Space Pharmaceuticals: Will the United States Fumble Another High Technology Industry

John F. Kohler
SPACE PHARMACEUTICALS: WILL THE UNITED STATES FUMBLE ANOTHER HIGH TECHNOLOGY INDUSTRY?

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I. INTRODUCTION

SPACE, WITH ITS absence of vibration, near-perfect vacuum, sterile environment, unfiltered sunlight, and lack of significant gravitational fields, provides an environment perfect for the production of pharmaceuticals. This environment allows pharmaceuticals to be produced in higher quantities and more efficiently than on earth. For example, earth's gravity concentrates sediment and other impurities during drug production, reducing yield and purity. In the weightlessness of space this problem does not exist, resulting in products with greater purity and strength.

U.S. companies are already conducting pharmaceutical production experiments in space. In one such experiment, McDonnell Douglas produced a drug 716 times more separated than could be produced on earth, while obtaining five times greater purity. These positive results have led to predictions that space production will revolutionize pharmaceutical development by enhancing our ability to produce drugs of sufficient purity to help

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2 Id.
3 Id.
fight many heretofore incurable diseases. As a result, using space as a laboratory for producing pharmaceuticals is a major goal of U.S. pharmaceutical companies.

Despite the potential that space production holds for the pharmaceutical industry, its development faces many practical and legal obstacles. Practical obstacles include the need for massive investment capital to establish space facilities and conduct space research, foreign competition by government subsidized firms, high insurance costs,

5 See Michael Schrage, *Putting the Final Frontier in Perspective*, WASH. POST, Feb. 2, 1990, at G3 (citing THE CENTER FOR SPACE POLICY, INC., COMMERCIAL SPACE INDUSTRY IN THE YEAR 2000: A Market Forecast 1-190 (1985)). A study by the Center for Space Policy estimates that, given a suitable environment for development, American companies could develop as much as $40 billion worth of pharmaceuticals and microchips in space by the year 2000. *Id.*

6 Before risking massive capital investments in space pharmaceutical production facilities, companies must procure space insurance, which is paid both on a launch-by-launch basis, for property damage to the launch vehicle or spacecraft, and also on an annual basis for commercial operating risk coverage and third party liability coverage for injury or damage to others not associated with the launch. *Review of Latest U.S. Space Activities*, 13 SATELLITE NEWS 44, 46 (1990). Such insurance, however, is extremely expensive, and insurance rates are unstable and subject to great fluctuation. *Insuring Space-related Risks*, BUS. INS., Sept. 30, 1991, at 37. Since 1990, industry claims total $490 million, resulting in current rates as high as 16%-18% of the insured value. James R. Asker, *U.S. Commercial Space Revenues Projected to Hit $5 Billion in 1992*, AVIATION Wk. & SPACE TECH., June 29, 1992, at 68. With some 20 commercial launches scheduled between 1993 and 1995, potential losses are astronomical, adding great uncertainty to the future of space insurance rates. Current high rates are not, however, the pharmaceutical industry’s only insurance problem. The typical insurance contract for a commercial space launch covers three phases: (1) launch; (2) placement into initial orbit; and (3) placement into final orbit coupled with a 180 day in-orbit testing period. *Space is a Risky Business*, FLIGHT INT’L, June 12, 1991, at 25. Space-produced pharmaceuticals require a fourth currently uncovered phase — successful return to earth of the pharmaceuticals produced. The addition of a fourth phase of insurance coverage, with a variety of new risks, would further increase insurance costs.

In addition to the problem of high rates, the availability of space insurance may become a problem since the low number of insurable payloads and the potentially high cost of a single loss requires that an insurance company stay in the market for a long period of time before realizing a profit. Carissa Christensen & Joel Greenberg, *The Commercial Launch Industry: Will it Fly on its Own?*, AEROSPACE AM., May 1992, at 32. The number of insurers willing to participate in the market might increase, however, if a greater number of insurable payloads were available, assuring profitability in a shorter period of time. The necessary number of payloads would be available if government launches would move from self-insurance to commercial insurance. This policy would be appropriate not only because of government participation in encouraging development of the commercial space in-
and potential competition from lower cost earth-produced products. These risks, coupled with major legal obstacles including the poor response of the U.S. Patent Office to the need for greater protection for pharmaceutical patents, outdated Food and Drug Administration (FDA) regulations, and the threat of liability under U.S. antitrust law for participating in joint ventures necessary to develop the industry, make the development of space pharmaceuticals a high-risk, yet high-reward, proposition.

II. ANTITRUST

Due to the enormous capital expenditures required to conduct space research and production, using space to develop pharmaceuticals is beyond the reach of most individual pharmaceutical companies. Conventional wisdom, therefore, dictates that joint ventures are necessary to raise the capital needed for space pharmaceutical development. When U.S. firms enter into joint ventures, industry, but also because such a policy would be more economically efficient for the government. Id.

Two other obstacles present themselves. First, and of primary concern, is the question of whether the space pharmaceutical industry is profitable. Without an acceptable return on investment there will be no financial incentive for pharmaceutical companies to invest in research and development or production. Goodrich et al., supra note 1, at 288-39. A second major problem is the actual operation of any space production facility. If humans are required to run the facilities, they may be required to stay in space for an extended period of time. As a result, they would face a number of potential health problems including bone decalcification and deterioration due to weightlessness, loss of red blood cells, impairment of the immune system, and cardiovascular de-conditioning. Id.

Since the pharmaceutical industry is highly competitive, the first to develop a new drug is generally able to control the market for a period of time. Therefore, proprietary protection is critical and must be assured because pharmaceutical markets are huge; companies seldom develop new drugs unless anticipated sales are more than $60 million per year. Patents in Space, 1989: Hearings on H.R. 2946 Before the Subcomm. on Courts, Intellectual Property and the Administration of Justice of the House of Representatives Comm. on the Judiciary, 101st Cong., 1st Sess. 50 (1989) [hereinafter Patents in Space Hearings] (testimony of Dr. Charles Bugg, Director, Center for the Commercial Development of Space, University of Alabama at Birmingham).

There are three types of joint ventures: research, production, and distribution. PHILLIP AREEDA, ANTITRUST LAW 348 (1986); see Douglas H. Ginsburg, Antitrust, Uncertainty, and Technological Innovation, 24 ANTITRUST BULL. 635, 670 (1979).
however, they risk antitrust liability. This risk of liability arises because U.S. antitrust law places emphasis on avoiding harmful market concentration and unfair trade practices. These laws, which may have been appropriate to regulate the domestic economy at the time enacted, are no longer viable because U.S. firms now compete in a global marketplace. To compete effectively, these firms must be allowed to compete according to the norms of that global marketplace. As only one of three major global competitors, the United States cannot dictate the rules governing global competition or survive unless it plays by them.

While U.S. antitrust laws are based on principles of competition, they also contain certain uniquely American notions of "fair play" designed to protect small business people. Additionally, the United States, because of its highly decentralized economy, has turned to "self regulation" to protect competition. These policies mandate that courts and, to a greater or lesser extent depending upon the current administration, the Justice Department examine joint operations between competitors very closely. The Japanese and the European Economic Community (EEC), on the other hand, take a different approach. The Japanese and the EEC view the protection of competition as only one aspect of the government's responsibility in creating the most effective industrial policy. The main thrust of their antitrust laws is prevention of monopolies and predatory practices. This premise underlies the attitudes of both the Japanese and the EEC when applying antitrust law to research and development (R&D) and production joint ventures. Therefore, when competing with the United States, these countries often encourage joint ventures to take advantage of efficiencies.

([A] joint venture can be seen as a partial rather than complete integration of two firms, which preserves pro tanto their capacity to compete with respect to the portion of their operations that is not integrated in the joint venture.

12 Id.
13 Id.
and economies of scale.\textsuperscript{14} Allowing U.S. firms to participate in joint ventures with the same freedom would allow them to achieve the same efficiencies and economies of scale, reduce risks through cost spreading, speed profitable results, and open new markets with greater ease.\textsuperscript{15} Despite these obvious benefits, joint ventures still raise legitimate antitrust concerns as excellent vehicles for hiding illegal price fixing, output restrictions, and monopolies.\textsuperscript{16}

A. The Japanese

Japan greatly influences the norms of conducting global high technology competition. The key to Japan’s international competitiveness is a strong government-business relationship that has greatly increased the ability of Japanese firms to spread the risk of high technology joint ventures. One half of this relationship is the Keiretsu,\textsuperscript{17} and the other half is the Ministry of International Trade and Industry (MITI).\textsuperscript{18} By coordinating the resources of government and industry, the MITI and the Keiretsu couple

\textsuperscript{14} Alvin F. Lindsay III, Comment, Tuning in to HDTV: Can Joint Production Ventures Improve America’s High-Tech Picture?, 44 U. MIAMI L. REV. 1159 (1990).

\textsuperscript{15} Id. at 1165.

\textsuperscript{16} Id. at 1166.

\textsuperscript{17} Keiretsu (Kay-rhet-sue) translates into “business alliance.” Of the six major horizontal Keiretsu in Japan, three were formed from pre-World War II family-owned industrial groups known as Zaibatsu, and three were formed around major banks. The Keiretsu are conglomerates of companies that conduct a variety of businesses. These alliances employ cross holding of shares, presidential counsels, intra-group financing by common banks, mutual appointment of officers, and joint investments in new industries. The six major horizontal Keiretsu are Mitsubishi, Mitsui, Sumitomo, Fuyo, DKB, and Sanwa. Almost all of these companies operate in the following industries: financial services; computers and electronics; automobiles; trading and retail; food and beverages; construction; metals; real estate; oil and coal; rubber and glass; chemicals; fibers and textiles; pulp and paper; mining and forestry; industrial equipment; cameras and optics; cement and shipping; and transportation. Carla Rapoport, Why the Japanese Keep on Winning, FORTUNE, July 15, 1991, at 77, 81, 84.

\textsuperscript{18} The prime mover behind industrial targeting is the MITI. The MITI’s director freely admits supporting industry attempts to target specific industries or technologies and justifies such action by stating, “Without the development of technology, we can’t assure the progress of living standards. This kind of technology development doesn’t pay in the short term, so we have to support it.” Id. at 84.
investment capital with high technology. The combination, aided by Japan's lax enforcement of its antitrust laws, has enabled Japan to capture world leadership in electronic products, automobiles, and computer chips. This success was due, at least in part, to the ability of Japanese firms to spread the risk of high technology ventures.  

1. Targeting  

Like the electronics and automobile industries before government intervention, Japan's pharmaceutical industry is in its infancy. The Japanese government, however, has begun attempts to stimulate pharmaceutical R&D by amending Japanese patent law to provide better protection for pharmaceuticals and beginning a program of discriminatory pricing against older drugs to stimulate the production of new ones. These governmental actions indicate a growing interest in developing a global pharmaceutical industry, thereby increasing the likelihood of direct government involvement.  

Japanese industrial powers also appear to be moving into the pharmaceutical industry. Most significant is the apparent move by the Japanese steel industry into pharmaceuticals. Companies such as NKK Corp., Nippon Steel, and Kobe Steel, all owned by the Keiretsu, are investing capital and diversifying into pharmaceuticals, and it is anticipated that they too will turn to joint ven-

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19 The MITI's activities include developing Japan's fully integrated electronics industry. Between 1961 and 1981, estimates indicate that the Japanese government provided $6 billion to computer makers and used government facilities to develop semi-conductors for the industry. As a result, Japan was able to effectively compete in the world market by 1980 despite the poor state of their electronics industry only 20 years before. Id.  

20 Currently over 6000 chemical and pharmaceutical companies exist in Japan; however, these firms are generally too small to be global competitors or to invest in space R&D. Emma Chynoweth, The Western Influence: Multinationals Mount a Steady Drive, CHEMICAL Wk., Nov. 27, 1991, at 40.  


tures involving other firms or the government to gain a competitive edge. Although experts disagree on the Japanese' ability to produce new products sufficient for global exploitation, Japan is a leader in discovering new chemical products, and its products get to market faster than products in the United States. As demonstrated by the losses in the U.S. semi-conductor industry in the mid-1980s to Japanese competition, the domination of the U.S. video cassette recorder (VCR) market by the Japanese, and the threatened loss of the new High Definition Television (HDTV) market, U.S. firms can currently do little but fall victim to the Japanese high technology steamroller. Japan now appears to be turning that steamroller toward the world pharmaceutical markets. This market will, in the coming years, necessarily include the high technology development of space pharmaceuticals, an ideal venture for Keiretsu/MITI exploitation.

2. Antitrust Laws

Japan's primary antitrust law is the Act Concerning the Prohibition of Private Monopoly and Maintenance of Fair Trade (Anti-Monopoly Act) enacted during the Allied Occupation of Japan after World War II. The Anti-Monopoly Act was modeled on U.S. antitrust law, but recent Japanese policies encouraging R&D and production joint ventures through tax incentives, government financial support, and relief from antitrust laws, have relaxed its restrictions.

Although the Japanese antitrust law appears similar to U.S. law, there is little similarity in reality. Enforcement

23 Id.
26 H. R. REP. No. 516, supra note 11, at 6. This relaxation represents a return to the pre-war arrangement in Japan as illustrated by the Key Industries Control Law of 1931, which was designed to increase market concentration in key industries. Id.
of the Anti-Monopoly Act rests with the Japanese Fair Trade Commission (JFTC), which wields quasi-judicial and quasi-legislative power. Although the JFTC has the power to bring both criminal and civil actions, civil penalties are inconsequential, including only consent decrees, cease-and-desist orders, and surcharges on gross earnings, while criminal actions are virtually non-existent. The JFTC has pursued only six criminal actions since passage of the Anti-Monopoly Act. Additionally, although the Anti-Monopoly Act, like U.S. antitrust law, gives a private right of action, private plaintiffs are rare. Since passage of the Anti-Monopoly Act, only seven plaintiffs have filed actions for damages, and no one has prevailed in a Japanese court.

The non-enforcement of Japanese antitrust law makes it necessary for U.S. pharmaceutical companies who aspire to compete in the coming race for space pharmaceuticals to receive immediate antitrust exemptions for joint ventures to allow risk-spreading commensurate with that enjoyed by the Japanese. The Japanese are on the move in the global pharmaceutical market and, if history is any indicator, this move is being accomplished by agreement between the Keiretsu and the MITI whose deals have never been prohibited by the JFTC.

B. **European Economic Community**

The European Economic Community (EEC), like the Japanese, promotes the creation of high technology industries and has done so by significantly adjusting its anti-
trust laws to encourage R&D and production joint ventures. The EEC antitrust law is contained in article 85 of the Treaty of Rome.\textsuperscript{36} Generally, article 85(1) prohibits agreements that restrict competition within the EEC,\textsuperscript{37} and article 85(2) makes void any agreement falling within the definition of article 85(1).\textsuperscript{38} Parties may, however, request exemptions under article 85(3) from the Commission of the European Community (Commission).\textsuperscript{39}

Because the Commission holds the exclusive right to grant exemptions under article 85, it controls, for all prac-

\textsuperscript{36} Treaty Establishing the European Economic Community, Mar. 25, 1957, art. 85, 298 U.N.T.S. 11, 47 [hereinafter Treaty of Rome].
\textsuperscript{37} Id. Article 85(1) of the Treaty of Rome provides that:
the following shall be prohibited as incompatible with the common market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may effect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market, and in particular those which:
(a) directly or indirectly fix purchase or selling prices or any other trading conditions;
(b) limit or control production, markets, technical development, or investment;
(c) share markets or sources of supply;
(d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
(e) make the conclusion of contracts subject to the acceptance by other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.
\textsuperscript{Id.}
\textsuperscript{38} Id. Article 85(2) states: "Any agreements or decisions prohibited pursuant to this Article shall be null and void." \textsuperscript{Id.}
\textsuperscript{39} Id. Article 85(3) provides that: the provisions of article 85(1) may be declared inapplicable in the case of:
— any agreement or category of agreements between undertakings
— any decision or category of decisions
— any concerted practice or category of concerted practices; which contributes to improving the production or distribution of goods or to promote the technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not:
(a) impose on the undertaking concerned restrictions which are not indispensable to the attainment of these objectives;
(b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.
\textsuperscript{Id.}
tical purposes, antitrust enforcement in the EEC. In 1984, the Commission adopted Commission Regulation (EEC) 418/85 concerning block exemptions for R&D joint ventures. The regulation gives automatic exemptions for three types of R&D joint ventures: (1) joint R&D coupled with joint exploitation of results; (2) joint exploitation of prior R&D results; and (3) joint R&D without joint exploitation of results for agreements falling within the scope of article 85(1). Joint exploitation under the regulation includes joint manufacturing and licensing, but not joint distribution or selling. EEC pharmaceutical companies can, therefore, engage in both R&D joint ventures and production joint ventures secure in the knowledge that compliance with the detailed guidelines of the Regulation insulates them from antitrust liability. The Commission is currently considering further relaxation of its competition rules governing production joint ventures.

C. United States

In comparison to their Japanese competitors, who face no joint venture limitations because of lax enforcement of Japanese antitrust laws, and EEC competitors, who have detailed guidelines allowing predictable enforcement of EEC antitrust laws, U.S. firms face both enforced and unpredictable antitrust laws. The Sherman Act, which states that "any contract or combination . . . in restraint of trade . . . is declared illegal," is the primary antitrust legislation impeding the development of joint ventures in the

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42 Id. at 1.1(a)-(c).
43 Id. at 1.2(d).
United States. Additionally, pharmaceutical companies probably cannot form corporations to conduct joint R&D or production in space because of the Clayton Act's prohibition against acquisitions lessening competition or creating monopolies. These laws, and their attendant treble damages provisions, place U.S. high technology firms at a competitive disadvantage internationally when compared with both Japanese and EEC firms. Recognizing this problem, Congress enacted the National Cooperative Research Act of 1984 (NCRA). The NCRA continues the steps began in the 1918 Webb-Pomerene Act of helping U.S. companies compete in the international arena by protecting them from unfair competition by foreign firms not restricted by U.S. antitrust laws.

1. National Cooperative Research Act of 1984

In interpreting the Sherman Act, U.S. courts developed two tests to determine legality under section one: the "per se test" and the "rule of reason." Under the "per se test," combinations are illegal per se and "are not evaluated in terms of their purpose, aim or effect." Under the "rule of reason," the alleged combination is judged
"taking into account all relevant facts affecting competition in properly defined, relevant . . . markets." The NCRA provides U.S. R&D joint ventures a measure of relief from the unpredictability of U.S. antitrust laws in two ways.

The first and most significant NCRA protection regarding R&D joint ventures is the codification of the "rule of reason" as the appropriate standard for testing the legality of an R&D joint venture under section one of the Sherman Act. This codification ensures judicial certainty previously missing from the Supreme Court's treatment of antitrust suits. Assuring pharmaceutical companies that joint ventures will not be held to be per se illegal and affording courts the flexibility to examine all relevant factors provides a significant measure of protection for R&D joint ventures. This still leaves U.S. joint ventures at risk, however, because applying the "rule of reason" only assures them that they can avoid a plaintiff's motion for summary judgment and does nothing to protect them at

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52 To qualify for NCRA protection, members of a R&D joint venture must file written notification with the Attorney General and the Federal Trade Commission (FTC) disclosing the identity of the members and the nature and objectives of the joint venture. Although that information becomes public record, the NCRA attempts to protect the R&D secrets of the joint venture by mandating that information received pursuant to any antitrust investigation and any other information received pursuant to the reporting requirements of the NCRA are immune from governmental disclosure requirements under the Freedom of Information Act, 5 U.S.C. § 522 (1988). 15 U.S.C. § 4305 (1988).
   In any action under the antitrust laws, or under any State law similar to the antitrust laws, the conduct of any person in making or performing a contract to carry out a joint research and development venture shall not be deemed illegal per se; such conduct will be judged on the basis of its reasonableness, taking into account all relevant factors affecting competition, including, but not limited to, effects on competition in properly defined, relevant research and development markets.
   Id.
trial. When this is compared with the environment of legal certainty enjoyed by Japanese and EEC firms who know that their actions will not create antitrust liability, U.S. participants in joint ventures bear a much greater investment risk.

The second significant provision of the NCRA allows R&D joint ventures to shield themselves from treble damages by complying with the NCRA registration requirements. The NCRA limits an antitrust plaintiff's recovery to actual damages, interest, and attorney fees and expressly denies recovery of treble damages under section four of the Clayton Act or under any similar applicable state law. Additionally, the NCRA expressly allows any joint venture that successfully defends against an antitrust claim to recover reasonable attorney fees.

Although the NCRA offers some protection to joint ventures, it is worthless to the space pharmaceutical industry because it does not fully extend protection to production joint ventures. Unlike some other high technology industries in which the market prohibitive cost

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57 Id.
58 The NCRA, as codified in 15 U.S.C. § 4301, narrowly defines the type of joint venture that receives its protection, excluding production joint ventures. Subsection 6(a) of § 4301 states:

The term "joint research and development venture" means any group of activities, including attempting to make, making, or performing a contract, by two or more persons for the purpose of:

(A) theoretical analysis, experimentation, or systematic study of phenomena or observable facts,

(B) the development or testing of basic engineering techniques,

(C) the extension of investigative findings or theory of scientific or technical nature into practical application for experimentation or demonstration purposes, including the experimental production and testing of models, prototypes, equipment, materials, and processes,

(D) the collection, exchange, and analysis of research information, or

(E) any combination of the purposes specified in paragraphs (A), (B), and (D), and may include the establishment and operation of facilities for the conducting of research, the conducting of such venture on a protected or proprietary basis, and the prosecuting of applications for patent and the granting of licenses for
is the R&D and not the production phase, the space pharmaceutical industry finds market prohibitive costs at both the R&D and the production phases. Without this type of antitrust protection for production joint ventures, pharmaceutical companies will be effectively prevented from developing sufficient space pharmaceuticals to compete in the global market place.

2. Amending the NCRA

Recognizing the NCRA's shortcomings, Congress began moving toward extending NCRA protection to production joint ventures in 1990.\textsuperscript{59} Congress is currently considering two separate amendments to the NCRA: one sponsored by Senator Strom Thurmond of South Carolina,\textsuperscript{60} and one sponsored by Senator Patrick Leahy of

the results of such ventures, but does not include any activity specified in subsection (b) of this section.

\textit{Id.} § 4301(6)(a). Subsection (6)(b) states:

The term "joint research and development venture" excludes the following activities involving two or more persons:

1. exchanging information among competitors relating to costs, sales, profitability, prices, marketing, or distribution of any product, process, or service that is not reasonably required to conduct the research and development that is the purpose of such venture,

2. entering into any agreement or engaging in any other conduct restricting, requiring, or otherwise involving the production or marketing by any person who is a party to such venture of any product, process, or service other than the production or marketing of proprietary developed through such venture, such as patents and trade secrets, and

3. entering into any agreement or engaging in any other conduct—
   (A) to restrict or require the sale, licensing, or sharing of inventions or developments not developed through such venture, or
   (B) to restrict or require participation by such party in other research and development activities, that is not reasonably required to prevent misappropriation of proprietary information contributed by any person who is a party to such venture or of the results of such venture.

\textit{Id.} § 4301(6)(b).


Vermont.\textsuperscript{61} These bills, entitled the Cooperative Production Act of 1991 (Production Act) and the National Cooperative Research Act Extension of 1991 (Research Act Extension) respectively, would extend NCRA protection to production joint ventures.\textsuperscript{62}

Currently, the Research Act Extension, passed by a vote of 96 to 1 in the Senate\textsuperscript{63} and forwarded to the House of Representatives for concurrence in March of 1992,\textsuperscript{64} appears to be the bill with the greatest chance of amending the NCRA. The Bush Administration, however, had opposed the Research Act Extension in favor of the Production Act because the Research Act Extension requires that, in order to obtain protection, a company must: (1) provide substantial benefits to the U.S. economy; or (2) have its principle facilities for production located in the United States or a third country whose law accords national treatment to U.S. companies conducting joint venture production.\textsuperscript{65} In contrast, the Production Act provides national treatment for all companies under its terms.\textsuperscript{66} These discriminatory requirements, at least according to the Bush Administration, would both violate a number of international agreements to which the United States is a party\textsuperscript{67} and also hamper attempts to open new markets for U.S. investment and trade. It is unclear at the time of this writing\textsuperscript{68} what position the Clinton Administration will take on this issue; however, despite strong bipartisan support for the Research Act Extension,\textsuperscript{69} Senator Howard Metzenbaum, Democrat from Ohio and Chairman of the Senate Judiciary Committee's Antitrust,

\textsuperscript{62} S. 1163 and S. 479 would strike the NCRA language in section 2, subsection 2, which states "joint research and development venture," replacing it with "joint research, development, and production venture."
\textsuperscript{65} 138 CONG. REC. S2457 (daily ed. Feb. 27, 1992).
\textsuperscript{69} Dec. 27, 1992.
\textsuperscript{69} 138 CONG. REC. S2482 (daily ed. Feb. 27, 1992).
Monopolies, and Business Rights Subcommittee, strongly opposes the Research Act Extension.\(^70\) This raises serious doubts as to this bill's future viability.

3. Traditional Antitrust Analysis Applied to Joint Ventures

As stated, antitrust enforcement involving R&D and production joint ventures is an uncertain area of the law.\(^71\) The NCRA resolves some of this uncertainty for registered R&D joint ventures but does nothing for production joint ventures. If courts apply the “per se test,” production joint ventures are doomed. However, even if the courts apply the “rule of reason” standard, the future of both R&D and production joint ventures is still less than certain. These uncertainties present risks that will materially affect investment decisions and likely retard growth in the industry.

At the threshold, joint operations between pharmaceutical companies must be truly joint ventures as opposed to mere agreements to collaborate on price or market control of new pharmaceuticals developed.\(^72\) Permissible joint ventures could include purely contractual collaborations, such as horizontal information exchanges, joint ownership and use of existing assets, or joint creation of new enterprises to conduct manufacturing.\(^73\) Because joint ventures are the only commercially practical way for the United States to develop space-produced pharmaceuticals, courts and federal agencies must carefully weigh both their competitive and anti-competitive ef-


\(^{71}\) Robert Pitofsky, A Framework for Antitrust Analysis of Joint Ventures, 74 Geo. L.J. 1605, 1605 (1986). Dean Pitofsky states that “[b]usiness complaints about the inadequacy of antitrust policy seem particularly valid in this area of law, not so much because the enforcement agencies or courts have made erroneous enforcement decisions, but because uncertainties in enforcement policy have almost certainly blocked, delayed, or raised the cost of legitimate undertakings.” Id.

\(^{72}\) Id. Generally, when a joint venture involves no integration of existing resources and no creation of new productive capacity, it creates no new efficiencies and, therefore, would be declared anti-competitive and illegal. Id.

\(^{73}\) Id. at 1606.
fects when determining their impact on competition in the relevant geographic and product market.

4. The Relevant Product Market

How courts and federal agencies will scrutinize pharmaceutical joint ventures depends in part on how the space-produced pharmaceutical industry is characterized. If space-produced pharmaceuticals are characterized as new products, these joint ventures are likely to be found legal. An example of this type of antitrust analysis appears in *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.*, where the Supreme Court refused to apply the “per se test” blindly to a price-fixing situation involving blanket licensing agreements. Under the licensing agreements scrutinized by the Court, the American Society of Composers, Authors and Publishers (ASCAP) and Broadcast Music, Inc. (BMI) were able to set prices for blanket use licenses covering musical works whose performance rights ASCAP and BMI controlled. Although this amounted to pricing by agreement rather than by market forces, the Supreme Court held that the agreement did not per se violate section one of the Sherman Act. The Court reasoned that the blanket licenses were the only practical way the industry could operate and that the licensing agreements were, to some extent, different products than the underlying performance rights they represented. Stating that individual music producers could not compete with the blanket licenses holders, the Court refused to apply the per se test.

A similar analysis can be applied to space pharmaceuticals. Traditionally, in joint ventures where the parties are already competing in a market, the parties argue with lit-

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74 The relevant geographic market is assumed to be the entire United States for simplification of the analysis.
75 Pitofsky, *supra* note 71, at 1609.
76 441 U.S. 1, 17 (1979).
77 *Id.* at 24.
78 *Id.* at 21-22.
79 *Id.* at 23.
tle success that the pro-competitive effects of increased efficiency and earlier market expansion justify any anti-competitive effect of the joint venture. The development of space pharmaceuticals can be distinguished from the traditional case. These high technology cases involve developing products so technologically advanced that they represent new products even though their sales impinge upon an existing market. Even without giving credence to arguments that joint ventures of space pharmaceuticals will move up the date at which they become available to the U.S. market, one hopes that the courts will reach this conclusion and not stifle an industry that would otherwise support U.S. economic interests. However, because these pharmaceuticals will supplant existing pharmaceuticals, they may also be characterized as competing products and be subjected to a more traditional antitrust analysis.

5. Pro-Competitive Effects

A key threshold consideration is that space-produced pharmaceuticals are an extremely expensive venture. Allowing joint ventures will allow firms to pool limited resources without abandoning their independent corporate structures. This pooling allows the efficiencies of integration without the loss of competition in other segments of the pharmaceutical industry. Additionally, such combinations will create a new segment of the industry that will increase U.S. market power in the international pharmaceutical market. This will increase competition while substantially enhancing the quantity and quality of drugs available to combat a variety of diseases. Also, allowing joint ventures will permit participating firms the greater management control and flexibility needed because of the speculative nature of these types of joint ventures.

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80 Pitofsky, supra note 71, at 1606-07.
81 Id.
82 Id.
83 Id.
allowing for the maximum possible management flexibility will enhance the joint venture's future development and avoid the need to anticipate and provide for all future problems and contingencies at the joint venture's creation, a problem that would have to be resolved if the venture were formed on a contractual basis.\textsuperscript{84} The pro-competitive effects of space pharmaceutical joint ventures must, however, be balanced against the anti-competitive effects.

6. \textit{Anti-Competitive Effects}

There are four recognized anti-competitive concerns regarding joint ventures that are relevant to the pharmaceutical industry. The magnitude of each of these factors must be examined on a case-by-case basis. These anti-competitive concerns include: (1) potential reductions in competition; (2) the threat of one or both original parties stifling future growth of the joint venture, or of the other party to the venture, for their own benefit; (3) "spill-over" effects regarding competition between the original parties to the joint venture; and (4) collateral restrictive agreements between the parties to the joint venture.\textsuperscript{85}

In applying the traditional antitrust analysis to joint ventures, courts are primarily concerned that joint ventures will diminish competition.\textsuperscript{86} The fact that entities in any joint venture historically competed independently suggests that collaboration is unnecessary to overcome entry barriers to the industry.\textsuperscript{87} The over-arching question is what the parents would have done in the absence of the joint venture.\textsuperscript{88} Therefore, even under this traditional joint venture analysis, it is possible that companies developing space pharmaceuticals will not be found in violation

\textsuperscript{84} Id. at 1608.
\textsuperscript{85} Id. at 1608.
\textsuperscript{87} Pitofsky, \textit{supra} note 71, at 1608.
\textsuperscript{88} Id.
of antitrust laws because, without joint ventures, the firms probably would never have entered the market at all.

A second concern is that joint venture members will eventually stifle the joint venture in favor of their own interests. Generally, however, courts are willing to wait until the members of a joint venture actually stifle it to intercede on this basis. This reluctance to interfere arises from common sense considerations based on the parents' express or implied promise not to compete with the joint venture and the fact that, realistically, the parents have little incentive to compete with their joint venture. This is of particular relevance in space joint ventures because the major impetus of the joint venture, capital risk, will similarly impede any collateral competition.

A third antitrust concern is the variety of "spill over" effects from the joint venture that could contribute to diminished competition. Since any of these anticompetitive activities would clearly be illegal, the real issue becomes whether such activities can be inferred from the mere fact that pharmaceutical companies are involved in joint ventures or whether actual collusion must be shown. U.S. antitrust law states that proof of collusion cannot be inferred, even when circumstantial evidence is available. Therefore, the mere existence of a joint venture, without the existence of other monopoly or illegal combination activities between the joint venture parties, will not prove the existence of an "agreement" under section one of the Sherman Act. Space joint ventures would, therefore, only face the same risks as any other U.S. firm. Outside the normal considerations that would make phar-

89 Id.
90 See Penn-Olin, 378 U.S. at 168.
91 These can include: (1) joint venture partners reaching price fixing agreements; (2) exchange of future price, capacity, or sales volume data; and (3) reduction of incentives of joint venture partners to compete. Pitofsky, supra note 71, at 1610.
92 Id. at 1611.
93 Id.
maceutical joint ventures illegal, U.S. public policy should support these operations, despite the danger of possible anticompetitive effects.

Clearly, Japanese and EEC pharmaceutical companies attempting to break into the space market are free from the antitrust concerns that hamper U.S. companies. The Japanese are free to combine their resources in R&D and production joint ventures, not because their laws so allow, but because their laws prohibiting such combinations are never enforced. The EEC firms, on the other hand, can legally participate in both R&D and production joint ventures, secure from antitrust liability due to detailed EEC guidelines. U.S. companies are at a competitive disadvantage for two reasons: first, they cannot participate in production joint ventures without facing uncertain levels of antitrust liability and will not be able to do so until the NCRA is amended; and second, current R&D joint ventures are open to the subjective scrutiny of the courts under the "rule of reason," robbing U.S. companies of any security when undertaking these risky and expensive joint ventures. This perception of risk is keeping many large U.S. firms from participating in high technology joint ventures at a time when they are most needed to keep the United States competitive in the global marketplace.

III. FDA REGULATORY SCHEME

One major barrier to the development of new pharmaceuticals in the United States is Food and Drug Administration (FDA) regulations. Although regulations are clearly needed to protect the consumer, the

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94 21 C.F.R. §§ 1.1-1316.99 (1992). The U.S. food and drug laws are designed to protect the public by ensuring the purity, efficacy, and safety of drugs on the market. In formulating food and drug laws, however, the government has never addressed the issue of space production of pharmaceuticals and thus has never statutorily indicated the FDA's regulatory jurisdiction in this area. Therefore, an issue remains whether any FDA jurisdiction conflicts with that of other federal agencies, such as NASA, which currently has regulatory jurisdiction over civilian space activities in the U.S. Goodrich, supra note 1, at 238.
complexity of FDA regulations makes the United States the world's most difficult country in which to obtain market approval for new pharmaceuticals.95 Studies suggest that in the United States it takes an average of twelve years and $200 million in R&D to develop each new product.96 This delay occurs in part because the FDA's review of new pharmaceuticals is twice as long as that conducted in most foreign countries.97 For the space pharmaceutical industry, concerns arise not only because of the complex regulatory environment in which pharmaceutical companies must operate, but also because of the simple fact that the drafters of current FDA regulations never envisioned the production of pharmaceuticals in space. Consequently, three major FDA regulatory requirements pose significant barriers to space pharmaceutical production, specifically, FDA regulations governing: (1) the enforcement of Good Manufacturing Practices (GMPs); (2) the inspection of pharmaceutical production facilities; and (3) investigational studies and pre-market clearance procedures.

The FDA's power to regulate pharmaceuticals arises under the Food, Drug, and Cosmetic Act (FDCA),98 which mandates that the FDA protect the American public by ensuring the purity, effectiveness, and safety of pharmaceuticals in the marketplace.99 The FDA is not, however, directed to facilitate the development of new pharmaceuticals, regardless of their value to consumers.100 Consequently, the FDA's mandate, directly con-

96 Id.
97 Id.
99 Id. The Food Drug and Cosmetic Act (FDCA) imposes the highest standard of care. United States v. Park, 421 U.S. 658, 672 (1975). The FDCA's objective is to prevent the use of the facilities of interstate commerce to convey impure or adulterated medicines or foods. McDermott v. Wisconsin, 228 U.S. 115, 128-29 (1913). In so doing, the FDCA was designed to protect not the merchants but rather the consuming public. United States v. Two Bags, Poppy Seeds, 147 F.2d 123, 127 (6th Cir. 1945).
100 Henry G. Grabowski, The Impact of Regulation on Innovation, 34 Food Drug
flicting with any notion that space pharmaceutical operations might be afforded special consideration when subjected to FDA regulations, requires that such operations strictly comply with all current regulations.

A. Good Manufacturing Procedures (GMPs)

Complying with current GMPs is the initial regulatory hurdle for space-produced pharmaceuticals. Such GMPs are periodically promulgated by the FDA and include extensive guidelines setting out minimum standards for all phases of pharmaceutical production, including the design and construction of production facilities, production and processing controls, and distribution procedures. These guidelines while adequate to meet the requirements of earth-based pharmaceutical production operations, are totally inadequate for regulating space production facilities because they do not contemplate the requirements of either closed-system manned production facilities or unmanned facilities. Additionally, a number of potential problems threatening the purity and effectiveness of space-produced pharmaceuticals are not addressed in the FDA's latest GMPs guidelines. One major problem is the unknown affect of cosmic radiation on space-produced biological products. A threat exists that the concentration and purity of such biological products will be unreliable or that such products might suffer from dangerous radiation levels. Biological experiments designed to study such exposure to cosmic radiation have been conducted aboard the joint Apollo-Soyuz Test Pro-

Cosm. L.J. 555, 558 (1979). "There is no corresponding mandate dealing with drug innovation, or, in particular, with the importance to society of obtaining improved medical therapies." Id.


102 Id.

103 Some possible problem areas include the FDA requirements for adequate ventilation, air filtration, heating and cooling, and sewage and refuse disposal. 21 C.F.R. §§ 211.46, 211.48-.50 (1992).

ject with inconclusive results. Until current GMPs can be successfully modified to address such space-specific issues, the FDA is statutorily required, as the watch dog of purity and effectiveness, to keep space-produced pharmaceuticals off the market, effectively barring the development of the U.S. space pharmaceutical industry.

B. Inspection of Pharmaceutical Production Facilities

One of the most obvious problems in applying current FDA regulations to space pharmaceutical production is the requirement that all pharmaceutical production facilities be inspected by FDA employees every two years. This type of inspection clearly will be impossible for the FDA to conduct, assuming that the actual production facilities are kept in orbit on a more or less permanent basis and that only the finished products are returned to earth periodically. Any failure by the FDA to conduct these inspections, however, will inhibit its ability to confirm compliance with GMPs. Since the FDCA defines adulterated drugs as those that are not produced in accordance with GMPs, the inability of the FDA to adequately confirm GMPs compliance in space production facilities requires otherwise marketable pharmaceuticals that are produced at an uninspected space production facility to be automatically branded as adulterated. A simple modification of this requirement, either allowing self-inspection, waiving inspection upon compliance with certain FDA-mandated

105 Id.
106 21 U.S.C. § 360(h) (1988). The requirement mandates that inspections be conducted by FDA employees, eliminating the possibility that companies could conduct self-compliance inspections. Id.
107 Id. § 351(a). Failure to comply with GMP is a violation of the statute, and the government has no burden to show that the drug in question was actually deficient as a result of non-conformance with GMPs. United States v. Western Serum Co., 498 F. Supp. 863, 867 (D. Ariz. 1980).
108 "[F]ailure to follow current GMP's means that the finished product is adulterated and in violation of the Act even though the finished dosage form is, in every respect, all it is supposed to be." Patrick Gibbons, Legal Implications of Good Manufacturing Practice Regulations, 31 FOOD DRUG COSM. L.J. 473, 475 (1976).
pre-launch inspections, or allowing remote monitoring through the use of sensing devices aboard the space facility, would remove this unnecessary barrier while assuring the quality and purity of space pharmaceuticals.

C. Investigational Studies and Pre-Market Clearance

The FDCA gives the FDA the responsibility of conducting investigational studies on "new drugs" and providing pre-market clearance. A "new drug" is defined as "any drug . . . the composition of which is such that such drug is not generally recognized among experts . . . as safe and effective for use under the conditions prescribed." The FDA, pursuant to its statutory authority, has promulgated regulations governing applications for pre-market approval of new drugs. Although an applicant for marketing approval can apply for a waiver of the application process, the FDA is unlikely to approve such waivers for space-produced pharmaceuticals. Waiver is unlikely because space-produced pharmaceuticals will differ in purity and strength from the same chemical compounds produced on earth. Because of these differences, space-produced pharmaceuticals will generally fall under the definition of "new drug" and, therefore, be subject to full investigational screening and the pre-market approval processes.

109 21 U.S.C. § 321(p)(1) (1988). Additionally, the statute contains a proviso that "new drugs" also include: "Any drug [determined effective under an investigation outlined in subsection one] but which has not . . . been used to a material extent or for a material time under such conditions." Id. § 321(p)(2). Space-produced drugs, although often the same chemical compound as existing earth-produced drugs, will have greatly increased purity, and their effect on the human body will be undetermined, consequently making them "new drugs." See also United States v. Undetermined Quantities of Various Articles of Drug, 675 F.2d 994, 1001 (8th Cir. 1982) (only general recognition plus material use can exempt a drug from FDA pre-market testing); Farquhar v. Food & Drug Admin., 616 F. Supp. 190, 192 (D.D.C. 1985) (finding that where neither the individual chemical ingredient nor the combination of ingredients has been marketed for the uses for which the producer proposes, it is a new drug).


111 Id. § 314.90.
Section 355 of Title 21 of the United States Code states that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug unless an approval . . . is effective with respect to such drug." An application for such approval requires submitting samples of the drug under consideration to the FDA. Presumably, this sample submission requirement will apply to space pharmaceuticals even though, at least for a majority of space pharmaceuticals, there will already be an earth-produced version on the U.S. market. This requires, therefore, that pharmaceutical companies begin at least limited space production prior to knowing whether the FDA will approve the space version of the pharmaceutical. Although this risk, necessarily inherent to the protection of the public, may be acceptable for earth-produced pharmaceuticals, the capital required for even limited space production may pose unacceptable investment risks. This will be especially true in the absence of any significant antitrust protection for pharmaceutical joint ventures that would allow companies to spread the investment risk.

IV. ENVIRONMENTAL CONSIDERATIONS

Although the production of most conventional pharmaceuticals, whether in space or on earth, poses little danger to humans or the environment, microbiological research and production, which is likely to be an integral part of the space pharmaceutical industry, is considered

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113 Id. § 355(b).
114 In a similar vein, § 355(c) gives the FDA 180 days in which to approve the application or offer the applicant the opportunity to have a hearing on the application. Id. § 355(c). This time-table may be unacceptable because of the massive investment that pharmaceutical companies make in their space production facilities. Allowing such large amounts of capital to be tied up in idle facilities during the approval process may drive the rate of return on such capital investments down to a point where the investment becomes unacceptable to both managers and shareholders. This issue may be avoided, however, if the FDA is liberal in allowing exceptions to permit the commencement of pre-clinical testing while the application is under consideration.
an ultrahazardous undertaking. Microbiological research involves the use of genetic engineering, recombinant DNA, and bacteria to produce drugs and antibodies. Because of their invasive properties, unknown behavior in space, and ability to reproduce, microbiological organisms pose significant environmental dangers in the event of an accidental release. Although performing microbiological experiments in space provides some measure of safety to the earth's environment, risks still exist. The most direct danger is the possibility of a crash of the microbiological payload, either on launch or out of a disintegrating orbit. Other risks are posed by either release on the moon or other space body, or by an accidental release into space. Although these alternative releases pose much less danger, it is possible that some microbiological organisms could survive the conditions of space and contaminate the Earth upon capture by the

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117 Even in the presence of adequate containment facilities and good decontamination equipment, the success of attempts to control microbiological contamination depends in part on the work techniques of the involved personnel. Although no inclusive list of correct techniques would be appropriate for all areas of application of microbiological contamination control, some fundamental notions are listed below:

a. Microbial contamination can exist and yet not be readily detectable in the usual sense.
b. The contamination may be odorless, tasteless, and invisible.
c. Instantaneous monitoring devices for microorganisms, comparable to devices for detecting radioactive contaminants, are not available.
d. It is important to understand the ease with which microorganisms can be made airborne and their ability to remain airborne in small particle form and to move from place to place in air currents.
e. It is significant that the physical state of a microbiological contaminant is related to the ease or difficulty of containment. Dried, micronized, powdered, or lyophilized microbial preparations are much more difficult to contain than contaminates in a wet or fluid state.

earth's gravity. Consequently, space research and production involving microbiological pharmaceuticals raises serious environmental issues.

To deal with these types of environmental hazards, Congress passed the National Environmental Policy Act (NEPA). The FDA recognizes that it has substantial responsibilities under NEPA and therefore mandates that environmental impact consideration be an integral part of its regulatory processes, including the approval of New Drug Applications (NDA). Under current regulations, unless a waiver is obtained, an Environmental Assessment Statement (EAS) must be prepared for every NDA in accordance with NEPA review procedures and Department of Health and Human Services guidelines. As a federal agency, the National Aeronautics and Space Administration (NASA) is also subject to NEPA requirements and must prepare either Environmental Impact Statements (EIS) or an EAS for any NASA actions having a potentially significant impact on the environment.

Although NEPA is limited to the territorial boundaries

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118 Martin Werber, Objectives and Models of the Planetary Quarantine Program NASA SP-344 (1975).
121 Id. § 25.22.
123 Environmental Assessments are prepared following the guidelines of 21 C.F.R. §§ 25.30-.34 and reviewed by the FDA under the procedures in §§ 25.40-.42.
125 NASA regulations state that either an EAS or an EIS is required when "NASA actions [are] expected to have a significant effect on . . . the . . . environment." 14 C.F.R. § 1216.305(c) (1992). The choice between an EAS or an EIS is dependent upon the perceived risk of the project under consideration. NASA regulations state that an EAS will be required when "specific spacecraft development and flight projects in space . . . [and] reimbursable launches of non-NASA spacecraft or payloads . . . lead, either directly or indirectly, to natural or physical environmental risks." Id. § 1216.305(b). An EIS, on the other hand, is required when the "development and operation of space vehicles [is] likely to release substantial amounts of foreign materials into the Earth's atmosphere or into space." Id. § 1216.305(c). Since most space launches, even commercial ones, will likely involve substantial NASA participation, these regulations will impose the burden of preparing either an EAS or an EIS before all launches. Id.
of the United States, consideration of potential extraterritorial impacts is required.\textsuperscript{126} Other countries, therefore, may have a role to play in determining the potential environmental effect of any space launch bearing a potentially environmentally dangerous payload\textsuperscript{127} since it is arguable that the public participation provision in NEPA\textsuperscript{128} would allow foreign party participation in pre-launch environmental impact assessments.\textsuperscript{129} This involvement would provide an instrument for foreign lobby groups in Washington to exert pressure in an attempt to undermine any commercial utilization of space by U.S. pharmaceutical companies.

Because of the potential impact on the environment, the scope of environmental impact assessments regarding microbiological research and production in space goes beyond anything previously encountered by pharmaceutical producers and represents an additional financial and regulatory burden. However, because of the launch and recovery risks and the risks of keeping microbiological research and production materials in space for extended periods of time, the added costs placed on the industry to produce an EAS or EIS are warranted when weighed against the potentially devastating results of a serious microbiological accident. The system must not, however, become a forum for foreign interest groups to hinder U.S. space pharmaceutical development.

V. PATENTS IN MEDICINE

The intellectual property of private industry is vital to its existence. The information and technology that make

\textsuperscript{126} Id. § 1216.321 (1992). These include potential effects on the global commons (i.e., oceans and the upper atmosphere) and on foreign nations neither participating with nor otherwise involved in the NASA activity. Id.


\textsuperscript{129} McGarrigle, \textit{supra} note 127, at 124.
up the proprietary data and trade secrets of a private industry are the lifeblood of that industry. To the extent that the right to retain and protect such technology is diluted or lost, the industry will be weakened or destroyed. Thus, a vital issue of security for private industry in its outer space activities is its ability to maintain its proprietary position.\(^{130}\)

The United States utilizes a first-to-invent patent system, under which patents are granted to the first party to prove invention of a particular item.\(^{131}\) In contrast, the patent systems used in both Japan and Europe are first-to-file systems, where the first-to-invent is immaterial with regard to patent rights, since the rights hinge merely on who files a patent application first.\(^{132}\) This difference may have a serious impact on U.S. pharmaceutical companies' efforts to protect new pharmaceuticals developed in space, thereby inhibiting the industry's development.

Generally, U.S. pharmaceutical companies have to choose between statutory patent protection or non-statutory trade secret protection to protect new products. By choosing to file for patent protection under the U.S. first-to-invent system, pharmaceutical companies, although gaining protection in the U.S. market, are vulnerable to European and Japanese pharmaceutical companies who may win the race to the patent office in first-to-file countries. This risk serves as a major deterrent to U.S. firms' willingness to engage in R&D because their return on investment is subject to higher risk. However, absent a special ability by European or Japanese firms to win the race to the patent office in their respective countries, U.S. pharmaceutical companies will be able to "steal" their share of the patent rights to new products. Unfortunately this type of competition, which increases investment risks, favors Japanese and European firms that are better able to


\(^{131}\) Andrew J. Young, Law and Policy in the Space Stations' Era 171 (1989).

spread the investment risk among joint venture partners.\textsuperscript{133}

In addition to problems raised by the first-to-file countries, the U.S. patent system provides a number of obstructions to the patenting of medical technology, all of which will adversely effect the space pharmaceutical industry. These have generally arisen because of the clash between the fundamental nature of medical technology and the operating framework of the U.S. Patent Office.\textsuperscript{134}

To obtain a U.S. patent, the applicant must prepare a patent application describing at least one embodiment of the invention in sufficient detail to enable any person skilled in the art to make and use the invention.\textsuperscript{135} The patent is then examined by the Patent Office and rejected if it is either anticipated by prior art\textsuperscript{136} or obvious.\textsuperscript{137} Since medical inventions are by their nature different than mechanical inventions, different types of patent practices have evolved that often deny patents to medical inventors\textsuperscript{138} and, even when issued, offer little real protection to the patent holder since current practice tends to restrict the scope of medical patents, making them difficult to defend. Additionally, lengthy FDA investigatory and pre-market clearance procedures consistently reduce the useful life of medical patents. Finally, much of the developing world refuses to acknowledge medical patents and

\textsuperscript{133} See supra notes 25-49 and accompanying text.


The Patent Office was founded in the 18th century and evolved during an age of progress in mechanical engineering. Many of the basic doctrines of patent law . . . reflect a bias toward the mechanical technology that patent law was designed to protect [therefore] patent law has repeatedly been modified in haphazard fashion to deal with more biologically oriented medical technology. These legal modifications have riddled the law of medical patents with numerous exceptions to the already complex rules that govern patents in other technologies.

\textit{Id.}


\textsuperscript{136} Id. § 102.

\textsuperscript{137} Id. § 103.

\textsuperscript{138} Noonan, supra note 134, at 271.
refuses to afford such patents any protection from infringement, claiming a right to copy such pharmaceuticals without regard for their patented status.\textsuperscript{139}

\section*{A. Patentability}

The first significant statutory hurdle to obtaining a medical patent is that a patent application must clearly state the patented item's intended use,\textsuperscript{140} meaning the utility of new pharmaceuticals must be clearly stated and often proved before a patent will be issued.\textsuperscript{141} Although a logical requirement, such proof is often difficult to provide except in the most abstract sense. The Patent Office, therefore, has developed a practice of presuming the utility of mechanical devices, making those patent applications more cost effective and less rigorous to obtain than the statutory requirements would indicate. The same is not true, however, for medical patents, making such patents extremely difficult to obtain.\textsuperscript{142} Because all pharmaceutical companies within the U.S. market are subject to the same increased costs and risks, this disparity of treatment may seem immaterial; however, this problem has an overall impact on the ability of U.S. firms to compete in the world market. U.S. companies, instead of seeking U.S. patent protection, may rely on non-statutory trade secret protection. This makes their new products vulnerable to copying through reverse engineering activities resulting in competitors quickly bringing competing products into the U.S. marketplace. This entrance is significant because the United States is one of the world's largest pharmaceutical markets and is currently a primary source of revenues for U.S. pharmaceutical companies. Like the Japanese and the Europeans, U.S. pharmaceutical companies depend largely on controlling their home markets to provide capital to finance global selling opera-

\begin{itemize}
\item \textsuperscript{139} Id.
\item \textsuperscript{140} 35 U.S.C. § 112 (1988).
\item \textsuperscript{141} Noonan, supra note 134, at 276.
\item \textsuperscript{142} Id.
\end{itemize}
tions. Once control of this home market is lost or threatened, U.S. firms may not have the capital needed to compete in the global space pharmaceutical market.

In addition to the utility requirement, U.S. patent law raises several other potential barriers that will have a unique effect on the space pharmaceutical industry. These include the statutory requirements of novelty, mandating that patents not be granted on existing pharmaceutical compounds, and non-obviousness. The majority of pharmaceuticals produced in space will merely represent increases in purity and strength over pharmaceuticals currently produced on earth. Whether companies will be able to obtain patent protection on such modified compounds, in light of the novelty and non-obviousness requirements, is questionable. Case law indicates, however, that increased purification will qualify them as patentable inventions and that pharmaceutical companies will be allowed some flexibility in this area, especially with pharmaceuticals exhibiting newly discovered therapeutic properties.

B. Patent Scope

Once a medical patent is obtained it must, of course, be defended against infringement. Typically, defending a medical patent is difficult because heightened requirements for medical patent enablement and proof of utility result in a patent whose scope is so narrow as to be virtually useless. This happens because any chemical’s activity is subject to a great deal of unpredictability. The Patent Office, therefore, requires that pharmaceutical patents be limited in scope to those chemical effects that can be de-

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144 See Noonan, supra note 134, at 281.
146 See Merck & Co. v. Orlin Mathieson Chem. Corp., 253 F.2d 156, 163 (4th Cir. 1958) (finding that the fact that a new and useful product results from processes of extraction, concentration, and purification of natural materials does not defeat its patentability).
147 See Noonan, supra note 134, at 287.
scribed and proven. This differs from mechanical patents that are routinely accorded a broad scope of protection. Pharmaceutical companies will, therefore, receive less patent protection on their products, resulting in increased difficulty and expense to protect medical patents from infringement simply because chemical principles are not afforded a substantial scope of protection.

C. Patent Life

U.S. patents are granted for seventeen years giving the holder a legal monopoly on a given product as a reward for innovation. Historically, however, pharmaceutical patents have a much shorter practical life, making recoupment of the massive investment required to develop patented pharmaceuticals difficult. This shortened practical life occurs because medical patents are generally obtained prior to marketing and subsequent periods of

148 Id. at 273.
149 Id.
150 Id. at 274.

151 During the period 1960-1980 the effective life of pharmaceutical patents decreased from 16 years to less than 10 years because of the increased time required for FDA review. New Life of Patents, 24 AM. FAM. PHYSICIAN 90 (1981).

Although no hard data exists on the costs of developing space pharmaceuticals, all projections point to increased costs over earth-produced pharmaceuticals. Government studies show that the average cost of bringing a new chemical entity to market is approximately $33 million (1976 dollars). OFFICE OF TECHNOLOGY ASSESSMENT, PATENT-TERM EXTENSION AND THE PHARMACEUTICAL INDUSTRY 13 (1981).

Additionally, new pharmaceuticals have fairly standard development lives that include the following stages: (1) Discovery Stage, involving the isolation of the new drug; (2) Preclinical Stage, involving initial toxicity testing on animals; (3) Patent Application Process, that might begin as early as the Discovery Stage; (4) Safety and Efficacy Testing Stage, involving clinical testing and long-term toxicity testing; (5) Patent Examination and Grant Phase, generally occurring at the same time as the Safety and Efficiency Testing Stage; (6) NDA Stage, during which the NDA is submitted and approved by the FDA; and (7) Marketing Stage, during which the pharmaceutical is sold to the public. Id. at 12-15.

The major time delays occur in the NDA stage which, in the 1980s, could last as long as seven years while the FDA conducted safety and efficacy tests. Additionally, the NDA is only approved by the FDA for its stated process and therapy. Any changes in the composition of the pharmaceutical or new uses require a supplemental NDA and new FDA approval. Therefore, by the time the new pharmaceutical makes it to the market, a substantial portion of the patent term is lost. Id.
mandatory federal pre-marketing and pre-manufacturing regulation reduce effective patent lives.\textsuperscript{152}

Concerned that decline in the average effective life of pharmaceutical patents would diminish profits, thereby decreasing the funds available for research and development and ultimately the number of new pharmaceuticals introduced in the United States,\textsuperscript{153} Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984.\textsuperscript{154} The Patent Term Restoration Act extends the period of pharmaceutical patent protection to compensate for periods of FDA review.\textsuperscript{155} Generally, the patent term is now extendable to include the time the drug was under FDA review as a New Drug Application (NDA) and one-half the time during which the drug was in clinical testing as an Investigational New Drug (IND).\textsuperscript{156} The Patent Term Restoration Act will have a significant facilitating effect on the space pharmaceutical industry and represents part of a growing trend in Congress to boost the competitiveness of U.S. pharmaceutical companies in the global market.

D. DEVELOPING NATIONS

One of the most difficult issues in international trade relations is the protection of intellectual property. Many developing countries reject developed countries' claims for intellectual property protection in areas such as pharmaceuticals, which the developing countries see as vi-
tal to their national well-being. These countries often have national policies and laws that encourage the "stealing" of pharmaceutical inventions. Regardless of any arguments justifying or condemning such practices, these "pirated" pharmaceuticals adversely affect the pharmaceutical industry in the United States and other developed countries by significantly reducing return on their investments in pharmaceutical development. Although these "pirated" pharmaceuticals will not directly compete with space-produced pharmaceuticals, they pose two threats to industry development. First, they reduce the overall financial health of companies thereby reducing the capital available for space research and development. Second, as the commercial use of space becomes increasingly available to developing countries, they may be able to develop their own space pharmaceutical programs, again raising the specter of "pirated" pharmaceuticals. Until the General Agreement on Tariffs and Trade (GATT) addresses such issues, two consequences are likely to develop. Either the space pharmaceutical industry's growth will be retarded altogether or such products will not be offered to developing countries until they offer meaningful protection, thereby excluding those countries from the benefits of industry development.

VI. INTERNATIONAL SPACE TREATIES

International space treaties to which the U.S. is a signatory affect all commercial uses of space, including the development of space pharmaceuticals. The principle

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157 The major developing countries providing no protection for pharmaceutical property rights are Brazil, China, India, Argentina, Chile, Mexico, Thailand, and the countries of Eastern Europe. Drug Trade Seeks Leverage on Patents, CHEMICAL MARKETING REP., Oct. 29, 1990, at 5.

158 Id.

159 Patent infringement in Brazil, for example, is estimated to cost the industry $100 million a year. Industrial Property Bill Suffers Setback in Brazilian Congress, INT'L BUS. DAILY (BNA), July 24, 1991.

agreement concerning the commercial use of space\textsuperscript{161} was prompted by the many anticipated international problems created by increased activities in space and the upper atmosphere.\textsuperscript{162} Its principal purpose is ensuring that "[t]he exploration and use of outer space . . . be carried out for the benefit . . . of all countries."\textsuperscript{163}

Developing countries are attempting to use the Space Treaty's broad purposes as justification for demanding access to scientific information gathered by developed nations' space programs. They argue that, under the Space Treaty, ratifying nations with space programs, either governmental or private, have an obligation to disclose scientific discoveries.\textsuperscript{164} This contention is grounded in the language of article XI of the Space Treaty, which calls for

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\textsuperscript{161} Space Treaty, supra note 160. Initially the United States and the Soviet Union advocated differing principles for the Space Treaty. In an unsuccessful attempt to inhibit the development of an American commercial space industry the Soviet version, which was never adopted, allowed only for governmental space programs stating that "[a]ll activities of any kind pertaining to the exploration or use of outer space shall be carried out solely and exclusively by States." U.N. Doc. A/AC.105.C.2/L.1, at 3 (1962).

\textsuperscript{162} JOSEPH G. STARKE, INTRODUCTION TO INTERNATIONAL LAW 171 (9th ed. 1984). These activities include not only manned and unmanned space launches but also research on the nature of space, cosmic radiation, radiation zones around the earth, magnetic fields surrounding the earth, the ionosphere, and micro-meteorite density. \textit{Id.}

\textsuperscript{163} Space Treaty, supra note 160, at art. I. Article I states: The exploration and use of outer space, including the moon and other celestial bodies, shall be carried out for the benefit and in the interests of all countries, irrespective of their degree of economic or scientific development, and shall be the province of all mankind. Outer space, including the moon and other celestial bodies, shall be free for exploration and use by all states without discrimination of any kind, on the basis of equality and in accordance with international law, and there shall be free access to all areas of celestial bodies. There shall be freedom of scientific investigation in outer space, including the moon and other celestial bodies, and States shall facilitate international co-operation in such investigation. \textit{Id.}

the results of all scientific activities to be disclosed to the international community to the greatest extent feasible. Any such disclosure required by private industry or the Patent Office before granting of a patent, however, would seem to run counter to the intent of Title 35, section 105 of the United States Code, which purports to extend U.S. patent law to outer space. To establish the effect of article XI on U.S. patent law, therefore, requires determining whether the Space Treaty is a self-executing treaty and, if so, whether it has been abrogated by subsequent congressional legislation.

Normally the passage of the Space Patent Act by Congress, extending U.S. patent protection to outer space, would make the question of whether the Space Treaty mandates pre-patent disclosure of patentable inventions a moot issue, since the later patent law would generally abrogate any disclosure requirement of the earlier Space Treaty. The Space Patent Act, however, leaves open the possibility that it does not always apply to space objects when they are "otherwise provided for by an international agreement to which the United States is a party." Since it is arguable that this language refutes any clear congressional intent to supersede the Space Treaty, it is necessary to determine whether the Space Treaty ever became effective U.S. law, and if so, whether

165 Space Treaty, supra note 160, at art. XI. Article XI of the Space Treaty states:

In order to promote international co-operation in the peaceful exploration and use of outer space, States Parties to the Treaty conducting activities in outer space, including the Moon and other celestial bodies, agree to inform the Secretary-General of the United Nations as well as the public and the international scientific community, to the greatest extent feasible and practicable, of the nature, conduct, locations and results of such activities. On receiving the said information, the Secretary-General of the United Nations should be prepared to disseminate it immediately and effectively.

Id.


the Space Patent Act was intended by Congress to supersede any mandatory pre-patent disclosure requirement that can be read into the Space Treaty.

The first issue is whether the Space Treaty ever became effective U.S. law. Once signed and ratified, a self-executing treaty becomes the supreme law of the land; however, when a treaty is too broad or vaguely-worded to effectively stand alone, it requires implementing legislation. Those who argue that the Space Treaty became U.S. law in the absence of any extraterritorial application of U.S. patent law are, therefore, in a “Catch-22” situation. The plain language of article I of the Space Treaty articulates two primary concerns: the “free right of access” to space and “freedom of scientific investigation” of space. Therefore, any narrow reading of the Treaty to avoid the need for implementing legislation would not reasonably allow the inference of a mandatory pre-patent full disclosure requirement, since article XI of the Treaty only requires discretionary disclosure to the “greatest extent feasible and practicable.” On the other hand, a broad reading requiring mandatory pre-patent full disclosure to the international community results in a treaty clearly not specific enough to become law without implementing legislation because it does not “establish affirmative and judicially enforceable obligations.”

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169 U.S. Const., art. VI, cl. 2.
170 See Saipan v. Department of the Interior, 502 F.2d 90, 97 (9th Cir. 1974). The extent to which an international agreement establishes affirmative and judicially enforceable obligations without implementing legislation must be determined in each case by reference to many contextual factors: the purposes of the treaty and the objectives of its creators, the existence of domestic procedures and institutions appropriate for direct implementation, the availability and feasibility of alternative enforcement methods, and the immediate and long-range social consequences of self- or non-self-execution.

Id.
172 Id. at cl. 3.
173 Id. at art. XI.
174 Saipan, 502 F.2d at 97; see Chew Heong v. United States, 112 U.S. 536, 554 (1884).
Additionally, regardless of the need for implementing legislation, any legal challenge to non-disclosure in a U.S. court will probably lead the court to harmonize the Space Treaty and existing patent law, but the court will still not require disclosure.175

The second issue is whether Congress intended the Space Patent Act to abrogate any possible disclosure requirements that can be read into the Space Treaty. In response to commercial concerns regarding the extraterritorial effect of U.S. patent law, the federal government undertook a two-step response to the need for protection of private commercial space operations. First, in an attempt to promote the commercial utilization of space, NASA waived its exclusive property right to inventions created during projects it supports.176 This waiver allowed private parties to acquire rights to any inventions or processes developed in space notwithstanding NASA involvement. Second, Congress extended patent protection to processes and inventions created in space.177 Prior

175 This type of harmonizing is often done by U.S. courts when conflicts arise between domestic law and international agreements. In Palestine Liberation Organization, 695 F. Supp. at 1456, the court harmonized the Agreement Between the United States and the United Nations Regarding the Headquarters of the United Nations (the Agreement) and §§ 5201-5203 of Title 22 of the United States Code, the Anti-Terrorism Act (ATA). The Agreement allowed the Palestine Liberation Organization (PLO), at the invitation of the United Nations, to “participate in the sessions and the work of the General Assembly in the capacity of observer,” which necessarily included the right of PLO representatives to enter the United States. Id. at 1459. The ATA stated that the PLO was a “terrorist organization and a threat to the interests of the United States . . . and should not benefit from operating in the United States.” 22 U.S.C. § 5201(b) (1988). The court held the ATA inapplicable to the Agreement because: (1) the ATA did not specifically mention the Agreement; (2) the ATA did not purport to apply notwithstanding any treaty; and (3) there was no clear congressional intent to supersede the Agreement. 695 F. Supp. at 1468-69.

176 42 U.S.C. § 2457(a) (1988). The National Aeronautics and Space Act gave the United States exclusive rights to any invention developed in connection with NASA. Id. Over the years, however, NASA implemented policies such as the Joint Endeavor Agreement to promote commercial investment, and laws have since limited NASA’s claim to exclusive rights. See, e.g., 35 U.S.C. § 200 (1988) (establishing congressional intent to use the patent system to promote the utilization of inventions arising from federally supported research and development).

to passage of Space Patent Act, U.S. patent laws would not have applied to U.S. spacecraft. Because the Space

Section 105 states:

(a) Any invention made, used or sold in outer space on a space object or component thereof under the jurisdiction or control of the United States shall be considered to be made, used or sold within the United States for the purpose of this title, except with respect to any space object or component thereof that is specifically identified and otherwise provided for by an international agreement to which the United States is a party, or with respect to any space object or component thereof that is carried on the registry of a foreign state in accordance with the Convention on the Registration of Objects Launched into Outer Space.

(b) Any invention made, used, or sold in outer space on a space object or component thereof that is carried on the registry of a foreign state in accordance with the Convention Registration of Objects Launched into Outer Space, shall be considered to be made, used, or sold within the United States for the purposes of this title if specifically so agreed in a international agreement between the United States and the state of registry.

All U.S. patent law prior to the enactment of the Space Patent Act extended United States patent jurisdiction on a territorial basis. Although often thought of as "territories," ships, embassies, and, in this case, spacecraft are not a nation's territory for patent purposes. See Cunard S.S. Co. v. Mellon, 262 U.S. 100, 123 (1923) (arguing that "the jurisdiction which [the "floating island" theory] is intended to describe arises out of the nationality of the ship, as established by her domicile, registry and use of the flag, and partakes more of the characteristics of personal than territorial sovereignty"). This concept of a ship as national territory is false. Jurisdiction over a ship or embassy actually arises from the ship's or embassy's nationality and the rights associated with that nationality under international law. Patents in Space Hearings, supra note 8, at 48-49 (statement of Professor Glenn H. Reynolds, Associate Professor, College of Law, Univ. of Tenn.).

U.S. patent law prior to the Space Patent Act did not provide extraterritorial protection, since 35 U.S.C. § 100(c) provided that for patent law purposes: "[t]he terms 'United States' and 'this country' mean the United States of America, its territories and possessions." 35 U.S.C. § 100(c) (1988). The Supreme Court held in DeepSouth Packing Co. v. Laitram Corp., 406 U.S. 518 (1972), that the United States patent system had no extraterritorial effect and was not intended to apply to activities taking place outside the country's territorial limits. Id. at 531. See also Lam Mow v. Nagle, 24 F.2d 316, 317-18 (9th Cir. 1928) (holding that a foreign baby born on a U.S. flagged ship was not born in U.S.); United States v. 12536 Gross Tons of Whale Oil ex rel the Charles Racine, 29 F. Supp. 262, 267 (E.D. Va. 1939) (holding that an American flag ship was not a "point" in the United States for purposes of statute prohibiting transportation "between points in the United States"). Cf. Gardiner v. Howe, 9 Fed. Cas. 1157, 1158 (C.C.D. Mass. 1856) (No. 5219) ("The patent laws of the United States afford no protection to inventions beyond or outside of the jurisdiction of the United States; but this jurisdiction extends to the decks of American vessels on the high seas, as much as it does to all the territory of the country . . . ."). Despite the accumulation of case
Patent Act rejects the traditional territorial limitation in favor of a jurisdictional scope identical to that used in the Space Treaty, U.S. patent law now clearly applies to U.S. flagged spacecraft.\textsuperscript{180} Article VIII of the Space Treaty provides for national jurisdiction over spacecraft under a State's national registry. Congress borrowed the term "space object" directly from the Space Treaty for use in the statute and clearly intended that term to have the broadest possible meaning.\textsuperscript{181} This portion of the patent laws, therefore, represents a conscious departure from prior practice, indicating that Congress meant the term to encompass national jurisdiction as used in the Space Treaty rather than territorial jurisdiction as previously applied to U.S. patent law by the Supreme Court. Congressional intent was clearly to protect U.S. entities inventing in space under the U.S. patent laws and to abrogate any disclosure requirements that could be read into the Space law, conflicts still arise. The general counsel of intellectual property at NASA stated the position that "an object in space is an extension of the launching nation" and, therefore, is protected by U.S. patent law. James Evans, One Giant Leap for the Space Bar, CAL. LAW., Nov. 1987, at 36, 83. Evans notes, however, that the Justice Department argued in Hughes Aircraft Co. v. United States, 717 F.2d 1351, 1356-63 (Fed. Cir. 1983), that United States patent law was restricted to United States territory. Evans, supra note 84.

\textsuperscript{180} There are several bases for asserting jurisdiction under international law:

(1) The Territorial Principle: The principle comes from the territorial nature of sovereignty which permits courts of the place where a crime or tort occurred to exercise jurisdiction.

(2) The Nationality Principle: This comes from a state's power to exercise jurisdiction over its nationals regardless of where they are located.

(3) The Passive Personality Principle: This principle bases jurisdiction on the nationality of the victim of a crime.

(4) The Protective Principle: This principle bases jurisdiction on where the act committed abroad has an adverse effect.

(5) The Universality Principle: Here the act committed is so universally condemned that any nation has jurisdiction.


\textsuperscript{181} Patents in Space Hearing, supra note 8, at 24 (testimony of Alan J. Kerczko, Deputy Legal Advisor, U.S. Dept. of State).
VII. CONCLUSION

The development of the space pharmaceutical market in the post cold war era will be a test of the ability of the three major industrial blocks, the United States, Japan, and the EEC, to adapt themselves for global competition in the next 100 years. To succeed, the U.S. must provide its major pharmaceutical firms with the same advantages enjoyed by Japanese and EEC companies. U.S. antitrust law must be amended to acknowledge the realities of the global marketplace by allowing production joint ventures and by removing from the courts the broad powers to impose antitrust liability based on their subjective belief in what is "reasonable." Without such protection, U.S. firms will not be able to raise the capital needed to effectively

182 Hearings on the Patents in Space Act made it clear that Congress intended to fully protect U.S. patent holders from any form of international disclosure requirement by applying the U.S. patent system to outer space. Chairman Kas tenmeier stated that the four principle objectives of the bill were: (1) providing that actions occurring in outer space can infringe on United States' patent law; (2) assuring that the United States "first-to-invent" system was extended to space inventions; (3) regulating "prior art"; and (4) protecting security by insuring that space inventions are governed by the Invention Security Act. Id. at 1 (statement of Rep. Robert W. Kastenmeier, Subcommittee Chairman). Additionally, testimony before the subcommittee indicated that the Act was designed to provide certainty for entities conducting space operations and to avoid any uncertainty that might arise if the right of an entity to a patented invention or idea was subjected to case-by-case judicial scrutiny. James E. Denny of the United States Patent and Trademark Office stated that:

Relegating [the issue of patent protection of space inventions] to time-consuming judicial interpretation would subject the industry to expensive litigation with case-by-case determinations based on individual fact situations. The time and expense required to obtain legal certainty under these circumstances pose potential dis-incentives to research and development in outer space. And because the result of such litigation cannot be assured, our industry deserves the certainty that can be provided by legislation.

Id. at 16 (statement of James E. Denny, Acting Assistant Comm'r for Patents, U.S. Patent and Trademark Office).

Clearly, one purpose of this legislation was to remove any possibility of judicial interpretation of the applicability of U.S. patent protection in light of the Space Treaty and any purported disclosure requirements.
utilize space as a production facility and will be unable to spread R&D risk.

FDA regulations also need to be revised to create a regulatory environment that is conducive to space development but that still fulfills the essential role of the FDA in protecting the American public. This rule should include ensuring environmental protection from the dangers of contamination by microbiological organisms. Because of the potentially devastating effect of a microbiological accident, environmental protection should be an issue in which few compromises are made in favor of industry development. It is also incumbent on the United States government to press for an international standard of safety and environmental review to prevent accidents by other nations and to ensure that other nations’ industries are subject to the same regulatory burdens as U.S. firms.

Patent protection, which is essential to pharmaceutical development, has been made stronger by providing for statutory extensions of patent terms during periods of FDA review and by extending U.S. patent protection to inventions aboard U.S. spacecraft. The U.S. Patent Office, however, still refuses to grant medical patents of sufficient scope to provide real protection. This lack of proprietary protection subjects U.S. firms to increased investment risk, thereby reducing their ability to compete in the global marketplace. Finally, patent protection must be extended under the General Agreement on Tariffs and Trade to allow pharmaceutical innovators protection under the laws of developing countries. Without this type of protection, developing countries will be denied access to space pharmaceuticals that would otherwise benefit them and there will be less incentive for advanced countries to develop space pharmaceuticals in the first place.