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U.S. v. RxDepot: The Battle Between Canadian Store-Front Companies, the FDA and Brand-Name Companies

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I. INTRODUCTION

Prescription drugs have traditionally been available to the consumer (or patient in this case) by obtaining a prescription from a doctor and purchasing the drug from a local pharmacy. If the patient is covered by a health insurance plan with prescription drug coverage, he or she will likely only pay a certain deductible fee. What about the millions of people without prescription drug coverage or those who cannot afford to pay the deductibles due to the high prices of drugs? What other option do they have?

Since 2002, companies that serve as store-front operations for Canadian price-controlled drugs have opened in the United States with the promise of providing prescription drugs at a substantially lower price than what they would be sold for in the United States. One such company was RxDepot, Inc.[1](RxDepot). Prescriptions were faxed to Canadian pharmacies, and were then shipped from Canada to the United States.[2] The consumer was able to pay Canadian prices on brand-name drugs or their generic equivalent instead of paying the price in the United States.

The Food and Drug Administration (FDA) became concerned with the activites of companies such as RxDepot, and "asked the [U.S.] Department of Justice to file a complaint for an injunction against RxDepot, Inc. . . . to stop them from importing drugs that pose a serious threat to the public health."[3] The FDA claimed companies such as RxDepot posed a threat to the health of the public because the FDA could not guarantee the safety of the drugs that come from Canada[4] and the FDA cited concern over the drugs' safety as well as the potential for

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1. *See* Jim Killackey, *Judge Hears Drug Import Arguments; Company Attorney Denies Agency's Claims its Medications are Unsafe*, DAILY OKLAHOMAN, Oct. 9, 2003, at 1A.

2. *See id.*

3. Press Release, FDA News, FDA Takes Action Against Companies That Are Importing Unapproved, Potentially Unsafe Drugs (Sept. 9, 2003), *at* http://www.fda.gov/bbs/topics/NEWS/2003/NEW00939.html (last visited Feb. 15, 2005).

4. *See id.*

counterfeit drugs entering the American market.[5] Brand-name drug companies, such as GlaxoSmithKline, supported the FDA's position against companies such as RxDepot and also cited health and safety concerns about these imported drugs,[6] which RxDepot denied.[7] In November 2003, the U.S. District Court for the Northern District of Oklahoma granted a request by the FDA to enjoin RxDepot from providing U.S. customers with prescription drugs shipped across the border.[8]

The patient/consumer in the United States is in the middle of this price war. On one side, brand-name pharmaceutical companies have secured their rights through the patent system and want to protect their intellectual property rights as well as earn a profit and recoup costs that were required to develop the drug. The FDA wants to protect its protocols for permitting drugs' administration to the public, which include domestic brand name, generic equivalents, and foreign manufacturers of pharmaceuticals. On the other side are companies like RxDepot that are attempting to provide American consumers with an affordable alternative to rising health care costs.

Somewhere caught in the middle are the patients/consumers. Unfortunately, they seem to have been lost in the battle, even though these are the people who need a solution the most. What is the balance between each of these "players"? Where should the solution be found? How should the "competitors" in this battle resolve their issues so that pharmaceutical companies are able to protect their intellectual property while allowing an affordable alternative for the consumer? Is the FDA really harming the public it intends to protect by making it more difficult for them to afford the drugs they needs? These are the issues that will be examined in this comment.

The first part of this comment will provide an introduction to the current situation of drug import businesses that have been in the news since 2002. The second section will provide a short description of pharmaceutical patents in the United States and the role generic drugs

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5. *See* Lew Kontnik, *Counterfeits: the Cost of Combat: Fake Prescription Drugs Are a Growing Problem. What can Pharma Do?*, 23 PHARM. EXECUTIVE 46, Nov. 1, 2003.

6. *See* Press Release, GlaxoSmithKline stands firm against illegal pharmaceuticals trade (Nov. 17, 2003), *at* http://www.gsk.com/media/archive-03.htm (last visited Feb. 15, 2002).

7. Brian Barber, *East Coast Witness to Testify for RxDepot*, TULSA WORLD, Oct. 5, 2003, at A1.

8. *See* United States v. Rx Depot, Inc., 290 F. Supp. 2d 1238 (N.D. Okla. 2003). RxDepot filed for a stay of the injunction while it planned to appeal the injunction, but was denied. *See* United States v. Rx Depot, Inc., 297 F. Supp. 2d 1306 (N.D. Okla. 2003).

play in the United States patent system. The third section will shift the focus to the American public; the individuals who may be finding it difficult to afford drugs. The section will also analyze the social impacts that the rising costs of health care coverage have had on the public. The fourth section will focus on the current situation with Canadian drug services, specifically RxDepot. This section will include arguments from all sides and an analysis of each perspective. The fifth section considers whether the FDA is helping or hurting the public through its actions. Finally, the conclusion makes recommendations and suggestions on how to address this topic, including a recommendation that Congress amend the law to permit approved generic drugs to enter the market in the spirit of the Hatch-Waxman Act to the Food, Drug, and Cosmetics Act.[9]

II. GENERIC PRESCRIPTION DRUGS AND PATENT LAW

A. The United States Patent System

Title 35 of the United States Code allows an inventor to obtain a patent for an invention, such as a compound for a drug.[10] The patent system for drugs is similar to all other areas of patentability save a few exceptions. A patent gives an inventor the right to exclude others from making, selling, or distributing the invention in any form.[11] This quasi-monopoly right is secured by the U.S. Constitution[12] and is intended to promote the furtherance of science and provide the inventor exclusivity for his or her invention.

B. The Hatch-Waxman Act

In the United States, if an inventor obtains a patent for a drug, a generic manufacturer has the ability to manufacture the drug without infringing a patent. Under FDA regulations, a drug must be approved

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9. *See infra* discussion Part II.B for a discussion on the Hatch-Waxman Act and the rationale for its enactment.

10. *See generally* Patent Act (codified at 35 U.S.C. §§ 101-376 (2000)).

11. *See* 35 U.S.C. § 271. The Patent Act states "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent." 35 U.S.C. § 271(a).

12. *See* U.S. CONST. art I, § 8, cl. 8. The clause authorizes Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." *Id.* Although the right is interpreted by many as a right to a quasi-monopoly, it is actually an exclusionary right. *See generally* 35 U.S.C. §§ 101 *et. seq.*.

by the agency before it may be made available to the public.[13] The agency's requirements make a New Drug Application (NDA)[14] expensive. The Hatch-Waxman Act of 1984 to the Food, Drug, and Cosmetics Act;[15] however, allows a generic manufacturer to obtain approval of their drug without the expensive process that the band-name manufacturer must go through. To be able to sell or market its version of the drug, the generic manufacturer must apply for an Abbreviated New Drug Application (ANDA). An ANDA requires that the generic manufacturer demonstrate that its version of the drug has an identical active ingredient to the brand-name company's version.[16] Upon this demonstration, the FDA approves the drug since the brand-name version of the drug already demonstrated its safety in the NDA.[17] The ANDA process is available to generic drug manufacturers that wish to enter the market under either an expired or unexpired patent of a brand-name drug. If a manufacturer wishes to do so on an unexpired patent, generic manufacturers may not use the claimed subject matter.[18] Instead, it is common for generic manufacturers to develop a polymorph[19] of the active ingredient of the drug that does not violate the patented drug's claims.

Since this procedure saves time and money for the generic manufacturer, it is readily apparent how the generic manufacturers' drugs cost less than the brand-name versions. The savings from not being subjected to the NDA tests theoretically can be passed along to the consumer. Therefore, it is highly desirable for a generic drug manufacturer to seek approval through an ANDA if they wish to capitalize on their version of the drug and potentially gain a part of the market share that the brand-name drug enjoys.

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13. *See* 21 U.S.C. § 355 (2000). Although this section provides the detailed protocol for obtaining approval, section (a) states, "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug." 21 U.S.C. § 355(a).

14. *See* 21 U.S.C. § 355(a).

15. The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585, codified in relevant part at 21 U.S.C. 355.

16. *See* 21 U.S.C. § 355(a).

17. *See* 21 U.S.C. § 355(a).

18. *See* 21 U.S.C. § 355(b)(2)(A)(iv). This section, known as Paragraph IV, of the Hatch-Waxman Act allows an applicant to seek approval of its drug by claiming "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(b)(2)(A)(iv).

19. A polymorph is "a specific crystalline form of a compound that can crystallize in at least two distinct forms." AMERICAN HERITAGE COLLEGE DICTIONARY 1060 (3d ed. 1997).

C. Problems with Counterfeit Drugs

A generic drug that has been granted approval by the FDA may have a higher level of security and safety than a drug that is simply imported from another country, such as Canada. There is a growing concern in the government about counterfeit drugs that enter the market.[20] Counterfeit drugs have been a larger problem outside the United States, an example of which is that Ponstan[21] doses found in Columbia contained, among other things, "yellow highway paint."[22] Nonetheless, the concern is also relevant in the United States because allowing unapproved drugs into the United States has the potential to increase the amount of counterfeit drugs. This was one of the arguments made by the FDA against companies such as RxDepot.[23] However, the brand-name drug manufacturers might also be concerned with importation of drugs because counterfeit drugs can lessen the public's trust in the safety of a particular drug, and thus the manufacturer may suffer despite having obtained the required FDA approval.

In a similar vein, a drug manufacturer may be concerned about its patent rights. If a drug is imported into the United States, it may be from a generic manufacturer that infringes on the drug's patent. A generic equivalent of a drug may not be sold or used in the United States if it violates a patent's claims;[24] however, if that drug is manufactured for a foreign market where a generic equivalent is not found to infringe on the patent, and that drug is imported into the United States, the importation violates patent law.[25] The brand-name

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20. *See* Kontnik, *supra* note 5, at 46. For more information on the history of RxDepot, see discussion *infra* Part III.B.

21. Ponstan (mefenamic acid) is a menstrual pain reliever. For more information on mefenamic acid, visit the FDA's website *at* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=PONSTEL. Ponstan is no longer a registered trademark assigned to Warner-Lambert Company, and was listed as a cancelled mark on Jul. 3, 2004.

22. Kontnik, *supra* note 5, at 46.

23. *See* Press Release, FDA News, *supra* note 3.

24. *See* 35 U.S.C. § 271(a). The statute forbids unauthorized parties to "make[], use[], . . . or import[] any patented invention." *Id.* at § 271(a). Section 271(e)(2) also "makes it an act of infringement to submit an ANDA 'for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose . . . is to obtain approval . . . to engage in [commercial activity] . . . before the expiration of such patent.'" DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 1207 (2d ed. 2001).

25. For more information regarding exhaustion of intellectual property rights, *see infra* notes 93-95; GRAEME B. DINWOODIE ET AL., INTERNATIONAL INTELLECTUAL PROPERTY LAW AND POLICY 1298-99 (2001).

manufacturers have not directly addressed this issue with respect to importation by companies such as RxDepot, partly because of the action by the FDA to enjoin RxDepot. These concerns by the government and pharmaceutical manufacturers have led to the development of the abovementioned process for obtaining drug approval as well as the process for obtaining approval for a generic drug sale in the United States.

III. THE SOCIAL IMPACT OF AFFORDABILITY OF DRUGS FOR AMERICANS

A. The Costs of Prescription Drugs

"Ten million Americans need drugs for chronic illness, yet have no insurance coverage."[26] This is a startling and sober reminder that in the United States, millions have to cope with paying for drugs for which they have no health care coverage. This has left the affected people with three options: they can go without the medications they need; make sacrifices to pay for their medications, or seek out alternatives to paying for high-cost drugs.[27] Obviously, a choice to go without a medication for an illness is not something one does easily. Going without medication can put a patient/consumer at risk for problems stemming from not properly following a doctor's suggested course of action for care. Neither is the choice to make sacrifices to pay for the medication a good one. For example, a "three-month supply of the . . . cholesterol-lowering drug Zocor®[28] costs $400.00 in the United States . . . ."[29] That figure multiplied for the cost of a year's supply makes it readily apparent that the costs of some medications can be a great financial burden. Additionally, the costs increase if the patient has multiple medications. This burden can seem unbearable. With a growing number of people

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26. Peter Stock, *Drug Peddlers, Life-Savers: A Small-Town Pharmacy Sells Cheap Medicine to Desperate Americans Via the Net*, REPORT NEWSMAGAZINE, Dec. 16, 2002, at 34.

27. *See* Ann Wlazelek, *Canadian Drug Imports Fill Valley Prescriptions*, MORNING CALL, Oct. 19, 2003, at A1.

28. Zocor® (simvastatin) is manufactured by Merck & Co., Inc. and "is a cholesterol medication proven to significantly reduce the risk of heart attack and stroke in people with heart disease or diabetes." Merck & Co., Inc., More information on a cholesterol medication and its benefits is available at zocor.com, *at* http://www.zocor.com/simvastatin/zocor/consumer/index.jsp (last visited May 14, 2005).

29. Wlazelek, *supra* note 27, at A1.

living longer[30] and retiring on fixed incomes, the burden only seems to increase as health care costs cut into seniors' savings.

This leads a patient without the ability to pay for his or her drugs to look for alternatives. The alternatives some seek are in the form of cheaper prescription drugs at the pharmacy while others look to other sources.[31] One of these other sources is companies that sell drugs that are imported from Canada. In the past, people have driven across the U.S.-Canadian border, obtained their prescription drugs, and driven back to the United States.[32] In fact, Americans have flocked to cities along the border to cross either by car or bus to purchase their prescriptions in Canada and to bring them back to the United States.[33] On CBS's *Sunday Morning* show on October 26, 2003, several individuals, mainly senior citizens, explained to the media why they felt they had little choice but to make their purchases in Canada.[34] CBS featured a woman who had traveled to Canada from Myrtle Beach, South Carolina to purchase her pain medications at a lower price than she could in the United States.[35] Traveling such great distances for prescription medications may appear like a drastic measure, but because the cost of drugs in America is two to three times greater than that of their counterparts in Canada, the traveling may be worth the effort.[36]

B. Canadian Prices for Drugs

Under U.S. patent laws, inventors are granted a limited monopoly for the disclosure of their inventions.[37] Such inventions may include pharmaceuticals and their chemical components. Therefore, an inventor such as a pharmaceutical company may charge however much it wishes, and is usually able to justify its costs in terms of research and development. Since millions of dollars potentially go into developing

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30. *See* U.S. Dept. of Health and Human Services, *Health, United States, 2004: with Chartbook on Trends in the Health of Americans* 143 (2004), *available at* http://www.cdc.gov/nchs/data/hus/hus04trend.pdf#027.

31. Wlazelek, *supra* note 27, at A1.

32. *See id.*

33. *See id.*

34. *See Sunday Morning: Drug war: seniors flocking to Canadian pharmacies to purchase prescription drugs* (CBS television broadcast, Oct. 26, 2003).

35. *See id.*

36. *See id.*

37. *See* 35 U.S.C. § 154. "[S]uch grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States." *Id.* § 154(a)(2).

and marketing a drug before it is introduced into the market, the manufacturer hopes to earn the money back through its sales.

However, in some countries, such as Canada, there are price controls with regards to pharmaceuticals.[38] For example, in Canada, a three-month supply of Pravachol®,[39] a cholesterol-lowering drug, costs $186.90, whereas in the United States the same supply will run a consumer $389.97.[40] Thus, in this scenario, a company that obtains a patent on a drug in the United States will potentially lose money if that drug is shipped to Canada and then re-imported into the United States. In the previous example, Pravachol® will cost $200.00 less in Canada than the same version would cost if purchased by a customer in the United States. It is clear from this example that a brand-name pharmaceutical company would be concerned with the profit loss when this price difference is multiplied by the number of people currently taking the drug.

C. The Emergence of RxDepot

The advent of mail-order prescription drugs shipped from Canada creates a unique alternative for the patient/consumer. These companies exist as store-front companies in the United States and operate by having a customer bring his or her prescription into the store. After bringing in the prescription, it can be faxed or sent via mail to a pharmacy in Canada. Upon receipt of the information, the Canadian pharmacy ships the drugs to the patient at his home address.[41] The drugs that are imported into the United States are either re-imported brand-name drugs or generic equivalents that may or may not have FDA approval. The company receiving the most attention in the news in this store-front campaign for imported Canadian drugs is RxDepot.

RxDepot,[42] was the creation of Carl Moore, a businessman who founded the company with money from his son, who is a professional

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38. *See* Wlazelek, *supra* note 27, at A1.

39. Pravachol® (pravastatin sodium) is a cholesterol-reducing drug manufactured by Bristol-Myers Squibb Company. More information on the drug is available at http://www.pravachol.com (last visited May 14, 2005).

40. *See Sunday Morning, supra* note 33.

41. *See* Wlazelek, *supra* note 27, at A1.

42. RxDepot no longer conducts its delivery business in the United States; however, in its short existence the company managed to catch the attention of the FDA and several large pharmaceutical companies. *See* Press Release, Pfizer, Inc., Pfizer Statement on Mayor Bloomberg's Rx Drug Importation Position (Oct. 29, 2003), *available at* http://www.pfizer.com/are/news_releases/mn_2003_1029.html (last visited Feb. 15, 2005). Although GlaxoSmithKline did not mention RxDepot by name, it mentioned a federal judge

soccer player for the New England Revolution.[43] His initial plan was to create a company for profit, but, according to him, "what started out as an idea for a profitable business has turned into a personal crusade" for making affordable drugs available to the public.[44] The company opened its doors in 2002 in Tulsa, Oklahoma and quickly expanded to 85 storefronts in 26 states.[45] RxDepot provided customers with the ability to purchase prescription drugs at a significantly lower price than if the customer purchased the same drugs in the United States. Needless to say, the rapid expansion of the stores is the result of people like those interviewed by CBS[46] who have found an even easier way than driving to Canada to obtain their medications. RxDepot and Moore believed that they were helping consumers by providing them with a cheaper alternative to buying drugs from pharmacies in the United States.

IV. THE FDA AND RXDEPOT'S LEGAL BATTLE

RxDepot's rapid growth did not go unnoticed by the U.S. government. The FDA took an interest in companies such as RxDepot and became concerned that the government's regulatory system was being undermined by these importation and re-importation companies.[47] The FDA's regulatory system requires that generic drugs meet certain standards and protocols to ensure public safety.[48] However, the FDA believed that companies such as RxDepot were circumventing these rules and regulations by providing their services to the public.[49] The FDA sent an RxDepot store in Arizona a "Warning Letter" dated March 21, 2003, which, among other things, listed what the FDA believed to be violations of U.S. laws.[50] The FDA also stated that it "is very concerned about the importation of prescription drugs from Canada . . . [, and] many drugs obtained from foreign sources that purport or appear to be the same as U.S.-approved prescription drugs

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in Tulsa, Oklahoma had ruled that importation of drugs could pose a threat to the public. *See id.*

43. *See* Barber, *supra* note 7, at A1.

44. *Id.*

45. *Id.*

46. *See Sunday Morning*, *supra* note 33.

47. *See* Press Release, FDA News, *supra* note 3.

48. *See* Office of Generic Drugs, *at* http://www.fda.gov/cder/ogd/index.htm (last visited Feb. 15, 2005).

49. *See* Press Release, FDA News, *supra* note 3.

50. *See* Letter from David J. Horowitz, Esq., Food and Drug Administration, to Harry Lee Jones, Store Manager, Rx Depot, Inc. (Mar. 21, 2003) *at* http://www.fda.gov/foi/warning_letters/g3888d.htm (last visited Feb. 15, 2005).

are, in fact, of unknown quality."[51] The letter also asked for RxDepot to reply to its claims with proof of compliance, and threatened "legal action without further notice" if the alleged violations were not corrected.[52]

Following RxDepot's resistance to the FDA's demands, the agency asked the Department of Justice (DOJ) to file suit against the company in federal court.[53] The DOJ filed a complaint with the U.S. District Court for the Northern District of Oklahoma asking for an injunction against companies such as RxDepot to stop importing or re-importing the drugs into the United States.[54] The crux of the FDA's argument was that RxDepot's practices "put[] the public at risk because the medicine's authenticity cannot be guaranteed."[55] RxDepot was already enjoined from operation at this point due to a state court suit,[56] and the FDA sought to enjoin RxDepot from carrying out its operations on a nation-wide basis.[57] The FDA complaint insisted that the "[d]rugs that are imported from foreign countries do not have the same assurance of safety and efficacy as drugs that are regulated by the FDA"[58] and that "[t]heir quality is unpredictable."[59] For these reasons, the FDA, through the DOJ, asked the U.S. District Court for the Northern District of Oklahoma to grant a nation-wide injunction against RxDepot, Inc. as well as another company, RxCanada, Inc.[60]

RxDepot responded to the suit by alleging that the FDA's motives were not driven by public safety, but by pressure from the brand-name pharmaceutical companies.[61] Companies such as GlaxoSmithKline[62] and Pfizer[63] have voiced their opposition and pledged to support the government in preventing the importation of drugs into the United

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51. *Id.*

52. *See id.*

53. *See* Press Release, FDA News, *supra* note 3.

54. *See id.*

55. Barber, *supra* note 7, at A1.

56. *See Restraining Order Forces RxDepot to Close*, SHAWNEE NEWS-STAR (Sept. 17, 2003) *available at* http://www.news-star.com/stories/091703/bus_31.shtml (last visited Feb. 15, 2005).

57. *See* Barber, *supra* note 7, at A1.

58. Terry Frieden, *U.S. Files to Stop Some Drug Imports*, *at* http://www.cnnmoney.com (Sept. 11, 2003).

59. *Id.*

60. *See id.*

61. *See* Killackey, *supra* note 1, at 1A.

62. *See* Press Release, GlaxoSmithKline, *supra* note 6.

63. *See* Press Release, Pfizer, *supra* note 42.

States market. RxDepot and its supporters claimed that enjoining RxDepot hurts the people who need the drugs the most, namely those on fixed incomes who face the choices presented earlier in this comment.[64] Supporters also claimed that the FDA's actions were unfair, because although it did not enforce the laws against people who drive across the border, it still targeted companies such as RxDepot that try to provide a service to those who cannot cross the border to Canada to obtain their prescriptions![65]

The FDA maintained its position that the authenticity of these imported drugs puts the public at risk.[66] In a press release, the FDA provided an example of how it placed a thirty-day (sixty doses) order for a powerful anti-depressant drug named Serzone®[67] through RxDepot.[68] The investigation team did not receive the order it placed, and instead received a ninety-nine dose, unapproved-version of Serzone®.[69] This situation was unacceptable to the FDA, which highlighted it as an example of how a customer could be put at risk by following what he or she thought were directions for an approved drug.[70] Additionally, the FDA cited that there is a real threat of counterfeit or dangerous drugs being brought into the United States through importation operations.[71] The information was provided to rebut arguments from proponents of

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64. *See* Killackey, *supra* note 1, at 1A.

65. *See* CBS NEWS TRANSCRIPTS, The Osgood File, *Seniors Getting Prescription Drugs Cheaper Through RxDepot and Others From Canada*, (Oct. 10, 2003).

66. *See* Press Release, FDA News, FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments (Sept. 29, 2003) *available at* http://www.fda.gov/bbs/topics/NEWS/2003/NEW00948.html (last visited Feb. 15, 2005).

67. Serzone® (nefazodone hydrochloride) is an anti-depressant manufactured by Bristol-Myers Squibb. FDA information is *available at* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=SERZONE.

68. *See* Press Release, FDA News, *supra* note 3.

69. *See id.*

> Rx Depot originally came to the attention of the FDA through its work with the states and because of RX Depot's aggressive and misleading promotion of sales of unapproved drugs to Americans for profit. During the course of investigating Rx Depot's practices, FDA investigators made undercover purchases of two products from Rx Depot's Oklahoma operation to determine the type and quality of products the firms were shipping to patients. The agency received drugs that were purported to be safe and effective, but were unapproved or illegally imported into the U.S., and potentially unsafe.

Id.

70. *See id.*

71. *See* Christopher Rowland, *FDA: Fake-Drug Probe Underway In Canada Agency Warns of Imports' Dangers*, BOSTON GLOBE, Nov. 8, 2003, at Business, D1.

import services such as Illinois Governor Rod Blagojevich.[72] Governor Blagojevich has sought to re-import drugs from Canada in order to save money for the state and has been joined by New York City Mayor Michael Bloomberg in petitioning the FDA to loosen its restrictions to permit drug importation.[73]

A. RxDepot Enjoined from Activity

After hearing testimony on the injunction issue, U.S. District Judge Claire Eagan of the Northern District of Oklahoma enjoined RxDepot from conducting its business.[74] Judge Eagan ordered the stores and website closed and ordered the company to notify its customers, among other things, that the "safety of the drugs obtained through [RxDepot] cannot be assured."[75] The court did, however, convey a sense of empathy toward the people caught up in this battle: the consumers. Judge Eagan said the court was "not unsympathetic to the predicament faced by individuals who cannot afford their prescription drugs," but that the company's policies violated federal laws.[76] In essence, the court stated that although it could understand the plight of people who may have to make sacrifices to afford their medications, the issue must be addressed by Congress and not by a company attempting to circumvent federal regulations.[77]

B. RxDepot Responds

RxDepot president Carl Moore obviously took notice of the court's ruling; however, the decision clearly impacted his business. Some speculated that if the injunction were to be granted, Moore would "take a loss"[78] because the profits from the company, in which store operators received about an eight percent commission for each sale, were reinvested in the company.[79] According to RxDepot's attorney, Fred

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72. *See id.*

73. *See* Press Release, Illinois Government News Network, Mayor Michael R. Bloomberg Joins Illinois Governor Rod Blagojevich In Petitioning the FDA To Let States and Cities Import Prescription Drugs From Canada (Oct. 29, 2003) *available at* http://www.illinois.gov/PressReleases/ShowPressRelease.cfm?SubjectID=6&RecNum=2351 (last visited Feb. 15, 2005).

74. *See Rx Depot*, 290 F. Supp. 2d at 1250-52.

75. *See* Brian Barber, *RxDepot Ordered to Close All Stores*, TULSA WORLD, Nov. 7, 2003, at A1.

76. *Id.* (quoting *RxDepot*, 290 F. Supp. 2d at 1248.

77. *Id.*

78. Barber, *supra* note 7, at A1.

79. *See* Killackey, *supra* note 1, at 1A.

Stoops, the company plans to ask for a stay of the injunction while it appeals its case to the United States Circuit Court of Appeals for the Tenth Circuit.[80] However, the company conceded that its prospects were dim if the injunction was not stayed; Stoops stated that if it is not "the company is essentially out of business."[81] Judge Eagan ruled against RxDepot's stay of the injunction on November 12, 2003.[82] The decision to deny a stay of the injunction was made because the court found that "there is not a substantial likelihood [the] defendants will succeed on appeal."[83]

The FDA, on the other hand, viewed the decision as a positive step in ensuring that the drugs that enter the United States are safe for the public. The decision will only bolster its resolve to face cities and state agencies that attempt to establish procedures to import cheaper drugs for their employees.[84] There was some confusion in 2003 about whether the FDA would target Springfield, Massachusetts for its importation program to provide its employees with Canadian-purchased drugs.[85] The FDA's director, William Hubbard, made a statement in November 2003 that although the FDA was not targeting Springfield at that time for legal action, it would not rule out the possibility.[86] The statement that the FDA says it is not sure of its course of action may have seemed contradictory to Springfield Mayor Michael Albano k—because the agency had pursued companies such as RxDepot that had clearly imported less-expensive drugs.[87]

The injunction against RxDepot may have been a starting point rather than a final decision for the FDA in dealing with imported drugs. While the FDA may have been victorious in its quest to protect the American public by effectively shutting down RxDepot, how will it face cities and states that want to save money by importing drugs? Where will brand-name companies stand during this battle? Most importantly, where does this leave the uninsured or under-insured American who has

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80. *See* Barber, *RxDepot Could Surrender Fight*, Nov. 8, 2003, at A15.

81. *Id.*

82. *See Rx Depot*, 297 F. Supp. 2d at 1311.

83. *Id.* at 1309.

84. *See* Christopher Rowland, *FDA Mulls Drug-Import Action: Agency Says It May Charge States, Cities*, BOSTON GLOBE, Nov. 7, 2003, at D2.

85. *See id.* As of September 5, 2004, the FDA had not pursued legal action against Springfield, and its imported drug program was scheduled to begin October 1, 2004. *See* John Laidler, *City to Offer Medications from Canada: Program to Start Oct. 1 for Workers and Retirees*, BOSTON GLOBE, Sept. 5, 2004, at Globe North, 1.

86. *See* Rowland, *supra* note 84, at D2.

87. *See id.*

to make sacrifices to pay for his or her medications? Perhaps the RxDepot ruling is only the beginning of the fight for the FDA.

C. U.S. Department of Health & Human Services Report on Importation

In 2004, the United States Department of Health and Human Services (HHS) created a special task force to investigate drug importation and its effects on patients and medical costs.[88] As previously stated, the FDA has taken the position that imported drugs could pose a health hazard and has sought legal action to address what it sees as a major problem. The HHS task force seeks to not only address the FDA's concern, but also to investigate how drug importation could affect the intellectual property rights of drug manufacturers.[89]

In December of 2004, the HHS task force released a report on prescription drug importation.[90] In the report, the HHS addressed, among other issues, how drug importation would affect intellectual property right holders.[91] It stated that those who "import[] a patented drug into the United States could be liable for patent infringement."[92] Although it may seem that patent holders would be subject to the exhaustion[93] of their patent rights after the sale of their product, in August 2001 the United States Circuit Court of Appeals for the Federal Circuit held in *Jazz Photo Corp. v. International Trade Commission*[94] that a drug that is manufactured for export for its first sale is not subject

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88. *See* Press Release, United States Department of Health & Human Services, HHS Names Members to Task Force on Drug Importation (Mar. 16, 2004), *at* http://www.hhs.gov/news/press/2004pres/20040316.html (last visited Feb. 15, 2005).

89. *See id.*

90. *See* Press Release, United States Department of Health & Human Services, HHS TASK FORCE ON DRUG IMPORTATION (Dec. 2004), *at* http://www.hhs.gov/importtaskforce/Report1220.pdf 9 (last visited Feb. 15, 2005).

91. *See id.* at 91. The HHS report stated that, "it is clear that importation could impact the intellectual property rights of developers of pharmaceutical products and could be subject to challenge under domestic law, including possibly the U.S. Constitution, and international intellectual property rules." *Id.*

92. *See id.* at 91. The report also cited *Jazz Photo Corp. v, Int'l Trade Comm'n*, 264 F.3d 1094 (Fed. Cir. 2001) in which the Federal Circuit decided that intellectual property rights were not exhausted if a drug was manufactured by the patent holder, and exported for a first sale that was abroad. *Id.* at 96.

93. Exhaustion is the concept that intellectual property rights "may be exhausted with respect to a particular good when that good is placed on the market by or with the consent of the rights owner." DINWOODIE *supra* note 25, at 1222. Essentially, once an intellectual property rights owner places his or her goods on the market, the "owner may not assert its intellectual property rights to restrain the free transfer of those goods." *Id.* For more information on the exhaustion doctrine, see generally *id.* at 1222-23.

94. 264 F.3d 1094 (Fed. Cir. 2001).

to the exhaustion doctrine. In the report the HHS thus makes the point that importation of drugs not subject to the first sale rule might subject those who are involved to liability for patent infringement.[95]

With respect to intellectual property, in the report, the HHS makes the final recommendation that importation of drugs poses a threat to intellectual property right holders and is not reconcilable with current patent law.[96] It suggests that current and pending legislation that provide for drug importation would "require major changes in current U.S. laws and international agreements."[97] However, the HHS did state that although it recognizes that changes to current laws would have to be made, the "issues are considerably beyond the functions [] handled by HHS, and are not primarily within its public health expertise."[98]

V. IS THE FDA HELPING OR HURTING THE PUBLIC?

Prescription drugs are vital to the practice of medicine. However, as health care costs increase and people find themselves without prescription drug benefits, there is growing concern about how individuals will cheaply and safely obtain the medicines they need. In the United States, the FDA is the agency in charge of making sure the drug supply is safe for the public. It is not improper to think of the agency as the "food taster" that existed during the Middle Ages. If a manufacturer wants to market a drug, the FDA "tastes" the drug and determines if it is allowable. It is a safeguard, similar to a watchdog, that the public relies on for their own safety. However, what happens when the "taster" or "watchdog" is actually causing the public to suffer? That, arguably, is the case with the RxDepot situation.

When the FDA, through the DOJ, shut down RxDepot's operation, legislators[99] and people with expensive medication regimens cried foul.[100] For example, Jerry Cox, a fifty-two year old heart transplant patient said "the ruling would take food from his family,"[101] and "[t]he federal government has put a lot of people like me a in a very bad spot."[102] It is

95. *See generally* 35 U.S.C. § 271(a).

96. *See* HHS TASK FORCE ON DRUG IMPORTATION, *supra* note 88, at 96.

97. *Id.*

98. *Id.*

99. *See* Tony Pugh, *FDA accused of favoring drug industry*, MERCURY NEWS, Oct. 15, 2003, *at* http://www.bayarea.com/mld/mercurynews/news/politics/7021660.htm (last visited Feb. 15, 2005).

100. *See* Barber, Nov. 7, 2003, *supra* note 75, at A1.

101. *Id.*

102. *Id.*

very interesting to notice that Mr. Cox feels that he is being harmed by the very agency that claims to have protected him from unsafe medications. It is easy to see the irony in this situation.

But why do people who are involved with this situation feel that they are being let down by the "watchdogs" of prescription drugs in this country? Perhaps it is because some people feel that the brand-name pharmaceutical industry has too much influence over the government. Additionally, people may feel that the FDA, the "watchdog" of the American public, is really catering to brand-name pharmaceutical companies' desires to keep drug prices high. RxDepot's attorney Fred Stoops shared this view when he stated, "[i]n the United States, the pharmaceutical industry is a government-sanctioned monopoly."[103]

So why have the major pharmaceutical companies allowed the FDA to take these measures to stop companies such as RxDepot from conducting their business? If the brand-name companies are concerned that an imported drug enters the United States without filing an ANDA, why do they not sue foreign suppliers of the drug? One answer could be that the FDA's actions are quicker and cheaper than patent litigation. For example, suppose RxDepot was supplying U.S. customers with a generic equivalent of a drug that was not FDA approved and that infringed a patent because it was of the same crystalline structure as a brand-name company's. The brand-name company might have a cause of action against the manufacturer if the equivalent infringed the brand-name's claims. The brand-name company would sue, and the matter could result in litigation that would be costly and time-consuming.

On the other hand, when the FDA takes an interest in the matter and uses its authority to obtain an injunction on the grounds that the imported drugs may put the public at risk, the action is much quicker. RxDepot was effectively shut down in a matter of months[104] and the matter was resolved much faster than if the brand-name companies had tried to sue unauthorized companies who wished to import their drugs in violation of patent laws. Thus, it may be to the advantage of the brand-name drug companies to allow the FDA to act in its capacity rather than for them to pursue litigation on their own.

Brand-name companies have an interest in protecting their intellectual property rights, but they should not assume that they are completely protected from losing profits to re-imported drugs from Canada because current law favors them. Considering the rising costs of

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103. Barber, Nov. 8, 2003, *supra* note 80, at A15.

104. *See* Barber, Nov. 7, 2003, *supra* note 75, at A1.

health care and rising number of Americans relying on prescription drugs as they age, it is possible that proposals such as the one by Illinois Governor Blagojevich[105] could eventually become a reality. If importation laws are relaxed and companies such as RxDepot are allowed to conduct business in the future, how will the brand-name companies fight to protect their intellectual property?

As previously mentioned, the FDA has made it a mission to protect Americans from potential counterfeits. This is not to say that the FDA is disregarding the American public's safety. As already stated, the FDA has well-documented proof of counterfeit or unapproved drugs being found in Canada that could have made their way into the United States.[106] "In May 2003, nearly 20 million doses of fake Lipitor®[107] . . . [were removed] from US pharmacy shelves."[108] The threat of counterfeit drugs on the market is certainly a problem that the FDA must address and take measures to protect the public; however, it is clear that the FDA's actions through the DOJ harm Americans who are simply looking for a way to afford the medications they need. This issue speaks to a larger problem; when an agency whose purpose is to protect, in fact, harms the neediest.

VI. CONCLUSION

Perhaps these events are a sign that the problem of affordability of prescription medications must be addressed here in the United States. Instead of relying on another country's price control measures for prescription drugs, Congress should seek to find a way to bring balance to the situation and make the drugs more affordable to the public.

The Hatch-Waxman provision of the Food, Drugs, and Cosmetics Act[109] reduces the cost of generic drugs to the public by allowing generic manufacturers to save money by demonstrating that their generic version is equivalent to the brand-name version of a drug.[110] If Congress were to relax the strict infringement rules that exist for pharmaceutical patents, generic drugs could break into the market and bring balance to pricing plans. This would increase the affordability of some medications

105. *See* Press Release, Illinois Government News Network, *supra* note 73.

106. *See* Rowland, *supra* note 71, at D1.

107. Lipitor® (atorvastatin calcium) is drug for the reduction of cholesterol levels in patients, and is manufactured by Pfizer, Inc. Information on Lipitor® can be found at Welcome to Lipitor.com, *at* http://www.lipitor.com (last visited May 14, 2005).

108. Kontnik, *supra* note 5, at 46.

109. *See* 21 U.S.C. § 355.

110. *See id.*

to patients. The Hatch-Waxman Act was an important step in breaking generic drugs into the market; however, it should not be the end. If Congress could take this step, it should continue by perhaps relaxing the standards for patent infringement of drugs when an ANDA is involved. Additionally, Congress should seek to find a way to mandate compulsory licensing for pharmaceuticals to generic drug companies that would willingly make their products available to people who need the drugs the most but may not have the coverage to pay for the drugs.

However, the intellectual property rights of brand-name companies must be protected as well. It would be unwise and unfair to force a company to take losses on a product that it has spent significant amounts of money researching and developing. Additionally, brand-name drug manufacturers should not have to worry about counterfeit products entering the United States and putting the public at risk.

Thus, a balance is needed, and the issue should be explored to help determine a course of action that benefits all the interested parties. Patients must be able to afford their prescription medications. The focus on intellectual property rights by brand-name companies and safety of the public by the FDA must also be considered, but the patients the companies intend to serve and the public the FDA intends to protect should not be forgotten or made victims of price wars.

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