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SENATE

{ REPORT
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PHARMACEUTICAL INDUSTRY SPECIAL EQUITY ACT OF 1996

OCTOBER 1, 1996.—Ordered to be printed

Mr. HATCH, from the Committee on the Judiciary,
submitted the following

REPORT

together with

MINORITY VIEWS

[To accompany S. 1277]

The Committee on the Judiciary, to which was referred the bill (S. 1277) to amend title 35, United States Code, with respect to patents on pharmaceutical products, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill as amended do pass.

CONTENTS

	Page
I. Purpose and summary of the bill	3
II. Background and need for legislation	5
III. The Committee on the Judiciary's hearing	19
IV. Legislative history	21
V. Section-by-section analysis	21
VI. Committee views	22
VII. Cost estimate	28
VIII. Regulatory impact statement	28
IX. Minority views of Mr. Brown	29
X. Minority views of Messes. Kennedy and Simon	39
XI. Changes in existing law	41

The amendment is as follows:

Strike all after the enacting clause and insert in lieu thereof the following:

SECTION. 1. SHORT TITLE.

This Act may be cited as the “Pharmaceutical Industry Special Equity Act of 1996”.

SEC. 2. APPROVAL OF GENERIC DRUGS.

(a) **IN GENERAL.**—With respect to any patent, the term of which is modified under section 154(c)(1) of title 35, United States Code, as amended by the Uruguay Round Agreements Act (Public Law 103–465; 108 Stat. (4983), the remedies of section 271(c)(4) of title 35, United States Code, shall not apply if—

(1) such patent is the subject of a certification described under—

(A) section 505(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV)); or

(B) section 512(n)(1)(H)(iv) of such Act (21 U.S.C. 360b(n)(1)(H)(iv));

(2) on or after the date of enactment of this section, such, a certification is made in an application that was filed under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act and accepted for filing by the Food and Drug Administration prior to June 8, 1995; and

(3) a final order, from which no appeal is pending or may be made, has been entered in an action brought under chapter 28 or 29 of title 35, United States Code—

(A) finding that the person who submitted such certification made a substantial investment of the type described under section 154(c)(2) of title 35, United States Code, as amended by the Uruguay Round Agreements Act; and

(B) establishing the amount of equitable remuneration of the type described under section 154(c)(3) of title 35, United States Code, as amended by the Uruguay Round Agreements Act, that is required to be paid by the person who submitted such certification to the patentee for the product that is the subject of the certification.

(b) **DETERMINATION OF SUBSTANTIAL INVESTMENT.**—In determining whether a substantial investment has been made in accordance with this section, the court shall find that—

(1) a complete application submitted under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act was found by the Secretary of Health and Human Services on or before June 8, 1995 to be sufficiently complete to permit substantive review; and

(2) the total sum of the investment made by the person submitting such an application—

(A) is specifically related to the research, development, manufacture, sale, marketing, or other activities undertaken in connection with, the product covered by such an application; and

(B) does not solely consist of that person’s expenditure related to the development and submission of the information contained in such an application.

(c) **COMPENSATION.**—(1) In connection with the entry of the order described in subsection (a)(3), the court may order that the patentee pay equitable compensation, to the person that submitted such an application, for the period commencing on the date a certification described in subsection (a)(1) was first made and ending on the date of the entry of the order described in subsection (a)(3).

(2) The court may order payment of equitable compensation under paragraph (1) if marketing of the product that is the subject of the certification was delayed as a result of an action brought pursuant to this section.

(d) **EFFECTIVE DATE OF APPROVAL OF APPLICATION.**—In no event shall the Food and Drug Administration make the approval of an application under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act, which is subject to the provisions of this Act, effective prior to the entry of the order described in subsection (a)(3).

(e) **APPLICABILITY.**—The provisions of this section shall not apply to any patent the term of which, inclusive of any restoration period provided under section 156 of title 35, United States Code, would have expired on or after June 8, 1998, under the law in effect on the date before December 8, 1994.

SEC. 3. APPLICATION OF CERTAIN BENEFITS AND TERM EXTENSIONS TO ALL PATENTS IN FORCE ON A CERTAIN DATE.

For the purposes of this Act and the provisions of title 35, United States Code, all patents in force on June 8, 1995, including those in force by reason of section 156 of title 35, United States Code, are entitled to the full benefit of the Uruguay Round Agreement Act of 1994 and any extension granted before such date under section 156 of title 35, United States Code.

SEC. 4. EXTENSION OF PATENTS RELATING TO NONSTEROIDAL ANTI-INFLAMMATORY DRUGS.

(a) **IN GENERAL.**—Notwithstanding section 154 of title 35, United States Code, the term of patent shall be extended for any patent which encompasses within its scope of composition of matter known as a nonsteroidal anti-inflammatory drug if—

(1) during the regulatory review of the drug by the Food and Drug Administration the patentee—

(A) filed a new drug application in 1982 under section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355); and

(B) awaited approval by the Food and Drug Administration for at least 96 months; and

(2) such new drug application was approved in 1991.

(b) **TERM.**—The term of any patent described in subsection (a) shall be extended from its current expiration date for a period of 2 years.

(c) **NOTIFICATION.**—No later than 90 days after the date of enactment of this Act, the patentee of any patent described in subsection (a) shall notify the Commissioner of Patents and Trademarks of the number of any patent extended under such subsection. On receipt of such notice, the Commissioner shall confirm such extension by placing a notice thereof in the official file of such patent and publishing an appropriate notice of such extension of the Official Gazette of the Patent and Trademark Office.

SEC. 5. SENSE OF THE SENATE.

It is the sense of the Senate that litigation pursuant to this Act will be concluded as expeditiously as possible.

I. PURPOSE AND SUMMARY OF THE BILL

The purpose of this legislation is to clarify a perceived ambiguity in the treatment of certain pharmaceutical patents stemming from the United States' adoption of an internationally negotiated treaty.

The Uruguay Rounds Agreement Act ("URAA"), which is the General Agreements on Tariffs and Trade ("GATT") implementing legislation, changed U.S. patent terms. Under the GATT treaty, as implemented by the URAA, all patents expire 20 years from date of application. Prior to the June 8, 1995, effective date of the URAA, U.S. patents expired 17 years from the date of issuance.

The URAA established special "transition" rules for any patents in force as of June 8, 1995; the patent terms would be the old 17-year or the new 20-year terms, whichever was greater. It is the applicability of this transition rule to the pharmaceutical industry which gives rise to the need for this legislation.

A special provision was inserted in the URAA that, in effect, immunized from infringement those who had commenced certain acts or made "substantial investment" in reliance of the patent expiration to utilize the patent during this transition period when those acts became infringing by reason of the new patent expiration dates. The law stated that those who met this test could seek judicial approval to market their inventions upon payment of a court-determined "equitable remuneration" to the patent holder.

The generic drug industry has argued that this provision would allow them to utilize the old effective dates for patent terms and send their FDA-approved products to market in advance of the URAA-revised dates, assuming that equitable remuneration were paid to the patent holder.

However, that argument neglected another provision of law which precludes the FDA from certifying that a generic drug can be marketed if the patent term has not expired. While that other provision of law, the "Hatch-Waxman Act" (98 Stat. 1585), was elsewhere modified in the URAA, the basic rule precluding ap-

proval of generic pharmaceuticals while the innovator's patent is in force was not modified.

Certain generic pharmaceutical firms which had planned on marketing their products prior to adoption of the URAA were not able to do so because the effective date of the innovator's patent had been adjusted by the URAA changes and the FDA could not certify the products for marketing. They argued that they should be allowed to go to market based on the old patent date, which was the purpose of Senator Brown's legislation, S. 1277.

However, S. 1277, as introduced, neglected a basic reading of the law that the change of patent terms, in fact, precluded any potential generic competitor, in any industry, from going on the market in advance of the GATT-revised patent term expiration—unless the generic met the test of having made substantial investment in reliance of the old patent expiration when that investment became infringing by reason of the new patent expiration dates. Now, over 1 year after implementation of that provision, it appears that no industry, pharmaceutical or other, has attempted to use the URAA provision to market a product.

Due to continuing concerns raised by the generic pharmaceutical industry about their treatment under the URAA, the Committee scheduled consideration of S. 1277, and approved a substitute authored by Chairman Hatch. That substitute will permit generic versions of patented pharmaceutical products, whose terms were redefined by the URAA, to enter the market without the legal challenges normally available to the patent holder *if* certain criteria are met.

Under the provisions of S. 1277, as amended, certain generic drug products may enter the market before the expiration of the patent of the pioneer product once a court issues a final order: (1) finding that the manufacturer of the generic drug made the URAA-required "substantial investment" prior to June 8, 1995, in anticipation of entering the market upon expiration of the pre-URAA patent term; and (2) establishing the "equitable remuneration" the generic drug manufacturer must provide to the pioneer patent holder, given that the proper certification application is made pursuant to the Federal Food, Drug and Cosmetic Act. Subsection (b) of S. 1277, as amended, provides standards to be utilized by the court in determining whether a particular generic applicant made the requisite substantial investment.

The bill, as amended, provides the court the discretion to order that the patent holder pay equitable compensation to the generic drug applicant if the lawsuit caused delay in the initiation of marketing by the generic drug company. The substitute also contains a specific provision authored by Senator Biden clarifying that patents in force on June 8, 1995, as a result of extensions under the Hatch-Waxman Act are entitled to the same benefits under the URAA as any other patent. Finally, the amended version of S. 1277 contains Senator Specter's provision which compensates for a deficiency in the FDA approval process and restores 2 years of lost patent life for the nonsteroidal anti-inflammatory drug Lodine.

II. BACKGROUND AND NEED FOR THE LEGISLATION

GATT-URUGUAY ROUND AGREEMENTS

On April 15, 1993, the United States and 122 other nations concluded the most recent series of international trade and tariff negotiations, a process begun almost 50 years ago.¹ The “Uruguay Round” of the General Agreement on Tariffs and Trade negotiation resulted in signature of a broad and comprehensive trade agreement which represented a major step in lowering international trade barriers and promoting increased competition in world trade. As a result of the Uruguay Round Agreements, it has been estimated that the world economy output will expand by \$5 trillion over the next decade.²

Negotiating the Uruguay Round was a difficult process. Ten years ago, President Reagan launched the discussions in Punta del Este. The negotiations were continued by President Bush, and finally concluded by President Clinton. The product of tough U.S. negotiations and careful bipartisan cooperation, the Uruguay Round Agreements won significant benefits for the United States. Throughout the negotiations, each Administration closely consulted with and consistently received input from both Congress and industry.³

The numerous benefits of the Uruguay Round Agreements that will accrue to the United States include provisions limiting discriminatory government subsidies, opening markets to agriculture, reducing tariffs, and protecting intellectual property.

In particular, the agreement on intellectual property rights, obviously relevant to any discussion of S. 1277, was a very contentious issue and the subject of intense debate and negotiations, both within and without the United States. The negotiations involved 122 countries and a large scope of issues, including provisions on the protection of copyrights and patents. In fact, the Uruguay Round has been cited as covering more industries in more countries than any other agreement in history.⁴

TRADE-RELATED ASPECTS OF THE INTELLECTUAL PROPERTY AGREEMENT

The intellectual property provisions of the Uruguay Round, commonly called the “Trade-Related Aspects of Intellectual Property Rights Agreement (“TRIPs”), won a new, substantially higher international standard of protection for a full-range of U.S. property rights. The TRIP’s agreement covered patents, copyrights, trademarks, industrial signs, trade secrets, integrated circuits, and geographical indications. While the TRIP’s agreement required some relatively minor conforming changes in U.S. law, as embodied in the Uruguay Round Agreements Act, it required our trading partners to upgrade their protections substantially.

¹ General Agreement on Tariffs and Trade, *opened for signature* Oct. 30, 1947, 61 Stat. A3. 55 U.N.T.S. 187.

² Warren Christopher, *Kick-Starting Global Economy*, U.S.A. Today, Dec. 16, 1993, at 13A.

³ Message from the President to Congress Transmitting the Uruguay Round Trade Agreements, H. Doc. 103-316, vol. 1, Sept. 27, 1994, 1.

⁴ Keith Bradsher, *U.S. and Europe Clear the Way for a World Accord on Trade, Setting Aside Major Disputes*, New York Times, Dec. 15, 1993, at A1.

For more than a decade, a major objective of U.S. international trade negotiations has been strengthening intellectual property protections worldwide.⁵ As multilateral trade negotiations under the GATT removed numerous “traditional” trade barriers, such as high tariffs and quantitative import restrictions, negotiators began to realize that weak or ineffective intellectual property protection in foreign countries proved an even more potent force blocking U.S. exports of goods and services in some of our most competitive and important sectors.⁶ As a result, our country began to formulate objectives to remedy such unfair competition which was costing U.S. industry and consumers billions of dollars a year.

Beginning in the early 1980’s, we began including provisions on intellectual property in various trade statutes, leading to one of our most powerful enforcement tools for intellectual property, referred to as “Special 301.” The Special 301 provision, part of the Omnibus Trade and Competitiveness Act of 1988, gives the U.S. Trade Representative the authority to implement sanctions and trade barriers against foreign nations who fail to provide “adequate and effective” intellectual property protection for U.S. goods and services.⁷ We have also included intellectual property provisions in other trade statutes such as: the Caribbean Basin Economic Recovery Act,⁸ which provides duty-free treatment for eligible articles of trade from 27 countries as long as those countries, among other things, have not repudiated or nullified any “patent, trademark, or other intellectual property of, a United States citizen or corporation.”; the Generalized System of Preferences,⁹ which permits the President to provide duty-free treatment for goods from certain developing countries as long as they respect U.S. intellectual property rights; and the North American Free Trade Agreement (“NAFTA”),¹⁰ which includes a comprehensive section covering all aspects of intellectual property rights.

During the Uruguay Round of the GATT negotiations, the United States persistently sought to include international protection of intellectual property as an element of free trade. This was at the top of our trade agenda and was considered to be an essential ingredient for a successful agreement.¹¹

There is no question that disagreements over intellectual property rights deadlocked negotiations at times during the lengthy 7-year process.¹² Our trade negotiators experienced ardent opposition from a number of developing countries,¹³ and even from certain de-

⁵ Bruce A. Lehman, *Intellectual Property Protection Under the Clinton Administration*, 27, Geo. Wash. J. Int’l L. & Econ. 395, 396 (1994).

⁶ See U.S. Framework Proposal to GATT Concerning Intellectual Property Rights, 4 Int’l Trade Rep. (BNA) 1371 (Nov. 4, 1987).

⁷ Omnibus Trade and Competitiveness Act of 1988, section 301, 19 U.S.C. 2411 (1988).

⁸ 19 U.S.C. 2701–2706 (1988 & Supp. V 1993).

⁹ 19 U.S.C. 2461–2466 (1988). A country may not benefit from the GSP program if it has previously violated the intellectual property rights of U.S. citizens or corporations, without providing a means of compensation. 19 U.S.C. 2462(b)(4). Furthermore, to be eligible to receive the GSP benefits, a country must extend “adequate and effective means under its laws for foreign nationals to secure, to exercise, and to enforce exclusive rights in intellectual property, including patents, trademarks and copyrights.” 19 U.S.C. 2462(c)(5).

¹⁰ North American Free Trade Agreement, Dec. 17, 1993, U.S.-Canada-Mexico, 32 I.L.M. 289.

¹¹ Memorandum of December 15, 1993, for the U.S. Trade Representative: Trade Agreements Resulting from the Uruguay Round of Multilateral Trade Negotiations, 58 Fed. Reg. 67,263, 67,289 (1993) [hereinafter Memorandum of Dec. 15, 1993].

¹² *The GATT Deal: The Longest Round of All*, Fin. Times, Dec. 16, 1993, at 5.

¹³ Among the developing countries, Brazil and India led the opposition to TRIP’s. These countries have repeatedly and intentionally refused to protect the intellectual property rights of U.S.

veloped countries in the European Community.¹⁴ This was an unacceptable piracy of U.S. creativity and innovation.

Studies have demonstrated that weak enforcement mechanisms and intellectual property laws in countries such as Singapore, Taiwan, Indonesia, Brazil, Egypt, the Philippines, Malaysia, among others, are common because piracy of intellectual property provides a “major source of income.”¹⁵ The United States is one of the world’s largest producer of new technologies, ranging from computer-related technologies to pioneering biotechnology to pharmaceutical inventions. Accordingly, we have become increasingly vulnerable to piracy and otherwise inadequate protection of our intellectual property rights in foreign countries. Recent U.S. Government and industry studies reveal that billions of dollars are lost each year to counterfeiters,¹⁶ resulting in thousands of lost jobs. As a result, increased protection of U.S. intellectual property was a critical objective for our trade negotiators during the Uruguay Round.

The Uruguay Round was completed on December 15, 1993, and included the TRIP’s agreement.¹⁷ Although it did not fully meet our objectives, TRIP’s was a major achievement in improving the mean level of international protection for all intellectual property rights, including patents, copyrights and trademarks.

Summarily, the key patent-related provisions of TRIP’s require that member nations: (1) provide product and process patents for virtually all types of inventions, including agrochemicals and pharmaceuticals, (2) limit the imposition of compulsory licensing, (3) provide a patent term of 20 years from the date of application, and (4) implement procedures to permit the filing of patent applications covering pharmaceuticals and agrochemicals.

Similarly, the United States won key copyright and trademark-related benefits from TRIP’s, as well as other intellectual property protections on trade secrets, computer chips, and products incorporating protected chip designs.

Despite the many gains of the agreement, there were downsides in the TRIPs agreement as well. The transition provisions were a deeply debated issue and the whole agreement almost failed as a result. Indeed, Commissioner Bruce Lehman has commented that “[o]ne of the downsides of the TRIPs, from the U.S.¹⁸ point of view,

nationals, including patent rights in U.S. pharmaceuticals. They have been identified in the past by the USTR as countries that fail to provide “adequate and effective” intellectual property protection as part of USTR’s Special 301 investigations.

¹⁴In the European Community, there are countries that impose quotas on all television station transmission time. In France, for example, 60 percent of all television programs aired must be French or EC in origin. This is discriminatory to the U.S. film and television industry by effectively locking them out of the market through such quota barriers. For U.S. industry view, see Jack Valenti, *Trade Bomb Scores a Direct Hit on Hollywood*, L.A. Times, Dec. 16, 1993, at A11.

¹⁵See Jan D’Alessandro, *A Trade-Related Response to Intellectual Property Piracy: A Comprehensive Plan to Aid the Motion Picture Industry*, 76 Geo. L.J. 417, 423–26 & n.78 (1987). See also Marshall A. Leaffer, *Protecting United States Intellectual Property Abroad: Toward a New Multilateralism*, 76 Iowa L. Rev. 273, 281 & 284 (1991).

¹⁶U.S. Int’l Trade Comm’n, USITC Pub. No. 2065, *Foreign Protection of Intellectual Property Rights and the Effect on U.S. Trade 4–2* (1985) (estimating U.S. losses to be as high as \$23.8 billion).

¹⁷The TRIP’s text was based on the “Dunkel Draft.” Draft Final Act Embodying the Results of the Uruguay Round of multinational Trade Negotiations, GATT Doc. MTN.TNC/W/FA (Dec. 20, 1991). This draft was proposed by Arthur Dunkel, the former Director General of the GATT, who resigned July 1, 1993.

¹⁸Bruce A. Lehman, *Intellectual Property Under the Clinton Administration*, 27 Geo. Wash. J. Int’l L. & Econ. 395, 409 (1994).

is the section on Transition Arrangements” which allowed certain developing countries up to 10 years to comply with TRIP’s. Absent major compromises on this point from several key industries, including the pharmaceutical and biotechnology industries, we may not have had a final agreement on the Uruguay Round and its accompanying benefits.

THE PHARMACEUTICAL INDUSTRY AND INTELLECTUAL PROPERTY

Pharmaceutical industry breakthroughs, including those from the biotechnology industry, have been one of the success stories in U.S. industry, creating new jobs and pioneering exciting therapies that improve our way of life. They provide the best and most cost-effective hope for new cures and treatments for life-threatening and debilitating diseases. This is evident upon consideration of the alternatives to drug therapy: surgery and hospitalization.

For example, in the case of ulcers, the advent of antacids, hydrogen antagonists and other drugs led to a decline in surgeries from 97,000 in 1977 to below 19,000 in 1987. It is estimated that this change alone resulted in the avoidance of approximately \$224 million in health care cost per year.¹⁹

The rigorous process of pharmaceutical innovation, given the complexities of developing cutting-edge treatments, is often expensive and takes many years before it yields practical results. According to an Office of Technology Assessment Report²⁰ 3 years ago, new pharmaceutical products can cost up to \$359 million to bring to market and take up to 12 years. That cost is undoubtedly much greater now.

Indeed, incentives are necessary to encourage researchers to invest in the much needed, but often expensive and risky endeavors of drug discovery. A major incentive is our 200-year-old patent code, which in effect allows inventors to exclude others from marketing their products or processes for a limited time. That incentive is grounded in article I, section 8, clause 8 of the United States Constitution, which gives Congress the power “ * * * 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.”

The pharmaceutical industry relies heavily on patent protection in recouping the costs of bringing new drugs to the market. Furthermore, adequate patent protection is vital in persuading investors to provide the necessary capital to the industry for further research.²¹ Research in the pharmaceutical industry is extremely

¹⁹ PhRMA, *Modern Medicines: Saving Lives and Money*, 1994.

²⁰ *Pharmaceutical R&D: Costs, Risks and Rewards*, Office of Technology Assessment, Congress of the United States, February 1993.

²¹ Fully capitalized costs of the R&D process appear to have risen from approximately \$350 million for drugs introduced in the period 1981–83 to over \$500 million for drugs introduced in 1990. These higher costs are reflected in other indicators of the expense of pharmaceutical R&D. The average number of clinical trials per New Drug Application doubled from 30 in 1981–84 to 60 in 1989–92. For each trial, the average number of patients rose from 1,321 to 3,567 over the same period. Thus independent studies of numerous indicators point toward a significant, sustained increase in the financial cost of pioneer pharmaceutical R&D. The Boston Consulting Group, *Sustaining Innovation in U.S. Pharmaceuticals*, (1996); see Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards*, pp. 10–23, (1993).

risky, with only a tiny fraction of total compounds, about one in 6,000, researched actually making it to the market.²²

While research into new medicines is extremely costly, most medicines can be copied at a small fraction of their development cost.²³ One recent investigation reported that “the nature and operation of a new product [is] reported to a firm’s rivals faster in pharmaceuticals than in nine other inventive industries.”²⁴ The factors that drive this process include readily available raw materials, fungible technology, and new reverse engineering chemical technologies.

The research-based pharmaceutical companies have doubled their research and development expenditures every 5 years since 1970 and, for several years, have been spending more than the entire Federal Government spends on all biomedical research. Last year, the industry spent an estimated \$14 billion on R&D. The ratio of R&D to sales for the industry was about 18.8 percent in 1994, which is more than four times the average rate for all U.S. industries engaged in R&D.

Without adequate and effective legal protection of intellectual property, free-riders, international as well as domestic, will produce versions of the pioneer drugs without significant investment. This will result in diminished incentives for pharmaceutical companies to invest in further research and development, ultimately creating a situation where there will be no innovative drugs for the generic manufacturers to copy.

California Representative Henry Waxman recognized this issue during the debates on the Hatch-Waxman Act in 1984, when he noted:

It would be fine to say that the consumer could get the same drug at a lower price if there were generics of the new drug. But there would not be a new drug to copy if the first company did not put in the money to develop it.²⁵

It must be noted, however, that patent protection for pharmaceuticals does not grant the pioneer companies a monopoly totally free from competition. A patent on an invention gives the patent holder the right to exclude others from making, using or selling the invention, and only for a limited time.²⁶ It does not prevent others from inventing different products that are not covered by the innovator’s patent yet accomplish the same tasks as the patented product. Once this second product is available, consumers can choose which of the two products they will purchase.

This is currently evident by the market for anti-ulcer class of pharmaceuticals, where several distinctively patented drugs directly compete with each other for market share. None of these drugs enjoy a monopoly of the market despite their patent on the innovative therapy.

²² J. DiMasi, *Risks, Regulation, and Rewards in New Drug Development in the United States*, *Regulatory Toxicology and Pharmacology* 19, pp. 228 (1994).

²³ Statement of Harvey E. Bale, Jr., Ph.D., before the Subcommittee on International Trade, Senate Committee on Finance, June 24, 1994.

²⁴ E. Mansfield, *Intellectual Property Rights, Technological Change and Economic Growth*, 1988.

²⁵ Remarks of Rep. Henry Waxman, Cong. Rec., Sept. 6, 1984, at H9124.

²⁶ 35 U.S.C. 101, *et seq.*

It must also be noted that pharmaceutical companies rarely enjoy the limited market exclusivity for their inventions for the full term of their patents. This is due to regulatory requirements imposed on this industry by the Federal Food, Drug, and Cosmetic Act. Before a drug may be marketed, it must first be approved by the FDA, even though the patent may be in force during the FDA review process. As a result, unlike any other industry in the United States, the pharmaceutical industry cannot fully enjoy its patent benefits. In certain cases, companies may obtain extensions for part of the regulatory delay, but rarely may they enjoy the full term of the patent.

OVERVIEW OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT

In the case *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), the U.S. Court of Appeals for the Federal Circuit, held that the manufacture or use of a patented drug in to generate test results for an application to the FDA constituted patent infringement. In 1984, Congress legislatively overruled *Roche* in the Drug Price Competition and Patent Term Restoration Act,²⁷ more popularly known as the “Hatch-Waxman Act.”

Hatch-Waxman contains two titles: (I) abbreviated new drug applications for generic drugs, and (II) patent extensions to partially restore the time lost by research based pharmaceutical companies to the FDA regulatory review process. The Act struck a careful balance between two important public policy goals. One goal was to “make available more low cost generic drugs by establishing a generic drug approval procedure * * *”,²⁸ and the other was to strengthen incentives for pioneering research and development expenditures by pharmaceutical companies through the “restoration of some of the time lost on patent life while the product is awaiting pre-market clearance” from the FDA.²⁹

As a result of Hatch-Waxman, the generic industry has an infringement-free right, unique in patent law, to use patented pharmaceuticals for pre-expiration testing purposes.³⁰ The pharmaceutical industry is barred from enforcing its patent against a generic drug manufacturer who is making, using or selling a drug for regulatory approval purposes to get a head start on marketing generic versions of the drug immediately upon expiration of the patent. This was a great compromise by the pharmaceutical industry and has gone a long way to foster the development of the generic drug industry in the United States.

During congressional debates on Hatch-Waxman, Congressman Waxman articulated that:

This bill represents a compromise among sharply differing interests. * * * After almost a year of data analysis and negotiations, we were able to fashion a compromise bill. * * * Mr. Chairman, this bill fairly and carefully balances the public’s need for low cost generic drugs and pri-

²⁷ Public Law No. 98-417, 98 Stat. 1585 (1984).

²⁸ H. Rept. 857 (Part I), 98th Cong., 2d sess., p. 14 (1984).

²⁹ *Id.* at 15.

³⁰ 35 U.S.C. 271(e)(1).

vate industry's need for sufficient patent life to encourage the development of innovative products such as drugs.³¹

As part of the compromise for allowing generic drug companies to use patented pharmaceuticals which they could not have under *Roche v. Bolar*, Hatch-Waxman provided for limited patent term restoration for part of the time lost in the lengthy regulatory review process.³²

However, numerous restrictions on the potential restoration period severely limit the extent of actual patent term restoration a pioneer drug company may obtain for its innovative pharmaceutical.³³ These restrictions are: (1) only 50 percent of the time spent in clinical trials testing can be restored; (2) there is a maximum of 5 years of restoration no matter how long a delay the product experienced; (3) the total patent life—including restoration—may not exceed 14 years to be eligible for Hatch-Waxman restoration; (4) only one product per patent is eligible for an extension under the Act; (5) only one patent per product is eligible for an extension; and (6) no regulatory activities that occur before patent issuance can be used in calculating the period of patent term restoration.

Development and sales in the American generic drug industry exploded as a result of Hatch-Waxman; the investment necessary to produce a generic drug was greatly reduced. Before the passage of Hatch-Waxman, all tests for generics had to be undertaken independently of the work done to prove the safety and efficacy of the pioneer drug. By using Abbreviated New Drug Applications (ANDA's) created by title I of Hatch-Waxman, a generic drug company can reference the proprietary research work done for the pioneer drug that is on file at the FDA. ANDA's are vastly less expensive to secure than approval for a pioneer drug. Some ANDA's are obtained with an investment of less than \$100,000 and most cost less than \$1 million.³⁴

These special privileges enjoyed by the generic drug industry are not enjoyed by any other industry in the United States. No other industry's generic competitors are permitted to conduct research during the pioneer's patent life. As a result, generic drugs are able to enter the market immediately upon expiration of the pioneer's

³¹ Cong. Rec. at H-8707 (Aug. 8, 1984).

³² 35 U.S.C. 154.

³³ Some members believed that the bill provided too much incentive for the generic industry while not providing a commensurate incentive for the pioneer drug firms. In fact, Congressman Bliley of the House Energy and Commerce Committee stated:

"[The Hatch-Waxman Act] is a bill described by its proponents as having something for everyone—restoration of patent terms for products subject of elaborate premarket approval requirements to provide incentives for pharmaceutical research and facilitation of approval of generic drugs by the Food and Drug Administration under abbreviated application procedures to increase drug price competition. * * * In my view, however, the legislation fails to achieve a proper balance between these two objectives.

"Instead of providing an appropriate patent term for pharmaceuticals by restoring the time devoted to periods of 'regulatory review,' the bill strictly limits the types of patents eligible for term restoration and the conditions and length of the restoration period. In short, the patent term restoration provisions of this bill are largely illusory." H. Rep. 98-857 part I, at p. 71, June 21, 1984.

³⁴ Chemicalweek, *Generics Set to Take Off: Opportunities Abound*, p. 30, Aug. 12, 1992.

patent—as opposed to waiting months or years for approval after the expiration of the patent.³⁵

THE REGULATORY FRAMEWORK OF HATCH-WAXMAN

Under the Hatch-Waxman Act, a pharmaceutical manufacturer seeking to introduce a generic version of a patented drug may submit an Abbreviated New Drug Application (ANDA) to get expedited FDA approval. The ANDA submission must certify one of four circumstances: (1) that the drug has not been patented—otherwise known as a “paragraph I” certification; (2) that any patent on the pioneer drug has expired—otherwise known as a “paragraph II” certification; (3) the date on which patents on a drug will expire if the drug is still under patent—otherwise known as a “paragraph III” certification; or (4) that the patent on such drug is “invalid or that it will not be infringing by the manufacture, use, or sale of the new drug” for which the ANDA is submitted—otherwise known as a “paragraph IV” certification. An applicant must give the patent owner notice of certification if it submits an ANDA that contains a paragraph IV certification.

Pursuant to Hatch-Waxman, the submission of an ANDA containing a paragraph IV certification constitutes “an act of infringement.” With an ANDA that contains a paragraph I or a paragraph II certification, FDA approval is effective immediately, provided that all applicable scientific and regulatory requirements have been met. If it contains a paragraph III certification FDA approval is effective on the patent expiration date.

Where an ANDA contains a paragraph IV certification, approval is effective immediately, unless the patent owner brings an action for infringement under 35 U.S.C. 271(e)(2)(A) within 45 days of receiving the notice required under paragraph IV, again provided that all applicable scientific and regulatory requirements have been met. When a patent owner brings such an infringement action, the FDA must suspend approval of the ANDA. The FDA cannot approve the ANDA until the earliest of three dates: (i) if the court decides that the patent is invalid or not infringed, the date of the court’s decision; (ii) if the court decides that the patent has been infringed, the date that the patent expires; or (iii) subject to modification by the court, the date that is 30 months from the patent owner’s receipt of notice of the filing of the paragraph IV certification.

As the U.S. Court of Appeals for the Federal Circuit recently held:

the Hatch-Waxman Act strikes a balance between the interests of a party seeking approval of an ANDA and the owner of a drug patent.³⁶

While the manufacture, use, or sale of a patented drug is not an act of infringement, to the extent it is necessary for the preparation

³⁵ We received testimony from Prof. Harold C. Wegner on Feb. 27, 1996; indicating that a recent Netherlands Supreme Court decision which deferred the generic marketing in the Netherlands for 14 months *after* patent expiration on the basis that approximately that much time was used in pre-patent expiration generic testing which was an infringement of the Dutch patent, and that such testing could only have commenced upon expiration of the patent. *Smith, Kline and French Laboratories Ltd. v. Generics BV*, [1996] 1 EIPR D-20.

³⁶ *Bristol-Myers Squibb*, 69 F.3d at 1132.

and submission of an ANDA, a patent owner can seek to prevent approval of the ANDA by bringing a patent infringement suit once the generic manufacturer wants to market the patented drug prior to the expiration of the patent.

TRANSITION PROVISIONS OF TRIP'S AND THE 20-YEAR PATENT TERM

Under the TRIP's agreement, all member countries must provide a patent term of at least 20 years measured from the time of application. Prior to the URAA, U.S. patent law provided for a term of 17 years measured from the date of issuance. As a result, Congress in the URAA amended the Patent Act to provide that the term of a patent shall end 20 years after the date on which the application for patent was filed.

The 20-year patent term was a very contentious issue. Congress held hearings on this matter and heard from many in industry, especially the pharmaceutical and biotechnology industry, who had concerns that the 20-year term might erode patent terms in this country.³⁷

In fact, a 20-year patent term measured from filing was not a new proposition. As early as 1966, such a term was recommended by President Johnson's Commission on the Patent System. The same type of 20-year term was recommended, in the context of patent law harmonization, by the Commerce Department's Advisory Commission on Patent Law Reform in 1992.

ELIMINATION OF SUBMARINE PATENTS

One of the benefits of a 20-year patent term measured from application is that it stimulates progress in technology. A term measured from grant can encourage applicants to file successive continuing applications on the same invention resulting in troublesome "submarine" patents that remain submerged in the Patent and Trademark Office in secrecy year after year. These "submarines" can emerge to displace the efforts of another company after that company has been successful in bringing the product to the market. Submarine patents can also delay the dissemination of technological information to the public and prolong the period of uncertainty about the status of legal rights in inventions.

It is important to note that, if the 17-year system had not been changed, the pharmaceutical industry could have used these "submarine" practice to delay the grant of their patents, while they sought FDA approval. Such a practice would have allowed them to ensure greater patent terms. It was a major sacrifice on the part of the biotechnology and the pharmaceutical industries to support the 20-year provisions of the URAA in favor of harmonized patent rules internationally. With a 20-year term from filing, applicants, including pharmaceutical and biotechnology applicants, are no longer able to extend their patent terms through intentional delay in the Patent and Trademark Office.

This is doubly important in the context of the GATT pharmaceutical patent debate, as it points up the necessity of ensuring continued adequate patent life for innovator pharmaceuticals.

³⁷ See Joint Hearing on General Agreement on Tariffs and Trade (GATT): Intellectual Property Provisions, Aug. 12, 1994, Senate Committee on the Judiciary, Serial No. J-103-77.

PHARMACEUTICAL AND BIOTECHNOLOGY CONCERNS

During URAA negotiations over the possibility of enacting a new 20-year term, there was an underlying assumption that applications are generally processed within 3 years, therefore a 20-year term measured from filing would in effect be comparable to a 17-year term measured from the date of grant of the patent.

Representatives of the pharmaceutical industry and the biotechnology industry were very hesitant to support the 20-year term; they argued that patent applications in their industry often take longer than 3 years to process due to the complex subject matter and administrative delays at the Patent and Trademark Office.³⁸

While the “average” patent is granted in less than 3 years, pioneer pharmaceutical patents generally are either granted more than 3 years after filing.³⁹ As a result, the pharmaceutical industry only agreed to the 20-year patent term after assurances the United States would work toward implementing both a new policies to grant extensions due to administrative delays which were outside the patent applicant’s control and to examine U.S. patent applications within 3 years of application.⁴⁰

When the URAA was being considered, few, if any, were aware that there were any important drug patents that could benefit from a switch to the 20-year patent term.⁴¹ With pharmaceutical patents often taking more than 5 years to be granted, it was imagined that the beneficiaries of the 20-year term would largely be other technologies—whose patents are often granted within 20 months—and “certainly *not* pharmaceutical companies.”⁴² In fact, most drug patents do not benefit from the new patent term because they have used far more than 3 years for the prosecution of their patent application.⁴³

TRANSITION PROVISIONS UNDER TRIP’S ARTICLE 70

In the final provisions of the TRIP’s agreement, article 70 provides for the treatment of existing subject matter by member nations. Specifically related to the change in patent terms, article 70.4 authorizes member nations to provide a “safe harbor” for those activities that *become infringing* with the implementation of TRIP’s.⁴⁴ Article 70.4 reads:

In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies avail-

³⁸ See Testimony of Genentech, Inc., before the Joint Hearing, Aug. 12, 1994, at pp. 4–8; see also, Testimony of Gerald J. Mossinghoff, president, Pharmaceutical Research and Manufacturers of America, before the Joint Hearing, Aug. 12, 1994.

³⁹ Testimony of Professor Wegner, before the Senate Judiciary Committee, Feb. 27, 1996, at p. 4.

⁴⁰ Testimony of Gerald J. Mossinghoff, *supra* note 39, at 6–7.

⁴¹ Testimony of Professor Wegner, *supra* note 39, at 5.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ GATT Agreement on TRIP’s, *supra* note 5, art. 70.

able to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.⁴⁵

The United States implemented this provision in section 532(a) of the Uruguay Round Agreements Act.⁴⁶ This section amended section 154 of title 35, United States Code, to provide that for certain patents which were issued and for pending applications which were filed prior to June 8, 1995, a guaranteed 17-year term, if it is longer than 20 years from the date of filing will be provided. This section also addressed the issue of the legal relationship between the patent holders of such transitional term-affected patents and those who had made substantial investment toward commission of acts which became infringing as a result of the changes brought forth by the URAA. Section 154(c), as amended by the URAA, provides:

(c) *Continuation*—

(1) *Determination*.—The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a),⁴⁷ or 17 years from grant, subject to any terminal disclaimers.

(2) *Remedies*.—The remedies of sections 283, 284, and 285 of this title shall not apply to Acts which—

(A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act; and

(B) became infringing by reason of paragraph (1).

(3) *Remuneration*.—The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)) of this title.”⁴⁸

In effect, the URAA created a limited “safe harbor” for persons who commenced particular acts, or made substantial investments toward commission of such acts before June 8, 1995, which acts became infringing because of the adjustment of the patent period by the transitional provisions of the URAA.⁴⁹ In circumstances involving the safe harbor provisions, a patent owner “will not be able to

⁴⁵ *Id.*

⁴⁶ Public Law No. 103–465, 108 Stat. 4809 (1994).

⁴⁷ Subsection (a)(2) of the URAA provides that the term of a patent “shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.” 35 U.S.C. 154(a)(2) (1994).

⁴⁸ 35 U.S.C. 154(c).

⁴⁹ *Bristol-Myers Squibb v. Royce Laboratories*, 69 F.3d 1130, 1132 (Fed. Cir. 1995).

obtain an injunction, recover a reasonable royalty, or obtain attorneys fees as provided for in sections 283 to 285 of title 35, but will be able to recover equitable remuneration from a third party who *infringes* the patent during the period in question.”⁵⁰

The transition provisions of the URAA do not make infringing conduct noninfringing during the “safe-harbor” period. As the U.S. Court of Appeals for the Federal Circuit recently held, “[the URAA] merely provides that infringing conduct will not give rise to the entire panoply of traditional statutory remedies for patent infringement. Such conduct will give rise only to the limited remedy of equitable remuneration,” which is to be “determined in an action brought under chapter 28 or chapter 29 of title 35.”⁵¹ The two chapters under which the equitable remuneration is to be determined under URAA authorize and govern the bringing of actions for *infringement*. Thus, the URAA specifically renders certain acts, performed by third parties during the extension periods provided by section 154(c)(1), as *infringing*, but then to provide a limited remedy for that kind of infringement, through an action for relief for infringement in the form of equitable remuneration.

As the Federal Circuit has properly interpreted, the statutory scheme of the URAA “does not say * * * [i]f normally you would infringe, you do not infringe during the delta period.”⁵² Rather the proper interpretation of the URAA is that you still infringe, but if you meet certain requirements, you may still continue to infringe, provided that you pay the equitable remuneration required by TRIP’s and the URAA.

JUDICIAL INTERPRETATIONS RELATED TO THE PHARMACEUTICAL INDUSTRY

After passage of the URAA, several parties affected by the transitional provisions codified in 35 U.S.C. 154 have brought actions. These cases all deal with the interpretation of the section as it relates to generic pharmaceutical companies and their actions which became infringing after the passage of the URAA. These actions have culminated in final decisions interpreting section 154 and its interplay with the Hatch-Waxman act as it relates to the pharmaceutical industry.

The following is a summary of the recent appellate court decisions that related to the interpretation of issues germane to the present bill:

*Merck & Co. v. Kessler*⁵³: Decided on April 4, 1996, this case involved an appeal by generic drug companies from a district court ruling which held that under the URAA, all patents in force on June 8, 1995, including patents in force only because of Hatch-Waxman extension, were entitled to add the time of the Hatch-Waxman extension to the new term afforded by the URAA pursuant to section 154(c).⁵⁴ The issue in that case was whether a holder of a patent in force on June 8, 1995, could

⁵⁰ Statement of Administrative Action, Uruguay Trade Agreements, *Message from the President of the United States*, 103d Cong., 2d sess., H. Doc. 103-316 Vol. 1, Sept. 27, 1994.

⁵¹ *Bristol-Myers Squibb*, 69 F.3d at 1136.

⁵² *Id.*; see also *Merck & Co. v. Kessler*, 38 U.S.P.Q. 2d (BNA) 1347 (Apr. 4, 1996).

⁵³ *Merck & Co. v. Kessler*, 38 U.S.P.Q. 2d (BNA) 1347 (Apr. 4, 1996).

⁵⁴ *Merck & Co. v. Kessler*, 903 F. Supp. 964 (E.D. Va. 1995).

add a previously granted patent restoration period to a 20-year term in determining when the patent expires.

The Federal Circuit, on appeal, affirmed in part and reversed in part, the district court's ruling. Agreeing with the lower court, the appellate court interpreted the URAA and the Hatch-Waxman Act in that all "patents in force on June 8, 1995 (except for those in force only because of a Hatch-Waxman extension), [are] entitled to have a [Hatch-Waxman] restoration extension, whenever granted, added to the longer term of either 17 years from issuance or 20 years from filing."⁵⁵ The Court held that for patents that were in force on June 8, 1995, only as a result of a Hatch-Waxman extension, were not entitled to reapply a restoration extension to a 20-year from filing term.

Bristol-Myers Squibb Co. v. Royce Laboratories:⁵⁶ This decision, handed down November 1, 1995, involved an appeal by a patent owner who brought an infringement action against a generic drug manufacturer who sought FDA approval of a generic version of its drug while its patent was still in force. The district court dismissed the infringement action ruling that the generic company's actions did not constitute infringement of the pharmaceutical patent pursuant to the URAA.⁵⁷ The Federal Circuit reversed the district court ruling that because "safe harbor" provisions of the URAA, 35 U.S.C. 154(c), did not render infringing acts of generic drug companies noninfringing, the patent holder was entitled to an order that the effective date of any generic drug approval through the Abbreviated New Drug Application procedures of the Hatch-Waxman Act would have to wait until the expiration of the pioneer patent's term as extended by the URAA.

DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co.:⁵⁸ Similar to the above two cases, the Federal Circuit Court of Appeals in this case held that a generic drug manufacturer infringes a drug patent when it files an ANDA for a generic version of a patented drug still under patent protection, pursuant to 35 U.S.C. 271(e)(2). The Court further held that the URAA did not convert such infringing activity by generic drug manufacturers before the expiration of the pioneer patent to noninfringing activity during the transitional period where the patent was extended by URAA. The Court noted that the generic drug manufacturer must pay equitable remuneration as provided under the URAA-amended section 154 of title 35, United States Code.

TRIP'S CONSIDERATIONS OF S. 1277

Due to the amendments made by the URAA, certain patents, from all industries, including the pharmaceutical industry, are entitled to limited extensions under 35 U.S.C. 154(a), if their patents were prosecuted in less than 3 years.

⁵⁵ *Merck & Co. v. Kessler*, 38 U.S.P.Q. 2d (BNA) 1347 (Apr. 4, 1996).

⁵⁶ *Bristol-Myers Squibb v. Royce Laboratories*, 69 F.3d 1130 (Fed. Cir. 1995).

⁵⁷ *Bristol-Myers Squibb v. Royce Laboratories*, 36 U.S.P.Q. 2d 1637 (S.D. Fla. 1995).

⁵⁸ *Dupont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397 (Fed. Cir. 1995).

Under the URAA, generic companies could only utilize the remedies in the law if their acts were commenced or for which substantial investment was made before June 8, 1995, and the acts became infringing by reason of the adjusted patents. It is important to note that the law did not make infringing activities noninfringing. As a result of the extended patent terms, companies that produce generic versions of products in all industries, including the pharmaceutical industry, are not able to market their products unless and until they meet the requirements outlined in the URAA.⁵⁹

The generic pharmaceutical manufacturers, affected in the same way other generic manufacturers are affected by the URAA, has persistently sought a special exemption from the patent term extensions of the URAA. They first sought relief through administrative interpretation of the URAA transitional provisions at the U.S. Patent and Trademark Office and the Food and Drug Administration. Then they sought relief through litigation, to no avail. And they also seek to ameliorate the effects of the URAA through legislative action.

Sympathetic to the concerns expressed by the generic pharmaceutical manufacturers, yet conscious of the danger of weakening our intellectual property system and our ability to seek increased protection of intellectual property in foreign countries (and the prompt implementation of the GATT/TRIP's agreement), the committee sought to craft a compromise to S. 1277 which would strike a fair balance in providing equitable relief for the generic pharmaceutical industry.

Congress must be cautious in adopting an interpretation of article 70.4 of TRIP's which does not lend aid and comfort to foreign governments, such as those in Brazil and India, who have refused to grant patent protection for drugs and agricultural products. Any U.S. exceptions to the TRIP's agreement will weaken our trade negotiators in seeking prompt and effective implementation of TRIP's or in other bilateral intellectual property negotiations or investigations on intellectual property, such as the Special 301 investigation under our Trade Laws.

The President's Advisory Committee on Trade Policy and Negotiations (ACTPN) has said "the ACTPN urges U.S. negotiators to make clear that reliance by any WTO member on this provision—70 (4)—to render moot any other provision of the TRIP's Agreement will be considered an impairment of the basic intellectual property obligations under the agreement."⁶⁰

Furthermore, former U.S. Trade Representative, Ambassador Yeutter noted in testimony before the Committee that "[w]e do not want developing countries, (or China and Russia for that matter) when they accede to the WTO, to be able to claim that modest investments by local pirates in future infringing acts * * * are grandfathered under TRIP's."⁶¹

In accordance with our concerns of not losing our credibility in the new World Trade Organization, and our equally important concern of providing cheaper drugs to the American consumer, S.

⁵⁹ 35 U.S.C. 154 (1994).

⁶⁰ See testimony of Ambassador Clayton K. Yeutter, before the Senate Judiciary Committee, Feb. 27, 1996.

⁶¹ *Id.*

1277, as amended, provides for equitable relief for the generic drug industry with respect to patents on pioneer pharmaceutical drugs, the term of which is modified by the URAA—yet does not raise the TRIP's concerns concomitant with the bill as introduced.

The amended legislation will permit generic versions of patented pharmaceutical products to enter the market, before the expiration of the patent, once a court issues a final order: (1) finding that the generic applicant has made a URAA-mandated substantial investment in anticipation of entering the market upon the expiration of the pre-URAA patent term, and (2) establishing the URAA-mandated amount of equitable remuneration the generic applicant is to pay the pioneer patent holder, given that the proper certification application pursuant to the Federal Food, Drug, and Cosmetic Act is made.

III. THE COMMITTEE ON THE JUDICIARY'S HEARING

The Committee on Judiciary convened on February 27, 1996, for the purpose of hearing testimony related to the issues raised by the URAA and adjusted pharmaceutical patent terms, including a discussion of the legislation introduced by Senators David Pryor, John Chafee, and Hank Brown. Present were Chairman Hatch, Senators Grassley, Specter, DeWine, Kennedy, Leahy, Heflin, Simon, and Feinstein.

The Committee first heard testimony from Senators Faircloth, Chafee, and Pryor. Urging a policy of fairness, Senator Faircloth noted the provisions of the Hatch-Waxman law and raised questions centering on the need for incentives for innovator pharmaceutical research. Senator Chafee argued that the Congress and the administration made a simple and inadvertent, but expensive, error in drafting the URAA, resulting in a costs to consumers, and State and Federal Governments. He urged that the Congress rectify that error. Senator Pryor summarized the legislative history of the issue and urged an immediate, simple, congressional amendment which he believed would close the URAA "loophole," restore competition in the marketplace, and correct a "multi-billion wind-fall" subsidized by consumers.

The Committee next heard from a panel comprised of U.S. Trade Ambassador Mickey Kantor, representing the Administration, and former USTR Clayton Yeutter. Ambassador Kantor told the Committee that the GATT transition provisions had been drafted to apply to all types of patented technology, without distinction, but that Congress and the Administration had failed to take into account the technical interrelationship between the patent code and the food and drug law putting the generic pharmaceutical industry at a disadvantage. He said that he supported the correction of this oversight. Such an amendment, he averred, would not undermine ongoing U.S. efforts to seek high levels of intellectual property protection around the world.

Ambassador Brock expressed major reservations about the legislative amendment and said that it would set an unfortunate precedent which would undermine the United States' ability to safeguard our intellectual property rights worldwide. He reviewed the history of U.S. efforts to win greater international intellectual property protections and urged that the United States not back off from

the leadership it had been exercising. He told the Committee he believed that adoption of S. 1277 would be read by other nations as the United States backing down from 15 years of negotiations.

Next, the Committee heard from a panel consisting of: the Honorable Gerald J. Mossinghoff, president, Pharmaceutical Research and Manufacturers of America and former Commissioner, Patent and Trademark Office; Charles J. Cooper, on behalf of the Pharmaceutical Research and Manufacturers; James P. Firman, chair of the Generic Drug Equity Coalition, and president, National Council on the Aging; Judith Simpson, president, United Patients' Association for Pulmonary Hypertension, Inc; and Robert J. Gunter, chairman, National Pharmaceutical Alliance, and president, Novopharm, USA.

Mr. Mossinghoff told the Committee that the generic drug industry is treated under the URAA equally to all other industries. Noting the complexity of the laws, he said that the legislative outcome of the URAA was intended, as supported by a recent court decision. Mr. Cooper concentrated his testimony on the takings clause secured by the fifth amendment, concluding that the change proposed in S. 1277 would trigger that constitutional protection.

Mr. Firman expressed strong support for S. 1277, estimating that the GATT changes will cost consumers \$2.5 billion by the end of the century. He said that this is an issue of fairness, and the arguments in support of the legislative change are clearcut. His testimony was followed by that of Judith Simpson, who urged that the legislation not be adopted, as she believed it would undercut the patent protections which support research and development in the pharmaceutical industry. She specifically mentioned the long-term need for continued support of research into diseases such as Primary Pulmonary Hypotension, which can now be treated by a life-saving even though the condition is so rare that sales could never recoup the development cost.

Finally, the Committee heard from Mr. Gunter, who discussed his company's experience in developing a generic drug and urged that his company, and others like it, who have met the statutory criteria for substantial investment be allowed to bring their products to the market prior to expiration of the URAA-adjusted patent expiration dates for the relevant innovator drug.

IV. LEGISLATIVE HISTORY

S. 1277, the Prescription Drug Equity Act of 1995, was introduced by Senators Brown and Pryor on September 27, 1995, and referred to the Committee on the Judiciary. Similar legislation, S. 1191, the Consumer Access to Prescription Drugs Act of 1995, was introduced by Senator Pryor on August 11, 1995, and referred to another committee.

During September 29, 1995, Finance Committee consideration of the Medicare/Medicaid provisions of the budget reconciliation legislation, Senators Chafee and Pryor attempted to offer an amendment to clarify the application of the GATT transition rules for pharmaceuticals. The Chair ruled that the amendment was non-germane, and a subsequent vote (9-7, with a two-thirds majority being necessary) failed to override that ruling.

Two months later, during Senate consideration of the Partial Birth Abortion Ban legislation (H.R. 1833) on December 5, Senators Pryor, Chafee, Brown, and Byrd offered amendment number 3082 which mirrored the Pryor legislation. During subsequent consideration of H.R. 1833 on December 7, Senator Smith (for Senators DeWine and Dodd) offered amendment number 3088 to amendment 3082. The DeWine/Dodd amendment expressed the sense of the Senate that the Judiciary Committee should conduct hearings to investigate the effect of the URAA patent provisions on the approval of generic drugs under section 505 of the Federal Food, Drug and Cosmetic Act. The Senate failed to table the DeWine/Dodd amendment by the vote of 48–49, and the Pryor amendment was withdrawn.

Consistent with the Senate vote, the Committee on the Judiciary held a hearing on the issue on February 27, during which testimony was heard as outlined above.

The Committee scheduled an executive session to consider S. 1277 on April 18, 1996, but recessed when a quorum was not attained. Later that day, Senator Brown filed amendment number 3678 to S. 1028, the Kassebaum-Kennedy health insurance reform bill. The Brown amendment was withdrawn.

S. 1277 was also on the agenda for the Judiciary Committee's April 25, 1996, session, but was held over pending deliberations on the immigration legislation. Markup was continued on May 2, 1996, at which time the Committee approved, 10–7 the Chairman's substitute for S. 1277.

[Note: Subsequent to the Committee's action on S. 1277, on June 27, 1996, Senator Pryor offered amendment number 4365 to S. 1745, the Department of Defense authorization Act. The Pryor amendment expressed the sense of the Senate that the generic drug industry should be provided equitable relief in the same manner as other industries under the transitional provisions of the URAA. By a vote of 53–45, the Senate agreed to the Hatch amendment number 4366 to the Pryor amendment, which embodied the text of the measure approved by the Judiciary Committee with a modification by Senator Specter to ensure speedy court consideration of any cases brought. Conferees for the defense bill dropped the GATT provision, and thus the final measure did not contain the Judiciary language.]

V. SECTION-BY-SECTION ANALYSIS

Section 1.—Short Title: The substitute is entitled the “Pharmaceutical Industry Special Equity Act of 1996”.

Section 2. Approval of Generic Drugs: Subsection (a) provides that the unique Hatch-Waxman remedies—available under current law when pioneer pharmaceutical companies' patent rights are challenged by generic applicants—shall not apply with respect to patents whose terms were redefined by the URAA if three criteria are met:

- (1) A generic applicant files a paragraph IV certification pursuant to the existing provisions of Hatch-Waxman with respect to the GATT-extended patent;
- (2) That paragraph IV certification is filed after enactment of the bill, and is submitted in connection with an application

that was found by FDA to be sufficiently complete to permit substantive review prior to the effective date of the URAA; and

(3) In accordance with the existing provisions of Hatch-Waxman, a lawsuit is brought against the generic applicant following receipt of that certification, and a final order from which no appeal can be taken or has been taken is entered finding that the generic applicant made a URAA-mandated substantial investment and establishing the URAA-mandated amount of equitable remuneration the generic applicant is to pay the pioneer patent holder.

Subsection (b) sets forth standards to be utilized by the court in the litigation filed pursuant to subsection (a), in determining whether a particular generic applicant made the requisite substantial investment. Specifically, the court must find that: (1) the generic applicant submitted a complete ANDA that was sufficiently complete to permit substantive review by FDA prior to June 8, 1995; and (2) the total sum of the generic applicant's investment was specifically related to the research, development, manufacture, sale, marketing, or other activities undertaken in connection with the ANDA; and does not consist solely of expenditures relating to preparing and filing its ANDA.

Subsection (c) provides that, at the conclusion of litigation filed pursuant to subsection (a), the court would have discretion to order that the patent holder pay equitable compensation to the generic applicant if the lawsuit caused any delay in the initiation of marketing by the generic company.

Subsection (d) provides that FDA cannot approve a generic application and thereby allow a generic to enter the market during the GATT delta period until both substantial investment and equitable remuneration are resolved in the court ordered required under subsection (a)(3).

Subsection (e) limits the bill's applicability. None of the bill's provisions would apply to any patent that would have expired on or after June 8, 1998, inclusive of any restoration period provided under Hatch-Waxman, under the law in effect prior to the date of enactment of the URAA, i.e. December 8, 1994.

Section 3.—Application of Certain Benefits and Term Extensions to all Patents in Force on a Certain Date: Provides for equivalent treatment of all patents in force on June 8, 1995. It specifically provides that patents in force on that date as a result of extensions under Hatch-Waxman are entitled to the same benefits under the URAA as any other patent.

Section 4.—Extension of Patents Relating to Nonsteroidal Anti-Inflammatory Drugs: Extends the patent for the nonsteroidal anti-inflammatory drug Lodine for 2 years to adjust for lengthy delays in its review at the Food and Drug Administration.

Section 5.—Sense of the Senate: Expresses the sense of the Senate that litigation pursuant to this Act should be concluded as expeditiously as possible.

VI. COMMITTEE VIEWS

The GATT/pharmaceutical patent legislation evokes a myriad of complex issues, with ties to laws under the jurisdiction of at least three congressional committees. The legislation we are considering,

S. 1277, would have serious ramifications for the U.S. food and drug statute, trade policy, and most importantly, intellectual property law. These aspects of the issue are intertwined, and cannot be separated easily. Nor should they be.

It is clear that intellectual property rights, a major issue which falls within this Committee's jurisdiction, were addressed on a multilateral trade basis for the first time in the history of GATT during the Uruguay Round. As a result of hard-fought compromises, worldwide standards for protecting and enforcing intellectual property rights were established, and intellectual property protection was significantly improved.

The Committee was involved substantially in drafting the Agreement on Trade-Related Aspects of Intellectual Property (TRIP's) after concluding that, as the world leader in inventive activity, the United States stood to gain substantially from that accord. Enhanced patent protection overseas will have a significant impact on the commercial interests of the United States and the resulting considerable economic gains and job creation.

The real test comes when other countries implement their multilateral obligations under GATT. The United States insisted on the inclusion of enhanced patent protections in the Uruguay Round agreements. We have historically been the leading international advocate for broadening patent rights, so it is essential that the United States be a world leader on GATT implementation.

Enhanced patent protection will be diminished abroad if the United States itself violates the TRIP's. It is almost certain that such an action would provide foreign-based pirates and patent infringers with potent ammunition in seeking to have their domestic governments devise measures that are inconsistent with TRIP's—thereby denying U.S. patent holders their rights secured by TRIP's.

Several developing nations, such as Singapore and Thailand, are already attempting “to dilute and evade” the patent protection commitments they accepted during the Uruguay Round. In this patent-unfriendly context, the proposed bill, if unamended, would be interpreted internationally as encouraging a minimalist's interpretation of GATT's improvements in patent protection. Having redefined patent terms domestically in order to secure enhanced patent rights overseas, it would be imprudent for this Congress to give the green light to erosion of this principle domestically.

But these international trade ramifications extend beyond questions of intellectual property protection. The positions advocated by proponents of this amendment are likely to be turned against the United States in future trade negotiations.

The Committee was mindful of the concerns expressed by then-Ambassador Kantor at its February 27 hearing on this issue. Mr. Kantor told the Committee that the changes proposed in S. 1277 would not have major international trade ramifications.

However, we must also note that the Committee has received a letter from the Vice President of the European Community, Sir Leon Brittan, who stated the bill “would contradict our mutual aim of providing a reasonably high and secure protection for the huge investments made by EC and US research-based pharmaceutical companies” and “send a negative and highly visible signal to those

numerous countries which are still in the process of preparing new legislation on the protection of pharmaceutical inventions.”

This view was bolstered by the views of former Ambassador Bill Brock, who has said that the nations which in the past have denied American inventors patent protection “will see this retreat on our part as a ready excuse to implement their own minimalist versions of intellectual property protection.” Thus, Ambassador Brock concludes, we would be unable “to force other nations to adhere to the TRIP’s agreement if we set this unfortunate precedent.”

The Committee was impressed by the multitude of testimony it heard from Members of Congress and interested generic pharmaceutical industry and consumer representatives who avowed that the GATT legislation had caused a loophole which inadvertently precluded generic manufacturers from going to market with products based on the pre-GATT innovator drug patent expiration dates. Indeed, this strongly held belief on the part of many presented a very moving and compelling case for enactment of S. 1277 unamended.

Unfortunately, though, the Committee’s laborious study of this issue led it to conclude that those arguments—while extremely well-intentioned—were without basis in legislative history and correct interpretation of the statute. The Committee also concluded that enactment of S. 1277 without change could undermine important incentives for pharmaceutical research and development which have made the United States the world leader in new drug development.

Three key statutory provisions come into play in any deliberation over this GATT issue.

First, there are the transition rules of the Uruguay Round Agreements Act of 1994, codified at 35 U.S.C. 154(c). As noted previously, a key provision in the GATT Treaty was a change-over by the United States from the old 17-year patent term—measured from the date of issuance—to the standard, international 20-year patent term, measured from date of application. Included in the URAA were special transition rules relating to this new patent term. These provisions stipulate the relief available when certain activities, presumably done in good-faith reliance on the old patent term, were initiated prior to the June 8, 1995, effective date of the URAA; and became infringing due to the effective date of the URAA.

Cited in these rules, but left undefined and unexplained, are such critical terms as “substantial investment” and “equitable remuneration.”

Also relevant to this debate is law against patent infringement.

Section 271(a) of the patent code contains a cornerstone of our Nation’s intellectual property laws: “whoever without authority makes, uses, *offers to sell*, or sells any patented invention, within the United States *or imports into the United States* during the term of the patent * * * infringes the patent.” The italicized words were added by the URAA, thus rendering ineffective arguments put forth by some that the Congress overlooked the existence of the patent infringement laws when it passed the URAA.

The Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman”) added a special provision to section 271

that reversed the Federal Circuit's 1984 decision in the case of *Roche v. Bolar*. An understanding of the Bolar amendment added by Hatch-Waxman is crucial to this whole debate. It created a unique exception to patent law which allows an applicant to undertake acts that would normally be considered infringing, that is, it made permissible the acts of generic drug manufacturers to ready their products for market.

The *Bolar* amendment provides (1) it is not an infringing act to make, use, or sell a patented invention solely for uses reasonably related to submitting a generic drug application to the Food and Drug Administration; and (2) it is, however, an act of infringement to submit the application to gain approval while the pioneer patent is still in effect.

Under the Hatch-Waxman law, a generic drug applicant must certify one of four things: (1) the pioneer drug has not been patented; (2) the pioneer patent has expired; (3) the pioneer patent is slated to expire at a specific future date; and (4) the patent of the pioneer is invalid or will not be infringed by manufacturing the drug in question. It seems clear that under current law, as interpreted by two Federal circuit court decisions, that generic drug manufacturers cannot introduce their products into the marketplace until the patent terms revised by GATT expire.

One reason the Committee took such a great interest in the GATT issue is that intellectual property rights are critical to all American industries and should not be lightly disregarded. They are particularly important to the pharmaceutical industry because they fuel the engine that drives the biomedical research enterprise and result in numerous therapeutic advances.

An amendment that eliminates the GATT patent benefits for pharmaceutical products would undermine a critically important incentive for research and development, as testimony before the Committee amply demonstrated.

As with other research-intensive industries in the United States, the pioneer pharmaceutical industry has benefitted significantly from America's patent system. Due to the high costs and risks associated with developing and marketing prescription drugs, patents have allowed manufacturers to attract the risk capital necessary to develop and clinically test innovative new therapies. The results of such ground breaking biomedical research flows directly to patients who have access to drugs for complex and life-threatening diseases which are developed only by pioneer pharmaceutical companies. We should continue to reward their ingenuity and encourage their innovation.

If Congress encourages curtailment of biomedical R&D by limiting incentives, it inevitably will cause a downturn in the rate at which biomedical innovations will become available to the public. For this reason, an array of patient and research groups—including the American Association for Cancer Research, the Alliance for Aging Research, the Cystic Fibrosis Foundation, the Allergy and Asthma Network/Mothers of Asthmatics, and the Autism Society indicated to the Committee that they opposed the legislation unamended.

These views are, perhaps, best summed up by former Surgeon General C. Everett Koop, who commented on this issue:

* * * we must resist the temptations of short-term thinking and look at the big picture. The only way to make a real difference in health care costs—and a real difference in people’s lives—is to find cures for AIDS, cancer, Alzheimer’s and * * * other diseases. The way to do that is to encourage support for medical innovation.

The Committee feels it is important to underscore that the courts have generally agreed with this panel’s conclusions on S. 1277 that the GATT change did not result in an unintended loophole or windfall for the innovator pharmaceutical companies.

On August 8, 1995, the U.S. Court of Appeals for the Federal Circuit issued a ruling in the case of *DuPont Merck Pharmaceutical Company v. Bristol-Myers Squibb*. Upon reviewing the relevant statutes, the court found that “* * * the URAA does not clash with the Hatch-Waxman Act” and precluded the generic manufacturers from entering the market via the Waxman-Hatch route until the expiration of the affected patent.

On October 16, 1995, the U.S. District Court for the Eastern District of Virginia issued an opinion (*Merck v. Kessler*) in a group of four consolidated cases that raised similar, but not identical, URAA/Hatch-Waxman issues. In this case, the court was unpersuaded by the arguments made by the generic drug industry and stated, “This was no more a windfall * * * than the windfall which benefitted many patent holders when the seventeen year term of patents was extended to twenty years.”

Two weeks later, on November 1, 1995, the Federal Circuit overturned a decision rendered by the U.S. District Court for the Southern District of Florida in the case of *Bristol-Myers Squibb v. Royce Labs*. The Federal Circuit ruling noted:

The parties have not pointed to, and we have not discovered, any legislative history on the intent of Congress, at the time of passage of the URAA, regarding the interplay between the URAA and the Hatch-Waxman Act. Therefore, we limit our inquiry to the wording of the statute.

In finding against the generic manufacturer, the Federal Circuit makes a number of other points about the *Royce* case. The decision notes the unique treatment afforded to new drugs by the 1984 law. The Federal Circuit said, “Yet, as the Supreme Court stated in *Eli Lilly Co. v. Medtronic, Inc.*, the Hatch-Waxman Act created ‘an important new mechanism designed to guard against infringement of patents relating to pioneer drugs,’ with enforcement provisions that ‘apply only to drugs and not to other products.’”

The *Royce* court also observed, citing as authority the 1990 Federal Circuit decision in the *VE Holding Corp.* case: “We presume ‘that Congress is knowledgeable about existing law pertinent to legislation it enacts.’” The court went on to say that, “We believe that if Congress had intended that the URAA affect the Hatch-Waxman Act’s finely crafted ANDA approval process in the manner urged by [generic manufacturers], at the very least it would have referred to 21 U.S.C. 355(j) and 35 U.S.C. 271(e) in the URAA.”

A key point often ignored in this debate was addressed in the Federal Circuit’s decision, when it boiled down the situation as follows: “The statutory scheme does not say, as [the generic manufac-

turer] argues * * *, 'If normally you would infringe, you do not infringe during the Delta period.' Rather, it says, 'If normally you would infringe, you also infringe during the Delta period.'" The Committee finds overly simplistic, thus, arguments put forth that the GATT changes were inadvertent and unintentionally created a loophole. They did neither.

Another counterargument to those who concluded that S. 1277 achieves a result that was clearly intended by the URAA can be found in a letter sent to the Congress by an FDA official. Although it appears that the FDA later reversed itself on this issue, its earlier statements are illustrative.

In September of 1995, the FDA noted that the URAA was silent on this controversy. A September 27, 1995, letter from the FDA, Deputy Commissioner for Policy, William Schultz stated, "The URAA does not address the effect of the URAA patent term extensions on the drug approval process under the Federal Food, Drug, and Cosmetic Act. * * *"

The Committee finds the characterization in the September FDA letter particularly interesting in light of an earlier May 25, 1995, FDA response to a citizen petition filed by several innovator drug firms. The May FDA statement of policy is quite explicit on what the law addresses.

In its May statement, FDA acknowledged that the Supreme Court's 1984 *Chevron* decision provides guidance in the area of statutory construction. In *Chevron*, the Supreme Court instructed: "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."

The Committee finds compelling several quotes from the Schultz letter. In that letter, the Deputy Commissioner stated, "The agency believes that interpretation of the interrelationship between the transitional provisions of section 532(a)(1) of the URAA and 35 U.S.C. 271(e)(4) is governed by the plain language of the URAA." He went on to say, "The URAA is not 'silent or ambiguous' on the question of applying the transitional provision to the generic drug approval process. * * * Moreover, this apparently is not an example of Congress having overlooked a statutory provision it might have been changed had it been aware of its existence. * * *"

Particularly revealing was the Administration official's statement that " * * * the agency does not believe that it can assert that Congress was unaware of the existence of these remedies for infringement of patents on drug products, and, therefore, did not include them among the unavailable remedies * * * of the URAA * * *. In the present matter, therefore, the plain meaning of the URAA is dispositive."

The Committee has also found that overly simplistic arguments in support of measures such as S. 1277 ignore a fundamental point, that patents are property and cannot be treated lightly. Legal experts have presented testimony to the Committee arguing that the proposed URAA amendment would clearly deprive the patent holders of their property rights since patents have traditionally been recognized and protected by American courts as property.

Based upon existing precedents, it can be argued that any legislation affecting either the exclusive use of a product to which a pat-

ent holder is entitled, or the time during which the patent holder is entitled to that exclusive use, affects core elements of the property right represented by a patent.

By repealing patent extensions granted under the URAA, and reducing vested patent terms to which existing patent holders are currently entitled, some have argued that S. 1277, if unamended, could trigger the fifth amendment guarantee that the property holders receive just compensation from the U.S. Treasury.

As Committee Chairman Orrin Hatch noted at the Committee's hearing examining the complex relationship between our trade, intellectual property, and drug laws:

The American people have a great stake in this dynamic. It is the public health—in the most literal sense—that benefits from the delicately-crafted statutory balance between incentives for the creation of new breakthrough drugs and production of lower cost generic copies.

Both the pioneer and generic segments of the pharmaceutical industry play important and valuable roles in our health care system. At times, there is an unavoidable, inherent tension between them * * * But that competitive tension is necessary for our balanced system which brings both innovative drugs and lower-cost copies to the patient's bedside.

As we continue our vital national debate on ways in which to balance the budget and lower Federal Government spending, there is no question that economic pressures will dictate an even larger role for generic products in the ever-changing health care marketplace.

At the same time, the only way America will retain its leadership role in the biological sciences is for our patent and drug regulation to encourage—not inhibit—the rapid progress of this scientific revolution.

Strong patent protection is necessary to attract the enormous financial and scientific resources necessary to develop and test diagnostic and therapeutic products. A good example is identification of a gene that appears to be involved in a common form of breast cancer. Identification of the “BRCA 1” gene emerged from the joint enterprise of NIH, the University of Utah and a startup Salt Lake City biotechnology firm, Myriad. Continued biomedical research, with a strong foundation of intellectual property protections, will be vital components of our national commitment to improve the public health. Revelation of that fact is, perhaps, one of the major achievements of our debate on the GATT legislation.

VII. COST ESTIMATE

The Congressional Budget Office had not concluded its estimate of this legislation at the time this report was filed.

VIII. REGULATORY IMPACT STATEMENT

The Congressional Budget Office had not issued its regulatory impact statement at the time this report was filed.

IX. MINORITY VIEWS OF MR. BROWN

We oppose the Judiciary Committee's reported Hatch substitute to S. 1277 and believe there are serious flaws in this "compromise." Here's why:

I. SUMMARY

A. WINDFALL FOR PHARMACEUTICAL INDUSTRY

An oversight in GATT implementation legislation created a windfall for branded pharmaceutical companies at the expense of consumers. The GATT loophole resulted from an inadvertent omission of a conforming amendment in the GATT implementation legislation to the Federal Food, Drug and Cosmetics Act. Consequently, the pharmaceutical industry is the only industry not covered by GATT patent transition rules. The cost to consumers will exceed \$2.5 billion. One drug alone is producing an unexpected windfall profit of more than \$3.8 million a day for its parent company.

B. "LITIGATION FIRST"

The Hatch substitute mandates "litigation first" over insurmountable legal hurdles. This substitute is a trial lawyers dream and ensures that generic drugs will be kept off the market by endless and needless court delays. For example, under the substitute, brand name companies can get an unlimited stay to keep generic drugs off the market for the entire duration of the GATT transitional extension. For Zantac, which had already received the benefit of a 5 months of no generic competition, the Hatch bill would protect this multibillion dollar windfall from generic competition for another 15 months.

C. NOT A COMPROMISE

The Hatch substitute is not a compromise. A compromise requires that the interests of both parties are served to some extent. This bill (drafted by the brand-name industry association) serves only the interests of the branded drugs by preventing all generics from entering the market. Medications such as Zantac, Seldane-D, a widely prescribed allergy medicine, and Toradol, a pain killer, will be kept off the market during the GATT patent extension period. As a result, consumers will pay an estimated hundreds of millions of dollars more for their medicines than they should.

D. "CHRISTMAS TREE" OF GOODIES

Rather than an evenhanded attempt to solve the GATT loophole, the Hatch bill is chock full of protection for special interests. It is a Christmas tree of "goodies" for a few big drug companies at the expense of American consumers. It includes an array of legal hur-

dles to protect the Zantac windfall, a cutoff date to protect a few chosen companies from competition, a “fix” to extend a few patents despite a recent federal appeals court decision and a specific patent extension for one mid-Atlantic company.

E. OVERTURNS CURRENT LAW

Current law is overturned by the Hatch substitute. Under current law, a generic pharmaceutical manufacturer is required to complete a series of tests and studies in the course of filing an abbreviated new drug application to prove to the FDA that the generic drug will in fact meet FDA standards when brought to market. These tests require substantial investment on the part of those generic manufacturers who file an ANDA. Just as in previous versions, the proposal categorically excludes from consideration as substantial investment virtually everything a generic manufacturer is required or even permitted to do in developing a legally marketable generic drug. The Hatch substitute would erect insurmountable barriers by creating a new definition of “substantial investment” that requires an even greater investment than that already required. The only avenue left by the Hatch bill would be illegal activity.

F. BLOCKS MARKETING

It automatically blocks marketing of the generic while the litigation proceeds, without any time limitation whatsoever, even if it consumes the entire “Delta period”, an advantage conferred by the URAA on patent holders in no other industry.

This substitute withholds from the generic drug industry the protection enjoyed by every other industry under the “acts commenced” prong of the URAA transition provision. It makes no provision whatsoever for redress to consumers, including Medicaid and other government programs, who were forced to pay higher prices during the “Delta period” because generics were kept off the market by the litigation, or for disgorgement of profits gained by patent holders during the period of delay.

We believe the Hatch substitute codifies the GATT loophole S. 1277 was designed to fix. We pushed for a proposal which would have effectively closed that loophole. Under our proposal, brand-name companies would receive a royalty payment from qualifying generic companies that go to market during the GATT patent extension period, as is provided in the transition rules for all other companies.

Most importantly though, under our proposal, consumers and taxpayers would save billions of dollars as those generic drug manufacturers who have met the standards of current law are able to go to market under the transition rules. According to The Seniors Coalition, the mistake has already cost America’s seniors, consumers, and taxpayers more than \$750 million, while a few major drug companies have realized windfall profits. One company alone will earn a projected \$2 billion in windfall profits unless Congress corrects this mistake made in December 1994.

Our proposal simply makes sense by supporting equitable treatment for the pharmaceutical industry and for American drug consumers.

II. "SPECIAL BENEFITS"

Brand name drug manufacturers receive seven "special benefits" under the Hatch-Waxman Act, conferred on no other industry:

Extension of drug (and food and color additive) patent terms for up to 5 years to compensate for delays in marketing caused by the need to obtain FDA approval;

Prohibition against marketing by a competitor challenging a drug patent without prior notice to the patent holder;

Prohibition against lawsuits challenging drug patents until 1½ months after the patent holder receives notice of the challenge, guaranteeing the patent holder the right to sue first in a court of its own choosing;

If the drug patent holder does sue, prohibition against marketing by the competitor challenging the patent for the first 2½ years of the litigation;

If the drug patent holder wins its lawsuit, prohibition against marketing by the competitor even if the ordinary requirements for an injunction are not met;

Even if the drug patent holder does not sue during the 1½ month "standstill" period, another prohibition against lawsuits challenging drug patents except in the patent holder's "home court";

Prohibition against marketing generics even where there is no patent on the brand-name drug, for 5 years in the case of brand-name drugs receiving their first FDA approval and for 3 years where a new use of a brand-name drug is approved.

The "special benefits" received by brand-name drug manufacturers under Hatch-Waxman have not prevented them from also receiving the full benefits conferred on all patent holders by the URAA. By the same token, Hatch-Waxman is no reason to deny generic drug manufacturers the full protection afforded every other industry by the GATT/URAA transition provision.

III. ANALYSIS OF HATCH SUBSTITUTE

Section 1

This provision is ironic but unexceptionable.

Section 2(a)

This provision purports to extend the terms of the URAA transition provision to some generic drugs, by making the pre-URAA patent expiration date applicable if certain conditions are met. The scope of the provision is narrowly confined, however, and even as to this limited class of drugs, the provision ingeniously avoids actually granting any transitional protection.

First, the provision applies only where the ANDA for the generic drug was both "filed" with FDA and "accepted for filing" by the agency prior to June 8, 1995. Strictly speaking, no ANDA can meet that standard, because in FDA parlance ANDA's are not "filed" but merely "submitted"; after the applicant "submits" the application, FDA decides whether the application is deemed "received." Moreover, although FDA regulations require the agency to notify an ANDA applicant if the ANDA is not deemed "received," there is no deadline within which it must do so. At best, therefore, the effect

of the provision thus is to make transitional protection available only where the ANDA was submitted at some point prior to June 8, 1995—perhaps well prior to that date.

Second, the provision does not become operative until both the existence of “substantial investment” (as narrowly defined in section 2(b)) *and* the amount of “equitable remuneration” to be paid by the generic manufacturer under the URAA have been conclusively determined by a court, and all possible appeals have been exhausted, no matter how long that may take. (The entry of a court order is required, even if the parties are in agreement on these issues.) Meanwhile, as a matter of patent law, the generic cannot be marketed because such marketing would constitute patent infringement. No such hurdle need be overcome by new competitors in any other industry under the URAA transition provision.

Section 2(b)

This provision creates a special and restrictive definition of the URAA term “substantial investment,” applicable only to the generic drug industry, that would be binding on the courts. The URAA itself imposes no such restriction on the courts when any other industry is involved. The definition is so restrictive that virtually no generic manufacturer can be expected to qualify for the transitional protection that the proposal purports to provide. The true effect of the provision is not “definitional,” but rather to eviscerate the proposal in its entirety.

First, subparagraph (1) forbids the courts to recognize a generic manufacturer’s “substantial investment,” regardless of when the investment was made, unless by June 8, 1995, the resulting ANDA was both submitted to FDA and found by the agency to be complete. Moreover, as noted above in connection with section 2(a), the latter does not occur until some time after the ANDA is actually submitted. The effect of the provision is thus to push back the qualifying date for “substantial investment” to some indeterminate time prior to June 8, 1995, which under the URAA is the qualifying date in every other industry.

Second, subparagraph (2) forbids the courts to recognize a generic manufacturer’s “substantial investment” unless it is “specifically related to the research, development, manufacture, sale or marketing” of the particular product in question. Because it is illegal to sell or market a generic drug prior to FDA approval, it is difficult to imagine that any investment in such activities prior to approval could qualify as “substantial.” As to “manufacture,” the FDA approval process—even for generics—is so lengthy, and the shelf life of drugs is so limited, that no significant quantities are likely to be manufactured prior to approval even if the firm were willing to “roll the dice” and take its chances that changes in the product or its method of manufacturing would not be required by FDA. What a generic manufacturer can do prior to FDA approval of the ANDA is limited, both by the general patent law and by the regulatory provisions of the Food, Drug, and Cosmetic Act, to “research, [and] development” of its product.

Third, however, whatever may be given by subparagraph (2) is promptly taken away by subparagraph (3). In stark contradiction to what precedes it, subparagraph (3) forbids the courts to recog-

nize a generic manufacturer's "substantial investment" that "solely consist[s] of * * * expenditures related to the development and submission of the information contained in [the ANDA]." This is the cruelest deception of all; "research and development undertaken in connection with" a proposed generic product is just another way of saying "development and submission of the information contained in" the ANDA. Under patent law both pre-URAA and post-URAA, and under the regulatory statute administered by FDA, generic manufacturers are not legally permitted to do virtually anything but "develop and submit the information" contained in the ANDA.

It is true that new manufacturing facilities may sometimes be constructed in anticipation of FDA approval (as was the case with at least one manufacturer's proposed generic form of Zantac). But even that sort of "investment" could be deemed "related to the development and submission of information" to FDA, inasmuch as full information on manufacturing facilities and controls must be included in an ANDA.

Section 2(c)

This provision purports to authorize (but does not require) compensation to generic drug manufacturers for delays in marketing that result from litigation brought by patent holders under section 2(a). The compensation must be "equitable." If the provision is intended to remove a patent holder's incentive to use the procedures of section 2(a) to keep generics off the market, it will do nothing of the kind. Or, it may be merely a cynical attempt to buy off generic manufacturers supporting efforts in Congress to correct the URAA mistake. In either case, the provision does nothing to recompense consumers or taxpayers for the higher prices they will be forced to pay during the URAA created "Delta period."

The latter point is self-evident. The first may require some explanation. The only "equitable compensation" to a generic manufacturer that would make sense would be its lost profits. But a drug patent holder would happily pay a generic manufacturer its lost profits into eternity if it could, rather than allow the generic to enter the market, because the profits made by the patent holder on the brand-name drug are so many times greater than the profits being lost by the far lower priced generic. Far from removing the patent holder's incentive to delay entry of the generic, this provision creates an overwhelming incentive for the patent holder to do exactly that.

Section 2(d)

This provision operates in tandem with section 2(a) to ensure that FDA is powerless to approve generic drugs during the URAA "Delta period" until—without any time limitation whatsoever—the bitter end of any litigation brought by a patent holder under section 2(a), including all possible appeals. This gives patent holders a lengthier delay in URAA transition-provision cases than existing Hatch-Waxman Act procedures authorize in cases where a proposed generic manufacturer wishes to challenge a patent as invalid or unenforceable, or to assert that the proposed generic product does not infringe a patent on the innovator drug. Under Hatch-

Waxman, the delay is limited to 30 months (2½ years). Under this proposal, the delay is limited only by the length of the “Delta period.”

Thus, rather than fix Congress’ inadvertent mistake in failing to conform FDA’s approval authority with the transition provision of the URAA, this provision of the proposal codifies and perpetuates that error. Indeed, it exposes the entire proposal as nothing but a cynical and duplicitous charade.

Section 2(e)

This provision limits the applicability of the proposal to cases where the pre-URAA expiration date of the patent on the innovator drug was less than three years after the URAA became effective. The URAA transition provision applicable in every other industry contains no such limitation.

Section 3

This provision would legislatively overrule the decision of the U.S. Court of Appeals for the Federal Circuit in *Merck & Co. v. Kessler*, Nos. 95–1068 et al., decided April 4, 1996, insofar as that decision refused to allow drug patent holders already enjoying Hatch-Waxman Act patent term extensions as of the URAA effective date (June 8, 1995) to claim a second Hatch-Waxman extension based on the lengthening of patent terms by the transition provision of the URAA.

This provision would legislatively grant a special patent term extension for an unnamed specific drug, approved by FDA 5-years ago. Whether this is in addition to a patent term extension under the general provisions of the Hatch-Waxman Act is not revealed.

Section 5

This provision purports to express the “sense of the Senate” that the litigation contemplated—indeed, compelled—by the proposal be “concluded as expeditiously as possible.” The provision is hortatory only. It can be expected to have no effect whatsoever upon the litigating tactics of drug patent holders seeking to keep generics off the market during the “Delta period” notwithstanding Congress’ contrary intent as expressed in the URAA transition provision. Nor can it affect the way in which overburdened courts attempt to discharge their many responsibilities (including numerous statutes requiring expedited hearing of various types of civil cases, not to mention the Speedy Trial Act provisions governing criminal trials).

HANK BROWN.

IV. LETTER FROM SECRETARY OF HEALTH AND HUMAN SERVICES

THE SECRETARY OF HEALTH
AND HUMAN SERVICES,
Washington, DC, June 13, 1996.

Hon. HANK BROWN,
U.S. Senate, Washington, DC.

DEAR SENATOR BROWN: This is in response to your letter concerning S. 1277, the “Pharmaceutical Industry Special Equity Act of 1996”, as recently ordered reported by the Senate Judiciary Committee. You asked the Department to respond to questions on particular aspects of the bill, which addresses the effect of the Uruguay Round Agreements Act (URAA) on the generic drug industry. In brief, despite the

bill's declared intent to eliminate the unequal treatment of generic drugs created by the URAA, S. 1277 as ordered reported would be ineffective in affording generic drugs the same transitional period benefits given to other technologies, leaving the generic drug industry for all practical purposes at the same disadvantage as under current law.

The URAA extended the terms of some existing patents. In recognition that businesses may have made investments based on the expectation that a patent would expire at the end of the original patent term, Congress provided that if a patent is infringed by an act that became infringing only because the patent was extended by the URAA, and the infringer made a substantial investment before June 8, 1995, the only remedy available to the patent holder against that infringer would be the right to equitable remuneration during the period of patent extension, or "Delta period". Because of an unintended loophole favoring manufacturers of innovator human drugs, this transitional provision is available to all U.S. industries with the single exception of generic pharmaceuticals.

1. *Does S. 1277 truly remedy the URAA loophole?*

In all other industries, infringers of patents extended by the URAA may put their products on the market, and then resolve, through litigation or otherwise, whether the infringer made a substantial investment by June 8, 1995, and the amount of equitable remuneration. The URAA does not define substantial investment or equitable remuneration for any industry. Legislation designed with the sole purpose of closing the URAA loophole would permit generic drugs to be approved upon the expiration of the pre-URAA patent term and would leave matters of substantial investment and equitable remuneration to subsequent judicial interpretation or agreement between the parties in a particular case.

S. 1277 does not close the URAA loophole, but rather imposes requirements on the generic drug industry that are entirely different from those that apply to other industries:

(A) The bill requires that *before* a generic drug can be marketed, all issues related to substantial investment and equitable remuneration must be finally resolved by a court from which no appeal may be taken.

(B) S. 1277 both defines substantial investment—a matter that the URAA left to the courts—and does so in a manner that would make it virtually impossible for a generic drug company to meet the requirement.

(C) Whereas the transitional benefit period for all other products is not time-limited, section 2(e) of S. 1277 would prohibit marketing of an infringing generic drug during the Delta period of any pharmaceutical patent that, but for the URAA, would have expired on or after June 8, 1998.

(D) In the unlikely event that the generic drug applicant prevails in litigation on the substantial investment issue, section 2(c) of S. 1277 provides for "equitable compensation" to the applicant if it can establish that its market entry was delayed by the litigation. Section 2(c), which assigns to the generic manufacturer the difficult burden of persuading the court of the existence and amount of financial injury, is not a meaningful equivalent to the option, available to qualifying infringers of all other URAA-extended patents, of marketing the product and paying equitable remuneration to the patent holder.

2. *Does S. 1277 represent a compromise between proponents of a legislative remedy and those seeking to preserve the loophole?*

No, the bill as currently written would effectively preclude entry onto the market of any generic drug during the Delta period, because it will be nearly impossible to meet the "substantial investment" requirement. Furthermore, given the difficulty of proving the full amount of damages, even those few who would be eligible for equitable compensation would be unlikely to be made whole. With few or no exceptions, the generic drug industry would be no better off than it is today.

3. *Would it be legally possible for a generic drug manufacturer to meet the "substantial investment" requirement of S. 1277?*

It would be virtually impossible for a generic drug manufacturer to meet the substantial investment requirement as it is defined in the proposed legislation. Section 2(b)(2) requires that the investment by the generic drug company be specifically related to the product for which the application was filed, but not consist solely of the company's expenditures related to the development and submission of the information in the application.

Because an application to market a generic drug is required to contain information on every important aspect of the drug product and its manufacture, it is difficult to imagine what investment the generic drug company could make that would be both specifically related to the product for which the application was submitted and not related to the development and submission of the application. For example, if the applicant were to invest in a new plant to manufacture the generic drug prod-

uct it would be required to submit to FDA, either in the original application or by amendment, information on the location of the plant, and on the manufacturing and packaging equipment and processes in the facility.

4. *Could any generic drug manufacturer obtain FDA approval during the Delta period for a drug that obtained a patent extension under the URAA transition provision?*

Given the requirements proposed in S. 1277, it would be virtually impossible for a manufacturer to obtain FDA approval for a generic drug product during the Delta period. Not only is substantial investment defined in such a way that it presents a nearly insurmountable obstacle to a generic company, but the bill also requires that patent litigation be completed prior to FDA approval of the generic drug. This requirement, particularly when coupled with the limitation in section 2(e) to patents whose original term expired before June 8, 1998, would assure that no generic drug will be marketed during the Delta period. Unlike section 505(j) of the Federal Food, Drug, and Cosmetic Act, which establishes a 30-month period for resolution of patent disputes after which FDA can approve the generic regardless of the status of the patent litigation, S. 1277 establishes no binding timetable for resolution of patent litigation. Because the pendency of patent litigation ensures that there will be no generic competition, there is no incentive for an innovator company to expedite litigation. The proposed "equitable compensation" would not be an adequate incentive to expedite litigation.

We are advised by the Office of Management and Budget that there is not objection to the presentation of this report from the standpoint of the Administration's program.

An identical letter is being sent to Senator Pryor.

Sincerely,

DONNA E. SHALALA.

V. LETTERS OF SUPPORT/ARTICLES OF SUPPORT

THE SENIORS COALITION,
Washington, DC, May 10, 1996.

Hon. HANK BROWN,
U.S. Senate, Washington, DC.

DEAR SENATOR BROWN: On behalf of the two million members of the Seniors Coalition, I am writing to urge you to support legislation offered by Senators Hank Brown (R-CO), John Chafee (R-RI) and David Pryor (D-AR) to correct a mistake made in the GATT Agreement implementing legislation, and to oppose the substitute reported by the Judiciary Committee.

The mistake has already cost America's seniors, consumer, and taxpayers more than \$750 million, while a few major drug companies, most notably Glaxo-Wellcome, have realized unintended windfall profits. Glaxo alone will earn a projected two billion in windfall profits unless Congress corrects this mistake made in December 1994.

Although its proponents call it a "compromise," the Judiciary Committee substitute does absolutely nothing to help seniors. It ensures that generic versions of such popular medications as Zantac, Glaxo's blockbuster anti-ulcer drug, Seldane-D, a widely prescribe allergy medicine, and Toradol, a pain killer, will be kept off the market during the GATT patent extension period. As a result, seniors will pay an estimated hundreds of millions of dollars more for their medicines than they should.

Only the Brown/Chafee/Pryor legislation applies the GATT transition rules to the pharmaceutical industry in a way that is consistent with the intent of the GATT Agreement and the implementing legislation. The Judiciary Committee substitute incorporates a "litigation first" policy, making it a trail lawyers dream and ensuring that generic drugs will be kept off the market by endless and needless court delays.

The Seniors Coalition strongly urges you to support the Brown/Chafee/Pryor legislation and oppose the Judiciary Committee substitute when the GATT issue comes to the floor for a vote.

Thank you.

Sincerely,

THAIR PHILLIPS,
Chief Executive Officer.

[From the Des Moines Register, Nov. 27, 1995.]

A COSTLY OVERSIGHT

FINE PRINT IN GATT LAW COULD COST ZANTAC USERS MILLIONS

The nation's prescription drug makers are at war again, with a \$1 billion-plus purse going to the winner. If the brand-name drug manufacturers win, the losers will include the millions of Americans who suffer from ulcers or heartburn, and take the drug Zantac regularly to combat the problem. It's going to cost each of them about \$1,600.

Zantac is made by Glaxo Wellcome, the biggest in the business.

Here's what started the current war:

When a new prescription drug hits the market, generic drug manufacturers await the patent expiration so they can enter the market with the same drug. They offer it for sale without the brand name, usually at a fraction of the brand-name price.

The new international GATT treaty signed by the United States and 122 other countries sets the life of a patent at 20 years from the date of application. Former U.S. law provided patent protection for pharmaceuticals for 17 years from the date of approval. Because the difference could have a significant impact on the number of years a firm could market its patented drug without competition. Congress made special provisions for drugs under patent at the time GATT was approved last summer.

But when the legal beagles got done reading all the fine print, it turned out that Zantac was granted a 19-month extension of its patent life—and it is such a hugely popular drug that that translates into a multimillion-dollar windfall.

Generic drug makers call the windfall a congressional oversight, and estimate the difference is worth \$2.2 billion to Glaxo, because the generics can't enter the market for 19 more months. Glaxo counters that Congress made no mistake, that the extension was part of the compromise with generics. It won't wash. Nothing in the GATT treaty was intended to further enrich the happy handful of brand-name drug makers who hold lucrative patents—or to penalize the users of the drugs.

A month's supply of Zantac ordinarily sells for around \$115; the generic price—meaning the same drug without the Zantac label—would be around \$35, the generic makers contend. Unless Congress changes the wording of the law regarding transition to GATT provisions, Zantac users will pay the difference for 19 months longer.

Some generic drug manufacturers had already spent a bundle preparing to enter the market before the GATT treaty took effect. They lose. So do taxpayers, who pay for Medicaid prescriptions. The Generic Drug Equity Coalition estimates that the higher cost of Zantac and some other drugs affected by the mistake (such as Capoten, for high blood pressure) will cost Iowa Medicaid \$3.5 million. Further, say the generic drug makers, it will tack another \$1.2 million onto the cost of health-insurance premiums for Iowa state employees.

Glaxo's political-action committee has doubled its contributions to Congress in recent months. Glaxo wants the mistake to stay in the law. Generic drug manufacturers want it out.

So should ulcer sufferers. So should taxpayers. So should Congress.

[From the Washington Post, Monday, Dec. 4, 1995]

THE ZANTAC WINDFALL

All for lack of a technical conforming clause in a trade bill, full patent protection for a drug called Zantac will run 19 months beyond its original expiration date. Zantac, used to treat ulcers, is the world's most widely prescribed drug, and its sales in this country run to more than \$2 billion a year. The patent extension postpones the date at which generic products can begin to compete with it and pull the price down. That provides a great windfall to Zantac's maker, Glaxo Wellcome Inc.

It's a case study in legislation and high-powered lobbying. When Congress enacted the big Uruguay Round trade bill a year ago, it changed the terms of American patents to a new worldwide standard. The effect was to lengthen existing patents, usually by a year or two. But Congress had heard from companies that were counting on the expiration of competitors' patents. It responded by writing into the trade bill a transitional provision. Any company that had already invested in facilities to manufacture a knock-off, it said, could pay a royalty to the patent-holder and go into production on the patent's original expiration date.

But Congress neglected to add a clause amending a crucial paragraph in the drug laws. The result is that the transitional clause now applies to every industry but

drugs. That set off a huge lobbying and public relations war with the generic manufacturers enlisting the support of consumers' organizations and Glaxo Wellcome invoking the sacred inviolability of an American patent.

Mickey Kantor, the president's trade representative, who managed the trade bill for the administration, says that the omission was an error, pure and simple. But it has created a rich benefit for one company in particular. A small band of senators led by David Pryor (D-Ark.) has been trying to right this by enacting the missing clause, but so far it hasn't got far. Glaxo Wellcome and the other defenders of drug patents are winning. Other drugs are also involved, incidentally, although Zantac is by far the most important in financial terms.

Drug prices are a particularly sensitive area of health economics because Medicare does not, in most cases, cover drugs. The money spent on Zantac is only a small fraction of the \$80 billion a year that Americans spend on all prescription drugs. Especially for the elderly, the cost of drugs can be a terrifying burden. That makes it doubly difficult to understand why the Senate refuses to do anything about a windfall that, as far as the administration is concerned, is based on nothing more than an error of omission.

X. MINORITY VIEWS OF MESSRS. KENNEDY AND SIMON

The relationship between the Uruguay Round Agreements Act and existing U.S. pharmaceutical patent laws posed an important question to members of this Committee regarding the treatment of generic pharmaceutical drugs. Although we commend Chairman Hatch for his hard work in this area, we oppose the legislation that was reported out of the Judiciary Committee.

Under the Uruguay Round Agreements Act (URAA, Public Law 103-465), the United States harmonized its patent laws with other nations in accordance with the trade agreements resulting from the Uruguay Round of multilateral negotiations under the auspices of the General Agreements on Tariffs and Trade (GATT), and pursuant to the Statement of Administrative Action (SAA) submitted to the Congress. Section 532 of the URAA states that, after June 8, 1995, new patents are valid for 20 years from date of filing. Patents approved before June 8 are extended to the greater of either 20 years from filing or the traditional 17 years from patent grant.

In implementing these changes, however, Congress recognized that in many instances the private sector had already made significant investments based on pre-GATT dates of patent expiry. As a result, the URAA includes a transitional provision in section 532 which allows any party that has made a “substantial investment” prior to June 8, 1995, in a generic version of a patented product to market it during the period of extended patent life granted under the URAA if “equitable remuneration” is made to the patent holder. This provision applies to all patents extended by the URAA and is both consistent and explicitly sanctioned in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIP’s Agreement).

According to the U.S. Trade Representative (USTR), the Secretary of Health and Human Services (DHHS), the Food and Drug Administration (FDA) and the Patent and Trademark Office (PTO), this transition provision was also intended to apply uniformly to all industries, including the pharmaceutical industry. As U.S. Trade Representative Mickey Kantor testified on March 13, 1996, before the Committee:

When we drafted this transitional provision, we intended it to apply to all types of patented technology, and expected no distinctions to be made between electronic products, pharmaceutical products, or any other type of patented products. By contrast, when we intended to distinguish between types of intellectual property in the URAA, we did so clearly and unambiguously—the lack of any distinctions in section 532 of the URAA or the relevant portions of the Statement of Administrative Action clearly indicates that we intended no distinction to be made.

Nor was it the intent of the Congress to single out a specific industry for special treatment under the transition provision. On August 12, 1994, the Senate Judiciary Committee and the House Judiciary Committee held a joint hearing to review the intellectual property provisions of the URAA. No reference to any industry-specific exemptions to the transition provision was made, including in the testimony of the pharmaceutical industry's trade association, the Pharmaceutical Research and Manufacturers Association (PhRMA). Nor did any other industries with compelling commercial interests at stake articulate the desirability, necessity or existence of exemptions to the transition provision. Moreover, no hearings, testimony or statements conducted or made in either the House or the Senate prior to enactment of the URAA refer to section 532, including the transition provision, in any manner save with reference to its universal scope and application.

Despite the intent of both the Congress and the Administration, the record clearly shows that an error was made in drafting the language of the URAA transition provision with respect to the technical interrelationship between the Patent Act and the regulation of pharmaceutical products by the Federal Food, Drug and Cosmetic Act (FD&C Act). In originally drafting this language, the PTO assumed that all forms of technology would be treated alike under section 532. In their review of the legislation, the Office of Legislative Counsel in both the House and the Senate similarly assumed that section 532, including the transition provision, was universal in scope. The Committees of jurisdiction, however, failed to account for the inconsistency between section 532 and the statutory language controlling the approval and marketing of generic pharmaceuticals in the 1984 Waxman-Hatch amendments to the FD&C Act.

As a result of the absence of a conforming amendment to the Waxman-Hatch amendments, the prescription drug industry is the only industry in the country which received the URAA patent extension but is unfairly exempted and shielded from generic competition. The Waxman-Hatch amendments require a manufacturer seeking to market a generic drug to receive FDA approval, upon which the manufacturer may go to market on the date of the innovator's patent expiry. While the URAA extends existing patents, it also provides under section 532 for generic manufacturers who have made a "substantial investment" to go to market on the *original* 17-year date of patent expiry so long as "equitable remuneration" is paid. However, in its exhaustive review of the congressional record of deliberations on the URAA, the FDA concluded:

Here there were neither hearings nor a single word of debate on the floor of the House or Senate on the impact of the URAA on the 1984 Waxman-Hatch Amendments. Nor do the committee reports indicate that Congress understood that the URAA would both grant a patent term extension for certain pioneer products *and* block FDA from approving generic versions of those drugs until the extended patent terms have expired. Nonetheless, the language of the URAA directs that result.

The absence of a conforming amendment has thus created a statutory loophole which benefits a few brand name drug companies, blocks the fair market competition called for in the URAA, delays the availability of less expensive generic drugs and forces American consumers to pay as much as \$2 to \$6 billion more for their medicines.

Consumers, health insurers, HMO's and hospitals are not alone in subsidizing this multibillion dollar windfall. Taxpayers must also subsidize higher government health care spending. The Congressional Budget Office (CBO) estimates that Medicaid will save \$150 million over 5 years if the loophole is closed. The Veterans Health Administration estimates it could save \$211 million and Public Health Service and Indian Health Service clinics could save \$15 million.

In no way did the Congress intend the URAA to obstruct the free market, hinder FDA product approvals or create special patent exemptions for particular industries. But in failing to adopt S.1277 as originally proposed by Senator Brown and Senator Pryor, the Committee has not acted to correct the statutory loophole and the resulting multibillion dollar windfall. In his testimony before the Committee, Ambassador Kantor stated that S.1277, as originally proposed, "would do nothing more than [fulfill] our obligation to be faithful to what we negotiated" in the URAA and confirmed that the bill would "carry out the intent, not only of the negotiations and what the Administration intended, but also what the Congress intended." Additionally, HHS Secretary Donna Shalala wrote on February 26, 1996, that "the [URAA] transitional rules should be applied to the generic pharmaceutical industry just as they are applied to other businesses."

In place of S. 1277, the Committee reported out substitute language which fails to correct the URAA loophole and, in effect, codifies its effect on the pharmaceutical industry. According to a comprehensive analysis by the FDA and DHHS, the substitute would block marketing of competing generic products and guarantees that litigation would consume any opportunity for the lower-cost generics affected by the loophole to enter the market as originally intended under the URAA.

In failing to amend the FD&C Act to correct the URAA loophole, the Committee has regrettably left a clear and costly statutory mistake to stand uncorrected, effectively rewarding a few companies with an unintended, unjustifiable multibillion dollar windfall which is being subsidized daily by American consumers and taxpayers.

EDWARD M. KENNEDY.
PAUL SIMON.

XI. CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, the committee finds no changes in existing law caused by passage of S. 1277.