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# In Search of the Golden Years: How Compulsory Licensing Can Lower the Price of Prescription Drugs for Millions of Senior Citizens in the United States

Debjani Roy

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IN SEARCH OF THE GOLDEN YEARS: HOW COMPULSORY  
LICENSING CAN LOWER THE PRICE OF PRESCRIPTION  
DRUGS FOR MILLIONS OF SENIOR CITIZENS IN THE  
UNITED STATES

I. INTRODUCTION .....	468
II. HISTORICAL OVERVIEW OF AMERICAN PHARMACEUTICAL PATENTS AND COMPULSORY LICENSING .....	471
A. <i>Patents and the American Pharmaceutical Industry</i> ...	471
B. <i>The Non-Compete Function of Patents</i> .....	472
C. <i>Adoption of Compulsory Licensing in the United States</i> .....	472
III. ANALYSIS OF THE 2003 MEDICARE REFORM ACT .....	473
A. <i>Introduction</i> .....	473
B. <i>A Closer Look at the Prescription Drug Benefit</i> .....	474
C. <i>Canadian Importation of Legal Prescription Drugs</i> ...	476
1. State and Local Governments Propose Canadian Drug Importation Plan.....	477
2. The Food and Drug Administration’s Response to Importation: <i>United States v. Rx Depot</i> .....	478
IV. UNITED STATES’ ENDORSEMENT OF COMPULSORY LICENSING DURING A NATIONAL CRISIS.....	481
A. <i>International Law Recognizes Compulsory Licensing as a Price-Lowering Measure</i> .....	482
1. The United States is Bound to the Agreement on Trade Related Aspects of Intellectual Property Rights.....	482
2. The United States is in a National Crisis.....	483
B. <i>United States Case Law Supports Compulsory Licensing as an Antitrust Remedy</i> .....	484
1. <i>Hartford-Empire Co. v. United States</i> .....	484
2. <i>American Cyanamid v. United States</i> .....	485
3. <i>United States v. Glaxo Group</i> .....	487
C. <i>Responding to Arguments Against Compulsory Licensing</i> .....	487
1. Compulsory Licensing is Extortion.....	487
2. Compulsory Licensing Compromises American Patent Laws and Stifles Business Judgment.....	489

V.	COMPULSORY LICENSING WITH REASONABLE ROYALTIES IN ACTION.....	489
A.	<i>The Creation of a Tripartite Health Care Commission</i> .....	490
1.	The Organizational Structure .....	490
2.	Implementing Compulsory Licensing in the United States .....	491
B.	<i>Beneficial Alliance with the Indian Pharmaceutical Industry</i> .....	492
1.	Continuous FDA-Supervision Can Allay Product Safety Concerns .....	492
2.	Indian Drug Manufacturers and Self-Sufficiency Through Higher Profits .....	493
a.	<i>Responding to General Criticism Against Outsourcing</i> .....	493
b.	<i>Outsourcing Benefits the Pharmaceutical Industry and India</i> .....	496
VI.	CONCLUSION.....	497

#### I. INTRODUCTION

His face was so peaceful—quiet and peaceful. Finally, the pain from the cancer that had metastasized from his colon had subsided. His wife knew that it was the morphine; he was, however, so much at peace now. Fifty-seven years ago in a faraway land, she promised him that she would not remove her wedding ring. The pain and torture that they suffered during the Depression and the War were tests to see if they could weather the trials and tribulations of life. After their children moved away, they would live the last years of their lives traveling the South Pacific to recapture their youth. They knew their children would take care of them. Their country, for which they had sacrificed so much, would help them. Patriotism, self-reliance, and hard work: those principles defined the American way. Foolish dreams built on a foundation of quick sand. They had spent \$2,300 last year on the medicine alone.<sup>1</sup> They had neither a deductible nor a “real” prescription drug plan. They could not afford the premiums. Medicare was there, but it was not enough. Pawning the ring that she had worn for fifty-seven loving years was the only way . . .<sup>2</sup>

<sup>1</sup>Patricia Barry, *Chasing Drugs: Many Readers Take Drastic Steps to Get Prescription Medicine*, Oct. 2003, available at [http://www.aarp.org/bulletin/prescription/Articles/a2003-09-29chasing\\_drugs.html](http://www.aarp.org/bulletin/prescription/Articles/a2003-09-29chasing_drugs.html) (on file with author). Senior citizens are spending on average \$2,300 a year on prescription drugs and are trying to save money by carrying out some very dangerous methods. *Id.*

<sup>2</sup>See Barry, *supra* note 1. The above fictitious account is inspired by Ms. Barry’s article that describes how a seventy-two year-old Pennsylvania woman actually sold her wedding ring to pay for her prescription drugs. See generally *Medicare Reform Carries Huge Fiscal Toll*, CHRISTIAN SCI. MONITOR, Oct. 17, 2003, available at <http://www.aarp.org/bulletin/news/>

Unfortunately, the above account is one of many that are occurring every day to senior citizens throughout the United States.<sup>3</sup> The high cost of prescription drugs and the depletion of social security benefits plague this country's elderly.<sup>4</sup> Consequently, many seniors travel across the border to Canada or to Mexico to find cheaper prescription drugs.<sup>5</sup> There are Americans who believe, however, that those who go abroad for their medicine are unpatriotic.<sup>6</sup>

In recent years, international health organizations have proposed the adoption of compulsory licensing to bring down the price of prescription drugs by allowing the creation of generic drugs for AIDS, tuberculosis, and malaria to be used throughout the developing world.<sup>7</sup> In response to these concerns, the World Trade Organization declared that member states could grant compulsory licenses to respond to the serious epidemic that has spread throughout much of the developing world.<sup>8</sup> India, Brazil, and other emerging markets have developed the technology necessary to create these generic drugs.<sup>9</sup> Multinational pharmaceutical companies, however, wish to block the manufacture and sale of generic versions of their brand-name drugs in these markets because they fear that the loss of profits will adversely affect the amount of money necessary for research and development of new drugs.<sup>10</sup>

This article will show that compulsory licensing is the best remedy for the escalating cost of prescription drugs in the United States. Under section forty-five of the Federal Trade Commission Act, the Federal Trade Commission ("FTC") can impose compulsory licensing of certain patented drugs that are necessary for the immediate benefit of public health and welfare if the pharmaceutical patent holder has "[used] unfair methods of competition in commerce and unfair or deceptive acts

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Articles/article.htm (on file with author). This article highlights Congressional cost-benefit analysis of the Medicare Reform Act. *Id.*

<sup>3</sup>*Id.*

<sup>4</sup>*Id.*

<sup>5</sup>See Paul Egan, *Michigan May Buy Canada Drugs; Granholm Seeks Solutions As Costs Climb To \$1 Billion State Orders Studies*, DETROIT NEWS, Oct. 1, 2003, at 1B. Michigan is studying Canadian importation proposals devised by Illinois, Minnesota, Massachusetts, and Iowa regarding the purchase of prescription drugs from Canada. *Id.*

<sup>6</sup>Barry, *supra* note 1, at 4.

<sup>7</sup>*The Declaration on the TRIPS Agreement and Public Health*, (WT/MIN (01)/DEC/2 20 November 2001) [hereinafter *Doha Declaration*]. In November 2001, the World Trade Organization met at Doha, Qatar and jointly declared that member states would issue compulsory licenses of certain brand name drugs to drug manufacturers to create cheaper prescription drug alternatives for victims of AIDS/HIV and other catastrophic diseases in developing and low-income countries. Hence, this declaration has been called the "Doha Declaration." *Id.* In August 2003, the World Trade Organization met in Geneva, Switzerland and established a plan on how the compulsory licenses would be issued to drug manufacturers to create generic drugs for the developing world. *See also Indian Pharmaceuticals: Patently Ambitious*, ECONOMIST, Sept. 6, 2003, at 56 [hereinafter, "*Indian Pharmaceuticals*"].

<sup>8</sup>*Doha Declaration*, *supra* note 7, at ¶ 5(b).

<sup>9</sup>*Indian Pharmaceuticals*, *supra* note 7, at 56.

<sup>10</sup>*Id.*

or practices in commerce.”<sup>11</sup> This article will show that multinational pharmaceutical companies can decrease the adverse effects of compulsory licensing on their profit margins if they license Indian pharmaceutical companies, whose manufacturing and labor costs are much lower than their U.S. counterparts, to create cheaper generic drugs for American consumer consumption.

The following analysis will be divided into six main sections. Section II will provide a historical overview of American pharmaceutical patent law and will introduce the concept of compulsory licensing as a method to decrease the high cost of prescription drugs for senior citizens in the United States.<sup>12</sup> Section III will look at the newly enacted Medicare Prescription Drug and Modernization Act, (“Medicare Reform Act”), and state and local government plans to import cheaper brand-name prescription drug from Canada.<sup>13</sup> Section IV will look at the United States’ international support for compulsory licensing, as seen with the signing of the Agreement on Trade Related Aspects of Intellectual Property Rights. Next, this section will show that United States case law supports the implementation of compulsory licensing when a corporation has violated antitrust laws.<sup>14</sup> Finally, this section will respond to arguments that have been made against compulsory licensing.<sup>15</sup> Section V will propose the creation of a tripartite health care

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<sup>11</sup>Federal Trade Commission Act, 15 U.S.C. § 45(a)(1), (a)(6) (2003). See *Doha Declaration*, *supra* note 7; see also The General Council Chairperson’s Statement, World Trade Organization, (Aug. 30, 2003), available at [http://www.wto.org/english/news\\_e/news03\\_e/trips\\_stat\\_28aug03\\_e.htm](http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm) (detailing how compulsory licensing can provide developing countries cheaper generic drugs if they do not have the capability to make the medicine themselves). See generally Dora Kriparuri, *Reasoned Compulsory Licensing: Applying U.S. Antitrust’s “Rule of Reason” to TRIPS’s Compulsory Licensing Provision*, 36 NEW ENG. L. REV. 669 (2002) (applying the American “Rule of Reason” in antitrust cases to decide when to apply compulsory licensing). This article is a great resource for anyone searching for U.S. cases that support the use of compulsory licensing against corporations that violate antitrust laws.

<sup>12</sup>See generally Jean O. Lanjouw, *A New Global Patent Regime for Diseases: U.S. and International Legal Issues*, 16 HARV. J. L. & TECH. 85 (2002). This article provides a model that would ensure a higher protection of patents in some parts of the world and lower patent protection in areas where prescription drugs are needed to respond to AIDS/HIV-related diseases. See also Kriparuri, *supra* note 11.

<sup>13</sup>See Medicare Prescription Drug and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066 (2003) [hereinafter “Medicare Reform Act”]; see also *Medicare Overhaul: How It May Affect You*, PLAIN DEALER (Cleveland), Nov. 25, 2003, at A1, A10 (explaining the provisions of the Medicare Reform Bill as passed by the House of Representatives). See also Egan, *supra* note 5, at 1B (reporting that Springfield, Massachusetts has implemented an on-line purchase plan this year for current and retired city employees “through CanaRx...at an estimated annual savings of more than \$4 million”). See also Tim Harper, ‘Buy Canada’ Drug Plan Sweeping U.S., TORONTO STAR, Oct. 26, 2003, at A06.

<sup>14</sup>See *Harford-Empire Co. v. United States*, 323 U.S. 386 (1945); *American Cyanamid Co. v. Fed. Trade Comm’n*, 363 F.2d 757 (6th Cir. 1966); *United States v. Glaxo Group Ltd.*, 410 U.S. 52 (1973).

<sup>15</sup>See Haochen Sun, *A Wider Access to Patented Drugs Under the TRIPS Agreement*, 21 B.U. INT’L L.J. 101 (2003); Stephen Barnes, Note, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*, 91 KY. L.J. 911 (2002); Merrill Matthews, Jr., *The*

commission (“Commission”) that will implement compulsory licensing in the United States and will sponsor legislation that responds to the health care crisis in the United States. Additionally, this section will propose that the multinational pharmaceutical companies license patents to, and enter into outsourcing agreements with, Indian pharmaceutical companies to reduce manufacturing costs, which will eventually balance the profit-making interests of pharmaceutical companies with the health care interests of the American public.<sup>16</sup> Section VI will conclude this analysis and restate the idea that America’s elderly deserve better treatment from their country and that compulsory licensing and an alliance with the Indian pharmaceutical industry are effective remedies for bringing down the high costs of prescription drugs in America.

## II. HISTORICAL OVERVIEW OF AMERICAN PHARMACEUTICAL PATENTS AND COMPULSORY LICENSING

### A. *Patents and the American Pharmaceutical Industry*

A patent is a federally granted exclusive right to an inventor to manufacture, use, or sell his “novel, useful, and nonobvious” invention for a fixed period of time that begins after the patent application has been filed.<sup>17</sup> In essence, the patent gives the patent holder a legal monopoly over the invention because the patent prevents anyone, other than the inventor, from using, selling, or making the invention.<sup>18</sup>

Suppose American pharmaceutical company Cosmore develops a new cholesterol-lowering drug.<sup>19</sup> The drug has met the “novel, useful, and nonobvious” criteria of a patentable invention.<sup>20</sup> From the moment of filing the application for the patent, Cosmore will have exclusive rights to the drug for twenty years.<sup>21</sup> This means that only Cosmore can profit from the manufacture, advertising, and sale of the drug for the next twenty years.<sup>22</sup> As a result, no other company or inventor can attempt to manufacture and sell the same drug for the life of the patent without the permission of Cosmore, the exclusive patent holder.<sup>23</sup> Therefore, patents are an important factor for progress and innovation in this country.

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*Ethical Dilemmas of Prescription Drug Reimportation*, IDEAS: INNOVATIVE INSIGHTS ON TODAY’S POLICY DEBATES, May 2003, available at <http://www.ipi.org>.

<sup>16</sup>*Indian Pharmaceuticals*, *supra* note 7.

<sup>17</sup>35 U.S.C. §§ 101-103 (2003). See also Myra Hart, Howard Zaharoff & Joshua Lerner, *The Protection of Intellectual Property in the United States*, HARV. BUS. SCH. No. 9-897-046 (Rev. Mar. 1998). Utility and plant patents have a twenty-year life span and design patents have a fourteen-year life span. *Id.* at 5. The inventor becomes the right holder or patent holder once he gets patent. *Id.*

<sup>18</sup>Hart, Zaharoff & Lerner, *supra* note 17.

<sup>19</sup>Hypothetical facts created by author.

<sup>20</sup>35 USC §§ 101-103 (2003). See generally Hart, Zaharoff & Lerner, *supra* note 17.

<sup>21</sup>Hart, Zaharoff & Lerner, *supra* note 17, at 5.

<sup>22</sup>See, e.g., Harper, *supra* note 13, at A06.

<sup>23</sup>Hart, Zaharoff & Lerner, *supra* note 17.

*B. The Non-Compete Function of Patents*

There are advantages to owning a patent. Patents protect individual inventors who have no ties with multinational drug manufacturers against “deliberate misappropriation and good-faith origination of the same or similar inventions.”<sup>24</sup> Thus, with a patent, a new inventor can establish credibility and gain recognition in his respective industry to attract larger research grants for the development of new products.<sup>25</sup>

Patents benefit the inventor and the public who will use or consume the patented invention. Suppose Cosmore has a patent on a cholesterol-lowering drug. Doctors find that the Cosmore drug is more effective than any other drug on the market;<sup>26</sup> therefore, they begin prescribing the drug to more patients.<sup>27</sup> In turn, Cosmore sells more of the drug. Thus, sales of the drug generate more profits for further research and development to create other drugs that can work even better for patients than the current drug can.<sup>28</sup>

The accumulation of higher revenues for research and development is an important advantage of patents. This exclusive patent protection means, however, that the patent holder can charge whatever price he wants. Moreover, a growing phenomenon is that revenue intended for research and development is actually being spent on advertising, marketing, public relations, and administration.<sup>29</sup> According to Illinois Governor Rod Blagojevich, “since the [Food and Drug Administration] relaxed advertising restrictions for U.S. drug manufacturers in 1997, spending on advertising jumped from \$719 million to \$2.5 billion annually.”<sup>30</sup> Therefore, while patents are advantageous in some respects, these advantages have been exploited by some businesses for pure profits and market control.<sup>31</sup>

*C. Adoption of Compulsory Licensing in the United States*

Compulsory licensing should be adopted in the United States because the skyrocketing costs of pharmaceutical drugs are an immediate public health care concern for millions of senior citizens.<sup>32</sup> The high cost of prescription drugs in the United

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<sup>24</sup>*Id.* at 8.

<sup>25</sup>*Id.*

<sup>26</sup>See Hart, Zaharoff & Lerner, *supra* note 17, at 2. This article explains that patents reward the ingenuity and the risks that inventors undertake to create new products and processes.

<sup>27</sup>*Id.*

<sup>28</sup>Barnes, *supra* note 15. “Without patent protection, pharmaceutical development would lose its profitability and ultimately its momentum.” *Id.* at 911.

<sup>29</sup>Harper, *supra* note 13.

<sup>30</sup>*Id.*

<sup>31</sup>*Id.*

<sup>32</sup>Barry, *supra* note 1, at 2 (reporting that senior citizens are sometimes using dangerous methods to cope with the high cost of pharmaceutical drugs); see also *Medicare Reform*, *supra* note 2.

States is adversely affecting the ability of many senior citizens to purchase necessary medicine.<sup>33</sup> Reports indicate that, on average, each senior citizen spends \$2,300 a year on prescription drugs.<sup>34</sup> In a large number of cases, these senior citizens do not have a suitable prescription drug plan that will pay for their expenses.<sup>35</sup> Furthermore, the recent enactment of the Medicare Reform Act has prohibited on-line purchases from many foreign sources, including Canada, where price controls have kept the cost of prescription drugs down to levels 50 to 75 percent lower than their American equivalents.<sup>36</sup> Therefore, compulsory licensing provides a swift solution to this health care crisis because it forces pharmaceutical companies to license important drug patents for the immediate manufacture of cheaper generic drugs.

### III. ANALYSIS OF THE 2003 MEDICARE REFORM ACT

Before the proposal for compulsory licensing with reasonable royalties is made, this section will look more closely at the Medicare Reform Act and how the prescription drug benefit will work.

#### A. Introduction

On December 8, 2003, President George W. Bush signed into law the Medicare Reform Act.<sup>37</sup> In theory, the Medicare Reform Act provides forty million Medicare recipients a newly revised health care plan with a prescription drug benefit.<sup>38</sup> In reality, after thirty-eight years of waiting and depleting hard-earned retirement savings on medical expenses and daily prescription drugs, seniors face a fiasco. The prescription drug benefit that was originally priced at \$400 million, prior to its passage two months ago, has been recalculated and projected to cost at least \$530 million in ten year—an increase of one-third.<sup>39</sup> More shockingly, even with this increased spending, Federal Medicare officials are finalizing their decision on whether to pay for all uses of some important cancer drugs.<sup>40</sup> Many in the medical field fear that the decision to not cover certain drugs will set a dangerous precedent that may have serious repercussions on the treatment of many diseases in this country.<sup>41</sup>

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<sup>33</sup>Barry, *supra* note 1; *see also Medicare Reform, supra* note 2.

<sup>34</sup>Harper, *supra* note 13.

<sup>35</sup>*Id.*; *see also Barry, supra* note 1; *Medicare Reform, supra* note 2.

<sup>36</sup>*See* Patricia Barry, *More Americans Go North For Drugs*, Apr. 2003, at <http://www.aarp.org> (on file with author); *see also infra* Chart 2 and accompanying note 64.

<sup>37</sup>Medicare Reform Act, *supra* note 13.

<sup>38</sup>*Id.*

<sup>39</sup>Robert Pear, *Bush's Aides Put Higher Price Tag on Medicare Law*, N.Y. TIMES, Jan. 30, 2004, at A1, A15.

<sup>40</sup>Gardiner Harris, *U.S. Weighs Not Paying For All Uses Of Some Drugs*, N.Y. TIMES, Jan. 30, 2004, at C1, C5.

<sup>41</sup>*Id.*



Many legislators from both the democratic and republican parties argue that the prescription drug benefit was a gift to the multinational drug manufacturers and pharmaceutical industry lobbies.<sup>42</sup> Conversely, drug manufacturers extol the Medicare Reform Act as “the most important, pro-patient Medicare reform in the program’s [thirty-eight] year history.”<sup>43</sup> To better understand the arguments for and against the new Medicare prescription drug benefit, the following section will analyze its various provisions and then discuss the option of importing prescription drugs from Canada.

### B. A Closer Look at the Prescription Drug Benefit

The purpose of the *voluntary* prescription drug benefit is to provide medicine to Medicare recipients at reasonable prices.<sup>44</sup> There are, however, serious concerns about whether the drug plan is worthwhile. The following will shed light on the provisions of the drug plan by defining who is covered, how much is covered, and what costs are associated with each.

First, all eligible Medicare recipients and eligible Medicaid recipients will be eligible for this drug benefit. For the first time, low-income seniors who were not eligible for Medicaid will have an opportunity to receive the prescription drug coverage.<sup>45</sup> The following chart will describe how the new change in benefits will affect low-income beneficiaries.

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<sup>42</sup>See generally Press Release, Edward M. Kennedy, Senator Edward M. Kennedy Intr[od]uces The Health Security and Affordability Act, (Jan. 22, 2004), at <http://kennedy.senate.gov>, (on file with the author) [hereinafter, Kennedy Press Release]; Donald L. Bartlett & James B. Steele, *Why We Pay So Much For Drugs*, TIME, Feb. 2, 2004, at 11-12; Ceci Connolly, *Drugmakers Protect Their Turf*, WASH. POST, Nov. 21, 2003, at A04 (on file with author).

<sup>43</sup>Alan F. Holmer, Statement by Alan F. Holmer, President and CEO, PhRMA, on Signing of the Medicare Prescription Drug Benefit into Law, (Dec. 8, 2003), at <http://www.phrma.org> (on file with the author).

<sup>44</sup>Medicare Reform Act, *supra* note 13; Patricia Barry, *The New Medicare And You*, AARP BULLETIN, Jan. 2004, at 16-18, 20. This informative article uses sources from inside and outside the American Association of Retired Persons to explain the impact the Medicare Reform Act will have on Medicare recipients. The author indicates that although the drug benefit is voluntary, the government encourages early enrollment to avoid higher premium penalties. *Id.* “The [government’s] rationale is to ensure that healthy as well as sick beneficiaries take part, spreading the insurance risk so costs are held down and the program remains viable.” *Id.* at 16.

<sup>45</sup>Elizabeth Auster, *Prescription Drug Plan Nears Senate Approval*, PLAIN DEALER (Cleveland), Nov. 25, 2003, at A1, A10. Republicans have argued that the new drug benefit provides low-income seniors “who are not poor enough to be eligible for Medicaid,” to have access to drug coverage for the first time. *Contra* Susan Jaffe, *Plan To Cost Ohio’s Poorest Seniors More For Drugs*, PLAIN DEALER (Cleveland), Nov. 25, 2003, at A10. According to Ohio Republican Sen. Mike DeWine and health care advocates, the Medicare drug benefit will provide less coverage for low-income seniors than their Medicaid counterparts. Edwin Park, senior health policy analyst at the Center on Budget and Policy Priorities in Washington, D.C. said, “People could be paying more and getting fewer drugs covered.” *Id.* “For the poorest of the poor, this is not a benefit . . . What they have now is much better than what they will get,”

CHART 1: Outline of Coverage for Qualified Low-Income Beneficiaries<sup>46</sup>

Income Level and assets (subject to inflation) for individuals (i) and couples (c)	In 2006, enrollee will receive health coverage from	Premiums and deductibles (to start in 2006)	Drug co-payments for generic drugs (g) and brand-name drugs (b) for a thirty-day prescription
Under \$9,630 (i) and under \$13,000 (c)	Medicare and Medicaid	No premiums and no deductibles	\$1(g) and \$3(b)
Up to \$13,000 (i) (with assets below \$6,000) and up to \$17,550 (c) (with assets below \$9,000)	Medicare	No premiums and no deductibles	\$2(g) and \$5(b)
Up to \$13,000 (i) (with assets from \$10,000) and up to \$17,550 (c) (assets from \$20,000)	Medicare	No premiums but \$50 deductible	15 percent(g) & 15 percent(b)
Up to \$14,450 (i) (with assets from \$10,000) and up to \$19,500 (c) (with assets from \$20,000)	Medicare	Sliding scale	Sliding Scale

While coverage for low-income individuals appears to be quite expansive, the new prescription drug plan will not cover all the out-of-pocket expenses for prescription drugs, which was common under Medicaid.<sup>47</sup> Therefore, the new prescription drug benefit will require everyone to pay out-of-pocket costs—even the poorest of the poor.<sup>48</sup>

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said Gail Long, director of Merrick House, “which serves 4000 seniors and other residents of Cleveland’s near West Side.” *Id.*

<sup>46</sup>Barry, *supra* note 44, at 17. Fortunately, qualified low-income citizens will not have to suffer from the consequences of the gap in coverage that many middle- and higher-income seniors will have to undergo.

<sup>47</sup>Jaffe, *supra* note 45, at A10.

<sup>48</sup>Auster, *supra* note 45; Jaffe, *supra* note 45.

Second, the plan establishes co-payments and premiums for prescription drug coverage on a graduated scale for middle-income and higher-income citizens.<sup>49</sup> In general, beginning in January 2006,<sup>50</sup> after *each* beneficiary has paid a \$250 deductible, he will be required to pay 25 percent for all prescription drugs up to \$2,250.<sup>51</sup> Then, once the beneficiary has personally spent \$3,600 in prescription drug costs, plus \$1,500 in premiums, the drug benefit will cover as much as 95 percent of all remaining costs.<sup>52</sup>

As the figures indicate, for all drug costs between \$2,250 and \$3,600, there will be no drug coverage available for most beneficiaries. This “doughnut hole” in coverage is another point of contention for opponents of the Medicare Reform Act.<sup>53</sup> For an average fixed-income couple that spends \$2,300 each on prescription drugs, adding up to \$4,600, this “doughnut hole” is increasingly burdensome because the plan requires that each beneficiary spend \$3,600 before he or she can receive the subsequent benefit.<sup>54</sup> To worsen matters, Medicare has forbidden the purchase of a supplemental drug benefit that will “fill in” the gap.<sup>55</sup> For this reason, many states are looking into importing prescription drugs from Canada where prices are considerably cheaper due to government-imposed price controls. (See *infra* Section IV.C.)

While the drug benefit attempts to provide better prescription drug coverage, the costs of the plan have raised great concern for bipartisan legislators and health care advocates.<sup>56</sup>

### C. Canadian Importation of Legal Prescription Drugs

Following the lead of many American seniors, many state and local governments have either implemented or are devising prescription drug plans in association with Canadian pharmacies to provide cheaper prescription drugs for their state citizens. For example, Springfield, Massachusetts has already begun importing prescription

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<sup>49</sup>Barry, *supra* note 44.

<sup>50</sup>*Id.* at 18. Until the plan becomes effective, in June 2004 through 2005, the federal government is providing any interested recipients a discount card that will help alleviate some of the cost of prescription drugs. The discount card will give a \$600-a-year credit for qualified low-income beneficiaries. *Id.*

<sup>51</sup>*Id.*

<sup>52</sup>*Id.*

<sup>53</sup>*Id.*

<sup>54</sup>*Id.* See also *Medicare Overhaul: How It May Affect You*, PLAIN DEALER (Cleveland), Nov. 25, 2003, at A1, A10. This article answers similar questions that senior citizens may have about the Medicare Reform Act and provides information from *CCH Inc.*, *Scripps Howard News Service*, and *Cox News Service*.

<sup>55</sup>Barry, *supra* note 44, at 18. In spite of the large gap in coverage, “the new law will not allow [the beneficiary] to have both the Medicare drug benefit and a medigap policy that includes drug benefits.” The author notes, however, that “retiree benefits from former employers could be used to fill in these gaps.” *Id.*

<sup>56</sup>*Id.*; Auster, *supra* note 45; Jaffe, *supra* note 45.

drugs from CanaRx Services, a Canadian on-line pharmacy located in Windsor, Ontario, for 1,600 of its insured city employees, retirees, and their dependents.<sup>57</sup> In one year alone, savings have been estimated at \$4 to \$9 million.<sup>58</sup> Despite the advantages of importation to so many seniors and fixed-income citizens, the U.S. Food and Drug Administration, (“FDA”), has moved to enjoin Canadian on-line pharmacies from supplying prescription drugs to Americans. The FDA’s rationale is that Canadian imports pose health risks to the consumer because improper shipping and handling pose the risk of contamination.<sup>59</sup> This section will analyze the FDA’s response to importation in view of the recent Oklahoma district court decision in *United States v. Rx Depot*.<sup>60</sup>

#### 1. State and Local Governments Propose Canadian Drug Importation Plan

Illinois, Michigan, Massachusetts, Vermont, Wisconsin, Iowa, California, New York, Kentucky, and Minnesota are all following Springfield, Massachusetts’s lead and are seriously looking into the importation of prescription drugs from Canada to battle the high cost of drugs being sold by the U.S. manufacturers.<sup>61</sup> All these states are chanting the need for cheaper prescription drugs for their citizens. With the recent passage of the Medicare Reform Act, which prohibits the federal government from negotiating drug prices, all these states see Canada as the immediate solution.<sup>62</sup> In fact, in 2002 alone, Canadian drug imports “topped \$700 million (U.S.) . . . a [fifty-fold] increase over three years.”<sup>63</sup> The following chart shows the price differential of a typical prescription in the United States and in Canada.

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<sup>57</sup>Elizabeth Mehren, *City Finds A Cure For Drug Costs in Canada*, L.A. TIMES, Nov. 1, 2003; Harper, *supra* note 13. “The average savings for the city [of Springfield] on each prescription is 40 per cent, but can range as high as 80 per cent . . . with its ‘Buy Canada Plan.’” *Id.*

<sup>58</sup>*Id.*; Egan, *supra* note 5, at 2; see also Christopher Rowland, *Democrats Embracing Drug Imports Presidential Hopefuls Hit Firms Amid Rising Interest in the Issue*, B. GLOBE, Nov. 6, 2003, at C1 (focusing on the favorable positions of the various Democratic Presidential candidates regarding prescription drug imports from Canada).

<sup>59</sup>Press Release, *FDA Strengthens Controls, Issues Consumer Alert On Importing Certain Prescription Drugs*, FDA NEWS, Dec. 9, 2002, available at <http://www.fda.gov/bbs/topics/news/2002/NEW00856.html> [hereinafter *FDA Press Release*]; Egan, *supra* note 5; Harper, *supra* note 13.

<sup>60</sup>290 F. Supp. 2d. 1238 (N.D. Okla. 2003).

<sup>61</sup>Harper, *supra* note 13; Egan, *supra* note 5; Mehren, *supra* note 57.

<sup>62</sup>Medicare Reform Act, *supra* note 13, at subpart 2(i) provides as follows:

(i) Noninterference.—In order to promote competition under this part and in carrying out this part, the Secretary—(1) may not interfere with the negotiations between drug manufacturers and pharmacies and [Prescription Drug Plan] sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

Medicare Reform Act, *supra* note 13.

<sup>63</sup>Harper, *supra* note 13.

CHART 2: Price Differential of Top-Selling Brand-Name Prescription Drugs in the United States and Canada<sup>64</sup>

Brand-Name Drug	United States (US \$)	Canada (US \$)
Lipitor (Pfizer)	\$272 to \$308	\$159 to \$199
Zocor (Merck)	\$372 to \$451	\$198 to \$244
Prilosec (AstraZeneca)	\$108 to \$126	\$62 to \$81
Procrit (Johnson & Johnson)	\$282	N/A
Norvasc (Pfizer)	\$128 to \$150	\$113 to \$136
Zyprexa (Eli Lilly)	\$526 to \$616	\$358 to \$433
Paxil (GlaxoSmithKline)	\$243 to \$309	\$152 to \$189
Prevacid (TAP Pharmaceutical)	\$382 to \$450	\$181 to \$210
Celebrex (Pfizer)	\$145 to \$177	\$63 to \$71
Zoloft (Pfizer)	\$222 to \$248	\$140 to \$172

Therefore, state and local governments want to establish plans that would permit the legal importation of Canadian drugs to provide their citizens with cheaper prescription drugs. This in turn will create considerable savings to state government health care budgets because they will be able to recoup some of the costs associated with subsidized prescription drug plans.<sup>65</sup>

2. The Food and Drug Administration's Response to Importation:  
*United States v. Rx Depot*

Responding to concerns about the safety of Canadian legal prescription drug imports, in late October, Illinois Governor Rod Blagojevich announced recent research findings that showed "that Canadian pharmacies were as safe as those in the U.S." and in some cases more safe.<sup>66</sup> The FDA and the multinational drug companies disagree and warn that unmonitored importation of foreign-manufactured drugs pose health risks. Thus, the FDA and the drug companies are targeting the American retail pharmacies that have entered into joint ventures with Canadian pharmacies to sell Canadian drugs in retail stores in the United States or through the Internet. GlaxoSmithKline has threatened to cut supplies to Canadian sellers that reimport American-manufactured drugs.<sup>67</sup> Eli Lilly has threatened criminal

<sup>64</sup>Bartlett & Steele, *supra* note 42, at 11-12 (investigating the reasons why prescription drugs cost more in the United States, dissecting the arguments made for and against importation, and providing financial statistical comparisons among the U.S. and several other countries).

<sup>65</sup>For more information regarding Michigan Governor Jennifer M. Granholm's state health care plan, see generally <http://www.michigan.gov> (last visited Aug. 18, 2004).

<sup>66</sup>Mehren, *supra* note 57.

<sup>67</sup>Jackie Judd, *Closing Options: Drug Companies, FDA Move To Block Import Of Low-Cost Canadian Prescriptions*, ABC NEWS, Mar. 13, 2003, available at <http://www.abcnew.go.com> (on file with author).

prosecution of Canadian wholesalers that defy the Food, Drug, & Cosmetic Act.<sup>68</sup> The FDA has already begun prosecuting retail stores that import or reimport prescription drugs from Canada.<sup>69</sup> *United States v. Rx Depot* illustrates the troublesome logic of the FDA's arguments against the importation of foreign-made drugs.<sup>70</sup>

Rx Depot, Inc. and Rx of Canada (collectively, "Rx Depot") are retail pharmaceutical suppliers, incorporated under the laws of Nevada, that operate eighty-five stores throughout Canada and the United States and serve 800 customers a day through their on-line service and/or through brick and mortar sales.<sup>71</sup> Its sales procedure is as follows: Once an Rx Depot customer has submitted his doctor's prescription and the requisite credit check and health information forms, a Canadian doctor then rewrites the prescription and submits that prescription to a Canadian pharmacy that fills the order according to that prescription.<sup>72</sup>

In *Rx Depot*, the FDA sued Rx Depot in Oklahoma federal district court to enjoin it from continuing to import and sell pharmaceutical drugs from Canada.<sup>73</sup> The district court held that Rx Depot was guilty of violating a federal law intended to protect the public health and safety. Thus, the court ordered a preliminary injunction against Rx Depot that would prohibit it from continuing to import and sell prescription drugs from Canada.<sup>74</sup>

Interestingly, while the overriding issue of the case was a *per se* violation of a federal statute, the court dedicated a large portion of its opinion to the purported dangers of importing drugs from Canada. Even though these arguments are made in dicta, they are, nevertheless, significant because they provide a faulty legal foundation for arguments against importation. The court's rationale is based on four questionable allegations made by the FDA.<sup>75</sup>

First, the FDA alleged, and the court agreed, that the manufacturing and storage safety guidelines used to produce Canadian imports are less predictable. Therefore, according to the FDA, Canadian imports may cause more adverse side effects on American consumers than the FDA-sanctioned guidelines for drugs manufactured and obtained in the U.S.; that is, because the imported drugs are not continuously monitored by the FDA.<sup>76</sup> Conversely, at a June 2003 bipartisan congressional

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<sup>68</sup>*Id.*; see Food, Drug, and Cosmetic Act, 21 U.S.C. § 331 (2003).

<sup>69</sup>*Rx Depot*, 290 F. Supp. 2d. at 1240.

<sup>70</sup>*Id.* at 1238.

<sup>71</sup>*Id.* at 1240.

<sup>72</sup>*Id.* at 1241.

<sup>73</sup>*Id.* at 1239.

<sup>74</sup>*Rx Depot*, 290 F. Supp. 2d. at 1247-50.

<sup>75</sup>*Id.* at 1241-43.

<sup>76</sup>*Id.* at 1241-42. Specifically, the court finds that "the drugs may be contaminated, counterfeit, or contain erratic amounts of the active ingredient or different excipients. Also, the drugs may have been held under uncertain storage conditions, and therefore be outdated or subpotent." *Id.* (emphasis added).

hearing on the issue of the safety of legal prescription drugs imported from Canada, Associate FDA Commissioner William Hubbard denied that Americans have been hurt from adverse effects of Canadian drug imports.<sup>77</sup> When Senators Dan Burton, (D-Indiana), and Gil Gutknecht, (R-Minnesota), asked Mr. Hubbard to present corroborative examples that showed that American consumers had been injured from imported Canadian legal prescription drugs, Mr. Hubbard answered that he had no such evidence.<sup>78</sup> Therefore, the FDA lacked concrete evidence that inferior Canadian manufacturing and storage safety standards pose a threat to public health.

Second, the court insisted that Rx Depot's frequent mistakes, in supplying more pills than prescribed, may cause unintentional overdose because the American patient could "take a drug for many days more than their physicians intend without supervision."<sup>79</sup> While this allegation is troubling, it is also based on an unproven presumption. The court presumes that the threat of overdose is prevalent in the United States only because foreign pharmacies are giving patients more pills than are prescribed by the patient's doctor. Actually, the American Association of Retired Persons ("AARP") reported that some senior citizens are trying to save money on prescription drugs purchased in the United States by consuming pills of a higher strength—taking forty (40) mg as opposed to the prescribed twenty (20) mg because they cost the same—and then skipping doses to accommodate for the higher strength.<sup>80</sup> Therefore, the allegation that purchasing medication from foreign sources, rather than domestic sources, can lead to danger is seriously misleading to the American public.

Third, the court found that, although no one has been harmed by any legal drugs imported by Rx Depot, this fact "does not diminish the legitimate safety concerns of the FDA."<sup>81</sup> As Mr. Hubbard explained above, there is no evidence that legal drugs imported via Rx Depot or any other Canadian source have injured anyone. By comparison, American statistics show that "[each] year an estimated 50,000 to 100,000 people die as a result of adverse reactions from FDA-sanctioned pharmaceutical drugs sold in the [United States]."<sup>82</sup> Therefore, this allegation of potential future harm to American customers of Rx Depot is also unjustified.

Fourth, the court found that an undercover investigation of Rx Depot's quality control revealed that the packaging of "foreign-manufactured version of Serzone, known as APO-Nefazodone," a particularly dangerous anti-depression drug, did not

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<sup>77</sup>Bartlett & Steele, *supra* note 42, at 6-7.

<sup>78</sup>*Id.*

<sup>79</sup>*Rx Depot*, 290 F. Supp. 2d. at 1242.

<sup>80</sup>Barry, *supra* note 1. For more on splitting pills, please refer to <http://www.aarp.org/bulletin/prescription/Articles/g2003-09-30-splittingpills.html>, which provides a guide on the "Do's and Don'ts of Splitting Pills".

<sup>81</sup>*Rx Depot*, 290 F. Supp. 2d. at 1242.

<sup>82</sup>Bartlett & Steele, *supra* note 42, at 6; *see* FDA Press Release, *supra* note 59: "According to a 1999 report by the Institute of Medicine, medical errors in hospitals alone cause annually 40,000 to 98,000 deaths. The IOM has estimated that preventable adverse events cost the United States economy \$17 billion a year." *Id.*

contain the requisite warning inserts that intake could cause liver failure.<sup>83</sup> Unlike the third allegation discussed above, substantial evidence of the dangers of the drug supports this allegation; therefore, Rx Depot's failure to warn the consumer against adverse effects of the drug is a *per se* statutory violation. The court used this omission to show that the FDA's health and safety standards are superior to those of many foreign countries, including Canada.<sup>84</sup> In the case of Serazone, the FDA's superior standards are somewhat questionable. While the FDA has only required that a stamp be placed on the drug's packaging, which warns the American patient of the drug's dangerous side effects, Canada has banned the use and sale of the drug completely.<sup>85</sup> Canada banned the domestic sale of Serazone after the drug patent holder Bristol-Meyers announced that it would withdraw the drug from Europe and Canada.<sup>86</sup> Therefore, although Rx Depot's failure to warn patients of the dangers of Serazone was an illegal act, the court's reliance on the superiority of the FDA's standards as a reason to ban importation of drugs is faulty.

*Rx Depot* affirms the United States' contrary stance on importation of legal prescription drugs from Canada as a remedy for the high cost of prescription drugs in the United States. For this reason, compulsory licensing provides the most immediate relief to millions of seniors as they await a final decision on the issue of importation.

#### IV. UNITED STATES' ENDORSEMENT OF COMPULSORY LICENSING DURING A NATIONAL CRISIS

*Rx Depot* affirms the United States' current policy of banning commercial importation of drugs from Canada as illegal and non-discretionary; thus, a federal policy that allows commercial importation is not a viable and immediate option that can help lower the cost of prescription drugs for millions of seniors.<sup>87</sup> Because many

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<sup>83</sup>*Rx Depot*, 290 F. Supp. 2d. at 1242-44.

<sup>84</sup>*Id.* at 1243. The court's tone used to criticize the Canadian instructions is not justified: "For example, the Canadian instructions do not specify some of the liver failure symptoms listed on the Serazone insert, do not mention drugs that should be avoided when taking APO-Nefazodone, and do not convey the sense of urgency reflected in the Serazone insert. *These substandard instructions* could increase the risk of adverse events . . ." *Id.* (emphasis added). The court ignores the importance of communication between doctors and patients when certain treatments have potentially dangerous side effects.

<sup>85</sup>Bartlett & Steele, *supra* note 42, at 7; see FDA Press Release, *supra* note 59. The FDA released this statement in December of 2002, five months prior to its undercover purchase through Rx Depot. Serazone is not listed on the Import Alert list.

<sup>86</sup>Bartlett & Steele, *supra* note 42.

<sup>87</sup>*Rx Depot*, 290 F. Supp. 2d. at 1248. "FDA's personal importation policy outlines specific circumstances in which the agency generally will decline to prosecute the illegal importation of small quantities of prescription drugs by individuals. By its express terms, this policy of enforcement discretion does not apply to commercial operations such as Rx Depot." *Id. Contra* Hughes v. Alexandria Scrap Corp., 426 U.S. 794 (1976) (holding that a state statute can discriminate against out-of-state suppliers if the state does so as a market participant and refrains from regulating the whole market structure itself). State and local legislation that permit the state and local government to enter into supply agreements with



in the federal government believe that health care should be available for senior citizens, a federally mandated plan to lower prescription drug costs must be immediately implemented. Thus, compulsory licensing with reasonable royalties is the measure that can meet this need.

The United States has recognized compulsory licensing with reasonable royalties as an appropriate remedy for antitrust violations in an international and a national context. The following section will look at the United States' international and national endorsement of compulsory licensing, and then respond to arguments made against compulsory licensing in an American context.

*A. International Law Recognizes Compulsory Licensing as a Price-Lowering Measure*

1. The United States is Bound to the Agreement on Trade Related Aspects of Intellectual Property Rights

As a founding signatory of the World Trade Organization ("WTO") and the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS Agreement"), the United States recognizes compulsory licensing with reasonable royalties to combat high prescription drug costs in the international arena.<sup>88</sup>

Upon signing the TRIPS Agreement, the United States agreed that the federal government may "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development."<sup>89</sup> This provision is a recognized endorsement of compulsory licensing of patents.<sup>90</sup>

Moreover, in November 2001, while meeting in Doha, Qatar, the WTO expressly declared that member states could grant compulsory licenses for patented pharmaceutical drugs to respond to a national crisis ("Doha Declaration").<sup>91</sup> In fact, paragraph four of the Doha Declaration states that the TRIPS Agreement should be interpreted to support "WTO Members' right to protect public health, and in particular, *to promote access to medicine for all.*"<sup>92</sup> Furthermore, paragraph five, section (b) affirms that each Member of the TRIPS Agreement "has the right to grant

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retail pharmacies in Canada could be protected under the Market Participant Exception of the Dormant Commerce Clause.

<sup>88</sup>See INTERNATIONAL TREATIES ON INTELLECTUAL PROPERTY 585-87 (Marshall A. Leaffer, ed., 2d ed., 1997). On April 15, 1994, in Marrakesh, 112 countries, including the United States, Canada, and India, formed the World Trade Organization. *Id.* at 585. Article II of the Marrakesh Agreement that established the World Trade Organization bound all member states to the Agreement on Trade Related Aspects of Intellectual Property Rights.

<sup>89</sup>Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81, art. 8, § 1 (1994) [hereinafter *TRIPS*].

<sup>90</sup>Kripauri, *supra* note 11, at 3.

<sup>91</sup>*Doha Declaration*, *supra* note 7, at ¶ 5(b), (c).

<sup>92</sup>*Id.* at ¶ 4 (emphasis added).

compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”<sup>93</sup>

As a member of the international community, the United States agrees that compulsory licensing is an appropriate remedy for national crises. Since the United States signed the TRIPS Agreement, it must implicitly recognize compulsory licensing for its citizens as well.

## 2. The United States is in a National Crisis

The World Trade Organization has left defining “national crisis” to the member state because each country has defined “crisis” according to its own circumstances.<sup>94</sup> The current health crisis in the United States is a major concern for Americans today.<sup>95</sup> Legislators and public interest groups have been trying for years to respond to the rising cost of prescription drugs and hospital care.<sup>96</sup> Forty million Medicare recipients in this country are looking for a solution.<sup>97</sup> In 2002, the median income for senior citizens in this country was \$13,994.<sup>98</sup> As mentioned above, the new prescription drug benefit prohibits seniors from purchasing supplemental prescription drug plans to bridge the coverage gap.<sup>99</sup>

These indicators fall within the scope of a national crisis as described by the Doha Declaration, which the United States has internationally endorsed. As the Doha Declaration states, nations must “promote access to medicine for all” and to do this, they can order compulsory licensing of important patented drugs to meet the public’s needs. In the United States, the rising cost of pharmaceutical drugs has prevented millions of people access to necessary medication.<sup>100</sup> Many seniors have been taking desperate measures to cope with this problem, such as, foregoing medical treatment, skipping doses and splitting pills.<sup>101</sup> Therefore, under international law, the United States has the power to implement compulsory licensing in order to respond to the health care crisis.

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<sup>93</sup>*Id.* at ¶ 5(b).

<sup>94</sup>*Id.* at ¶ 5(b), (c).

<sup>95</sup>Kathleen Pender, *Study: Fewer Companies Offering Pensions*, S.F. CHRON., Nov. 23, 2003 (reporting that there are more retired persons than employed persons and that the available funds in retirement pensions have been shrinking).

<sup>96</sup>*See, e.g.*, Kennedy Press Release, *supra* note 42.

<sup>97</sup>Barry, *supra* note 1.

<sup>98</sup>*Income of the Elderly Population*, EBRI Notes Executive Summary, Nov. 2003, at <http://www.ebri.org/notesx/1103note.htm>.

<sup>99</sup>Barry, *supra* note 44, at 18.

<sup>100</sup>*See, e.g.*, *Pfizer Statement on Maine Rx Ruling*, PR NEWSWIRE, May 22, 2003.

<sup>101</sup>Barry, *supra* note 1.

*B. United States Case Law Supports Compulsory Licensing as an Antitrust Remedy*

Often, the United States' international position is not aligned with its national stance on particular issues.<sup>102</sup> Fortunately, the United States case law has historically accepted compulsory licensing of patented products to respond to serious antitrust violations. This section will analyze three cases that have established compulsory licensing as an appropriate solution to unfair commercial trade practices in the United States: (1) *Hartford-Empire Co. v. United States*; (2) *American Cyanamid v. United States*, and (3) *United States v. Glaxo Group*.

1. *Hartford-Empire Co. v. United States*

*Hartford-Empire Co. v. United States* is a seminal case that dealt with patent misuse and the imposition of compulsory licensing as a proper judicial remedy.<sup>103</sup>

The Supreme Court held that compulsory licensing with reasonable costs and royalties can be imposed against a corporation if its "system of restricted licensing" prohibits the "invention" of a product, prevents "the manufacture and sale or licensing of" that product, "suppresses competition" and establishes a price-fixing scheme.<sup>104</sup> The Supreme Court said that compulsory licensing "covers every kind of invention and every patent, present or future, in any field if owned or controlled or distributed by [the violating corporation]."<sup>105</sup> Thus, the Supreme Court recognized that compulsory licensing with reasonable royalties is an acceptable antitrust remedy.<sup>106</sup>

*Hartford* illustrates when compulsory licensing with reasonable royalties is an appropriate-, and sometimes only, remedy to stop corporations from destroying the free market system.<sup>107</sup> Twelve major glass-manufacturing companies created an oligopoly by combining their exclusive patents on important glass manufacturing equipment designs.<sup>108</sup> The oligopoly unfairly restricted individual glass manufacturers from competing in the industry because it collusively held these patents.<sup>109</sup> Eventually, the oligopoly controlled 94 percent of the glass manufacturing equipment industry.<sup>110</sup>

Compared to *Hartford*, the multinational pharmaceutical companies are pursuing unfair trade practices because they are misusing their patent rights to restrict competition in the American market and are prohibiting international legal

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<sup>102</sup>Examples include the International Court of Justice, the Kyoto Agreement on CO<sub>2</sub> emissions, and the 1997 Mine Ban Treaty.

<sup>103</sup>323 U.S. at 400-02.

<sup>104</sup>*Id.* at 400, 419.

<sup>105</sup>*Id.* at 422-23.

<sup>106</sup>*Id.* at 419-23.

<sup>107</sup>*Id.* at 392, 400.

<sup>108</sup>*Id.*

<sup>109</sup>*Id.*

<sup>110</sup>*Id.*

prescription drugs sales to American citizens.<sup>111</sup> This anticompetitive behavior is adversely affecting consumers' ability to purchase cheaper prescription drugs.<sup>112</sup> The recent controversies that surrounded the eventual passage of the Medicare Prescription Drug and Modernization Act ("Medicare Reform Act") show that the major lobbying tactics of the pharmaceutical industry in the United States led to stricter efforts to prevent importation of cheaper prescription drugs from Canada and Europe, and moreover, the inclusion of a provision in the Act itself that "explicitly prohibits the federal government from negotiating prices on behalf of Medicare recipients."<sup>113</sup> In accordance with *Hartford*, the courts should order the pharmaceutical industry to license their patents to drug manufacturers to produce generic versions of certain patented drugs, which would reduce prescription drug prices. While limiting the exercise of patents will adversely affect shareholder wealth maximization and the amount of future investments, consumers make up another equally important constituency, which corporate governance requires pharmaceutical companies to recognize, because consumers are the end-users of the pharmaceutical companies' product.<sup>114</sup>

## 2. *American Cyanamid v. United States*

In *American Cyanamid v. United States*, the Sixth Circuit Court of Appeals considered several allegations of patent misuse and collusion against American Cyanamid, Pfizer, and three other multinational pharmaceutical companies.<sup>115</sup> First, the court considered whether American Cyanamid and Pfizer had made false and misleading statements to the U.S. Patent Office during an interference proceeding, which is a procedure that the patent office uses to determine which inventor has priority status over a specific invention; in this case, the invention was tetracycline.<sup>116</sup> Second, the court analyzed allegedly misleading testimony that American Cyanamid and Pfizer gave to the U.S. Patent Office to make sure that Pfizer received the patent on tetracycline.<sup>117</sup> Third, the court considered whether there was enough evidence to show that American Cyanamid and Pfizer had entered into a subsequent cross-licensing agreement.<sup>118</sup> Next, the court evaluated an alleged price fixing scheme that American Cyanamid, Pfizer and three other multinational

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<sup>111</sup>Patricia Barry, *Crackdown In Canada*, AARP BULLETIN, Feb. 2004, at 18. According to this article, Pfizer, Inc. has sent a letter to all Canadian pharmacies "threaten[ing] to cut off all supplies of its products to any pharmacy that helps the cross-border trade." *Id.*

<sup>112</sup>*Id.*

<sup>113</sup>Connolly, *supra* note 42; see Medicare Reform Act, *supra* note 13: "Subpart 2, Prescription Drug Plans" contains three paragraphs that make it illegal for the federal government from negotiating drug prices with drug manufacturers.

<sup>114</sup>See generally ROBERT A.G. MONKS & NELL MINOW, CORPORATE GOVERNANCE (2d ed. 2001).

<sup>115</sup>363 F.2d 757, 761-62 (6th Cir. 1966).

<sup>116</sup>*Id.*

<sup>117</sup>*Id.*

<sup>118</sup>*Id.*

pharmaceutical companies had established.<sup>119</sup> Finally, the court determined whether the activities of the five pharmaceutical companies had “the effect of hindering, foreclosing, and eliminating competition in the sale of antibiotics and . . . continue to have the dangerous tendency of creating a monopoly in Pfizer.”<sup>120</sup>

Although the court eventually vacated and remanded the case after the Commission was dismissed from the case because of a conflict of interest, the court relied on *Hartford* and other past precedent that recommended the restraint of the impervious quality of patent protection.<sup>121</sup> First, the court said that patent holders are prevented from creating monopolies that would adversely affect the public interest, which patents are designed to protect.<sup>122</sup> Thus, comparing the facts in *American Cyanamid*, currently, the pharmaceutical companies have returned to their collusive ways to accumulate profits to meet shareholder expectation by misusing their patent protection and charging unconscionable brand-name drug prices to millions of fixed-income Americans who are forced to pay for multiple prescriptions for various chronic and temporary ailments.<sup>123</sup>

Second, the court said private suits can be brought against patent holders under section four of the Clayton Act for Sherman Antitrust violations.<sup>124</sup> In the current era of soft-money donations and powerful special interest groups, senior citizens and other fixed income individuals need a strong public interest group that will be able to formidably fight for and win lower prescription drug prices for Americans.

Third, and most important, the court stated that compulsory licensing with reasonable royalties is a permissible antitrust remedy against patent misuse, especially when there is substantial evidence that a pharmaceutical patent holder has placed its own interests above the needs of the public that it truly serves.<sup>125</sup>

Therefore, *American Cyanamid* provides a persuasive method to determine how compulsory licensing with reasonable royalties can be imposed against the pharmaceutical industry.

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<sup>119</sup>*Id.*

<sup>120</sup>*Id.* at 762.

<sup>121</sup>*Id.* at 770-72.

<sup>122</sup> “[A] patent by its very nature is affect with a public interest . . . The far-reaching social and economics of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct . . .” *Id.* at 770 (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)).

<sup>123</sup> See *supra* Chart 2 and accompanying note 64.

<sup>124</sup> [T]hat private suits maybe instituted under [section four] of the Clayton Act to recover damage for Sherman Act monopolization knowingly practiced under the guise of a patent procured by deliberate fraud . . . Hence, as to this class of improper patent monopolies, antitrust remedies should be allowed room for full play. *Id.* at 770 (quoting *Walker Process Equipment, Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 179-80 (1965) (Harlan, J. concurring)).

<sup>125</sup> *Id.* at 771-72 citing *Hartford*, 323 U.S. at 386: “Compulsory licensing [with royalties] of patents by the courts for patent misuse is a permissible remedy in antitrust cases.”

### 3. *United States v. Glaxo Group*

Relying on *Hartford* and *American Cyanamid*, in *United States v. Glaxo Group*, the Supreme Court held that Glaxo Group (“Glaxo”) and Imperial Chemical Industries Ltd. (“ICI”) were guilty of *per se* restraint of trade in griseofulvin, which is used for fungal illnesses, because they would only sublicense patents on the dosage form of griseofulvin to those companies that would not sell the compound in bulk-form without Glaxo’s consent.<sup>126</sup> Consequently, the Court ordered mandatory sales and compulsory licensing against Glaxo and ICI.<sup>127</sup>

The Supreme Court held that if the public is in immediate need of a patented drug for its health and welfare, compulsory licensing would make patent holders sell the product in bulk, “create new competition among wholesalers, by enabling other companies to convert the bulk drug into dosage and microsize forms and sell to retail outlets, and would presumably lead to price reductions as the result of normal competitive forces.”<sup>128</sup>

Therefore, the pharmaceutical industry should take heed: While holding a patent is a constitutional privilege, using patents as economic leverage and self-interest will lead to major regulatory repercussions.

#### C. *Responding to Arguments Against Compulsory Licensing*

While U.S. case law supports the application of compulsory licensing with reasonable royalties when public interest outweighs commercial interests, its opponents still criticize its application.<sup>129</sup> This criticism has been concocted to scare the public, rather than help prevent and/or resolve the commercial abuse for which compulsory licensing was ordered in the first place. The following section responds to these arguments by showing the fallacies in each.

##### 1. Compulsory Licensing is Extortion

A commentator has equated compulsory licensing of pharmaceutical companies with a thief coming into the home of an unassuming homeowner and forcing him to either sell his possessions at whatever price the thief wants to pay, or else stand by and watch as the thief takes the items and sells them at a profit.<sup>130</sup> This description misleads the public, and obscures the main rationale for compulsory licensing in the United States. As U.S. case law has shown, the United States Supreme Court has declared that compulsory licensing is a recognized federal regulatory method to “vindicate the public interest”<sup>131</sup> from patent misuse<sup>132</sup> by a patent holder. Thus, the United States uses compulsory licensing as a remedy for anti-competitive behavior.

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<sup>126</sup>410 U.S. 52, 59-62 (1973).

<sup>127</sup>*Id.* at 60.

<sup>128</sup>*Id.* at 63.

<sup>129</sup>*See, e.g., Hartford*, 323 U.S. 386; *Am. Cyanamid*, 363 F.2d 757; *Glaxo*, 410 U.S. 52. *But see Matthews*, *supra* note 15.

<sup>130</sup>*Matthews*, *supra* note 15.

<sup>131</sup>*United States v. United States Gypsum Co.*, 333 U.S. 364, 388 (1948).

Compulsory licensing can provide a resolution to the current prescription-drug price war that has pitted proponents of pharmaceutical companies against numerous consumer advocates. The American drug manufacturers assert that Canadian and European governments have imposed price controls on prescription drugs that artificially keep prices down.<sup>133</sup> These price controls force American drug manufacturers to compensate for the loss of profits from international sales needed for new research and development by increasing the American prescription drug prices.<sup>134</sup> The pharmaceutical industry's objective is the same as the objective of any other product manufacturer: to sell its product with the hopes of maximizing profit and meeting shareholders' expectations.

While this aim may seem overly simplistic and selfish, the macroeconomic principle of supply and demand governs the way the market works.<sup>135</sup> According to the pharmaceutical industry, American drug prices are set at levels the market is willing to bear.<sup>136</sup>

Proponents of lower drug prices argue that the pharmaceutical companies have been unfairly taking advantage of the market pricing structure.<sup>137</sup> In recent months, the pharmaceutical industry has blocked legislation that would provide cheaper prescription drugs to senior citizens in this country.<sup>138</sup> For instance, the debates on the Medicare Reform Act reveal that the pharmaceutical industry forced the House of Representatives to drop a provision that would "allow Americans to legally import drugs from Canada and Europe, where medications retail for as much as 75 percent less than in the United States."<sup>139</sup>

Rather than vilifying one side and praising the other, compulsory licensing provides a balanced solution to this problem. Compulsory licensing with reasonable royalties offers smaller pharmaceutical companies the ability to compete in the market by allowing them to produce and sell cheaper generic versions of brand name drugs and provides the patent holder/licensor a share in the profits. Therefore, the

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<sup>132</sup>*Glaxo*, 410 U.S. at 71 n.5 (Rehnquist, J., dissenting); *see also* *Int'l Salt Co. v. United States*, 332 U.S. 392, 398-402 (1947); *Hartford*, 323 U.S. 386.

<sup>133</sup>Christopher Bowe, *US Attack on European Drug Price Controls*, FINANCIAL TIMES (London), Sept. 26, 2003, at 11 (offering a European perspective on the high American drug prices and responds to American criticism of the failure of European countries to spend more money on research and development).

<sup>134</sup>*Id.*

<sup>135</sup>Jerry Heaster, *Canadians Paying For Our Eagerness to Buy Their Drugs*, PLAIN DEALER (Cleveland), Nov. 23, 2003, at G3.

<sup>136</sup>*Id.*

<sup>137</sup>[The] clearest indication that the [Medicare Reform Act] offers a brighter future for the [pharmaceutical] industry came from Wall Street, where pharmaceutical stock prices [rose] . . . as the legislation's prospects for passage improved. Analysts at Goldman Sachs & Co. project the new Medicare benefit could increase industry revenue by 9 percent, or \$13 billion a year. Connolly, *supra* note 42.

<sup>138</sup>*Id.*

<sup>139</sup>*Id.*

extortion myth is false because compulsory licensing is a recognized remedy for anti-competitive practices that adversely affect public interest.

## 2. Compulsory Licensing Compromises American Patent Laws and Stifles Business Judgment

American pharmaceutical companies believe compulsory licensing infringes on their exclusive rights under U.S. and international patent laws.<sup>140</sup> The fears associated with compulsory licensing are understandable. American pharmaceutical companies can, however, and have already begun to, face the situation by joining forces with their counterparts in the developing world to protect their interests. In fact, in October 2003, GlaxoSmithKline (“Glaxo”) entered into a joint venture with Ranbaxy, India’s largest pharmaceutical company.<sup>141</sup>

The language of this joint venture stated: “Under the new alliance, Ranbaxy will identify promising potential drugs and perform early clinical trials in India, while [Glaxo] takes care of the later-stage development. For Glaxo, one benefit would be to accelerate the development of new products at lower cost.”<sup>142</sup> Although Glaxo will have exclusive commercial rights outside of India, there is the potential for Ranbaxy “to take part in joint promotion in the U.S. and Europe.”<sup>143</sup> Joint ventures and outsourcing with foreign pharmaceutical companies will help American pharmaceutical companies to efficiently use their financial resources for research and development, which will decrease the cost of the final end-product.<sup>144</sup> Therefore, compulsory licensing cannot be considered as detrimental to international patent laws as initially feared.

## V. COMPULSORY LICENSING WITH REASONABLE ROYALTIES IN ACTION

For compulsory licensing with reasonable royalties to work properly in the United States, this section makes two proposals. First, this section recommends the formation of a tripartite healthcare commission. Second, this section proposes an implementation strategy that encourages multinational drug companies to solidify their relationship with Indian drug manufacturers to help keep manufacturing costs down and profit levels up. The execution of these two recommendations will provide the United States with greater access to cheaper prescription drugs.

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<sup>140</sup>See generally <http://www.phrma.org>.

<sup>141</sup>*UK drugs giant in India tie-up*, BBC NEWS, Oct. 23, 2003, available at <http://www.bbc.co.uk/2/hi/business/3207169.stm>, (discussing the joint venture of a multinational pharmaceutical company and an Indian pharmaceutical company) [hereinafter, *UK-India tie-up*].

<sup>142</sup>*Id.*

<sup>143</sup>*Id.*

<sup>144</sup>*Id.*



*A. The Creation of a Tripartite Health Care Commission*

## 1. The Organizational Structure

A tripartite health care commission (“Commission”) should be formed to ensure that compulsory licensing with reasonable royalties is properly administered. The Commission will be composed of three main branches: (1) a Bipartisan Congressional Health Care Committee, (2) PhRMA, the pharmaceutical lobby, and (3) the American Association of Retired Persons, (“AARP”), the senior citizens’ lobby. Each branch will have its own function.<sup>145</sup> First, the Bipartisan Congressional Health Care Committee will propose legislation regarding compulsory licensing and foreign drug importation safety. Second, PhRMA, the pharmaceutical industry lobby, will act in its representative capacity to make sure that the reasonable needs of the pharmaceutical industry are met: balancing lower drug costs with the maintenance of optimal shareholder wealth maximization. Third, AARP, the senior citizens’ lobby, will act in its representative capacity to make sure that drug prices are affordable and accessible to all fixed income citizens. Each party will have 33 1/3 percent of the total voting rights in the Commission.

An ombudsman will act as a mediator among the legislators’ interests, the pharmaceutical industry’s interests, and the senior citizens’ interests to make sure that two of the parties do not place undue pressure on the third party to vote a certain way. Only in the event of a stalemate, will the ombudsman be given the right to cast the deciding vote on any bills that will be sent to Congress.

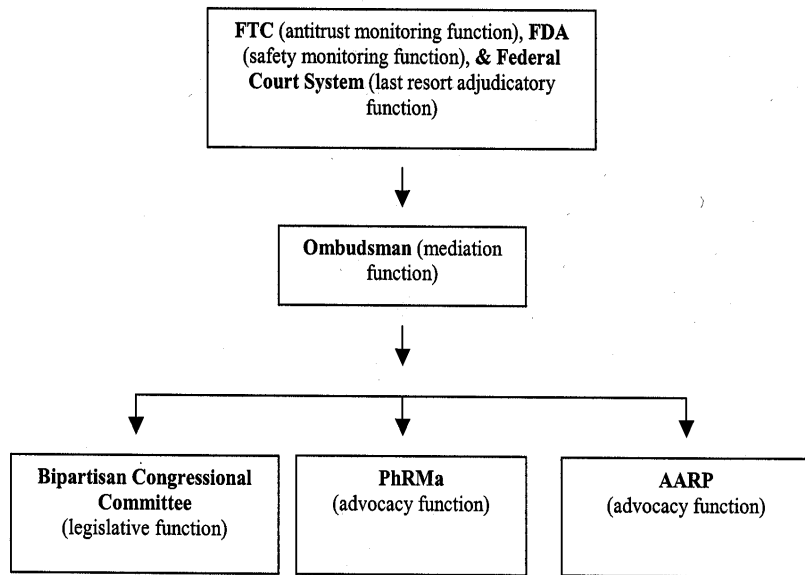
The Commission will be overseen by the Federal Trade Commission (“FTC”), which will monitor antitrust issues, and the FDA, which will monitor drug safety issues. All conflicts that cannot be resolved by the Commission and the ombudsman will be decided in the federal court system as a final resort mechanism.

Therefore, this organizational structure of the proposed Commission will provide an “equal access” forum for citizens and the pharmaceutical industry to meet, discuss, propose, and, then, implement market strategies that can provide affordable health care for citizens and guarantee adequate profit margins that generate research and development funds for innovative medicine. (The following chart presents how the Commission will be organized.)

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<sup>145</sup>The inspiration for this Commission comes from the U.S. Environmental Protection Agency’s (“EPA”) state implementation plans for solid waste management. The joint federal-state plan allows states to retain their autonomy while the U.S. EPA makes sure that the states are complying with federal environmental standards. *See generally* OLGA L. MOYA & ANDREW L. FONON, FEDERAL ENVIRONMENTAL LAW (2d ed. 2001).

CHART 3: Organizational Chart for the Tripartite Health Care Commission



## 2. Implementing Compulsory Licensing in the United States

To execute compulsory licensing with reasonable royalties properly, the Commission should establish a three-year plan with essential benchmarks. The benchmarks are dates when the cheaper generic drugs will be introduced into the American market. Because the newly enacted prescription drug benefit of the Medicare Reform Act will not become effective until 2006, the first benchmark should be met immediately. The newly-formed Commission should come together and determine which prescription drugs are most widely imported. Then, the multinational pharmaceutical companies ("licensor") must license the drug patents to FDA-approved drug manufacturers ("licensee"). While strict compliance to this strategy is essential to the effectiveness of compulsory licensing, the licensor should be given the flexibility to negotiate with the licensee an appropriate royalty for using the patent. Once a deal has been reached between the licensor and the licensee, the Commission will have the final approval of the licensing contract between the two parties to ensure that the goals of compulsory licensing as described in section IV are achieved.

The purpose of this measure is to provide low-cost prescription drugs for all current and future Medicare prescription-drug plan beneficiaries. For this reason, the amount of drugs produced under the compulsory licensing measure will be limited to a supply that meets the needs of Medicare beneficiaries. Therefore, senior citizens and other qualified fixed-income citizens will be the ones who benefit from this policy.

Compulsory licensing will not adversely affect the drug industry as much as has been reported. Recent press releases from the pharmaceutical industry reveal that the

drug industry is aware of the high cost of prescription drugs in this country.<sup>146</sup> In fact, even on the day that President Bush signed the Medicare Reform Act into law, many of the major drug manufacturers were offering need-based free and low-cost prescription drugs through their lobby website.<sup>147</sup> This pharmaceutical industry's public service effort proves that drug manufacturers are able to supply cheaper or free prescription drugs to the American consumer in spite of some loss of profits. Therefore, the pharmaceutical industry will be able to accommodate for the loss in profits caused by compulsory licensing.

### B. Beneficial Alliance with the Indian Pharmaceutical Industry

To ensure continued good faith compliance with the implementation strategy discussed in subsection A, the major drug manufacturers should decide which drug manufacturers they will grant the licenses to produce the cheaper generic drugs. The most beneficial business alliances are those that keep production costs down and sales profits up.<sup>148</sup> The Indian pharmaceutical industry provides the multinational drug manufacturers this benefit. The following section will respond to concerns regarding product safety and the expenditures related to constructing and maintaining manufacturing facilities in India, that is, if Indian pharmaceutical drug manufacturers are given licenses to produce generic drugs for the American market.

#### 1. Continuous FDA-Supervision Can Allay Product Safety Concerns

The FDA and drug manufacturers claim that legal drugs made in India for American consumption pose the risk of adverse side effects because the drugs are produced according to lower safety control standards. The FDA and the drug manufacturers can be assured strict quality control standards for two reasons. First, India's top two pharmaceutical companies, Ranbaxy, Ltd. and Dr. Reddy's, already supply Indian-made generic versions of drugs to the American market in compliance

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<sup>146</sup>See <http://www.pfizer.com> (last visited Aug. 18, 2004). Pfizer gives away free or cheaper drugs at a 37% discount to families with incomes less than \$31,000.

<sup>147</sup>See generally <http://www.phrma.org> (last visited Aug. 18, 2004). This site contains press releases from the pharmaceutical lobby regarding the Medicare Reform Act.

<sup>148</sup>*Pharmacia captures stake in Abbott India*, CHEM. MKT REPORTER, Feb. 4, 2002, at 3. Pharmacia, a multinational pharmaceutical company, increased its presence in the Indian pharmaceutical industry with its acquisition "of a 51.5 percent stake in Abbott Laboratories India Ltd. Abbott will maintain a strong position in the region through its majority ownership of Knoll Pharmaceuticals India Ltd." *Id.* This article also reaffirms the benefits of doing business with Indian pharmaceutical companies.

A Pharmacia spokesperson calls the acquisition "a long-term proposition" in an evolving market. "We are essentially trying to increase our business capabilities in a country that has a lot of potential in the region. India will have enforceable patent and intellectual property protection coming, WTO status and a middle class population with an income level that gives it access to the latest Western medicine," he adds.

Pharmacia gains the Ankleshwar, India-based manufacturing facility as well as licenses for some products sold by Abbott in India. Abbott will retain the rights to certain products, though details have not been announced. Abbott India Ltd. had sales of Rp.964 million for the fiscal year ending in March 2001.

*Id.*

with the strict standards of the FDA.<sup>149</sup> (Ranbaxy sells its generic version of Ceftin, an antibiotic drug. Dr. Reddy's sells its generic version of Eli Lilly's antidepressant Prozac.<sup>150</sup>) Therefore, Ranbaxy and Dr. Reddy's are proof that FDA-approved safety standards are already in place in India for those generic drugs that are imported into the United States.<sup>151</sup>

Second, the FDA can ensure that Indian drug imports comply with its safety guidelines by requiring the presence of an FDA-approved on-site inspector at all licensed Indian manufacturing facilities. The USDA regulates the import of foreign cattle and poultry for the American public with the constant monitoring of an on-site USDA inspector.<sup>152</sup> Similarly, the FDA can have an on-site FDA inspector at the various Indian manufacturing facilities that will monitor the production of those drugs that will be exported to the American market. This proposal is actually offering a stricter standard for imports than the current standard applied to foreign-manufactured brand-name drugs that are imported into this country by the large drug manufacturers themselves.<sup>153</sup> A recent investigation indicates that Americans are actually buying more and more prescription drugs that were manufactured under "minimal FDA oversight" at foreign facilities that are owned and operated by the big drug manufacturers.<sup>154</sup>

Therefore, if multinational drug companies grant licenses to Indian drug manufacturers who guarantee the continued presence of FDA inspectors during the manufacture of all drugs exported to the United States, imported drug safety concerns can be allayed.

## 2. Indian Drug Manufacturers and Self-Sufficiency Through Higher Profits

### *a. Responding to General Criticism Against Outsourcing*

In the 2004 presidential campaign, the candidates and their supporters made outsourcing (or *offshoring*) a hot-button issue.<sup>155</sup> From the Democrats' perspective, outsourcing has hurt the U.S. job market with the transfer of many service-oriented

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<sup>149</sup>Indian Pharmaceuticals, *supra* note 7, at 56.

<sup>150</sup>*Id.*

<sup>151</sup>*Id.*; see also Anu Saraf, *A Dose In Time*, BUS. INDIA, Dec. 22, 2003-Jan. 4, 2004, at 34-35 (on file with author) (discussing how India has become more serious about "tackling the problem of spurious, illegal and sub-standard drugs" and has upgraded its Central Drugs Standard Control Organization to the Central Drug Administration. The Central Drug Administration will be implemented in three phases; the first phase is expected to begin in late 2004.).

<sup>152</sup>See generally <http://www.fas.usda.gov/itp/ofsts/us.html> (providing general information on the USDA's importation standards).

<sup>153</sup>Bartlett and Steele, *supra* note 42, at 7.

<sup>154</sup>*Id.*

<sup>155</sup>Ken Belson, *Outsourcing, Turned Inside Out*, N.Y. TIMES, Apr. 11, 2004.

and manufacturing jobs to low-wage countries, such as India and China.<sup>156</sup> Furthermore, Democrats have shone a garish light on many U.S. corporations that have received tax breaks for outsourcing many U.S.-based jobs.<sup>157</sup> Republicans, industry insiders, and many economists view outsourcing as a necessary outgrowth of free trade that “drives investment in the U.S. economy and raises our standard of living by increasing consumer choice and creating better jobs.”<sup>158</sup> This section will first respond to some of the criticism made against outsourcing, and then explain how outsourcing the production of generic drugs to India will best implement the compulsory licensing strategy proposed.

Opponents of free trade attack U.S. companies that outsource jobs to lower-wage countries by highlighting many current realities that result from the forced displacement of U.S. workers. First, and foremost, critics of outsourcing highlight the displacement of well-educated and productive American workers for lower-paid Indian workers. While they agree that short term job loss is a “painful reality,”<sup>159</sup> economists and other proponents of free trade counter that many of the jobs being outsourced are low-skilled jobs “that lack prestige and suffer from high turnover rates,” such as call-center agents, in the United States.<sup>160</sup>

Economists alleviate some of the controversies associated with this argument by relying on the theories of absolute and comparative advantage to explain that the outsourcing of jobs using older technology helps generate resources that can be reinvested to create newer and more higher-valued jobs in effected industries. In its testimony to Congress in early part of 2004, the Council of Economic Advisors relied on Adam Smith’s theory of absolute advantage and said, “When a good or service is produced at a lower cost in another country, it makes sense to import it rather than produce it domestically. This allows the United States to devote its resources to more productive purposes.” For instance, in the 1980s, Japan took away the United States’ dominance of many segments of the semiconductor industry.<sup>161</sup>

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<sup>156</sup>Jonathan Weisman, *Democrats Seize On Offshoring As Campaign Issue; Focus On Jobs Lost During Recovery*, WASH. POST, Mar. 6, 2004, at E01; Jim Miller, *Outsourcing is Front Page News in 2003: Outsourcing is in the Public Eye as Politicians Debate the Lag in Job Growth Despite a Recovering Economy, and the Bush Administration Seeks to “Competitively Source” More Agency Activities; Outsourcing Outlook*, BIOPHARM INT’L, Oct. 1, 2003, at 20.

<sup>157</sup>Belson, *supra* note 155; *see also* Weisman, *supra* note 156. Sung Won Sohn, chief economist at Wells Fargo & Co., declared, “[O]utsourcing of jobs overseas may be playing a part in the job market’s stagnation, helping companies increase profitability and productivity while keeping hiring and wages depressed. With an economic recovery nearly three years old, the economy should be producing 200,000 to 300,000 jobs a month.” *Id.*

<sup>158</sup>Don Hicks, Commentary, *Dispelling The Myths of Outsourcing*, ROCKY MTN. NEWS (Denver), Jul. 30, 2004.

<sup>159</sup>Martin N. Bailey & Diana Farrell, *Exploding The Myths of Offshoring*, MCKINSEY Q., at <http://www.mckinseyquarterly.com> (July, 2004) (on file with author).

<sup>160</sup>*Id.* Critics will dispute that prestige is not as high a motivator in parts of the United States, where many workers must work two to three jobs a week to earn enough money for rising health care costs and other necessities.

<sup>161</sup>*Id.*

Consequently, Texas Instruments, Intel, and Motorola shifted their focus to newer technologies, such as cellular phone technology. Therefore, outsourcing of certain jobs generates higher-valued jobs.<sup>162</sup>

To counter the argument that many of the displaced U.S. workers could do better jobs than their Indian counterparts, economists rely on David Ricardo's comparative advantage theory. Although more difficult to grasp, in essence, the theory explains that the United States should outsource low-value businesses, such as insurance processing and telephone-call centers, and "concentrate on building up business like publishing and entertainment, where the displaced workers can be employed more productively."<sup>163</sup> In fact, research over the past twenty years indicates where the United States has seen a significant decline in manufacturing jobs, net employment in areas such as educational and health services, professional and business services, trade and transport, government, leisure and hospitality, and financial services have created approximately 43 million new jobs.<sup>164</sup> Therefore, although short-term job losses result from outsourcing, U.S. companies are using their ingenuity to create newer jobs by repatriating some of profits that they earn from outsourcing.

Another argument that opponents of free trade raise is that outsourcing is a one-way street that causes an "agonizingly slow pace of job growth in the United States."<sup>165</sup> Proponents of free trade paint a very different picture.

Foreign direct investment, once an object of scorn, fear and recrimination in the United States, is increasingly regarded as a source of new jobs, production and exports....

Throughout the United States, from high-tech corridor of central Texas to the automobile plants of the Deep South to the pharmaceutical laboratories scattered throughout New Jersey and Massachusetts, foreign companies are spending billions of dollars to build or expand operations. In the process, they are lifting local economies and offsetting some of the jobs being sent offshore by American companies.

[Some] economists say [...] that insourced jobs tend to be higher paying and more stable than the ones moving out of the country. Besides, they add, were it not for foreign companies buying American companies, many of those jobs would have vanished.<sup>166</sup>

Therefore, foreign companies are helping to offset outsourced jobs by providing higher paying jobs in many of the areas in the United States effected by outsourcing.

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<sup>162</sup>*Id.*

<sup>163</sup>John Cassidy, *Winners and Losers; The Truth About Free Trade*, THE NEW YORKER, Aug. 2, 2004 ("[T]he copyright business, which includes film, music, books, and software, accounts for about 5 percent of the GDP, which means it is the biggest sector in the economy, bigger even than the auto industry."). *Id.*

<sup>164</sup>Bailey & Farrell, *supra* note 159.

<sup>165</sup>*Id.*

<sup>166</sup>Belson, *supra* note 155.

A third criticism is that the United States economy suffers, when American companies outsource. In fact, research indicates that the opposite is true. According to a 2003 study by the McKinsey Global Institute, outsourcing is directly benefiting the United States. “For every dollar of corporate spending outsourced to India, the U.S. economy captures more than three-quarters of the benefits and gains as much as \$1.14 in return.”<sup>167</sup> As for more tangible results of outsourcing, consumers are directly benefiting in the form of lower prices.<sup>168</sup> Therefore, research indicates that outsourcing benefits the U.S. economy.

The debate over outsourcing is actually a debate between public policy experts and international economists. The public policy experts are looking at the immediate short-term adverse effects of outsourcing. On the contrary, the economists are looking at the eventual positive impact that outsourcing has on the American and other global economies. While the theorists continue to battle over outsourcing in the marketplace of ideas, Americans need a resolution to important issues like the rising cost of prescription drugs. For this reason, outsourcing is currently the best option available.

*b. Outsourcing Benefits the Pharmaceutical Industry and India*

Outsourcing is a growing phenomenon in U.S. business policies.<sup>169</sup> The question remains whether the multinational pharmaceutical companies can upgrade current Indian manufacturing facilities, construct new facilities, and have adequate reserve funds for their own brand-name drugs.<sup>170</sup> With the significant investments that have been made, the pharmaceutical industry is very interested in the results of the outsourcing debate.<sup>171</sup> India provides the pharmaceutical industry with “substantially lower labor costs” (“50 to 90 percent lower, depending on the position”), a larger pool of “highly educated technical and professional people,” and a “huge population for clinical trial subjects.”<sup>172</sup> While the multinational companies will have to help pay for the improvements to the Indian infrastructure, the biggest advantage of doing

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<sup>167</sup>Bailey & Farrell, *supra* note 159; *see also* Hicks, *supra* note 158. Don Hicks is the owner of a family-owned and operated car dealership in Colorado and is also the vice chairman of the American International Auto Dealers Association. Hicks indicates that competition from international automakers has forced domestic automakers “to improve the average initial quality of domestic nameplate vehicles” by 32 percent in the last seven years. *Id.*

<sup>168</sup>Bailey & Farrell, *supra* note 159.

<sup>169</sup>*Id.* Protectionism is not a feasible option. The federal government and state governments have been trying to pass legislation to curb outsourcing of American jobs. Earlier this year, the Senate passed a watered down amendment that prohibited the government entering into service agreements with foreign contractors. *Id.* In Ohio, a similar bill failed when legislators discovered that practically all of its current contractors were already outsourcing some of their services. *Id.*

<sup>170</sup>Manjeet Kripalani & Pete Engardio, *India: Will A Shocking Election Upset End the Economic Boom?*, BUS. WK., May 31, 2004, at 42, 43.

<sup>171</sup>Bartlett & Steele, *supra* note 42.

<sup>172</sup>Miller, *supra* note 156.

business with Indian pharmaceutical companies is cheaper labor and lower manufacturing costs.<sup>173</sup> Moreover, these operational cost savings will eventually offset the revenue that the multinational companies invested and still provide profits that can be distributed to shareholders or accumulated for research and development. Therefore, an alliance with Indian pharmaceutical companies equally benefits the multinational company and the public who will have access to cheaper generic drugs.

The Indian drug manufacturers will also benefit from this alliance. The Indian drug manufacturers will learn more about the American standards for drug safety that they can apply to their domestic manufacturing programs. They will be able to reduce operational costs because they will have to establish more efficient production methods that can meet the demands of the international and domestic markets. Also, as they save more money from their operational expenditures, Indian drug manufacturers will be able to make more profit from their American drug sales, which will make them more self-sufficient and enable them to maintain their own facilities according to FDA-compliant guidelines without depending on loans from the multinational companies. Therefore, the multinational pharmaceutical companies will eventually be able to keep more of their own revenues for costs related to their brand-name drugs, rather than indefinitely spending their own cash reserves on the Indian manufacturing facilities.

#### VI. CONCLUSION

There is a national crisis in the United States. American senior citizens are spending their hard-earned retirement pension funds on high prescription drug prices. The FDA and multinational drug companies have hampered American consumers' efforts to import prescription drugs from Canada. This reality makes a solution to

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<sup>173</sup>The following is a brief look at the development of Indian outsourcing over the past decade.

The Indian outsourcing business grew out of a more basic industry providing Indian computer programming and code-writing expertise to American hardware and software giants. When Indian firms entered the outsourcing business serving firms of all sorts, a business then dominated by the likes of IBM and EDS, much lower labour costs held the key to its rapid revenue growth: over 50% a year in 1994-2001. The time difference also gave India a selling-point. [T]he ten-hour time gap between America and India, American clients could offer 24-hour service by switching to Indian workers during the American night.... Just as the established global outsourcing firms are increasing their presence in India, so the leading local firms are becoming more multinational. In part, this is because customers need to be reassured that outsourced services would not be disrupted by, say, a nasty further deterioration in political relations between India and Pakistan. Less speculatively, they have been trying to meet client demands for global outsourcing for 24 hours a day by opening operations across America, Europe and the Asia-Pacific region.... At some point, the Indian firms may find themselves facing a choice similar to that now confronting IBM, EDS and others: move to a lower-cost location or become uncompetitive. [Currently, India believes that it has] a window of three to five years [of outsourcing dominance before] China, Russia or the Philippines emerges as a seriously competitive threat to Indian outsourcing.

*America's Pain, India's Gain*, ECONOMIST, Jan. 11, 2003.



the prescription drug issue more crucial. Thus, compulsory licensing of necessary brand-name pharmaceutical patents is the answer that millions of Americans seek.

This article proposes the creation of a tripartite health care commission that will bring the pharmaceutical industry, the senior citizens' lobby, and the federal government together on an equal footing to resolve the high cost of prescription drugs while providing adequate patent protection for inventors. This article also proposes that an alliance with Indian pharmaceutical companies will provide cheaper generic drugs for American senior citizens and will help the multinational drug companies generate future profits and create a strong relation with India that can help them with the manufacture of their own brand-name drugs. If these proposals are enacted, Medicare will finally realize its goal to provide some of the most valuable members of American society—its senior citizens—fair and equal access to health care benefits.

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