop around for cheap drugs. Since Americans usually pay flat co-payments regardless of the worth of a drug, there is no reason for them to distinguish between cheaper versus more expensive drugs. Finally, drug companies have historically based their drug prices on the median income of countries. This, along with socialized health care, helps explain why countries like Canada, for example, charge much cheaper prices. When taken together, all of these reasons help explain why the prescription drug companies can (and do) get away with charging high drug prices in the United States.

As this is a class about patents, we also would like to introduce the patent law issues that perpetuate the monopolistic pricing structure of prescription drugs in the United States. The reason why patents matter *in re* the prescription drug issue is because, as we have learned, they give companies the exclusive right to manufacture a product. As applied to pharmaceuticals, this exclusive right extends for 20 years. Part of the motivation for patenting prescription drugs is that it motivates companies to continue their exhaustive research efforts; nevertheless, this occurs at the expense of the high pricing. Certainly, it is not the role of Congress to eliminate patents. While free market economics are undoubtedly necessary to promote competition and drive down prices in the long-term, it would be nearly impossible to provide incentives for future research pursuits by the companies without them.

Still, there is definitely a point at which a pharmaceutical patent is no longer net-beneficial to society. Is a twenty year patent really necessary to recoup the original R&D investment? Can pharmaceutical companies survive on five year patents, for example? Perhaps the FDA could grant an extension that would start the five year period after FDA approval is received for the drug. After five years these companies would still have the name recognition to market and sell drugs, and the generic production wings of most pharmaceutical companies generate large income. In the meantime, many people who may have struggled to obtain the drug for fifteen more years would be able to secure it. This saves lives and money.

Surely, a privately funded creation by a pharmaceutical company is a private good and should be protected in some form. But prescription drugs are not the same as say, a new computer chip designed by Intel or Advanced Micro Devices; prescription drugs, in some cases, are necessary for survival. Should they thus be treated more like a public good and produced such that they are essentially non-excludable to the public at large? Many drug companies apply

this principle when they send drugs to prevent the spread of AIDS to Africa for a fraction of the cost the same drugs are sold for in the United States. Why not apply this principle to the citizens of the United States as well? If we are to ever balance the needs of society with the money-making interests of pharmaceutical companies, we believe that Congress needs to consider reducing the length of pharmaceutical patents. Prescription drugs are a commodity in the truest sense of the word. They shouldn't be treated like microprocessors.

Other issues that could potentially be addressed by Congress relate to the potential loopholes that exist in patent laws. Many of these loopholes contribute further to the high prices of prescription drugs. One such loophole exists in patent extension law. This law gives a patent holder an effective extension to a patent whenever a patent is challenged. This generally occurs when a generic drug-maker attempts to introduce a generic version of a brand-name drug. The brand name's exclusive right to produce its own drug (and in effect, its patent) is then extended by 30 months. This effective extension occurs because the court issues a *stay* until the decision goes to trial. Since pharmaceutical companies have skilled attorneys, they are often able to keep disputed cases in court for at least 30-months, thereby extending their patent as long as possible while preventing the generic companies from entering the market. Unless the original patent actually runs out in the 30-month *stay* period, the patent will remain without, without a competitor.

Additionally, drug companies can approach Congress to extend patents through other laws. For example, the chemical composition of a drug may be patented. At the point at which the patent for the chemical composition becomes invalid, the drug companies have the ability to patent other aspects of the drug through law. For example, they can obtain patents for a new process to make the drug, a new dosage form, or a new use. In fact, this technique was used to

provide extensions to Prozac's original patents. If Congress were to limit these special loopholes and provisions, this would be yet another way to incrementally reduce prescription drug costs in this country. Yet, as we will see in the following paragraphs, Congress has not taken the steps necessary to solve this problem.

During the current 108th session of the United States Congress, the issue of importing prescription drugs has received widespread public attention. Different pieces of legislation were introduced, both in support and opposed to the importation of prescription drugs. The issue also became a heated debate topic during the 2004 election cycle, both at the federal, state, and local levels. While perhaps it was most notable in the presidential campaign, the Congressional debates on the issue emphasized similar concerns and it is in the Congress where changes would have to take place in order to affect significant changes from the status quo.

In the 108th Congress, a variety of bills were introduced which dealt with the issue of importing prescription drugs from foreign countries, generally with an emphasis on imports from Canada. The bill which generated the most publicity was the Safe Importation of Medical Products and Other Rx Therapies Act of 2004, also known as the Safe IMPORT Act of 2004, which was introduced with bipartisan support in the House and Senate as H.R.4923 and S.2493 respectively. Other notable bills included the Prescription Drug Parity for Americans Act, the Pharmaceutical Market Access Act of 2003, and efforts to amend the preexisting Federal Food, Drug, and Cosmetic Act.

Final votes were never taken in either house of Congress on any of these bills after they were referred to committees. However, the hearings and testimony in the various committees helped to shed some light on the wide array of issues related to the importation of prescription drugs. In general, the testimony of experts related to the effect the imports would have on the

prices of prescription drugs in the United States. Some of the outside experts did raise the maintenance of strong intellectual property rights in the United States as a reason to block importation. Rather than consider the current patent laws as a block to the importation of prescription drugs, they described the effect on patents within the context of their effect on the economic and financial welfare of biotechnology firms and pharmaceutical companies.

In particular, the testimony of the Biotechnology Industry Organization (BIO), a biotechnology trade group, described how legislation that would allow widespread importation of prescription drugs could erode the American intellectual property system. One of the introduced bills would prevent U.S. manufacturers from enforcing their patents against foreign, imported products, which under current law, would violate the patent on the U.S. product. The sale of the foreign product, in direct competition with the American, FDA-approved drug, could not be challenged under the proposed law. BIO then continued that this situation would have a tremendous impact on biotechnology companies, many of which own very little other than their intellectual property. If the company is not able to protect its intellectual property rights, it would be unable to raise capital and attract investment, thereby stifling attempts to

innovate and develop new products

BIO also described pharmaceutical patents as part of the large, overarching intellectual property policies of the United States. They claimed that it would be hypocritical for the U.S. government to espouse the importance of intellectual property protection in its policy debates with other countries over trade policy, treaties, international health policy, and other subjects, and then allow its patent system to collapse in the area of prescription drugs. BIO also said that the strong patent system in the United States had allowed it to become the premiere researching nation in biological science, medicine, and biotechnology. They continued, stating that allowing

importation to erode the patent system would have negative implications and would not be in the best interest of patients, despite popular claims otherwise.

Despite the worries of the pharmaceutical industry regarding intellectual property, most of the testimony heard by the Congressional committees focused on the safety aspect of importation. This has occurred primarily because existing laws are in place which allow for the importation of prescription drugs, but only after the Secretary of Health and Human Services can declare that the imported drugs are safe. In both the Clinton and Bush administrations, the Secretaries have refrained from making such a proclamation. Therefore, most of the bills introduced in Congress have contained provisions that involve repealing the part of the existing laws that require the Secretary's approval for importation to begin. Despite efforts that would allow for only the re-importation of drugs, which would only allow drugs manufactured in the United States, then exported, to be imported back to the United States. The bills have all contained provisions that limited the degree to which the drug could change hands after leaving the United States, and that a clear record of all transactions would have to be maintained and submitted to the FDA so that it would be able to interdict shipments should the need arise to block the sale of fraudulent or counterfeit drugs.

While Congress has received some testimony from industry groups wishing to block importation legislation, they have still not heard nearly as much regarding intellectual property as they have about the possibility of health risks posed by importing drugs. In what may prove to be a seminal work concerning the patents and intellectual property associated with prescription medicine, Daniel R. Cahoy of Pennsylvania State University's Smeal College of Business has authored a forthcoming study entitled “Patent Fences and Constitutional Fence Posts: Property Barriers to Pharmaceutical Importation.” Cahoy highlights the fact that the patent rights of

prescription drugs have received little attention despite their tremendous importance. He found that when he applied full constitutional property protections to the importation conflict that:

> (1)private organizations and municipalities share the same, crushing liability under the Patent Act; (2) despite Eleventh Amendment immunity in federal courts, state governments face nearly equivalent liability for takings claims based on the Fourteenth Amendment; (3) the federal government confronts liability under the Fifth Amendment that broadens its exposure under the recognized just compensation statute; and (4) attempts by Congress to modify the Patent Act to permit importation would likely constitute an unconstitutional taking."

Applying the principles aligned against importation, Cahoy analyzed current efforts of municipalities, states and cities, to allow access to Canadian prescription drugs as a means of reducing the cost faced by Americans. This has become a much more common action as it has become more politically desirable for leaders to succumb to the demands of citizens who want reduced drug prices. The state governments of Minnesota, Illinois, Wisconsin, Vermont, New Hampshire, and Iowa, along with the cities of Springfield and Boston, Massachusetts, Montgomery, Alabama, and Los Angeles, California, have proposed drug import plans with varying degrees of government involvement. Due to the current legal ambiguities concerning drug imports, some of the municipalities have only established Internet portals to Canadian pharmacy websites, thereby allowed consumers to make their own choice on whether or not they should purchase imported drugs. Other municipalities have developed more involved plans that generate reimbursements favoring the purchases of cheaper imported drugs. The most active

approach has involved government importation on behalf of citizens. The municipality would act as a wholesaler, selling the imported drugs to its citizens.

Cahoy, unlike many other critics of importation policies, delves into the patent-protection aspects of the policies. He discusses the issue of patent exhaustion and the idea that once a drug covered by one or more patents is sold, the pharmaceutical company has no power to limit further use or resale of that drug by the purchaser, since the patent-holder has already received compensation. However, Cahoy notes that while this may seem clear-cut, it is difficult to extend the exhaustion principle into the international arena. The United States, unlike many of its counterparts, does not uphold the exhaustion principle regarding patents in international trade.

An additional concern for the cities engaged in establishing importation programs is the development of Supreme Court jurisprudence that Eleventh Amendment protection of states does not extend to cities and counties. Therefore, Cahoy concluded that "any city within the state that imports or induces the import of patented pharmaceuticals from another country without the authorization of the patent owner will be on the hook for all attendant damages."

It remains unclear whether or not importation of prescription drugs could be pursued without the possibility of companies seeking compensation for damages. Since there is little definitive information on the intellectual property and other legal implications of drug importation, states and other municipalities have forged ahead in their efforts to establish programs that please their citizens. The Council of State Governments (CSG), whose goal is to interpret changing national and international conditions to prepare states for the future produced a document offering a brief analysis of the legality, safety, liability, and feasibility issues involved in importing prescription drugs. They outlined several of the already existing programs and in their discussion of legality noted that importation efforts generally violated one or more

provisions of the Federal Food, Drug, and Cosmetic Act. Currently, the FDA regards importation plans as illegal and has threatened legal action against state and local governments but have not, as of yet, taken action to prosecute state officials who either assist citizens in importing drugs or establish programs that directly act as intermediaries between citizens and foreign pharmacies. The CSG also noted that there are frequently existing state laws that require that drugs may only be sold and dispensed from pharmacies licensed in that state, a requirement that foreign pharmacies rarely fulfill.

When discussing patent laws, the CSG also noted the ambiguities asserted by Cahoy and promulgated that a large scale drug importation program from Canada to the United States would likely negate the effects of pharmaceutical patents and many other national patent regulations, and would effectively import Canadian patent policy into the United States. While not taking a clear position on the issue, the CSG sought only to provide information to state governments to ensure that the many relevant aspects of an importation program are taken into consideration. Before widespread importation can occur, there are many aspects of legislation and jurisprudence that must be resolved before definitive action can be taken.

Currently, it appears that the potential for a nationally sponsored drug re-importation bill is growing even more. According to a HealthIssues Daily Briefing obtained on December 2, 2004, public pressure is producing bipartisan support for bills that would advocate re-importation. Senate Finance Committee Chair Chuck Grassley claims that, upon possible consideration of such a bill in January, "it will pass." Nevertheless, the 6.901 Congress committee questions whether this move is a good idea.

First, this move would hurt other nations, particularly Canada. In a November 14th Article featured in the Toronto Star, the Canadian federal health minister, Ujjal Dosanjh, said that "it is a

matter of common sense that Canada cannot be the drugstore of the United States." The United States is a country of over 280 million people. How can a country with only about 32 million people provide enough drugs for such a proportionately larger country? Moreover, why should the government take part in such an inefficient endeavor? Extensive time and resources are used to export the drugs to Canada in the first place. The cost of state-level re-importation requires Americans to spend additional tax dollars. Thus, in obtaining seemingly "cheaper" drugs, citizens could actually be expending more money than they had bargained for. Research has not really been done to answer this question. Until it is, we feel that re-importation is a foolish idea.

Americans need to acknowledge the burden re-importation places on Canadians (or any other country that it considers re-importing from). Canadians, like anyone else, need to be treated for their diseases and should not be taken advantage of at the expense of a wealthier nation. American re-importation, simply put, could leave the Canadian population at a loss for drugs. In cases of "national emergency or extreme urgency," Canada has cancelled patents altogether and has allowed for the at-large creation of generic replacement drugs. This possibility would undoubtedly anger pharmaceutical companies. Moreover, Canadian prices would probably increase if Americans practiced systematic importation. This is because, in calculating their prices, drug companies will take the American purchases into account. Not being able to charge separate prices to Americans and Canadians purchasing in Canada, the effect is that the overall price will increase. Americans need to understand that Canadian drugs are not the answer to reducing prescription drug prices, and that much better solutions are possible.

The general effect of drug re-importation on American spending would also be minimal. In a study conducted by the Congressional Budget Office in 2004, it was found that the additional volume of drugs that would be imported to the U.S. upon legalizing importation would

be low. Even if legalization was broadened to many countries beyond Canada, such as through H.R. 2427, drug spending would only be reduced by $40 billion over 10 years. At first glance, this may seem like a lot of money. But, when compared to the overall expenditures on prescription drugs, $10 billion dollars is only indicative of a 1% reduction over that time period.

The reality of the re-importation proposals is that they are purely politically motivated. Congress simply wants to pass this bill to appease the average American who believes that re-importation will actually lead to systematic decreases in prescription drug prices. However, individual Americans need to realize that, although re-importing cheaper Canadian drugs may seem like a good idea on an individual level (e.g., for my uninsured grandmother who has to pay full price for her prescription drugs), they undoubtedly cannot solve the problem for the nation as a whole. While my grandmother can get away with saving a few dollars now, things will be much different, as we have seen above, if there is an overall legalization.

Still, there are many constitutional roadblocks that stand in the way of Congress' ability to make real and substantive changes. In "Patent Fences and Constitutional Fence Posts," Cahoy also performs an analysis of some of these issues. In general, he argues that the constitutional roadblocks to limiting patent rights for pharmaceutical companies can be eliminated. In general, excisions of patent rights have been coupled with extensions so as to not create a net-infringement of rights. Per the Fifth Amendment, property rights have been stringently protected by the courts for some time now, and pure reductions in property rights (as would be the case by restricting patents) would be deemed unconstitutional. Despite this, there are two ways that Congress can get around this Constitutional impediment; either it can create a mechanism to pay just compensation or draft a law prospectively so as to only affect patents that have not yet been issued. Since patents are generally issued years before the formal release of a product, however,

products exempt from a prospective law would be released for years to come. Thus, even a prospective law would not provide us with a short-term solution to the issue.

Ultimately, then, we see that the stalemate that continues in Congress over the prescription drug fiasco has much to do with the conflict between limiting property rights and serving the public interest. Despite this problem, however, we feel that Congress can embark on many solutions over the next Congressional term to at least move towards solving the problem. For example, some of the patent laws that allow pharmaceutical companies to patent a "new process" or "new combination" associated with a long established drug can be removed from the books. Receiving these extra benefits was not the intended consequences of these laws, and removing them would not represent any real constriction of property rights. Congress, as Cahoy suggests, can promote negotiations between government entities and insurers to extract lower prices as well. The government certainly has more negotiating power than it has shown, and, if it really wanted to, it could use these negotiations to drive down prices. Another interesting idea is to draft a law that creates a government commission to report and assess the effectiveness of drugs. Establishing a rating system would make the drug companies more accountable to the consumer and would drive their prices up or down depending on their actual worth to society.

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