


Spring 1999

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Recommended Citation

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DELETING THE BOLAR AMENDMENT TO THE HATCH-WAXMAN ACT: HARMONIZING PHARMACEUTICAL PATENT PROTECTION IN A GLOBAL VILLAGE

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Furnished as all Europe now is with Academies of Science, with nice instruments and the spirit of experiment, the progress of human knowledge will be rapid and discoveries made of which we have at present no conception. I begin to be almost sorry I was born so soon, since I cannot have the happiness of knowing what will be known a hundred years hence.¹

INTRODUCTION

The Framers of the United States Constitution agreed with inventor Benjamin Franklin in his respect for technological progress and invention. The Framers found it so important that they dedicated a clause in the Constitution to the protection of intellectual property.² Congress followed the Constitutional provision by enacting laws that conferred exclusive time-limited rights to an inventive entity that successfully patented a new discovery.³ Furthermore, the United States government created the U.S. Patent and Trademark Office (PTO) which will soon occupy an eight-building 2.4 million-square foot complex in Arlington, Virginia.⁴

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1. *Benjamin Franklin Quotes and Sayings* (visited Feb. 23, 1999) <<http://www.kagi.com/micromatt/benf.htm>>. This site contains interesting and useful quotes by historical inventor and patriot Benjamin Franklin.

2. See U.S. CONST. art. I, § 8, cl. 8 (desiring “to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”).

3. See generally 35 U.S.C. § 154(a)(2) (1998) (stating “a term beginning on the date which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States . . .”).

4. See *\$250 Shower Curtain? Relocating the U.S. Patent and Trademark Offices Might Be a Cost-Saver, but Items Such as \$100 Coat Racks are*

The traditional European view of patent protection was to reward an inventor with a time-limited exclusive right to a patent free from risk of infringement.⁵ The Framers settled on the European view that an inventor was entitled to a limited monopoly for the benefit of social welfare.⁶ This view persists today. However, the research-based pharmaceutical industry is one sector of modern technology that is exempt from these traditional views of exclusive patent protection.⁷

The U.S. research-based pharmaceutical industry seeks strong patent laws to protect its research and development.⁸ Countries such as Italy saw pharmaceutical research and development (R&D) increase by 600% after strengthening its own patent laws.⁹ This is easier to appreciate when one considers it is much easier to copy a new drug product than it is to invent one.¹⁰

Drawing Heat, CHI. TRIB., Sept. 24, 1998, § 1, at 10 (describing the transition into new PTO facilities and emphasizing potential price abuses through gross over-payment of items that are typically a fraction of the cost).

5. See A. Samuel Oddi, *TRIPS - Natural Rights and a "Polite Form of Economic Imperialism"*, 29 VAND. J. TRANSNAT'L L. 415, 421 (1996) (describing the French view during the "Age of Enlightenment" that an invention belonged exclusively to the creator and holding otherwise would be a "violation of the rights of humanity" and was reflected as such in the preamble to the French Patent Act of 1791); see also WILLIAM H. FRANCIS & ROBERT C. COLLINS, *CASES AND MATERIALS ON PATENT LAW* 5 (4th ed. 1995) (stating that one of the earliest patent protection statutes appeared in Venice, Italy in 1432 A.D.). But see Oddi, *supra*, at 421-22 (stating that some economists were opposed to the idea of patent rights). The Netherlands repealed its patent statute temporarily, but reenacted it within 40 years. *Id.*

6. See *Graham v. John Deere Co.*, 383 U.S. 1, 7 (1965) (stating that Thomas Jefferson was opposed to monopolistic grants, but that he tempered this attitude toward inventions and literature). Jefferson thought the granting of a monopoly was more of a privilege than a natural right and was necessary for the furtherance of new discovery. *Id.* at 8-9.

7. See *GATT and Pharmaceutical Patents: Hearing Before the Senate Judiciary Comm. on Hatch-Waxman generic drug legislation and GATT*, available in 1996 WL 88348, at *3 (statement of Lauch Faircloth, Senator from North Carolina) [hereinafter *Faircloth*] (stating that generic drug companies are the only industry permitted to test and produce a patented product prior to its expiration as a result of the Bolar amendment, which will be further described *infra*).

8. See *Phrma: Issues & Policy* (visited Feb. 23, 1999) <<http://www.phrma.org/issues/protect.html>> [hereinafter *Phrma*] (discussing reasons why strong pharmaceutical patent protection is essential to the industry).

9. *Id.* Other countries like Canada had pharmaceutical R&D increase by 4.6% of sales within four years after strengthening of patent laws. *Id.* Another notable statistic includes a study by the World Bank that determined 65% of drugs on the market would not be available in the absence of strong patent laws. *Id.*

10. See *GATT & Pharmaceutical Patents: Hearing Before the Senate Judiciary Comm. on Hatch-Waxman Generic Drug Legislation; GATT and Global Patent Law*, available in 1996 WL 283660, at *4-5 (statement of Gerald J. Mossinghoff, President of Pharmaceutical Research and Manufacturers of

Strong patent protection gives the inventive entity, as well as others, the incentive to continue to invent knowing that their intellectual property will be secure while benefiting society.¹¹

The research-based pharmaceutical industry is responsible for over 90% of new market drugs,¹² with U.S. companies providing a major role in the development of the world's pharmaceuticals.¹³ The research industry seeks to collaborate with other pharmaceutical companies in developed countries worldwide for the purpose of streamlining drug-regulatory laws while maximizing patent protection.¹⁴

Similarly, the U.S. government has an interest in engaging in

America) [hereinafter *Mossinghoff*] (noting that a medication that has development costs in the hundreds of millions of dollars and takes up to 15 years to develop can be duplicated quickly and inexpensively). Estimates by the International Trade Commission indicate that \$5 billion of patented pharmaceuticals are pirated annually. *Id.* See also *Patent Restoration Act and Drug Price Competition: Hearing Before the Senate Judiciary Comm. On the Economic Impact of Hatch-Waxman generic drug legislation and the pharmaceutical marketplace*, available in 1996 WL 103668, at *3 (statement of Henry G. Grabowski, Ph.D., Professor of Economics, Duke University) [hereinafter *Grabowski*] (stating that the pharmaceutical industry has "the lowest ratio of imitation costs to innovation costs" of all the hi-tech industries).

11. JOSEPH SCHUMPETER, CAPITALISM, SOCIALISM, AND DEMOCRACY 81-86 (1950). New technology serves society positively through a process known as creative destruction, in which new technology eliminates old technology through improvement. *Id.*

12. *Mossinghoff*, *supra* note 10, at 1. Most all new pharmaceuticals are researched and developed in the research pharmaceutical industry with enormous risks. *Id.* at 4. Each chemical structure isolated has a 1 in 6,000 chance of making it to market with an average cost of \$359 million. *Id.* at 2; *accord Phrma*, *supra* note 8 (noting that time involving drugs with a high risk of failure prior to market can take 12-15 years to bring to market at a cost of \$500 million).

13. *Phrma: Publications: Leading the Way* (visited Feb. 23, 1999) <<http://www.phrma.org/publications/brochure/leading/lead9.html>>. In the past 20 years, the United States has developed almost half of the world's 150 breakthrough medications. *Id.* Pharmaceutical companies are currently developing over 1,000 new medications for various illnesses with a work force of over 250,000 people that include 50,000 scientists. *Id.* The average cost of developing a new drug is \$500 million, which is three times the value of a new Boeing 747 jumbo jet. *Id.* See also *Phrma: Facts & Figures: Phrma Facts* (visited Feb. 23, 1999) <http://www.phrma.org/facts/phfacts/8_97a.html> (asserting that U.S. pharmaceutical companies are responsible for 36% of the entire world R&D with the Japanese a "distant second" at 19%, followed by Germany at 10%, and France at 9%).

14. *Phrma: Issues & Policy* (visited Feb. 23, 1999) <<http://www.phrma.org/issues/intl.html>>. The International Conference on Harmonization (ICH) is one example of collaboration between research drug companies in the U.S., Europe, and Japan and has been formed to decrease and streamline drug regulatory procedures with the intent to minimize delays of marketing a drug. *Id.* Harmonizing regulatory laws in these three regions would decrease costly and time consuming repetition of the same procedures, thereby reducing marketing delays while the patient accesses new medication more quickly. *Id.*

international trade agreements and tariff reductions, while protecting global interests.¹⁵ Accordingly, the United States is a strong advocate of global patent protection.¹⁶ This is evidenced by its strong support for global agreements such as GATT¹⁷ and TRIPS,¹⁸ to which the United States is a signatory. The United States enforces these global agreements by way of a dispute resolution system developed in the World Trade Organization (WTO)¹⁹ against offending member nations.²⁰

Prior to the U.S. global commitments to GATT, and subsequently the WTO, Congress enacted the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) in 1984.²¹ The Hatch-Waxman Act amended the Federal Food, Drug, and Cosmetic Act.²² The Hatch-Waxman Act sought to:

- 1) encourage generic²³ 'competition' in the pharmaceutical industry by streamlining the process of regulatory approval for generics, 2)

15. See *infra* Part I.A for a discussion of GATT.

16. Faircloth, *supra* note 7, at 3. Senator Faircloth insisted "the U.S. was the leading advocate for intellectual property protection in GATT." *Id.* Faircloth expressed concern about continuing congressional interest in undermining pharmaceutical protection and described any further modification of the law as possibly "seriously damaging" intellectual property laws. *Id.* at 1. He further expressed concern that creating exceptions to the industry would "encourage developing countries to do the same" in their efforts to whittle away at their GATT commitments. *Id.* at 3.

17. See *infra* Part I.A for a discussion of GATT.

18. See *infra* Part I.B for a discussion of TRIPS.

19. See *infra* Part I.C for a discussion of WTO.

20. See *infra* note 66 for a description of some of the enforcing activities the U.S. engaged in at the WTO.

21. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 [hereinafter Hatch-Waxman Act] (codified in scattered sections of Titles 21 and 35). See also Diane Furman, *Pharmaceutical and Biotechnology Licensing and the Patent/Regulatory Background*, 514 PLI/PAT 7, 14-15 (1998) (stating the objectives of the Hatch-Waxman Act). The Drug Price Competition and Patent Term Restoration Act is commonly referred to as the Hatch-Waxman Act, its regulation aims to modify patent laws as they pertain to new and generic drug approval methods. *Id.*

22. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-93). Hatch-Waxman included several amendments to this earlier legislation. *Id.* One notable amendment was that generics were no longer required to duplicate costly research and submit test data to the FDA for purposes of drug approval. Furman, *supra* note 21, at 14. This dramatically decreased generic costs and would have the effect of decreasing the amount of time necessary to get the generic equivalent to market after the research drug patent expires. *Id.*

23. Generic drug companies do not typically engage in novel drug research, but rather re-develop an already discovered drug and market it at a much lower cost upon its patent expiration. They are able to do this because there are very little research dollars necessary to re-develop the drug compared to what it would cost to actually discover it.

stimulate investment in pharmaceutical research and development by restoring to the patent owner a part of the patent term consumed by regulatory delay, and 3) facilitate immediate competition in the marketplace upon patent expiration by securing for the generic industry an exemption from infringement activities relating to FDA submissions.²⁴

The Hatch-Waxman Act attempted to strike a balance between competing interests. The Act weighed the public interest in gaining faster access to a cheaper generic drug against the research industry's financial incentive to discover a new drug product.²⁵

This Comment addresses a single amendment encompassed in the Hatch-Waxman Act known as the Bolar Amendment.²⁶ The Bolar Amendment enables a generic drug manufacturer to use an inventor's drug product prior to patent expiration for purposes of meeting FDA requirements for market approval.²⁷ Therefore, the Bolar Amendment exempts what would otherwise be classified as patent infringement of the proprietary drug. This patent exception is inconsistent with the United States negotiating position, which sought maximal patent protection, in the global agreement known as GATT-TRIPS.²⁸ Furthermore, Article 30 of the GATT-TRIPS agreement only allows exceptions to patent exclusivity in very limited situations.²⁹ Therefore, the Bolar

24. Furman, *supra* note 21, at 15; Hatch-Waxman Act, *supra* note 21.

25. See generally *Judiciary Committee Revisits the Hatch-Waxman Act*, J. PROPRIETARY RTS., May 1996, at 26 (describing the intent of the Act at the time of its creation in 1984 and the extent to which it has been successful to date in achieving its stated goals, taking into account any amendments to the Act which may be needed in light of changing societal expectations and market forces).

26. 35 U.S.C. § 271(e)(1). Commonly referred to as the Bolar Amendment, section 271(e)(1) states:

[i]t shall not be an act of infringement to make, use, offer to sell, or sell a patented invention [other than new animal drugs or veterinary biological products using genetic manipulation techniques] solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

Id.

27. See Gregory J. Glover, *Impact of Hatch-Waxman Goes Beyond Generics*, NAT'L L.J., June 16, 1997, at C7 (explaining the exemption to patent infringement granted to generics for activities related to submission of information for product approval).

28. S. REP. NO. 103-412, at 112-17 (1994) [hereinafter SENATE REPORT].

29. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement]. Article 30 of TRIPS states, "[m]embers may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate

Amendment may be in violation of Article 30 of the GATT-TRIPS agreement to which the United States is a signatory.

This Comment examines the validity of the Bolar Amendment in light of Article 30 of GATT-TRIPS. Part I explains GATT, TRIPS and the WTO. Part I further describes the binding nature of the WTO and the ability of one nation to bring a legal complaint against another member nation violating any of the WTO provisions. Part I then explains United States interests in maximizing global patent protection. Part II explains the origins of the Bolar Amendment and compares the European view on the Bolar Amendment that contrasts the United States position. Part III analyzes the degree to which the Bolar Amendment prejudices the research pharmaceutical industry while considering the public interest the amendment serves. Part III also examines a possible outcome of a complaint against the United States in the WTO regarding the Bolar Amendment. Finally, Part IV proposes deleting the Bolar Amendment and offers an alternative method for providing cost-effective drugs to the public.

I. GATT, TRIPS, AND THE WTO

Global efforts to reduce tariffs and increase trade, while protecting national interests, have led to several global agreements between developed and developing nations. This Part describes an important agreement called the General Agreement on Tariff and Trade (GATT). GATT began as an attempt to stimulate the global economy in 1947 and eventually evolved into the present day World Trade Organization (WTO).³⁰ The WTO is a permanent international organization that regulates transnational trade.³¹ This Part also explains the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement, which is the section of GATT that addresses international intellectual property rights and protection.

A. GATT

After World War II, the United States and England attempted to stabilize the world economy.³² Concurrently, a panel

interests of third parties." *Id.*

30. KONSTATINOS ADAMANTOPOULOS, AN ANATOMY OF THE WORLD TRADE ORGANIZATION 1-8 (1997).

31. See *infra* Part I.C for a discussion of WTO.

32. ADAMANTOPOULOS, *supra* note 30, at 1-8. Discussions of regulating post-war trade were imperative to combat global protectionist obstacles. *Id.* While the U.S. and England began their bi-lateral talks, a committee was established to create what would be a pre-cursor organization known as the International Trade Organization (ITO). *Id.* Additionally, 23 other nations began to have trade and tariff reduction negotiations in which 45,000 tariff reductions resulted in the elimination of \$10 billion in trade tariffs. *Id.* at 1-2.

of twenty-three countries worked together in an effort to stimulate the world economy by signing a global agreement, known as GATT, in Geneva, Switzerland on October 30, 1947.³³ The initial GATT agreement was meant to create a temporary administrative body whose mission would be to carry out economic stimulating measures taken up by a separate group, called the International Trade Organization (ITO), which was primarily composed of the United States and England.³⁴ However, United States support for the ITO collapsed when Congress refused to endorse the organization.³⁵ This left GATT as the sole instrument for promoting world trade, and the only major stabilizing mechanism for the post World War II global economy.³⁶

GATT was used as a means for opening up protectionist markets and increasing transnational trade.³⁷ GATT began in 1947 but evolved via eight "Rounds" which ultimately led to the 1994 version of GATT and eventually the WTO in the final negotiating round known as the "Uruguay Round."³⁸ GATT became increasingly expansive with the conclusion of every negotiating "Round" and addressed many trade barrier concerns

33. *Id.* at 2. The signatories ratified what is known as GATT-1947, which is distinguished from GATT-1994, although the latter is an outgrowth from the former and encompasses a majority of its original principles. *Id.*

34. *Id.* The two groups comprising GATT and ITO existed in parallel and ultimately both worked toward the same goal of creating a more stable world economy. *Id.* At the time, the ITO had the benefit of working together with the World Bank and the International Monetary Fund. *Id.* at 1.

35. MICHAEL BLAKENEY, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A CONCISE GUIDE TO THE TRIPS AGREEMENT 31-34 (1996). Congress opposed the ITO due to perceived failures by the British government to "restore convertibility" and also because of the ensuing Cold War and the global impact that ITO would have in light of the presence of the USSR. *Id.* at 31. It is notable to consider that although the ITO failed to pass Congress at the time, it would live again because the ITO charter had all the "configurations" of the modern World Trade Organization (WTO). *Id.*

36. *Id.* In order for GATT to be accepted as a global agreement after the ITO was rejected by Congress, it had to take the form of a provisional agreement. *Id.* GATT was also referred to as a "trade agreement" and was within the United States Trade Agreements Act of 1945, thereby avoiding the requirement of Senate ratification. *Id.* It is of historical interest and relevancy that great pains were taken to refer to the signatories as "contracting parties," rather than "signatories" or "members." *Id.*

37. See GILBERT R. WINHAM, THE EVOLUTION OF INTERNATIONAL TRADE AGREEMENTS 43-44 (1992) (stating that GATT was used to prevent national market protectionism through tariff reductions and agreements).

38. See ADAMANTOPOULOS, *supra* note 30, at 2-4 (describing the progression of the GATT agreement through eight rounds of talks, which culminated in the Uruguay Round). The Uruguay Round began in 1986 and concluded in 1993 with a total membership of 125 countries. *Id.* GATT rules were once again expanded and for the first time given force through the establishment of the WTO which granted the world a binding dispute resolution system. *Id.*

including nondiscriminatory treatment of other GATT members, the abolition of quantitative restrictions on imports/exports, and special exemptions for developing member countries.³⁹ After the Uruguay Round, GATT took its most complete form for creating global trade regulations.⁴⁰ Countries worldwide signed GATT which took the appropriate name, "Draft Final Act" (DFA).⁴¹ The U.S. Congress passed the GATT agreement, and following President Clinton's signing in December 1994, the United States officially committed itself as an international signatory.⁴²

B. TRIPS

During the Uruguay Round, discussions were expanded to include intellectual property protection.⁴³ Developed countries had valid concerns regarding piracy of intellectual property and lobbied heavily for strong international rules to protect an inventive entity from suffering financial ruin as a result of infringing activity.⁴⁴ These negotiations gave rise to an agreement

39. *General Agreements on Tariffs and Trade* (visited Feb. 23, 1999) <<http://www.econ.iastate.edu/classes/econ355/choi/gatt.htm>> [hereinafter *GATT*]. This web-site provides a truncated history of GATT and its evolution into a more expansive global commitment that eventually became binding on the signatories at the Uruguay Rounds. *Id.*

40. See BLAKENEY, *supra* note 35, at 36-38 (discussing the transfer of the GATT to the WTO with all previous Rounds encompassed within the scope of transfer which was consummated at the Marrakesh Conference).

41. Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND, 33 I.L.M. 1125 (1994). See also BLAKENEY, *supra* note 35, at 35-36 (describing the culmination of the Uruguay Round and the groundwork of the WTO).

42. See Robert M. Storwick, *GATT's Effects on Patents* (last modified Oct. 20, 1995) <<http://www.patent-it.com/gattpat.html>> (describing the ratification of GATT along with the TRIPS agreement). TRIPS is a sub-section of GATT that addresses global intellectual property protection, including patent protection. *Id.*

43. See BLAKENEY, *supra* note 35, at 39-43 (discussing the basic principles of the TRIPS agreement); see also *Trade in Intellectual Property* (visited Sept. 3, 1998) <<http://www.wto.org/intellect/intell2.htm>> (discussing the implementation of global patent protection, global trademark protection, and global copyright protection in the field of intellectual property).

44. See Oddi, *supra* note 5, at 424 (discussing industry concerns regarding impostor "counterfeiting" of intellectual property and efforts to minimize these illegal activities); see also SEYMOUR J. RUBIN & MARK L. JONES, CONFLICT AND RESOLUTION IN US-EC TRADE RELATIONS AT THE OPENING OF THE URUGUAY ROUND 230-33 (1989) (describing the reasons why the United States thought it was important to begin global talks on intellectual property protection). Among the many reasons were concerns about cheap, high quality imitations by countries such as Korea, Hong Kong, Taiwan and Singapore resulting in widespread piracy and counterfeiting. RUBIN & JONES, *supra*, at 230-33. The U.S. noted there were innovations on the horizon that were of significant importance necessitating increased protection. *Id.* at 231. Another major factor leading to discussions of the TRIPS agreement involved the

known as TRIPS.⁴⁵ TRIPS is a single section of the vast GATT agreement, concerning itself entirely with global intellectual property protection.⁴⁶ TRIPS signaled a global commitment toward securing intellectual property rights of inventors in order to reward new discoveries and ensure future research and development. TRIPS is a comprehensive agreement devoted to intellectual property, and Articles 27-34 of TRIPS address member nations' responsibilities related to patent law.⁴⁷

Article 30 of TRIPS prohibits infringement of a patent only if the legitimate interests of a patent owner are unreasonably prejudiced.⁴⁸ Opponents of the Bolar Amendment contend that the amendment violates TRIPS because it discriminates against an industry by allowing exploitation of a patent prior to its expiration.⁴⁹ The currently prevailing European view insists the Bolar Amendment runs counter to the TRIPS agreement because the innovator should have exclusive rights to a patent.⁵⁰ Although Congress probably did not contemplate the TRIPS agreement in 1984 when it enacted the Bolar Amendment, an increasingly interdependent global economy suggests that domestic laws should be modified to accommodate global commitments.

C. WTO

At the conclusion of the Uruguay Round, the U.S. government ratified all of GATT, including the TRIPS agreement.⁵¹ However,

dissatisfaction of WIPO's ability to enforce IP laws. *Id.* at 232-33 n.5. Both WIPO and UNESCO are specialized United Nations (UN) agencies that address intellectual property and "educational, scientific and cultural matters." *Id.*

45. See ADAMANTOPOULOS, *supra* note 30, at 22-23 (describing the TRIPS agreement); see also *The Roots of the WTO* (visited Sept. 3, 1998) <<http://www.econ.iastate.edu/classes/econ355/choi/wtoroots.htm>> (describing the history surrounding GATT, TRIPS, and the WTO).

46. TRIPS Agreement, *supra* note 29.

47. TRIPS Agreement, *supra* note 29, arts. 27-34.

48. TRIPS Agreement, *supra* note 29.

49. *EU Court Ruling Deals a Setback To Generics Arm*, CHEMICAL MARKET REPORTER, Aug. 4, 1997, available in 1997 WL 8497538 [hereinafter CHEMICAL MARKET REP.]. Brian Yorke, the corporate head of intellectual property at Novartis stated "[t]he Bolar provisions discriminate against a specific industrial sector by allowing third parties to exploit a product . . . before its patent expires." *Id.* at 3.

50. *Id.* at 2. Another opponent of the Bolar amendment believes that a recent European court ruling described *infra* demonstrates that "[i]t is an endorsement of the prevailing political view . . . in the [European Union] that the way to jobs and prosperity is through innovation and generation of new products," and he adds, "[t]he U.S. position on TRIPS and the Bolar amendment is unsatisfactory . . . the European Court has reinforced the view that the Bolar amendment is in contradiction of TRIPS." *Id.* at 5.

51. JOHN H. JACKSON & ALAN O. SYKES, IMPLEMENTING THE URUGUAY ROUND 175-76 (1997). Although the GATT agreement was controversial and

the signatories of GATT had an interest in advancing the temporary nature of the agreement by creating a permanent organizational structure.⁵² The DFA at the Uruguay Round contained a provision expressing the desirability of such measures, and discussions were planned to create such an organization at the conclusion of the Round.⁵³ Once all the attending countries approved the DFA, a ministerial-level meeting concluded the Uruguay Round and prepared for the Marrakesh Conference of Trade Ministers to create a permanent body known as the WTO.⁵⁴

By January 1, 1995, the United States had accepted the WTO agreement along with 76 of the original 125 nations present at the Uruguay Round.⁵⁵ The remaining nations needed to take additional steps domestically to satisfy membership requirements,⁵⁶ which was accomplished through an application process.⁵⁷

There are six differences between GATT and the WTO.⁵⁸ All

involved heated debate, the House of Representatives passed the agreement by a vote of 288-146, and the Senate by a vote of 76-24. *Id.* at n.2.

52. BLAKENEY, *supra* note 35, at 34. The provisional nature of the GATT meant it was a temporary body that presented member nations with guidelines in their global agreements. *Id.* at 31. Countries could easily balk at provisions that were not agreeable to them and frequently disregarded them if contrary to national interests. *Id.* The desire to transform GATT into a permanent organization was to combat such attitudes. *Id.* In 1993, GATT was no longer an agreement attempting to stimulate a floundering post World War II economy, but rather an attempt to streamline international trade by eliminating barriers. *Id.* at 36-37.

53. *Id.* at 34-35. The idea of creating a permanent organization was not to begin an organization independent from GATT and the Uruguay Round Agreements, but rather to absorb the approved contents of the "Draft Final Act" (DFA) into the new organization. *Id.* at 35.

54. *See id.* at 36-38 (stating on April 14, 1994, the Marrakesh agreement was signed and transfer of all property and financial assets of GATT to WTO were effectuated thereby concluding the GATT rounds and the creation of a permanent global organization charged with the task of overseeing world trade); *see also* ADAMANTOPOULOS, *supra* note 30, at 28-30 (describing the transition from GATT to the WTO).

55. ADAMANTOPOULOS, *supra* note 30, at 56.

56. *Id.* Because some member nations present at the Uruguay Round did not satisfy criteria to accede to the WTO from GATT "membership," the two organizations co-existed for a one year period in order to maintain continuity in multi-lateral agreements. *Id.* Since the original GATT agreements were fully encompassed in the WTO, maintaining duality of these organizations afforded acceding countries the benefits of the guidelines established in GATT prior to meeting their WTO prerequisites for membership. *Id.*

57. *Id.*

58. *Id.* at 29-30. The first major difference is that in the predecessor GATT, side agreements were created through the various "rounds" which fostered the evolution of GATT. *Id.* The WTO absorbs all previous agreements created and administers them as one unified proposal. *Id.* Additionally, the WTO has an expanded role in that it includes Trades in Services, intellectual property, and a major role in the environment. *Id.* Further, the GATT rules, which

of the differences are designed to improve the status of the WTO as a binding, permanent and legitimate international trade organization with enforcement capabilities. Along with this permanency came the responsibility of member countries to abide by the intellectual property rules set forth in the TRIPS agreement.⁵⁹ The TRIPS agreement was pursued vigorously by the United States in the Uruguay Round and supported by all developed nations.⁶⁰ The end result of this Round was to include global intellectual property rights issues within the jurisdiction of the WTO and its binding dispute resolution authority.⁶¹

were crafted in the Uruguay Round (known as GATT-1994), are re-stated in the WTO and strengthened regarding goods trading. *Id.* Another major difference between GATT and the WTO is that provisions in GATT, which gave exceptions to specific trade sectors, will be phased out. *Id.* This means that countries can no longer decline to adhere to WTO rules as they once did in GATT. *Id.* All aspects of international trade will be governed by the new WTO rules. *Id.* Additionally, WTO will have a broader membership potential than GATT. *Id.* Finally, WTO members will not have the luxury of blocking decisions against them within the dispute settlement mechanisms set forth in the WTO dispute panel as they did in GATT. *Id.*

59. THE WTO AND INTERNATIONAL TRADE REGULATION 62-66 (Philip Ruttley et al. eds., 1998). Aggrieved individual intellectual property rights holders will seek dispute resolution through the WTO against offending persons. *Id.* This, however, will be effectuated through domestic governments. *Id.* For example, if company A in Serbia is aggrieved by company B in South Africa, the government of Serbia will bring action against the government in South Africa on behalf of company A or the industry in which company A resides.

60. SENATE REPORT, *supra* note 28, at 112-17.

61. See THE WTO AND INTERNATIONAL TRADE REGULATION, *supra* note 59, at 62 (stating “[t]he WTO could become the Global Supreme Court of intellectual property.”). Advocates of the TRIPS agreement in developed countries were eager supporters of strong intellectual property rights and many countries were faced with the daunting task of having to learn “highly protective [intellectual property] laws.” *Id.* at 64. Scores of countries that had weak intellectual property laws had to learn new standards of protection, including a new vocabulary. *Id.* Failure to master these newfound laws meant potential liability in the global marketplace at the mercy of the WTO. *Id.* See also *About the WTO* (last modified Feb. 6, 1998) <<http://www.wto.org/wto/about/dispute/.htm>> (stating “no review of the achievement of the WTO would be complete without mentioning the dispute settlement system, in many ways the central pillar of the multi-lateral trading system and the WTO’s most individual contribution to the stability of the global economy.”). This web-site also sets out the stages of dispute resolution that creates the timetables for resolving each stage of the dispute. The first stage begins with consultations between the parties. *Id.* The second stage is the panel appointing stage in the event consultations fail. *Id.* Hearings, interim reports, reviews, and a final report follow this. *Id.* The final report then becomes a ruling that may be appealed. *Id.* See also DISPUTE RESOLUTION IN THE WTO 28-53 (James Cameron & Karen Campbell eds., 1998) (detailing the dispute resolution system in the WTO).

D. Global Enforcement: Policing Through the WTO

Shortly after the Uruguay Round, Congress and the President committed the United States to the WTO through enactment of the Uruguay Round Agreements Act (URAA).⁶² During the Uruguay Round, the United States was the leading proponent for strong global intellectual property protection.⁶³ At the Uruguay Round, and subsequently at the time of the URAA enactment, the United States continued to voice concerns about discriminatory acts by foreign signatories and insisted the WTO be used as a continuing mechanism for maximally protecting U.S. interests in intellectual property.⁶⁴ This was not a novel concern for Congress either, as it sought a means for creating a global dispute settlement system as part of its mandating negotiating objectives in the Uruguay Round.⁶⁵ With the creation of the WTO, the United States will make good on its promise to enforce WTO rules against violating countries; it has successfully brought complaints against several nations since the inception of the WTO and its dispute settlement body (DSB).⁶⁶ Despite the TRIPS agreement,

62. See generally Lauren A. Degnan, *Does U.S. Patent Law Comply with TRIPS Articles 3 and 27 with Respect to the Treatment of Inventive Activity?*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 108 (1996) (discussing the impact of the URAA on current U.S. law regarding intellectual property and the ways in which the URAA changes domestic law to conform to U.S. global commitments set forth in the WTO).

63. SENATE REPORT, *supra* note 28, at 117. The Committee report states in part "it is the U.S. objective to seek to prevent or eliminate discrimination with respect to matters affecting availability, acquisition, scope, maintenance, use and enforcement of intellectual property rights." *Id.* It further states "the Committee recognizes that much progress has been made over the past decade in the intellectual property area, but believes it is clear that more work needs to be done to ensure the strongest possible protection for U.S. intellectual property abroad." *Id.*

64. See *id.* (stating Congress' concern that U.S. interests continue to be addressed through the WTO after enactment of the URAA).

65. THE WTO AND INTERNATIONAL TRADE REGULATION, *supra* note 59, at 123.

66. *WTO Seeks Change in Patent Laws*, INDIA TIMES, Jan. 23, 1998, at 1-3, available in 1998 WL 11448152. The U.S. brought complaint against India in the WTO because India did not provide adequate mechanisms for domestic pharmaceutical patent protection. *Id.* The ruling was granted in favor of the U.S. and India was given 30 days to report to the Dispute Settlement Body (DSB) to inform it of what corrective action it would take. *Id.* See also *India faces curbs threat from WTO*, THE HINDU, Dec. 22, 1997, at 1-4, available in 1997 WL 16015550 (describing further the power of the WTO to enforce global cooperation of its membership and compliance with its rules). *Accord*, *Thai Herb decision angers Americans: US says local law violates WTO rules*, BANGKOK POST, Aug. 23, 1997, at 1-2, available in 1997 WL 13374115. The U.S. brought complaint against Thailand because of the local Thai Traditional Medicine Bill that the U.S. thought would inhibit pharmaceutical research in violation of WTO rules. *Id.* The Thai government argued against this complaint in the DSB by stating that it was an agricultural country, therefore

which was adopted by the WTO rules, many countries continue to undermine their global obligations in the area of intellectual property.⁶⁷ These countries may find themselves in the uncomfortable position of answering complaints to the WTO and suffering global trade sanctions if they fail to take prompt corrective action.

II. THE BOLAR AMENDMENT

U.S. interests in maximally protecting intellectual property internationally through support of the TRIPS agreement are in sharp contrast with the domestic enactment of the Bolar Amendment. Section A explains the judicial and legislative background surrounding the Bolar Amendment. Section A also discusses the Bolar inconsistency in U.S. domestic policy regarding intellectual property protection compared to its global position. Section B explains the difference between the prevailing European view on the Bolar Amendment and the U.S. position.

A. *The Bolar Amendment: Origins and Effects*

Prior to the Hatch-Waxman Act, generic drug makers were required to perform costly tests and generate independent data for purposes of FDA drug approval, despite the fact that a drug had already been discovered and tested by the research industry.⁶⁸ The Bolar Pharmaceutical Company, a generic drug maker, became a defendant when Roche Products, Inc., a research company, complained that Bolar was using its product for purposes of FDA approval prior to patent expiration.⁶⁹ Bolar admitted it had

it ought to be able to enact laws to protect its "agricultural products" without conflict with the TRIPS agreement. *Id.*

67. See *GATT and Pharmaceutical Patents: Hearing Before the Senate Judiciary Comm. on URAA, TRIPS and Legislation Affecting the U.S. Pharmaceutical Industry*, available in 1996 WL 287067 (Feb. 27, 1996) (statement of William E. Brock, former U.S. Trade Representative and Secretary of Labor under President Reagan) [hereinafter *Brock*] (stating that several countries including Japan, Portugal, Australia, Argentina, and Brazil have attempted to undermine TRIPS in various ways ranging from failing to modify domestic patent terms to not implementing the TRIPS agreement at all despite representing that they have).

68. Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified at 21 U.S.C. § 355) (Supp. 1962) (amended 1984). The original act maintained that the generic drug industry needed to submit its own independent data for obtaining FDA marketing approval. *Id.* The work was redundant because the initial invention had to sustain this same FDA standard. Perhaps the logical reason for this requirement was that the FDA did not have a separate generic "track" for market approval at the time, but rather treated all applications for drug approval in the same way.

69. *Roche Prods., Inc. v. Bolar Pharm. Co.*, 572 F. Supp. 255, 256-57 (E.D.N.Y. 1983). See also Susan Kopp Keyack, *The Drug Price Competition and Patent Term Restoration Act of 1984: Is it a Healthy Long Term Solution?*,

possession of the drug, but argued this was permissible for purposes of FDA drug approval.⁷⁰ Although the trial court agreed with Bolar,⁷¹ the appellate court reversed and stated that Bolar was not limiting its possession of the drug to "scientific inquiry," but rather intended to ultimately exploit the drug product for profit and was therefore in violation of existing patent laws.⁷² The appellate decision reflects a historic judicial posture that frowns upon infringing activity unless its purpose is for "philosophical curiosity" and nothing more.⁷³ Therefore, the Federal Circuit Court of Appeals deemed defendant Bolar as having engaged in infringing activity.⁷⁴

Subsequently, Congress legislated the Bolar Amendment⁷⁵ into the Hatch-Waxman Act.⁷⁶ The Bolar Amendment enables a generic drug maker to use the patented drug for purposes of seeking FDA market approval without liability for patent infringement.⁷⁷ This enables a generic drug maker to market on the first day of patent expiration by having FDA requirements satisfied in a timely manner. The coined phrase "Bolar Amendment" came into existence because Congress essentially overruled the Federal Circuit Court ruling.

The pharmaceutical industry is the only industry that

21 RUTGERS L.J. 147, 153-56 (1989) (describing the facts of the *Bolar* case which ultimately led to the legislative enactment allowing the activity to which the appellate court was opposed).

70. See Keyack, *supra* note 69, at 153 (describing Bolar's position during the litigation).

71. *Bolar*, 572 F. Supp. at 256-58.

72. See, e.g., *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (stating that Bolar's use of the drug constituted "a violation of the patent laws in the guise of 'scientific inquiry'...[which] has definite, cognizable, and not insubstantial commercial purposes").

73. Thomas F. Poche, *The Clinical Trial Exemption From Patent Infringement: Judicial Interpretation of Section 271(E)(1)*, 74 B.U. L. REV. 903, 909-10 (1994) (characterizing the experimental use exception in the case of *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600)). Justice Story was 'riding the circuit' when he spoke from the Massachusetts Circuit Court bench stating "it could never have been the intention of the legislature to punish a man, who constructed... a machine merely for philosophical experiment, or for the purpose of ascertaining the sufficiency of the machine to produce its described effect." *Id.*

74. *Id.* at 910. Bolar asserted "public policy favors generic drugs and thus mandates the creation of a new exception." *Id.* It further insisted it was prejudiced by the added delay to market because of the FDA process thereby unjustly giving the research company an extended time frame of exclusivity. *Id.* However, the Federal Circuit ruled that Bolar's intended use was for commercial purposes and was infringing on Roche's patent. *Id.*

75. 35 U.S.C. § 271(e)(1).

76. Hatch-Waxman Act, *supra* note 21. See also Poche, *supra* note 73, at 911 (stating that it took Congress only five months to legislate the Hatch-Waxman Act after the judicial decision).

77. 35 U.S.C. § 271 (e)(1); Keyack, *supra* note 69, at 160-61.

exempts a prospective infringer from violating long-standing principles of patent exclusivity.⁷⁸ Ironically, this runs counter to the U.S. negotiating position during the Uruguay Round, when it so vehemently supported maximal patent protection.⁷⁹ Domestically, Congress sought to benefit the general public by enacting a patent infringement exception by way of the Bolar Amendment;⁸⁰ however, internationally, Congress mandated that negotiations at the Uruguay Round be geared toward securing the strongest possible patent laws.⁸¹

This inconsistency has met resistance in the European Union (EU), which recently decided that this type of activity infringes on the research company and is prohibited.⁸² In addition, the Bolar debate has continued in countries such as Canada, which is currently under attack in the WTO on the Bolar Amendment issue.⁸³ Among the many issues surrounding the Bolar Amendment is the argument that the amendment violates Article 30 of TRIPS.

B. Europe vs. United States—Opposing Views

The European Court of Justice (ECJ) has ruled that an act of patent infringement occurs when a generic drug maker uses a patented drug for purposes of regulatory approval.⁸⁴ This has

78. See *Faircloth*, *supra* note 7, at 3 (stating that the generic pharmaceutical industry enjoys advantages free from patent infringement that exists in no other industry).

79. SENATE REPORT, *supra* note 28, at 117.

80. H.R. REP. NO. 98-857, at 14 (1984). Bill co-sponsor Representative Waxman from California stated:

What we have is a total bill that I think is very good. It provides low-cost, generic drugs for millions of Americans, saving maybe a billion dollars over a several year period Twenty percent of the people who buy drugs in this country are elderly. Medicare does not pay for drugs . . . so that is coming out of the pockets of the elderly.

Id.

81. SENATE REPORT, *supra*, note 28, at 117.

82. See, e.g., Case C-316/95, *Generics BV v. Smith Kline & French Lab. Ltd.*, 1997 CEC (CCH) 1029 (1997) (stating that a patent holder of a pharmaceutical had a right to oppose infringing activity for purposes of drug approval in Europe).

83. Jill Wechsler, *Equivalence, Equity & Exclusivity*, PHARMACEUTICAL EXECUTIVE, May 1, 1998, at 11. This article describes global problems related to the Bolar amendment and discusses countries currently embroiled in the Bolar debate. *Id.* Some of them include Australia, which currently has pending legislation, Israel, which has recently approved such legislation, and Canada, which is currently being challenged on the Bolar issue in the WTO. *Id.* at 12.

84. See *Generics BV*, 1997 CEC (CCH) 1029. See also *Judgment of EU Court on Generic Medicines and Patent Rights*, IPL NEWSL. (Section I.P. Law, A.B.A., Chicago, Ill.), Summer 1998, at 47. The *Generics BV v. SKF* case decision reflects a similar viewpoint held by the U.S. judiciary. There is no legislation currently in the EU that overrules the judicial decision, therefore

caused continuing debate from both generic and research groups who are increasingly embattled in the legitimacy of the Bolar Amendment.⁸⁵ While the U.S. position is that the Bolar provision is allowed within the meaning of TRIPS, the European view runs counter by insisting that such legislation is not permitted within the global patent provisions of TRIPS.⁸⁶ Resolution of this issue will promote global harmony on patent protection, while continued discord serves the purpose of undermining efforts of the Uruguay Round that created TRIPS. A breakdown of a consistent global policy on patent protection may hamper U.S. efforts to subdue global piracy protection of an inventive entity.⁸⁷ The United States would be setting a world example by deleting legislation that calls for "feel-good" exceptions to the principle of exclusive patent protection.

While the research industry presses Congress to re-examine the Hatch-Waxman legislation,⁸⁸ the international community is watching to see whether the Bolar Amendment violates the TRIPS agreement, to which the United States is a signatory and subject to WTO review. While research companies complain of unreasonable prejudice resulting in unfair patent infringement, the Bolar Amendment has opened a global Pandora's box of inconsistencies as the EU fears economic backlash if U.S. generics seek alternative markets to obtain their bulk active ingredients.⁸⁹

the current law forbids generic drug companies from using the patented drug for regulatory approval unlike in the U.S. *Id.*

85. CHEMICAL MARKET REP., *supra* note 49. European research pharmaceutical makers insist that the U.S. Bolar amendment is in violation of TRIPS because of its discriminatory nature in violating the rights of a specific industry. *Id.* However, bulk active producers (generics) insist upon legislation that is of the Bolar-type. *Id.*

86. *Id.*

87. See J. H. Reichman, *Compliance with the TRIPS Agreement: Introduction to a Scholarly Debate*, 29 VAND. J. TRANSNAT'L L. 363, 381 (1996) (stating that nations such as the U.S. have undermined the provisions of the TRIPS agreement while demanding compliance from other member nations). If the U.S. cannot lead by example through compliance of its obligations in the TRIPS agreement, other nations will soon decline to comply also. *Id.* at 382.

88. Wechsler, *supra* note 83, at 13. Congress is expected to take up the legislation again in order to re-examine whether the public interest in receiving a generic alternative is being outweighed by financial injury to the pharmaceutical companies that may inhibit research and development. *Id.* Although profitable innovator companies may have trouble demonstrating this, sharp price increases in the generic sector may render generics in the awkward position of excessive profitability at the expense of the research industry. *Id.* at 13-14.

89. *Id.* at 11. This is just one possibility whereby the EU may feel financially oppressed as a result of lack of uniformity in interpretation of a law. European generic companies may also relocate their businesses to the U.S. where they may find a safe-haven in the U.S. law not available in Europe. This runs counter to the idea of GATT that sought to harmonize and streamline transnational policy and laws to facilitate trade and decrease

III. PREJUDICING THE PHARMACEUTICAL INVENTOR: THE BOLAR AMENDMENT HAS FINANCIAL EFFECTS THAT PUNISH THE INVENTIVE ENTITY WHILE REWARDING INFRINGERS WITH A BRIGHT FUTURE.

Carving out a patent exception financially deprives an innovator while rewarding a "copier."⁹⁰ Although the public benefits in the short term, the question of long term public harm due to inhibition of research is not so clear. Additionally, the United States may lose in the event of an international legal complaint through the WTO for violating Article 30 of TRIPS.

A. *Adverse Financial Effects*

The Congressional Budget Office (CBO) has recently issued a report that determined new drug investment return for the research industry has decreased by 12% since the introduction of the Hatch-Waxman Act.⁹¹ This amounted to a \$27 million decline on average return per drug in 1990 dollars.⁹² The final draft also reported that the rapid market onset created by the Bolar Amendment resulted in an average generic market share of 60% within three years of marketing, contrasted with 5.1% before the Hatch-Waxman Act.⁹³ This demonstrates that while the generic company did not invent the proprietary drug,⁹⁴ the Bolar Amendment benefits generics by speeding FDA approval and allowing marketability immediately upon patent expiration, thereby enabling generics to penetrate the market quickly. This contrasts market timing for the inventive entity because a research company must labor many years after receiving a patent to obtain FDA approval, while fighting the patent clock.⁹⁵

The National Association of Pharmaceutical Manufacturers (NAPM), representing the generic industry, contends that

tariffs. The current Bolar debate could have the opposite effect of destabilizing global cooperation if it is not resolved soon. *Id.* at 13-14.

90. *New Drug Investment Return Down 12% Since Waxman/Hatch - CBO Report*, PINK SHEET, Aug. 3, 1998, at 5, available in 1998 WL 8441708 [hereinafter *CBO Report*].

91. *Id.*

92. *Id.*

93. *See id.* at 4 (explaining that the new data will be used by the research industry to seek repeal of the Bolar amendment when it is reviewed in 1999).

94. *See Brock, supra* note 67, at 12-13 (stating that generic companies exist because of research drug companies, and although they provide a valuable service, they should not be allowed to infringe upon the proprietary drug if the patent is valid).

95. *Senate Panel Considers Impact of 1984 Law on Drug Development and Availability*, PATENT, TRADEMARK & COPYRIGHT LAW DAILY (BNA), Mar. 15, 1996, at 6 [hereinafter *BNA*]. Gerald Mossinghoff stated that it cost about \$100 million and eight to ten years of research in 1984 (when Hatch-Waxman was enacted) compared to \$500 million and fifteen years today to bring a drug to market. *Id.* He added that patent protection has shrunk by five years since the passage of the Hatch-Waxman Act. *Id.*

blockbuster drugs such as Viagra® re-coup their costs within the first six months of marketing.⁹⁶ However, the CBO found that only the top six drugs marketed earned \$1 billion, and only the top twenty drugs earned more than \$200 million, which is less than the average cost of developing a drug.⁹⁷ The CBO also noted that peak sales of a drug are typically reached after a decade on the market.⁹⁸ This implies that some drugs never attain a reasonable rate of return on investment while some generics arrive immediately upon patent expiration and become profitable.⁹⁹ With substantial profits dwindling and the risks of failure so great, the future holds a decrease of drugs in the research pipeline. This will ultimately lead to a decrease in social welfare.¹⁰⁰ The generic industry points to record levels of research and development investment by research companies.¹⁰¹ This, however, may be a reflection of the complex research that is presently required to initiate new discoveries such as with recombinant DNA biotechnology, rather than solely from increased profits from sales.¹⁰² Further, although a proprietary drug has a minimum five-

96. Telephone Interview with Dr. Leon Shargel, Vice-President and Technical Director, National Association of Pharmaceutical Manufacturers (NAPM) (Oct. 19, 1998).

97. *CBO Report*, *supra* note 90, at 4-5. This indicates that the majority of drugs on the market are not as lucrative as one may believe given the overall research and development costs that need to be returned. *Id.* Additionally, one should consider the degree to which a new start-up pharmaceutical company would be precluded from investing into research given the risks of not meeting the return on investment. *Id.* See also Kerry Capell, *Will Zeneca Get an Offer it Can't Refuse?*, *BUS. WEEK*, July 20, 1998, at 3, available in 1998 WL 8133302 (describing that although there is much research to be done in the pharmaceuticals sector, research continues to become increasingly costly leading to difficulties in pioneering research while trying to please share-holders).

98. *Id.* at 8. See also Henry G. Grabowski & John M. Vernon, *A Sensitivity Analysis of Expected Profitability of Pharmaceutical Research and Development*, 3 *MANAGERIAL & DECISION ECON.* 36, 37 (1982) (demonstrating in a study that an inventive entity may take between 12-19 years to recoup research costs and a reasonable profit).

99. See Poche, *supra* note 73, at 908 n.38 (stating that a study indicated the rate of return on an innovation was so low that the inventive entities would not have invested in it had they had the benefit of hindsight, yet society perceived its benefit to be so great, that they thought the investment was worth the return).

100. See *id.* at 908-09 (discussing that evidence suggests that there is not enough protection of pharmaceutical patents). Additionally, the author indicates that "exemptions from liability for patent infringement manifestly decrease the scope of patent protection and should not be implemented without a careful analysis of their impact on social welfare." *Id.*

101. See *Judiciary Committee Revisits the Hatch-Waxman Act*, *supra* note 25, at 27 (noting the research industry has boasted "record sales, record profits" with an increase in R&D up to \$16 billion in 1996 from \$3.7 billion in 1984).

102. See *id.* (stating that R&D investments and sales are at record-breaking

year guarantee of patent extension built into the Hatch-Waxman Act, the CBO determined this period was too short for protecting a drug.¹⁰³ Although the CBO cautions against shortcomings within the study, it appears to be accurate.¹⁰⁴

The CBO report indicates the research industry is being financially deprived of its rightful earnings.¹⁰⁵ Although generic companies provide a valuable service, they should not be allowed to deprive the research industry of any legitimate financial interest. United States law allowing the Bolar exception conflicts with Article 30 of TRIPS because the legitimate interests of the patent owner are prejudiced financially as demonstrated by the CBO report. Both the ECJ and the United States Court of Appeals for the Federal Circuit have agreed that this activity constitutes an act of infringement.¹⁰⁶ Domestic lawmaking should be in conformity with international law promulgated by the United States. Therefore, the Bolar Amendment must be reevaluated in light of the TRIPS agreement.

EU countries may seek redress against the United States in the WTO for perceived violations of the TRIPS agreement by the enactment of the Bolar Amendment. Because of strong United States backing in the Uruguay Round for maximal patent protection of the inventive entity, a plea for an exception in light of the CBO statistics may fall on deaf ears.

levels compared to 1984 when Hatch-Waxman was legislated). *But see Mossinghoff, supra* note 10, at 4-5 (describing the added costs and time required to receive marketing approval since 1984).

103. *CBO Report, supra* note 90, at 8. In its analysis, the CBO determined that an additional ten proprietary drugs of the 101 approved between 1992-95 would benefit from an increased minimum patent exclusivity period. *Id.* See also Hatch-Waxman Act, *supra* note 21 (legislating to benefit the research industry with a five year patent-extension in return for allowing the generic industry to use the proprietary drug thus circumventing lengthy FDA approval processes). *But see* 35 U.S.C. § 156 (1988 & Supp. V 1993) (stating that this extension to research companies is limited to one patent per drug). This means that if a drug has multiple patents, only one patent will be extended with the risk of not fully compensating the inventive entity for any other patents on the drug.

104. *CBO Report, supra* note 90, at 6. Some limitations include lacking account of changes like R&D costs related to technology, and demand for prescription drugs. *Id.* It has however been demonstrated that R&D costs have increased and with a geriatric population explosion, prescription drug use is sure to be on the rise.

105. *Id.* at 1. For an article discussing outsourcing of work in order to ration funds, see Pete Engardio, *The 21st Century Economy: How It Will Work: Strategies*, BUS. WEEK, Aug. 31, 1998, at 5, available in 1998 WL 8133747 (indicating that the costs of researching a new drug are so high and the risk of failure so great, that it is prohibitive for many companies to enter the pharmaceuticals business).

106. See *supra* Part II for a discussion of the judicial opinions related to Bolar-type legislation.

B. Bright Future for Generics

Generic companies stand to gain much in the coming years with the help of the Bolar Amendment. Estimates of generics controlling 20% of the total multi-source market in 1995 is projected to grow to 70% in the next decade.¹⁰⁷ The majority of the market growth is attributed to the Hatch-Waxman Act, which has increased the number of dispensed generic prescriptions to nearly 50% in 1997.¹⁰⁸ Further, by 2008 many proprietary drugs totaling a market value of \$41 billion will be off patent and in the hands of the generic industry.¹⁰⁹ These so-called "blockbuster" drugs will enable generic sales to increase dramatically, since these drugs are leading therapeutic agents in their respective pharmacological categories.¹¹⁰ The financial detriment to research companies will be even greater in these cases because of the infringing activity enabled by the Bolar Amendment.¹¹¹

Internationally, generic drugs enjoyed \$2.3 billion in sales in 1994 and projections indicate a 14% annual growth to \$50 billion by the year 2000.¹¹² Perhaps the most shocking figure is that research companies will only sustain 6% growth comparatively.¹¹³

While research companies are financially prejudiced, generic companies have additional help from health maintenance organizations (HMO's).¹¹⁴ One cannot ignore that HMO's are becoming the main source of health care for a growing and aging

107. *The Road Ahead For Generics*, CHAIN DRUG REV., Feb. 17, 1997, at 2, available in 1997 WL 10433371 [hereinafter *Road Ahead*]. Two-thirds of all drugs on the market have an available generic alternative. *Id.*

108. *Generics Will Play Major Role in Limiting Health Care Costs*, CHAIN DRUG REV., Sept. 22, 1997, at 3, available in 1997 WL 13789956 [hereinafter *Health Care Costs*]. Generic drugs had an 18% dispensing rate in 1984 when Hatch-Waxman was introduced and is projected to continue to increase beyond the 50% mark in 1997. *Id.*

109. *See id.* at 2 (describing the future of generics as successful drugs come off patent). *Accord Road Ahead*, *supra* note 107, at 3.

110. *Id.*

111. *See CBO Report*, *supra* note 90, at 5 (stating that research drug companies will soon have to aim high to invent "blockbuster" drugs that grant high returns quickly rather than focus on less profitable yet useful therapeutic agents).

112. *See Road Ahead*, *supra* note 107, at 5 (describing the growth of the generic industry and projecting a major increase in the percentage share of the total drug market). The generics had a total world market share of 11% in 1994. *Id.*

113. *Id.*

114. *See Grabowski*, *supra* note 10, at 3-5 (stating that generic drugs are given "priority" on a managed care formulary; physicians are encouraged to prescribe, and pharmacists to dispense, generics whenever possible). Dr. Grabowski further states, "[t]hese managed care policies for encouraging generic prescribing have become a major factor contributing to the rapid erosion of branded drugs sales revenues when patents expire." *Id.*

population.¹¹⁵ HMO's have crafted restrictive drug formularies utilizing generic drugs whenever possible.¹¹⁶ HMO's typically steer patients toward generics by decreasing their co-pay while awarding pharmacists increased dispensing fees for making generic substitutions.¹¹⁷

By avoiding research costs and having a streamlined FDA approval process, the generic industry benefits the public by providing a cheaper drug. However, generics would not be in business if the industry that invented the drug disappeared. Yet smaller technology companies may never develop, and existing ones may merge into non-existence, due to outrageous costs to bring a new drug to market.¹¹⁸ The Bolar Amendment catalyzes this process by allowing the generic industry to infringe on the patented drug, thereby granting the generics a windfall by shifting profits away from the research company in the name of benefiting the consumer patient.¹¹⁹ Although providing the public with a cost-

115. *Quick View - Prescription Growth*, HEALTH & SCIENCE, Nov. 9, 1998, at 31 [hereinafter *Quick View*].

116. See interview with Mark Pietroski, Regional Director of Managed Care, Bindley Western Drug Company, in Oakbrook, Illinois (Sept. 19, 1998) (indicating that the presence of total health care packages for families means that patients who are enrolled will get their prescriptions through the plan as well). See also *Grabowski*, *supra* note 10, at 3-4 (stating that over 60% of employers use pharmacy benefit management (PBM) firms covering over 137 million people). PBM's promote generic use by charging lower copayments, and giving maximum reimbursement. *Id.* Physicians who write prescriptions for brand drugs only can expect poor ratings on drug utilization reviews and can expect to be contacted by their local PBM representative. *Id.*

117. *Road Ahead*, *supra* note 107, at 3-4. While providing a cheaper drug that in many cases is accomplishing the same therapeutic effect, the HMO provides a better price to the consumer patient while enabling the pharmacist to make a bigger profit. *Id.* See generally James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433 (1986) (describing the Hatch-Waxman Act and its impact on generic substitution). Although research companies were successful in enacting legislation to forbid generic substitution by pharmacists in the 1950's leading to an almost total ban by 1972, by the late 1970's almost every state repealed these laws. *Id.* at 437.

118. See Paul Judge, *Speeding Drug-Trial Data to the FDA*, BUS. WEEK, July 13, 1998, at 1, available in 1998 WL 8133190 (describing that each day of delay to market can mean up to \$1 million or more of lost revenue for a pharmaceutical inventor).

119. A classic counter-argument by the generic industry is that the research industry has no rights to an exclusive market after the patent expires. However, this argument must fail for two reasons. First, a research drug company must submit to a much longer deprivation of marketability until the FDA approves its drug. This means that the drug may have a patent running for 10-15 years before it is able to go to market. Forcing a generic industry to wait to go through an FDA approval process in contrast takes only 1-3 years. Second, there is nothing that the pharmaceutical company is doing illegally to promote an exclusive market at the termination of the patent. Similar to the

effective drug is a legitimate concern, doing so by legalizing patent infringement is the wrong approach. The wrong message is sent to inventors and infringers, both domestically and internationally.

C. Third Party Interests

The Bolar Amendment has benefited Americans by saving a substantial amount of money.¹²⁰ There is no doubt prescription drug use continues to grow nationwide.¹²¹ Congressman Waxman praised the Hatch-Waxman Act as enabling a "speeded up process for marketing generics" and declared that "generics now account for 45% of the prescriptions filled compared to 14% in 1985."¹²² The Bolar Amendment serves the needs of the elderly nicely, as almost half of patients over the age of fifty request generic drugs and 30% routinely inquire about them.¹²³

However, there is mixed reaction from consumer groups on the Hatch-Waxman Act. Although some interest groups for the elderly believe the Act strikes the balance needed for the public, others place an emphasis on protecting the patent holders rights to ensure research in diseases of the aging.¹²⁴ Both viewpoints are important enough to co-exist. The public should derive benefits of a cost efficient drug product, but research companies should not be

approval process for a new drug, it is the FDA that stifles access to the market for a generic drug maker. If the FDA would allow the generic company to enter the market immediately on patent expiration, it would be within its discretion, however, it does not follow that the inventive entity should be infringed upon in order to effectuate this process. In summary, this demonstrates that the FDA and not the research company is responsible for hindering market access by the generic maker which should not translate into the right to deprive an industry (that bestows welfare on society) of the right to a time limited patent exclusively free from infringement.

120. See BNA, *supra* note 95, at 2 (stating that Senator Hatch has estimated cost savings to the consumer as a result of the Hatch-Waxman Act are \$1 billion per year).

121. See *Quick View*, *supra* note 115, at 31 (demonstrating that the two biggest contributing factors to increased use of prescription drugs include: (1) aging of the population; and (2) the growth of managed care which depends upon prescription drug therapy).

122. See BNA, *supra* note 95, at 2 (Congressman Waxman declaring that the burden will be heavy on anyone attempting to change the Hatch-Waxman legislation given the successful market transformation created by allowing the generic industry to infringe without liability); see also *id.* at 3 (Waxman declaring that a proper balance was created when the Hatch-Waxman Act was enacted).

123. See *Health Care Costs*, *supra* note 108, at 2.

124. See BNA, *supra* note 95, at 4 (describing the interest of Alliance for Aging Research who warns that federal funding for research is declining, therefore the private sector needs to be maximally protected and compensated for the time it takes to market a drug). Calls from this group invite a reassessment of the Hatch-Waxman Act. *Id.* But see *id.* at 9 (discussing the Gray Panthers position that generic drugs are more affordable to the elderly and research drugs can cost up to 25% of the elderly monthly income).

infringed upon.

Proponents of generic drugs boast about the savings their product bestows on society.¹²⁵ However, the research industry is the true contributor of social welfare. A 1994 drug study showed that a cholesterol-lowering drug decreased total mortality by 30%.¹²⁶ Another study published in 1998 suggests that the treatment of post-menopausal osteoporosis in women prevents bone fracture.¹²⁷ These are just a few examples of many studies that demonstrate the benefits of drug therapy. When one considers the costs deferred by drug treatment, such as: (1) surgical intervention, (2) pain and suffering, (3) loss of time from work, (4) quality of life decline, and (5) pre-mature loss of life, it becomes apparent that society should reward the pharmaceutical industry for inventing the drug with the most complete patent protection rather than allow a generic drug maker to infringe.¹²⁸ Allowing infringement promotes the extinguishment of lifesaving research.

Promoting human longevity through research and development of new drugs should outweigh allowing infringement of a patented drug.¹²⁹ Providing new pharmaceuticals to the public can be achieved by means other than prejudicing a research entity.¹³⁰

125. See *id.* at 2 (boasting that the generic industry is the only health care industry that has decreased healthcare costs).

126. See generally Dr. Terje R. Pedersen et al., *Randomized trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S)*, 344 LANCET 1383-89 (1994) (demonstrating that Zocor®, a cholesterol lowering agent, reduced total mortality by 30%, reduced coronary mortality by 42%, reduced the need for invasive coronary surgery by 37%, and reduced the risk of over-all coronary events by 34%).

127. See generally Dr. Richard Eastell, *Treatment of Postmenopausal Osteoporosis*, 338 NEW ENG. J. MED. 736-46 (1998) (reviewing present drug therapy available for postmenopausal women at risk for and with osteoporosis with a separate review of future modalities of drug therapy).

128. Preventive medicine is a known medical strategy that has been recently promoted in our society. It places a greater emphasis on stopping the harm before it occurs, rather than reacting after an adverse health incident renders one medically compromised. An example of preventive medicine is a smoking cessation program. It is based on the premise that it is much cheaper to pay for someone to stop smoking today, than to treat that person for heart disease, lung cancer or other preventable smoking related disease later in their life.

129. See Jack Burney, *Extending Life Span May Be Possible, Experts Say*, INTERNAL MED. WORLD REP. – GERIATRIC MED. 1998, Oct. 1998, at 8 (stating that there will be 100,000 centenarians by the turn of the new century and crediting better healthcare as the reason). The article also addresses research in genetic discoveries aimed at better understanding the aging process in order to slow it down. *Id.*

130. See *infra* Part IV for a discussion on an alternative proposal of enabling the public to receive prescription drugs at the same cost benefit level provided by Hatch-Waxman, but without infringing on the inventive entity.

D. WTO Dispute Settlement of TRIPS Violations

The WTO has the power to hear disputes arising under TRIPS.¹³¹ Although individual private citizens are not able to bring grievances directly to the WTO dispute settlement body (DSB), action is typically brought by, or defended by, a member nation.¹³² An aggrieved industry could compel its government to bring a complaint against another government for an alleged breach of TRIPS. Should the EU, or any member nation, bring an Article 30 TRIPS complaint against the United States regarding the Bolar Amendment, the outcome would be unclear and involve risks for U.S. interests.

The DSB looks to customary rules taken from the Vienna Convention and "decisions, procedures, and customary practices" under the 1947 version of GATT.¹³³ Interpretation of TRIPS may arise within three separate categories.¹³⁴ The first involves rules of multilateral intellectual property rights (IPR) conventions, incorporated by reference into the text of TRIPS.¹³⁵ The second involves rules that did not arise in TRIPS as a result of prior IPR conventions but rather are specific to TRIPS.¹³⁶ The third category is known as a hybrid because it analyzes segments of TRIPS that are "derived or amended" from a multilateral IPR.¹³⁷

131. ADAMANTOPOULOS, *supra* note 30, at 30.

132. See 19 U.S.C. § 3501 (1994) ("No person other than the United States (A) shall have any cause of action or defense under any of the Uruguay Round Agreements or by virtue of congressional approval of such an agreement . . .").

133. See Frederick M. Abbott, *WTO Dispute Settlement and the Agreement on Trade-Related Aspects of Intellectual Property Rights*, in, INTERNATIONAL TRADE LAW AND THE GATT/WTO DISPUTE SETTLEMENT SYSTEM 418 (ERNST-Ulrich Petersmann ed. 1997) (describing the general approach to interpreting TRIPS). It should be noted that the U.S. was not a signatory to the Vienna Convention, however, it viewed the principles of that convention analogous to custom, which is important since the main thrust of TRIPS interpretation in the WTO will rely on customary principles of the global community. *Id.*

134. *Id.* at 419. The WTO anticipates that disputes will arise in the TRIPS agreement for two reasons: (1) if a member nation has not met its responsibility of implementing the TRIPS agreement into its national laws; and (2) if a member nation has not "provided and given operational effect to adequate enforcement mechanisms for the substantive standards provided." *Id.*

135. *Id.* at 419-20. These rules have been incorporated into the text of the TRIPS agreement from previous multilateral conventions that have addressed intellectual property concerns and already agreed to by member nations. *Id.*

136. *Id.* During the Uruguay Round, new rules were adopted that were previously not addressed in former conventions and represented new intellectual property rights material. *Id.*

137. *Id.* at 420. This third category represented a category that adopted multilateral convention agreements into TRIPS but amended or clarified them at the Uruguay Round prior to incorporating them into the new agreement. *Id.* Thus, the name "hybrid" because the old agreement was retained but modified through the new forum.

1. Multi-Lateral Type

To establish whether a country is in breach of TRIPS under the first category, the DSB looks to the Vienna Convention,¹³⁸ and the Berne Convention where applicable, which has been incorporated by reference into TRIPS.¹³⁹ The Vienna convention restricts interpretation of TRIPS by omitting any State practice derived from activity prior to January 1, 1995.¹⁴⁰ This would limit the United States argument of existing Bolar legislation prior to TRIPS for purposes of demonstrating established State practice. The United States could argue it was not a signatory to the Vienna Convention and therefore not subject to this analysis.¹⁴¹ In that case, the DSB may consider U.S. state practice in light of the Vienna Convention to the extent those rules are incorporated into TRIPS.¹⁴² But U.S. state practice is inconsistent due to its schizophrenic approach in carving out the Bolar Amendment exception to its otherwise strong domestic patent laws. Further, legislative and judicial history involving the Bolar Amendment could be used to aid the DSB in establishing State practice, but this would hurt the United States due to additional discrepancies of the diametrically opposed legislative and judicial views on the Bolar Amendment domestically.¹⁴³ The DSB may also compare the short period of the Bolar Amendment with a much longer historical custom of exclusive patent protection for pharmaceuticals. Viewed in a global context, the DSB will likely find that although the Bolar Amendment is gaining popularity with other member nations, a well-established customary international rule on an infringement exception to pharmaceutical

138. See N. A. MARYAN GREEN, INTERNATIONAL LAW, LAW OF PEACE 54 (1982) (describing how the Vienna Convention on the Law of Treaties shall be used to enforce international rules of an organization). The Vienna Convention became enforceable on January 27, 1980 and contained the procedural rules necessary to enforce international treaties. *Id.*

139. See Abbott, *supra* note 133, at 420-21 (stating that the Vienna convention provides that "a treaty shall be construed in accordance with the ordinary meaning of its terms, and in its context").

140. *Id.* at 421. This harsh rule has been introduced because the new TRIPS approach is necessarily stricter and more comprehensive than any prior contemplated national or global intellectual property protection endeavor. *Id.* The drafters intended to adopt prior intellectual property rules in their "strict textual form without the surrounding context of state practice" interpreting the agreement. *Id.*

141. *Id.* This would be a good defense, however, the U.S. may then either be dropped from this category of analysis in favor of the second category, or may be subject to a State practice analysis in light of TRIPS. *Id.*

142. *Id.*

143. Although judicial decisions are not the exclusive source of State practice in the Vienna Convention, tribunal opinions are given great deference for applying international law principles. See, e.g., LAUTERPACHT, OPPENHEIM'S INTERNATIONAL LAW § 15-17 (8th ed. 1955).

patents does not exist. Given these facts, the DSB will likely rule unfavorably for the United States within this category.

2. *Specific TRIPS Rules*

The U.S. position becomes even weaker if the DSB analyzes the Bolar Amendment under Article 30 as a rule specific to TRIPS because the DSB would rely strictly on the TRIPS text.¹⁴⁴ The DSB may look to national court decisions or legislature's to aid its decision in these matters, but this is not a procedurally required part of the analysis.¹⁴⁵ The text of Article 30 indicates the legitimate interests of a patent owner cannot be prejudiced, taking into account the legitimate interests of third parties. Strictly construed, Article 30 would include any legitimate financial interests that are unreasonably prejudiced such as those reported by the CBO. The United States would need to demonstrate that there is no other alternative to benefit the public other than through an act of infringement. Further, the United States would be required to demonstrate that the infringing act that allows access to generic drugs outweighs the harm done to the research industry. This burden would be heavy given that the legitimate interests of the research industry are unreasonably prejudiced and other means of providing a more cost-effective drug to the public exist.

3. *Hybrid Analysis*

If the DSB considered the Bolar Amendment in the third category, it would look to State practice first, then seek to determine how the TRIPS agreement intended to modify the state practice.¹⁴⁶ The United States argued the Bolar Amendment was within the narrow exception of Article 30 during the Uruguay Round.¹⁴⁷ However, the DSB is unlikely to agree with this contention because of the degree of quantifiable financial prejudice elicited by the CBO report and the qualitative adverse effect this would have on future research endeavors by innovators.

Although the DSB is new and standards of judicial resolution of global disputes are not clear at this point, it is reasonable to conclude that the Bolar Amendment violates Article 30 of TRIPS.

144. See Abbott, *supra* note 133, at 424 (stating that the DSB would tend to strictly interpret the text of the TRIPS agreement).

145. *Id.*

146. *Id.* at 426.

147. See Brock, *supra* note 67, at 10 (describing the U.S. position on Bolar during the Uruguay Round and adding that the U.S. went through "pains" to demonstrate that Bolar did not violate TRIPS).

IV. SMOKING OUT BOLAR WHILE PROVIDING A COST-EFFECTIVE DRUG

This Comment argues that the Bolar Amendment places the United States in violation of its global commitments. Congress should consider an alternative means of delivering cost-effective pharmaceuticals to the public. This would avoid an international confrontation at the WTO and preserve U.S. credibility on global issues of patent protection.

A. *Deleting the Bolar Amendment*

Intellectual property protection is critical to U.S. foreign interests and exceptions such as the Bolar Amendment undermine U.S. goals toward maximal patent protection. Congress should delete the Bolar Amendment and abstain from creating patent protection exceptions. Research and innovation will maximally flourish absent patent infringement exceptions. Anything less invites other countries to engage in acts of piracy by using the Bolar Amendment as a pre-text to engage in infringing activity. If the United States violates the global treaties that it seeks to enforce, then it cannot be heard to complain to the WTO about other nations. Finally, disrespect for global collaboration may unravel the harmonious transnational relationships developed this century.

B. *Providing Prescription Drugs to the Public*

Upon deleting the Bolar Amendment, the United States should seek alternative means to provide funding for prescription drugs.¹⁴⁸ An alternative would be to levy a tax on all tobacco products and alcohol.¹⁴⁹ A nominal national tax would raise at least \$5 billion annually.¹⁵⁰ These products are responsible for

148. For a look at how easily the U.S. government can spend its money on arguably less important matters. See *Military Can't Do 2-War Mission, Senators Told*, CHI. TRIB., Sept. 30, 1998, § 1, at 7 (stating that the U.S. has spent \$9 billion on peace-keeping since 1995 on Bosnia-Herzegovina, when it originally was expected to cost \$2 billion). When one compares this with Senator Hatch's statement in saving the public \$1 billion per year, it seems that the U.S. is quicker to interject itself into a foreign conflict in which it has no vital national interest than to provide its own citizens with the difference in savings that Bolar creates.

149. For an example of a "sin tax" levied for the public funding of a stadium project, see Timothy Heider, *Cleveland Business League Endorses Tax for Stadium*, PLAIN DEALER, Oct. 24, 1995, at 2B, available in 1995 WL 11012585 (discussing an alcohol and tobacco tax in order to fund the local stadium renovation).

150. See CDC's *TIPS-1995 Nat'l Household Survey on Drug Use: Tobacco Statistics* (visited Feb. 23, 1999) <<http://www.cdc.gov/tobacco/samhsa.htm>> (estimating 61 million Americans were smoking in 1995, representing 29% of the U.S. population). Of these 61 million, 4.5 million were adolescents age 12-

many preventable diseases,¹⁵¹ and an individual who purchases these products would benefit society by displacing the cost of prescription medication. The revenue could be dispersed through block grants to the individual states and would then be implemented to subsidize the difference created by deleting the Bolar Amendment. Patent rights of the research pharmaceutical industry would be respected, and the public would continue to benefit from State subsidies. The generic industry would have the right to begin research on the proprietary product only when the patent expires. The interest of the public would be served through the tax subsidy,¹⁵² and drug makers would be assured of maximal patent protection.

17. *Id.* An average package of cigarettes costs approximately \$3. A 2% tax would raise more than \$1.3 billion per year on an average one pack per day. This statistic does not include smokeless tobacco or cigars, nor does it include beer or liquor. Factoring in these additional products would raise more than \$5 billion annually.

151. *CDC's TIPS-Cigarette Smoking-Related Mortality* (visited Jan. 16, 1999) <<http://www.cdc.gov/tobacco/mortali.htm>>. The CDC estimates 400,000 Americans die annually from smoking related diseases with direct medical costs exceeding \$50 billion. *Id.* Smoking related diseases include cancer, hypertension, heart disease, stroke, pneumonia, bronchitis, emphysema, chronic airway obstruction and burn deaths. *Id.*

152. It is arguable that this may cause the consumer to spend less money on other goods, however \$5 billion is minimal in a \$5 trillion economy. Given the price inelasticity of tobacco and alcohol, it is unlikely that either the tobacco or alcohol industry will suffer a tremendous loss.