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PATENT TERM EXTENSION OF PHARMACEUTICALS IN JAPAN: SO YOU SAY YOU WANT TO RUSH THAT GENERIC DRUG TO MARKET IN JAPAN....GOOD LUCK!

William T. Christiansen II[†]

Abstract: With the passage of the Drug Price Competition Act of 1984 in the United States, the recent German Supreme Court decision allowing for experimental use of patented pharmaceuticals, and indirectly through the adoption of the Supplemental Protection Certificate in Europe, Japan seems to be the lone large pharmaceutical market which does not allow in some way for the experimental use of patented drugs to gain regulatory approval for a generic equivalent. Japanese generic pharmaceutical manufacturers had, until recently, operated under the assumption that the testing of a generic equivalent to a patented drug to gain regulatory approval was allowable as long as the drug was not marketed until after the patent had expired. This assumption proved incorrect in a recent Nagoya District Court decision, which essentially relied on the logic of an earlier decision to find that pre-patent experimental use for commercial exploitation is not allowable under the Japanese Patent Law. However, with Japan's society graying more rapidly than many other industrialized nations, the Ministry of Health and Welfare has taken a hard look at generic pharmaceuticals as a mechanism for reducing health-care costs. The favorable view that generic pharmaceuticals are receiving from the Ministry of Health and Welfare combined with the move toward greater transparency between the government and industry leads to the logical conclusion that the Ministry of Health and Welfare, through the Diet, will likely propose a change to the Japanese Patent Law which would allow for the pre-patent expiry testing of generic pharmaceutical equivalents. While there are drawbacks to such an experimental use doctrine, the long term benefits are many. From helping a Yen-conscious government reduce health-care costs to bolstering domestic pharmaceutical innovation by fostering greater competition, an experimental use allowance for generic pharmaceuticals is right for Japan.

I. INTRODUCTION

As we move toward the age of a more global economy and technologically dependent society, intellectual property rights are becoming of paramount importance. Specifically, the patent protection afforded pharmaceuticals has a serious effect on the pharmaceutical market and innovation. A recent study has demonstrated the importance of adequate patent protection in finding that the average new drug costs approximately \$231 million to bring from discovery through approval by the United States Food and Drug Administration.¹ Additionally, it typically takes an average of twelve years, from discovery to regulatory approval, to bring a new drug to market.² Thus, if drug manufacturers perceive patent rights to be weak in

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¹ American Bar Association, 1993-94 A.B.A. SEC. INTELL. PROP. LAW REP. 63. See also PMA, FDA Team Up on Orphan Drug Act 241, 10 CHEM. MKT. REP. 3, 15 (Mar. 1992).

² *Id.*

a country, then pharmaceutical innovation will be severely hindered.³ Perceiving a potential detrimental affect on the market, most industrialized nations have declined to allow generic manufacturers to test generic versions of patented drugs, before the patent expiry, in order to meet mandated regulatory approval guidelines.

While clinical studies done with patented pharmaceuticals aimed at expediting the introduction of generic versions of those same pharmaceuticals have, in the past, been held to infringe the name-brand drug manufacturer's patent, almost everywhere in the industrialized world, recently countries have reassessed this stand.⁴ During this period of reassessment, the economics of the pharmaceutical industry have played a considerable role. In most countries the decision to allow experimental use has only been agreed upon when there is also a period of patent term extension allowed for name-brand manufacturers. However, economics dictate that entry of a generic competitor must begin before the name-brand product's growth has slowed to such a low level that no generic producer could secure a return from manufacturing the drug.⁵

When the Nagoya District Court, on March 6, 1996, found experimental use by a generic manufacturer to obtain data to submit for regulatory approval to constitute infringement of the name-brand drug manufacturer's patent, it sent shockwaves through Japan's generic industry and also set in motion a flurry of similar infringement actions.⁶ However, Japan's Ministry of Health and Welfare has indicated its willingness to embrace generics as a method for reducing the health-care costs it must pay for a steadily graying society.⁷ With the recent move toward greater transparency (i.e. greater clarity of the separation between industry and government) between industry and government⁸ combined with the desire to

³ OFFICE OF TECHNOLOGY ASSESSMENT, BIOTECHNOLOGY IN A GLOBAL ECONOMY 89-93 (Bart Brown, ed. 1991) (OTA-BA-494) [hereinafter OTA REPORT].

⁴ David Gilat, *Experimental Use and Patents*, 16 IIC STUD. 31, 32 (1996).

⁵ James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 470-71 (1986).

⁶ Judgment of Nagoya District Court March 6, 1996 (Unpublished Opinion) [hereinafter Nagoya District Court Decision]. A summary is reported in CHITEKI ZAISANKEN HANKETSU SOKUHO (May 20, 1996).

⁷ *Patent Troubles Give Drug Firms Headaches: Several Japanese Makers of Generic Medicines Sued Over Alleged Violations*, NIKKEI WEEKLY, June 24, 1996, at 9, available in LEXIS, Asiapc library, NIKKEI File. See also Brian Mertens, *Pharmaceuticals: Japan Heads into an Industry Shakeout*, AM. CHAMBER OF COM. IN JAPAN J., Aug. 1, 1996, available in 1996 WL 11700040.

⁸ *Japan's Drug Approval System to be Reformed*, MARKETLETTER (UK), Sept. 9, 1996, available in 1996 WL 10714942.

reduce state reimbursed health-care costs,⁹ Japan must balance the interests of its name-brand pharmaceutical industry in promoting innovation through an incentives policy with that of the generic industry which seeks to decrease overall drug costs. To do this, the current patent law of Japan already has a liberal term extension provision, but requires a clearer experimental use provision.

This Comment explores in the following section the current status of the law regarding experimental use of patented pharmaceuticals by generic manufacturers in the United States, Japan, and the European Economic Community. Part III evaluates the likelihood that Japan will change its current law on experimental use after examining advantages and disadvantages to such a change. Part IV discusses the ways in which change to the current law could be effectuated and how that change would likely occur. This Comment concludes that when change does occur it will be spearheaded by the Ministry of Health and Welfare in an effort to reduce health-care costs and with the additional goal of harmonizing Japan's experimental use exception with that of the United States and the European Community.

II. BACKGROUND

A. *A Brief Introduction to the Policies Behind the U.S. and Japanese Patent Systems*

At the outset it should be noted that the policies which define patent use and protection in the United States diverge substantially from those in Japan.¹⁰ While the Japanese system is designed to promote technological development by disseminating technology to industry, the U.S. patent policy seeks to promote technological development by awarding individual patentees exclusive rights to their inventions.¹¹ The focus of the Japanese law is spelled out clearly in section 1 of the Japanese Patent Law, which states, "The purpose of this Law shall be to encourage inventions by promoting their protection and utilization so as to contribute to the

⁹ Brian C. Cunningham & Joyce C. Chow, *The Biotechnology Industry in Japan: A Framework for Entry*, 4(7) J. PROPRIETARY RTS. 13 (July 1992).

¹⁰ Stephen Lesavich, *The New Japan-U.S. Patent Agreements: Will They Really Protect U.S. Patent Interests in Japan?*, 14 WIS. INT'L L. J. 155, 162 (1995).

¹¹ *Id.*

development of industry.”¹² Thus, the differing philosophies behind the patent laws of the United States and Japan have led to the development of very different patent systems.¹³ This difference is exemplified by comparing the Drug Price Competition and Patent Term Restoration Act with the Japanese equivalents, namely section 67(2) and section 69(1) of the Japanese Patent Law.¹⁴

B. *History of the U.S. Act*

In 1984, the United States Congress passed the Drug Price Competition and Patent Term Restoration Act (“DPA”) (also known as the Hatch-Waxman Act for the Congressmen who sponsored the bill).¹⁵ The passage of this act was the result of lobbying efforts of both the pharmaceutical industry as well as consumer interest groups.¹⁶ The passage of the DPA had the result of overruling *Roche v. Bolar*, in which the Federal Circuit held that one company’s use of another’s patented drug to perform the necessary tests to gain Food and Drug Administration (“FDA”) approval for marketing a generic version of the patented drug was an infringing use under the patent statutes.¹⁷ The goal of the pharmaceutical lobbyists was to induce passage of a bill that would allow restoration of portions of the patent life lost in the premarket regulatory review of new drug products (e.g., FDA approval procedures). Competing with this objective was that of the consumer groups which called for a quicker entry into the market for generic drug manufacturers.¹⁸

Senator Orrin Hatch, referring to the DPA, noted that it “represented a finely tuned balance which reflected the dynamics of the healthcare marketplace.”¹⁹ He noted additionally that “on the one end was the need of the innovator drug companies to rely on adequate intellectual property

¹² Tokkyohō [PATENT L.] art. 1 (Japan), as translated in JAPANESE LAWS RELATING TO INDUSTRIAL PROPERTY (1995) [hereinafter PATENT L.].

¹³ Lesavich, *supra* note 10.

¹⁴ PATENT L., *supra* note 12, at §§ 67(2) & 69(1).

¹⁵ Drug Price Competition and Patent Term Restoration Act, Pub.L. No. 98-417, Title II, 98 Stat. 1585.

¹⁶ See H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 16-18 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2686.

¹⁷ *Roche Prods., Inc. v. Bolar Pharmaceuticals, Inc.*, 733 F.2d 858 (Fed. Cir. 1984), cert. denied, 469 U.S. 856 (1984).

¹⁸ Wheaton, *supra* note 5, at 440.

¹⁹ Reginald Rhein, *BIO, PhRMA Call For Longer Patent Lives to Make Up for FDA Review Lags*, BIOTECH. NEWSWATCH, Mar. 18, 1996, available in LEXIS, News Library, BIOTEC file.

protection to ensure that they attract sufficient capital for research and development [while] on the other end were the fledgling generic drug companies, who were not able to bring their products to market quickly because of the FDA approval process and the patent law."²⁰ The resulting bill changed U.S. patent law and allowed for a patent term extension of up to five years for qualifying pharmaceuticals.²¹

Patent term extension is permitted for any drug product whose patent has not expired, if a patent extension application has been submitted, if the product was subject to regulatory review by a federal authority before the product's commercial marketing or use, and if the commercial marketing or use after the regulatory review period was the first marketing or use under the law under which the regulatory review occurred.²² However, the extension provision is limited. The sum of the amount of patent protection left after regulatory review plus the patent extension can not exceed fourteen years, with five years the maximum extension allowable.²³ Additionally, 35 U.S.C. § 271 (e)(1) states that

[I]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal Law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

This section has been further supported in a recent Federal Circuit decision holding: "A generic drug manufacturer is not guilty of infringement by filing an application for approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent."²⁴ Only the patent term extension portion of the Hatch-Waxman Act is contained in the analogous Japanese patent law.

²⁰ *Id.*

²¹ American Bar Association, *supra* note 1.

²² 35 U.S.C. § 156.

²³ *Id.*

²⁴ Merck & Co., Inc. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996).

C. *The Closest Japanese Patent Law Equivalent to the Hatch-Waxman Act*

The term extension allowed by Japanese law is set forth in section 67(2) of the Japanese Patent Law:

The term of the patent right may be extended, upon application for registration of an extension, by a period not exceeding five years if, because of the necessity of obtaining an approval or other disposition which is governed by provisions in laws intended to ensure safety, etc. in the working of the patented invention, and which is provided for in a cabinet order as being such that, in view of the object of the relevant disposition, proceedings, etc., a considerable period of time is required for proper action for the disposition, it was not possible to work the patent invention for two years or more.²⁵

This extension term allows protection of fifteen years from the date of publication of the patent application, but not to exceed twenty years from the filing date.²⁶ Moreover, this patent term is further limited in that it allows for a total market exclusivity of eighteen years for the drug.²⁷ Additionally, the experimental use exception under Japanese Law is fairly narrow, as section 69 indicates:

- (1) The effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research.
- (2) The effects of the patent right shall not extend to the following:
 - (i) vessels or aircraft merely passing through Japan or machinery, instruments, equipment or other accessories used therein;
 - (ii) products existing in Japan prior to the filing of the patent application.

²⁵ PATENT L., *supra* note 12, at § 67(2).

²⁶ *Id.* at § 67(1).

²⁷ Edward H. Mazer, *Supplementary Protection Certificates in the European Economic Community*, 48 FOOD & DRUG L.J. 571, 574 (1993).

(3) The effects of the patent right for inventions of medicines (namely, products used for the diagnosis, cure, medical treatment or prevention of human diseases—hereinafter referred to as “medicines” in this subsection) to be manufactured by mixing two or more medicines or for inventions of processes for manufacturing medicines by mixing two or more medicines shall not extend to acts of preparing medicines in accordance with the prescriptions of physicians or dentists or to medicines prepared in accordance with the prescriptions of physicians or dentists.²⁸

It appears from this section that only laboratory research and physicians treating patients are exempt from patent infringement suits.

1. *Japanese Court Decisions Relevant to Generic Drug Pre-Patent Expiration Clinical Trials*

While a literal reading of the statute does not indicate whether experimental use like that of clinical trials is allowed, Japanese businesses operated under this premise.²⁹ Until March 1996, generic pharmaceutical manufacturers had operated under the understanding that they could begin clinical testing two to three years before the expiration date of the patent, but were foreclosed from actually marketing until the patent expired.³⁰ In March 1996, the Nagoya District Court ruled that clinical testing of generic copies of Synthelabo Groupe of France’s patented hydrochloric-tiapride medication before the patent expired constituted infringement.³¹ Following this decision a flurry of new lawsuits were filed by such giants as Bayer AG³² and Glaxo-Wellcome also alleging that certain Japanese pharmaceutical manufacturers had infringed their patents by clinically testing generic equivalents.³³

²⁸ PATENT L., *supra* note 12, at art. 69.

²⁹ *Patent Troubles Give Drug Firms Headaches: Several Japanese Makers of Generic Medicines Sued Over Alleged Violations*, *supra* note 7, at 9.

³⁰ *Id.*

³¹ Nagoya District Court Decision, *supra* note 6.

³² *Patent Troubles Give Drug Firms Headaches: Several Japanese Makers of Generic Medicines Sued Over Alleged Violations*, *supra* note 7, at 9.

³³ *Glaxo Wellcome Sues 3 Generic Makers Here*, COMLINE DAILY-NEWS BIOTECH. & MED. TECH., July 4, 1996, available in LEXIS, News Library, COMLINE File. See also *Ono Suing 10 Foipan Generic*

Why generic manufacturers were previously under the belief that they could use patented drugs for regulatory approval before expiration of the patent seems unclear, but the most obvious basis is lack of enforcement. The argument that the law in Japan has not changed recently in this regard is supported by an older court ruling in *Monsanto Company v. Stauffer Japan K.K.*³⁴ The *Monsanto* case was just one of a series in various countries involving the use of a generic version of a herbicide to meet regulatory approval for marketing after Monsanto's patent expired.³⁵ In that case the court noted that the legislative intent behind section 69 of the Japanese Patent Law was that "experiments or research are inherently intended to advance technology to the next stage and not for purposes associated with the manufacture or marketing of a patented product."³⁶ Under this construction by the Tokyo District Court, it is unlikely that the generic pharmaceutical companies had the legal view that clinical tests were protected under the experimental use exception.

The rationale enunciated in the Tokyo District Court's decision in *Monsanto*, as well as in the Nagoya District Court's decision in *Synthelabo*, comports nicely with that of the law in many other countries including the European Community ("EC") and the United States before the statutory overruling of *Bolar*.³⁷ The important difference between the U.S. and Japanese laws in this regard are the protections afforded generic drug manufacturers.

D. *The EC Stance on Pre-Patent Expiration Experimental Use*

Until recently it was clear that the EC used the experimental use exception much the same way as articulated in Japan and as set forth in *Roche v. Bolar* in the United States.³⁸ The EC typically disallowed arguments of experimental use when it appeared that the use was strictly aimed at the commercial exploitation of the patented product.³⁹ As with the

Firms, COMLINE DAILY NEWS-BIOTECH. & MED. TECH., July 15, 1996, available in LEXIS, News Library, COMLINE File.

³⁴ The July 10, 1987 decision of the Tokyo District Court, 29th Civil Division, reported in 20 INT'L REV. INDUS. PROP. & COPYRIGHT 91 (1989).

³⁵ See generally David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 HOUS. J. INT'L L. 615 (1994).

³⁶ *Id.* at 653.

³⁷ See generally GILAT, *supra* note 4.

³⁸ *Id.* at 31-34.

³⁹ *Id.* at 4.

case of generic pharmaceuticals seeking approval before patent expiration, the experimental use question presented in the Monsanto series of cases was whether demonstrating to a third party (the regulatory agency of interest) the efficacy with which one could duplicate the patented invention was allowable under the current experimental use exception.⁴⁰ As commentators have noted, the state of the law in nearly all industrialized nations, before the passage of the DPA in the United States, was that clinical trials for merely a generic copy of a name-brand drug constituted infringement.⁴¹

As Gilat points out, clinical trials conducted specifically for demonstrating that a generic drug has the corresponding properties of the patented drug "do not contribute to the promotion of progress."⁴² However, this commentator points out that "clinical trials conducted with a view to establishing that a newly-developed drug has properties that are advantageous over an existing patented drug do contribute to the promotion of progress" and thus have been afforded experimental use protection.⁴³ This basic premise of what is protected and what is not under the Community Patent Convention is now on unstable ground due to a recent Federal Supreme Court decision in Germany.⁴⁴

1. *The Recent Decision by the German Supreme Court Moves the EC Experimental Use Exception Closer to that of the United States.*

Commentators have stated that "judging from the court decisions over the last century, it is fair to say that a private defendant whose only defense is the research exemption would do well to attempt to settle the case out of court."⁴⁵ However, this premise may be changing based not only on the DPA in the United States but also on the German *Klinische Versuche* case reported by Kern.⁴⁶ In that case the German Federal Supreme Court analyzed the experimental use exception codified in section 11(2) of the German Patent Act which is based on article 31(b) of the Community Patent

⁴⁰ *Id.* at 4 n.13.

⁴¹ *Id.* at 65.

⁴² *Id.*

⁴³ *Id.* at 65-66.

⁴⁴ BGH, 11 July, 1995, GRUR 1996, 109. See also Michael Kern, *Recent Federal Supreme Court Decisions on Experimental Use and Compulsory Licensing*, 3 CASRIP NEWSLETTER (Center for the Advanced Study and Research on Intellectual Property, University of Washington School of Law, Seattle, WA) 8 (1996) (discussing the "Klinische Versuche" ruling).

⁴⁵ Kern, *supra* note 44.

⁴⁶ *Id.*

Convention (CPC 1975; now article 27(b) CPC 1989).⁴⁷ The Court found in overturning the Dusseldorf Court of Appeals that "experiment" means "any (systematic) action for obtaining knowledge, independent of the purpose for which the new knowledge will ultimately be employed."⁴⁸ The one caveat to what appears to be a very broad rule is that the experimentation must be directed towards the "subject matter of the patented invention."⁴⁹

While what is specifically meant by the phrase "subject matter of the patented invention" cannot be clearly understood from the literal wording of section 11(2), the Court tried to clarify, reasoning that a "natural" (or literal) interpretation of the statute's wording indicated that all experimental uses directed at gaining knowledge were exempt.⁵⁰ Additionally, the Court noted that section 11(2) does not literally limit experimental activities.⁵¹ Therefore the "legitimacy of the use cannot depend on whether the experiments only relate to the analysis of the invention's alleged characteristics or whether they focus on uncovering further research results and concern an ulterior motive, e.g., commercial interests."⁵² The Court went on to note that the restrictive old German case law did not apply in this case because section 11(2) was based on article 31(b) CPC.⁵³

As the commentator reporting this case noted, "accordingly . . . the leading case under the former statute, 'Ethofumesate' gave no guidance, how to decide the case under [§11(2)]."⁵⁴ In the *Ethofumesate* case the Court held that submitting an agent containing a patented substance to a plant protection authority for regulatory approval while the patent was still in effect infringes the patent.⁵⁵ Moreover, this result was in accordance with the pre-DPA law in the United States (even now this particular use would not be experimental in the United States because the DPA does not include an exception for agricultural chemicals) as well as that of other EC countries and Japan (*see, e.g., Monsanto v. Stauffer Japan K.K.*).⁵⁶

⁴⁷ *Id.* at 9.

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.* (discussing the *Ethofumesate* case), reported in 22 INT'L REV. INDUS. PROP. & COPYRIGHT 541 (1991).

⁵⁵ *Id.*

⁵⁶ *See* 35 U.S.C. §156.

It is important to further examine the reasoning of this German case since Japan typically follows the German lead in patent issues.⁵⁷ Moreover, patent harmonization is important between industrialized nations in this technology-driven age. If this ruling of the German Supreme Court is accepted in the rest of the EC, it would likely be a heavy influence on Japan due to the allowance of similar experimental use in the United States.⁵⁸ To gain insight into the specific meaning of "relating to the subject matter of the patented invention," in section 11(2) the Court looked at the legislative materials of the CPC.⁵⁹ After examining the CPC materials, the Court noted that in reference to article 31(b) the materials stated that patented substances could be used for experimental purposes to assess such things as "possibilities of application as well as further development."⁶⁰ Therefore, the Court concluded that section 11(2) should not be restricted to the functioning of the invention, but that the exception for experimental use should cover more, e.g., "the development of specific applications."⁶¹ The Court also looked at the law in relation to the German Constitution and noted that the public interest in the furtherance of technology demands that clinical tests and experiments remain "privileged" under section 11(2), even if this encumbers the patentee's rights.⁶²

The Court discarded the distinction between commercial and purely research uses to demarcate infringing from noninfringing uses. Instead, as the commentator notes, the Court found:

For every grant of an experimental use exemption, it is also irrelevant that the defendants intended to receive the health authority's approval for their product and to exploit it commercially. As [section] 11(2) exempts all acts from the effects of a patent that are done for experimental purposes relating to the subject matter of the patented invention, the permissibility of such experiments cannot be contingent on

⁵⁷ Interview with Toshiko Takenaka, Professor of Law at University of Washington School of Law, in Seattle, Wash. (November 14, 1996) (discussing the influence of other countries patent laws on Japan). See also TOSHICO TAKENAKA, INTERPRETING PATENT CLAIMS: THE UNITED STATES, GERMANY AND JAPAN, 17 IIC STUD. 39-43 (1995).

⁵⁸ Interview with Toshiko Takenaka, *supra* note 57.

⁵⁹ Kern, *supra* note 44, at 10.

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

what the purposes they are to achieve, be they pure scientific or regulatory in nature.⁶³

While Germany is a civil law country and thus the Supreme Court's decisions are not absolutely binding on lower courts, nevertheless "the Court seems indeed to have opened the floodgates with respect to clinical experiments."⁶⁴

E. A Brief Note on Patent Extension in the EC

On July 2, 1992, the European Parliament enacted the supplementary protection certificate ("SPC") legislation which was hailed as the most significant development in patent law regarding pharmaceuticals in the EC in recent years.⁶⁵ The goal of the SPC is to compensate the manufacturers of pharmaceuticals for the reduction of effective patent life which is caused by the delays of the regulatory approval process.⁶⁶ The SPC legislation effectuates its goal by allowing market exclusivity, but not full patent rights, during the extension period.⁶⁷

Therefore, even if the German Supreme Court ruling is not strictly followed in the EC, most pharmaceuticals will still be allowed to be tested while the now patent-expired drug is covered by the SPC. The SPC legislation seems on its face to achieve the same goals in one action that the DPA does in two. Instead of allowing for both formal patent term extension and clinical trials before the patent expires, the SPC allows generic drug companies to conduct clinical trials following patent term expiration but before SPC expiration.⁶⁸ Since most important pharmaceuticals will be subject to the use of an SPC, it is likely that the type of problem the Japanese system poses (i.e., patent term extension with no allowance for clinical trials until expiration) will happen only rarely. The SPC is similar to the U.S. DPA in its protection aspects: there is a fifteen-year maximum market exclusivity grant compared to fourteen in the U.S., and the

⁶³ *Id.*

⁶⁴ *Id.* at 11.

⁶⁵ Trevor M. Cook, *Pharmaceuticals and IP in Europe*, 23 *MANAGING INTELL. PROP.* 15, 16 (1994), available in LEXIS, Busfin Library, ABI File.

⁶⁶ *Id.*

⁶⁷ Mazer, *supra* note 27, at 571.

⁶⁸ *Id.* at 573.

maximum SPC grant is for five years, the same as the maximum patent term extension in the United States.⁶⁹

With the assumption that most drugs will be covered by an SPC, it is likely that generic drug manufacturers will be able to finish the required abbreviated clinical trials during the SPC term. Thus the EC system will be functionally identical with the U.S. system. The two systems will be fully identical in this regard if the German Supreme Court decision sways the other EC countries. Therefore, it seems that, in regard to the other major high tech player, Japan, change in the allowance of experimental uses will soon follow. This assumption is complex and definitely not assured, for Japan may have other domestic needs that weigh the decision more heavily in favor of keeping the current policy regarding the infringing nature of pre-patent expiration clinical trials.

III. LIKELIHOOD OF CHANGE IN JAPANESE PATENT LAW

A. *Advantages to Changing the Current Law*

It is assumed in this section that the current law of Japan is reflected by the Nagoya District Court decision finding clinical trials to be infringing uses of the patented pharmaceutical.⁷⁰ If, however, this turns out to not be the case, these arguments are still useful in analyzing the differences between systems which allow for these clinical trials compared to those that do not. Generic manufacturers in Japan want to challenge the Nagoya Court ruling, saying it is just a judicial precedent and cannot be generally accepted.⁷¹ This is a common argument put forth by generic manufacturers in Japan and should be a motivating factor in changing the law back to the common understanding before the ruling.

⁶⁹ *Id.* at 574.

⁷⁰ Nagoya District Court Decision, *supra* note 6.

⁷¹ *Patent Disputes Seem Unavoidable for 70 Generic Drugs*, COMLINE DAILY NEWS-BIOTECHNOLOGY AND MEDICAL TECHNOLOGY, July 22, 1996, available in LEXIS, News Library, COMLINE File. It is important to remember that because Japan is a civil law country, its courts' rulings are not necessarily binding precedent on other courts.

1. *Motivations Provided by Harmonization Efforts and the World Market*

The emphasis that industrialized nations have placed upon patent harmonization through the Geneva Patent Harmonization Treaty, GATT-TRIPS,⁷² and the recent International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH")⁷³ are evidence that, in order to stay globally competitive in a high technology age, a country needs to strike a balance between paternalism in its domestic market and opening the domestic market to enhance competition and induce outside investment. Additionally, the United States, the EC, and Japan account for seventy-five percent of the world's pharmaceutical market.⁷⁴ Moreover, these countries make up ninety percent of the world's pharmaceutical research.⁷⁵ These facts alone make evident the importance of harmonization amongst these countries. Moreover, as Japanese companies look to penetrate global markets, technology transfer agreements with the domestic pharmaceutical companies of other countries become increasingly important.⁷⁶ These domestic companies typically are looking for reciprocal arrangements whereby they want to market a generic drug in Japan.⁷⁷ Without consistent regulations the domestic companies will have some trepidation about entering into such an agreement with a Japanese firm.

The pitfalls of inconsistent regulations in various countries were addressed in an Office of Technology Assessment Report.⁷⁸ This report noted that the differing regulations and protections afforded pharmaceuticals increase the costs for manufacturers as well as consumers and cause significant delays in the introduction of new products.⁷⁹ To alleviate these problems, the United States, European Community, and

⁷² Akim F. Czumus, *Biotechnology Protection in Japan, the European Community, and the United States*, 8 TEMP. INT'L & COMP. L.J. 435, 459 (1994).

⁷³ Rosemarie Kanusky, *Symposium: Intellectual Property: Comment: Pharmaceutical Harmonization: Standardizing Regulations Among the United States, the European Economic Community, and Japan*, 16 HOUS. J. INT'L L. 665, 667 (1994).

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ OTA REPORT, *supra* note 3, at 86.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.* at 91.

Japan signed a commitment to standardize pharmaceutical tests.⁸⁰ By changing the law in Japan to reflect what appears to be the current law in the European Community as well as the United States, the Japanese government can more quickly harmonize their system with that of the other major global competitors. Japan, with a thirty-one billion dollar pharmaceutical market in 1989,⁸¹ is no minor player in the pharmaceutical marketplace. In fact, Japan is second only to the United States in drug consumption.⁸² In addition, the Japanese take twice the number of ethical drugs⁸³ as the typical American or European.⁸⁴ Also, recent studies indicate that by 2025 over thirty million people in Japan will be over sixty-five, resulting in the highest ratio (one in four) of individuals over sixty-five to the general population among industrialized nations. So it is no surprise that the Japanese government would want the best, most cost-effective pharmaceuticals available.⁸⁵ In order to achieve such a goal, regulatory standardization is favored.⁸⁶ Lastly, as evidence of the positive effect of harmonization, a 1994 World Bank survey indicated that foreign investment rose noticeably in Japan⁸⁷ as did domestic research and development spending, following recent patent reforms and harmonization.⁸⁸

2. *Motivation Provided by National Health Insurance*

As previously noted, Japan's elderly population is growing faster than that of almost any developed country.⁸⁹ While the pharmaceutical companies are eager to have such an elderly population as customers, the

⁸⁰ EC, U.S. and Japan Sign Commitment to Standardize Pharmaceutical Tests, 8 INT'L TRADE REP. (BNA) 1702 (Nov. 20, 1991), available in Westlaw, BNA-ITR Database.

⁸¹ Brian C. Cunningham & Joyce C. Chow, *The Biotechnology Industry in Japan: A Framework for Entry*, 4(7) J. PROPRIETARY RTS. 13, 14 (July 1992).

⁸² OTA REPORT, *supra* note 3, at 85.

⁸³ Ethical drugs are those drugs which are intended to be used or prescribed by physicians or dentists. See, e.g., STANDARDS & CERTIFICATION SYSTEMS CONCERNING DRUGS IN JAPAN 31, (Pharmaceutical Affairs Bureau of the Ministry of Health and Welfare ed., 1988).

⁸⁴ Cunningham, *supra* note 81, at 14.

⁸⁵ *Id.*

⁸⁶ Teresa P. Buono, *Biotechnology-Derived Pharmaceuticals: Harmonizing Regional Regulations*, 18 SUFFOLK TRANSNAT'L L. REV. 133, 134-135 (1995).

⁸⁷ Suresh Koshy, *The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective*, 1 B.U. J. SCI. & TECH. L. 4, 51 (1995).

⁸⁸ *Finance: Foreign Investment May be Related to Patent Protection*, INTER PRESS SERVICE, Mar. 15, 1994, available in LEXIS, Market Library, IACNWS File.

⁸⁹ Takeshi Nakanishi & Shinya Mori, *Insurance Claim Cap Seen Boosting Generic Drugs; Health Ministry Keen to Limit Cost of Society's Graying*, NIKKEI WEEKLY, Aug. 16, 1993, at 9.

Ministry of Health and Welfare ("MHW") is fretting over the expected increase in insurance claims.⁹⁰ As is the case with other major industries of Japan, the Japanese government, primarily through the MHW, has played an important role in the development and growth of the pharmaceutical industry by working closely with the industry to effectuate its goals.⁹¹ The MHW is similar to the U.S. Department of Health and Human Services.⁹² Among its several divisions are the Pharmaceutical Affairs Bureau, which regulates drug approval, and the Health Insurance Bureau, which sets drug prices.⁹³ The Central Social Insurance Medical Council (Chuikyo), organized under the MHW, is also integral to the functioning of the Health Insurance Bureau. The Chuikyo makes recommendations to the MHW on prices and prospective listings in the National Health Insurance ("NHI") reimbursement price list.⁹⁴

A major goal of the October 1996 meetings of the Chuikyo was to simplify and rationalize the NHI pricing system.⁹⁵ This simplification involves more aggressive pricing and promotion of generic equivalents of name-brand drugs.⁹⁶ Currently, the government insurance program is spending significant sums of money on name-brand drugs even though the patents have expired and generic versions are available in other countries at much lower prices. Hostility toward generic drugs is evidenced by the relative weak market share of generics in Japan.⁹⁷ Compared to the United States where generic drugs currently hold a forty percent market share, generics in Japan only account for eight percent of the total drugs prescribed.⁹⁸ If the cost savings of using generic drugs in the United States is any indication, then changing Japan's current law to allow generic drug manufacturers to gain a market foothold would help in reducing the overall price tag of national insurance.⁹⁹ The MHW, while adopting these recommendations, wants also to encourage innovation by mandating price

⁹⁰ *Id.*

⁹¹ Cunningham, *supra* note 81, at 13.

⁹² DRUG REGISTRATION REQUIREMENTS IN JAPAN 7 (3rd ed. 1988).

⁹³ *Id.* at 193.

⁹⁴ *Chuikyo Gears Up For Complex Decisions*, COMLINE DAILY NEWS BIOTECHNOLOGY AND MEDICAL TECHNOLOGY, Oct. 8, 1996, available in Westlaw at 1996 WL 8002450.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Assessing the Worldwide Market for Generics*, MARKET LETTER, Oct. 28, 1996, available in LEXIS, Market Library, PROMT File.

⁹⁸ *Id.*

⁹⁹ Susana Antunes, *Drug Stocks Find it Hard to Stay on Top*, INTERNATIONAL HERALD TRIBUNE, July 27, 1991 (Money Report), available in LEXIS, Asiapc Library, IHT File.

reductions in generics while allowing high premiums on new innovative drugs during the first few years of their life.¹⁰⁰ The typical pricing of a new generic is eighty percent of the name-brand drug.¹⁰¹ However, if more than twenty generics are available for a particular drug, then these generics are priced at ninety percent of the original. Still a third type of pricing exists to motivate generic manufacturers to experiment with old drugs. This third type of pricing allows the Ministry to set a premium price for a new generic that has expanded usefulness, such as an improved dosage form or an improved combination.¹⁰² The effectiveness of this Ministry plan may be significantly impaired due to the Nagoya District Court ruling finding clinical trials constitute patent infringement.¹⁰³

Further evidence of the MHW embracing generics is that the Ministry is considering introducing a system to basically equalize the prices of name-brand and generic drugs.¹⁰⁴ If the MHW does introduce this system, name-brand manufacturers would likely lose ten to twenty percent of their current sales.¹⁰⁵ In addition, the importance of decreasing pharmaceutical costs for the government cannot be overlooked because pharmaceuticals now constitute approximately one-third of Japan's total health care costs.¹⁰⁶ Allowing clinical trials before the end of the patent term would allow generic drugs to enter the marketplace as soon as possible after the expiry of the patent.¹⁰⁷ However, without this sort of protection, generic manufacturers will lose two to three years in delays due to regulatory approval following patent expiration, thereby giving an additional de facto patent extension to the patentee.¹⁰⁸ In order for generic drugs to gain a foothold in the marketplace, not only must they be able to arrive on the market soon after patent expiry, but they also must be competitively priced.

While patent extension due to regulatory delays is already available in Japan, any further de facto extension of patent rights will all but destroy

¹⁰⁰ Cunningham, *supra* note 81, at 13.

¹⁰¹ *578 Generics Added to NHI Drug Price List*, COMLINE DAILY NEWS BIOTECH. AND MED. TECH., July 15, 1996, available in LEXIS, News Library, COMLINE File. See also *Number of GE NDAs Increases Sharply to 644 this Year*, COMLINE DAILY NEWS BIOTECH. AND MED. TECH., May 27, 1996, available in LEXIS, News Library, COMLINE File.

¹⁰² *578 Generics Added to NHI Drug Price List*, *supra* note 101.

¹⁰³ Nagoya District Court Decision, *supra* note 6.

¹⁰⁴ *Patent Troubles Give Drug Firms Headaches*, *supra* note 7, at 9.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Patent Disputes Seem Unavoidable for 70 Generic Drugs*, *supra* note 71.

¹⁰⁸ *Patent Troubles Give Drug Firms Headaches*, *supra* note 7, at 9.

the ability to have available reasonably priced generics.¹⁰⁹ The reasons for this are purely economic, for just as name-brand manufacturers must calculate the potential commercial benefits of proceeding with drug development, generic drug manufacturers must weigh the costs of production and market entry against the potential commercial gain of the remaining market life of the drug.¹¹⁰ In many cases generic marketability will be so delayed that the costs of marketing and regulatory approval will outweigh any possible return in sales revenue.¹¹¹ In this regard, the Nagoya District Court ruling contravenes the goals of the MHW in enabling a supply of reduced-cost pharmaceuticals.¹¹² There is little doubt that if such a ruling were to remain the law, generic manufacturers would have diminished incentives to enter the market.

3. *Motivation Provided by the Generic Industry Itself*

The eagerness of the Japanese government to keep the pharmaceutical market competitive is evidenced by the decision of the MHW to continually list generics on the NHI, but not to impose too severe price reductions on the generics to promote their manufacture.¹¹³ To facilitate generic introduction, the government must minimize the time to market for a generic following name-brand drug patent expiration. The generic manufacturers will no doubt emphasize this fact. Additionally, the generic drug manufacturers of Japan are not going to sit still in this adversity. As Itsuro Yoshida, senior managing director of Towa Pharmaceutical Company stated, "There are court decisions to allow clinical development before the expiration of patents in the U.S. and Germany. We will point that out in the court."¹¹⁴

The generic manufacturers' organization, Iyakkyo, feels that the MHW is on its side when it comes to the experimental use exception.¹¹⁵ Generic drug manufacturers cite the fact that during its 1993 report the MHW, in the first general administrative recognition of generic drug importance, noted that generic drugs play a significant role in the nation's

¹⁰⁹ Wheaton, *supra* note 5, at 471.

¹¹⁰ *Id.* at 470.

¹¹¹ *Id.* at 471.

¹¹² Nagoya District Court Decision, *supra* note 6.

¹¹³ *Number of GE NDAs Increases Sharply to 644 This Year*, *supra* note 101.

¹¹⁴ *Patent Troubles Give Drug Firms Headaches*, *supra* note 7, at 9.

¹¹⁵ *Id.*

health-care system.¹¹⁶ The panel for the Ministry noted that securing a supply of low-cost generic drugs will reduce the burden on a national health-care system faced with soaring costs.¹¹⁷ Furthermore, the Ministry is testing a method to combat the over-prescription of drugs by utilizing a fixed pricing system for reimbursing doctors.¹¹⁸

Currently, unlike in the United States, Japanese pharmaceutical companies sell directly to doctors and hospitals who then dispense the drugs to their patients.¹¹⁹ This procedure creates an obvious problem in a system where a government-run insurance program reimburses doctors and hospitals for the pharmaceuticals at a fixed government price (NHI listing price).¹²⁰ This problem is further exacerbated by drug companies' discounting the price to physicians.¹²¹ This creates not only the moral dilemma that physicians over-prescribe to make a profit by way of government reimbursement payments, but also the level of discount is weighed in as a factor by the MHW when it does yearly reviews to reduce prices; the bigger the average discount, the greater the price cut.¹²² This creates a vicious cycle of severe discounting for generics whose prices are dependent on name-brand drug pricing (e.g., the typical generic is set at eighty percent of the name-brand price).¹²³ By continually attempting to undercut the price of the name-brand drug, the generics in this cycle are eventually driven from the market.¹²⁴ This problem can be partially alleviated by allowing earlier market entrance when the name-brand drug price is still relatively high, thus allowing the generic producer to make a substantial profit before discounting diminishes profits.¹²⁵ The MHW is also implementing ceiling mechanisms at some hospitals specializing in geriatric care.¹²⁶ This system results in a reimbursement on a nonfixed fee basis, which gives an incentive to choose the cheaper drug (generic) in

¹¹⁶ *Id.*

¹¹⁷ *Id.* See also Takeshi Nakanishi, *supra* note 89.

¹¹⁸ Jason James, *Monday Briefing: Generic Drug Makers Face Uphill Struggle*, THE DAILY YOMIURI (JAPAN), July 17, 1995, at 4, available in LEXIS, Asiapc Library, YOMIUR File. See also Cunningham, *supra* note 9, at 13.

¹¹⁹ OTA REPORT, *supra* note 3, at 86.

¹²⁰ Cunningham, *supra* note 9, at 13.

¹²¹ *Id.* See also James, *supra* note 118, at 4.

¹²² James, *supra* note 118, at 4.

¹²³ *Number of GE NDAs Increases Sharply to 644 This Year*, *supra* note 101.

¹²⁴ James, *supra* note 118, at 4.

¹²⁵ *Id.*

¹²⁶ Takeshi Nakanishi, *supra* note 89, at 9.

absolute terms, regardless of discount.¹²⁷ Under this reimbursement scenario, the prescribing entity receives no profit for prescribing the drug; rather it is reimbursed for the actual amount paid for the drug, thus favoring the cheaper generic drugs.

The involvement with which the MHW has undertaken to minimize drug costs seems to indicate that the Ministry's stance on the issue of an experimental use exception for clinical trials would be a rule which favored generic drug manufacturers. A move that further indicates the intent of the MHW to favor generics was the introduction this year of a new system which inflicts additional price cuts on name-brand drugs experiencing greater than expected sales growth.¹²⁸ This move toward favoring generics appears to be an action by the MHW to foster further growth in original research leading to newly patentable drugs.¹²⁹ This "tough love" approach to domestic industries is relatively new to Japan, prompting one industry observer to say that "these drastic changes suggest an end to the cozy relationship between industry and government, and a move toward a greater transparency."¹³⁰

B. *Disadvantages to Changing the Current Law*

If the recent Nagoya District Court decision is a pronouncement of the current law on experimental use in Japan, then the disadvantages of changing the status quo are few.¹³¹ One disadvantage of allowing experimental use during the patent term is that this use diminishes the property right vested in the patent holder. In addition, with the traditionally long patent pendency times in Japan, the additional time it takes for a generic company to test a drug after patent expiration only gives the original patent owner a length of protection approaching that granted to other patentees who do not have to meet regulatory approval.¹³² A second disadvantage is that traditionally the government of Japan has worked closely to promote industry, and endorsing a change in the law to allow generic drug competition early may undermine the domestic pharmaceutical

¹²⁷ James, *supra* note 118, at 4.

¹²⁸ *Patent Troubles Give Drug Firms Headaches*, *supra* note 7, at 9.

¹²⁹ James, *supra* note 118, at 4.

¹³⁰ *Japan's Drug Approval System to be Reformed*, *supra* note 8.

¹³¹ Nagoya District Court Decision, *supra* note 6.

¹³² Mark S. Cohen, *Japanese Patent Law and the WIPO Patent Law Harmonization Treaty: A Comparative Analysis*, 4 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 847, 870 (1994).

industry. However, with the United States and the European Community leading the way in pharmaceutical research, maybe Japan would rather embrace a fledgling generic industry; additionally, the government may have in mind an agenda to compete in a more head-to-head fashion with the United States and the European Community in areas of pharmaceutical innovation.¹³³

1. *Competition as a Driving Force for Maintaining the Status Quo*

What the Japanese government has in mind is difficult to anticipate without a further understanding of the political undercurrents of Japan. But what is known about recent government agency pronouncements is that the MHW has expanded the use of set pricing for geriatric hospitals reimbursement for drugs and has been influenced by the cost advantage to the national insurance programs of embracing generic pharmaceuticals. This has caused generic drug company officials to believe that the MHW is on their side of the current battle between generic and name-brand manufacturers.¹³⁴ Alternatively, industry experts have noted that to have a competitive advantage in the global pharmaceutical market ultimately depends on maintaining a constant supply of new drugs that are differentiated and offer real cost benefits.¹³⁵ This prospect can be more easily realized by a domestic system that fosters longer protection in order for the name-brand drug company to maintain increased revenues for further research and development.¹³⁶ These concerns inevitably lead to the conclusion that the Japanese government must balance protectionism of the domestic market while also realizing that pharmaceutical production is a global industry requiring harmonized regulations for effective foreign investment.

¹³³ Poh-Lin Yeoh, *Speed to Global Markets: An Empirical Prediction of New Product Success in the Ethical Pharmaceutical Industry*, 28 EUR. J. MKTG. 29 (1994).

¹³⁴ *Patent Troubles Give Drug Firms Headaches*, *supra* note 7, at 9. See also Takeshi Nakanishi, *supra* note 89; Cunningham, *supra* note 9, at 13.

¹³⁵ Poh-Lin Yeoh, *supra* note 133, at 31.

¹³⁶ Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169, 2180 (1991).

2. Full Patent Term Realization and Patent Law Consistency

While diminishing the vested rights of a patent holder by allowing experimental use during the patent term, Japan has arguably offset this loss to the patent holder by allowing patent extension for regulatory delays. However, the problem lies in the fact that the granting of a Japanese patent is a rights confirming act, not a contract between society and the patent holder as in the United States.¹³⁷ From this perspective, any allowance of use during the confirmed patent term may be rightly viewed as infringement. Supporting this argument are the traditionally long pendency times before a patent issues in Japan (six to seven years was not uncommon).¹³⁸ Long pendency periods combined with patent terms running from the application date, there is no wonder industry representatives want patent term extension laws to remain as is. Under the current system they not only get the patent term plus the extension term but also a de facto market exclusivity period of two to three years while generic firms conduct trials after the patent expires. Moreover, further protection was called for based on the expected market loss after a generic pharmaceutical hits the market. Currently, market price loss due to generic competition in the first year can be as high as seventy percent, but generally hovers around twenty percent.¹³⁹ However, the fact that the length of overall protection in Japan, including the extension period, creates a market exclusion of eighteen years indicates that with many products very little effective life will remain and not many companies will choose to go to the expense of creating a generic substitute for an obsolete medicine.¹⁴⁰

Additionally, it must be reiterated that Japanese law does allow experimental use in some form under section 69(1), which states that the effect of the patent right shall not extend to the working of the patented invention for the purpose of experiment or research. One commentator has noted that "[e]xperiment and study using a patented invention is hence not forbidden and pre-patent expiration activities conducted in order to obtain

¹³⁷ Cohen, *supra* note 132, at 849.

¹³⁸ Lesavich, *supra* note 10, at 168. See also M. Brendan Chatham, Note, *The Impact of the 'Technology Transfer Surplus' on the Trade Deficit with Japan and Its Cures*, 25 GA. J. INT'L COMP. L. 561, 591 (1996) (discussing how the JPO has reduced the pendency time to 36 months with 19 months remaining the U.S. average).

¹³⁹ Polastro, Enrico T., *Generics Moving Ahead: The Emergence of a Pan-European Supply System and the Introduction of U.S.-Style Product Discounts are Shaping the European Generics Market*, 248 (23) CHEM MKTG. REP. SR6, (1995).

¹⁴⁰ Mazer, *supra* note 27, at 574.

data for submission to a government regulatory agency will not constitute infringement as being of a non-commercial or at least pre-commercial character."¹⁴¹ This analysis, however, does not agree with the Tokyo District Court's view of section 69(1) in the Monsanto case. The court pointed out that data for regulatory approval is absolutely commercial in character because there is no other purpose.¹⁴² The commentator, however, goes on to state that "[a]lthough Japanese law does not explicitly demand the non-commercial character of these activities this precondition can be concluded from the context."¹⁴³ The tension in these two statements comes down to what is considered commercial in character. If the Monsanto case and the recent Nagoya District Court case are an indication of the law in Japan, then experimental use to improve a product may be allowed, but experimental use for the sole purpose of meeting the same regulatory requirements as the patented product does not advance technology to the next stage as required for experimental use protection.¹⁴⁴

3. *Political Reasons for Maintaining the Current Law*

One of the most influential arguments set forth for not allowing an expanded definition of experimental use is that allowing such use actually decreases innovation.¹⁴⁵ If decreased innovation would occur in the pharmaceutical industry as a result of expanding the experimental use exception, then this would act as a very strong disincentive to change the law. Not only would experimental use have a disparate impact on smaller pharmaceutical firms, it would dissuade inventors from using patent law to protect their ideas, thus reducing public disclosure.¹⁴⁶ The disclosure aspect of the patent system is important for Japan, as industries rely on each other for the most current technology. Additionally, Japanese companies are relying more heavily on cross licensing technologies in order to gain a greater global market.¹⁴⁷ With an expanded experimental use doctrine, there will be little incentive to license in order to improve upon or create a

¹⁴¹ Willem A. Hoyng & Florika Fink-Hooijer, *The Patent Term of Pharmaceuticals and the Legal Possibilities of Its Extension*, 21 INT'L REV. INDUS. PROP. & COPYRIGHT 161, 173 (1990).

¹⁴² Parker, *supra* note 35, at 653.

¹⁴³ Hoyng, *supra* note 141, at 173.

¹⁴⁴ Parker, *supra* note 35, at 653.

¹⁴⁵ Karp, *supra* note 136, at 2183.

¹⁴⁶ Karp, *supra* note 136, at 2183.

¹⁴⁷ OTA REPORT, *supra* note 3, at 86.

generic alternative, for a competitor could just use the patented article without paying the patentee.¹⁴⁸

Another effect of changing the current law would be to increase the newly developing tension between the government and industry. In Japan the government and industry have historically worked as a unit.¹⁴⁹ In fact, as noted earlier, the patent system in Japan is expressly set up to promote industry. Continuing to disallow the experimental use of drugs in Japan allows larger Japanese chemical and pharmaceutical companies a selective advantage over smaller companies.¹⁵⁰ Only the companies with the resources to conduct foreign clinical trials for a generic equivalent could effectively enter the market rapidly at the end of the patent term. Whether the government of Japan wants to reinforce this system is unclear. As noted previously, there has been a push in Japan to reform its pharmaceutical regulatory guidelines as well as the insurance system.¹⁵¹

IV. JAPAN'S LIKELY CHOICE

To understand whether Japan will change the law as it exists or merely maintain the status quo, one must first understand, at least in a limited manner, the way in which law functions in Japan. As Professor John Haley has stated, "[b]asic to any understanding of the role of law in Japanese society is its limited function."¹⁵² Japan is a society built more on social restraints than law.¹⁵³ Societal censure has a great coercive impact, as would be expected of a society of such homogeneity and cohesion as Japan. For contracts and industry too, social restraints of the marketplace provide mechanisms for enforcement.¹⁵⁴ As Professor Haley notes, "Legal rules serve as *tatemaes*, guiding principles, and as such relate directly to the development of social or political consensus."¹⁵⁵ As *tatemaes*, even unenforced law is significant, for it acts as a policy or guiding principle for

¹⁴⁸ Karp, *supra* note 136, at 2183.

¹⁴⁹ Ken Duck, *Now that the Fog has Lifted: The Impact of Japan's Administrative Procedures Law on the Regulation of Industry and Market Governance*, 19 FORDHAM INT'L L.J. 1686, 1687 (1996).

¹⁵⁰ GILAT, *supra* note 4, at 8.

¹⁵¹ *Japan's Drug Approval System to be Reformed*, *supra* note 8. See also Kanusky, *supra* note 73, at 704; Cunningham, *supra* note 81, at 13.

¹⁵² John O. Haley, *Introduction: Legal vs. Social Controls*, in LAW AND SOCIETY IN CONTEMPORARY JAPAN: AMERICAN PERSPECTIVES I (John O. Haley ed., 1988).

¹⁵³ *Id.* at 2.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.* at 4.

a way of interacting with others."¹⁵⁶ But the question remains, what is the current law in relation to experimental use? Is it as the Nagoya District Court has stated or is it something else? Will the Diet act to change the latest ruling?

A. *Likelihood of Change Through Judicial Review*

The fact that the Nagoya District Court's ruling comes in a civil law country seems to indicate that it should be taken as nonprecedential. Even some generic industry representatives in Japan stated that the ruling was *just* a judicial precedent and could not be generally accepted.¹⁵⁷ It is usually taken as true that in most civil law countries the judge is merely limited to interpreting the codes.¹⁵⁸ However, while Japan is a civil law country, there seems to be some precedential effect in court decisions.¹⁵⁹ This precedential effect has been attributed to the "career" system for judges which inevitably leads to de facto following of upper court decisions by the judges of the lower courts. The undeniable judicial activism which occurs in Japan can be seen clearly in the area of labor law, where "[c]ompanies are deeply aware of the importance of judicial decisions."¹⁶⁰ As Professor Haley has stated, "[t]he courts plow the field, and the legislature freezes it."¹⁶¹ This sentiment is echoed by Hideo Tanaka, "It seems to be undeniable that the Japanese courts have played a very important role in the making of the law through their 'interpretation' of statutes Today, analysis of cases is an indispensable part of legal scholarship."¹⁶²

Therefore, it seems that, as in the United States, a higher court need not hold as precedent a lower court's holding. This premise is implied from the Court Organization Law (Saibansho-hō) (Law No. 59, April 16, 1947) which states under article 4 that "a conclusion in a decision of a superior

¹⁵⁶ *Id.* at 5.

¹⁵⁷ *Patent Disputes Seem Unavoidable for 70 Generic Drugs*, *supra* note 71.

¹⁵⁸ Daniel H. Foote, *Judicial Creation of Norms in Japanese Labor Law: Activism in the Service of—Stability?*, 43 UCLA L. REV. 635, 636 (1996).

¹⁵⁹ *Id.* at 637. See also Leon Wolff, *The What, Where, Why and How of Japanese Cases: Through the Window of Japan's Emerging Law against Sexual Harassment* 13-16 (1996) (unpublished independent study essay, University of Washington School of Law) (on file with the University of Washington Law Library).

¹⁶⁰ Foote, *supra* note 158, at 683.

¹⁶¹ Andrew Marcuse, *Why Japan's New Products Liability Law Isn't*, 5 PAC. RIM LAW & POL. J. 365, 366 n.8 (1996).

¹⁶² HIDEO TANAKA, *THE JAPANESE LEGAL SYSTEM* 143 (9th printing, 1994).

court shall bind courts below in respect of the case concerned.”¹⁶³ The negative implication being that superior court holdings are binding on lower courts only in the same case and not in similar future cases.¹⁶⁴ But, the practice is that in similar cases, upper court case decisions are “substantially” binding on the lower courts.¹⁶⁵ Additionally, the courts in Japan will follow their own past decisions, only overruling precedents for strong reasons.¹⁶⁶ There also exists strong inferences in the procedural aspects of Japanese law to support the premise of binding precedents. For example, in the Code of Civil Procedure, article 394 states: “Re-appeal may be made only on the grounds that the judgment attacked is in contravention of law or ordinance [hōrei].”¹⁶⁷ As with most codes, what article 394 means is up to court interpretation. An appropriate question is whether a case decision is law within the meaning of “law and ordinance” (hōrei).¹⁶⁸ This question has been answered in the affirmative by both Japanese courts and scholarly writers.¹⁶⁹ As Professor Haley puts it, “[T]he well informed Japanese lawyer if asked whether case precedents are law in Japan will say, ‘Substantially, yes; but formally, no.’”¹⁷⁰ While the case for experimental use of generic pharmaceuticals has yet to reach a High Court one can only speculate as to the result if it does.

Moreover, the precedential weight of *Monsanto Co. v. Stauffer Japan K.K.* may have minimal effect on more recent decisions. Since the Monsanto case was only a Tokyo District Court decision, the precedential effect in any other district court will be minimal.¹⁷¹ Therefore, while instructive to industry on how one of the major district courts in Japan views the matter of experimental use for regulatory purposes, the decision will likely carry little weight except in the Tokyo District Court itself. However, as in the United States, whenever one court visits a matter of some importance, other courts will typically look to the reasoning of those courts who have dealt with this matter. As previously mentioned, it can not

¹⁶³ LAW AND THE LEGAL PROCESS IN JAPAN 494 (John O. Haley & Dan Fenno Henderson eds., 1987) (unpublished materials assembled for use by students in an introductory course on Japanese Law) (on file with the University of Washington Law Library).

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ *Id.* at 495.

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ *Id.* at 497.

¹⁷⁰ *Id.* at 494.

¹⁷¹ Judgment of Tokyo District Court, 29th Civil Division, reported in 20 INT’L REV. INDUS. PROP. & COPYRIGHT 91 (1989).

go unnoticed that the Monsanto case in Japan was decided by similar reasoning as that found in the German Monsanto case,¹⁷² lending further support to the notion that the new German policy pronounced in *Klinische Versuche*¹⁷³ may lead to a 180 degree judicial turnaround as to the interpretation of experimental use.

The activism of the judiciary in similar areas of vague policy pronouncements and the regularity with which the courts in Japan look to the German model in patent issues lead to the conclusion that judicial review is a likely vehicle for effectuating a change in the current law.¹⁷⁴ The holding of *Klinische Versuche*,¹⁷⁵ if it stands, will likely have the consequence of motivating the Japanese judiciary to accept an experimental use exception for generic pharmaceuticals.¹⁷⁶ Moreover, the dynamics of a changing economy in Japan and the recognition of a world economy may force the judiciary of Japan to do as the foreigners do and make room for some form of pharmaceutical experimental use. With the influence of German case law on the issue as well as the need for consistency between the industrialized nations weighing on the Japanese judiciary's minds, Itsuro Yoshida, senior managing director of Towa Pharmaceuticals, the largest generic-drug maker in Japan has stated that his company will point out to the court that in the United States and Germany such clinical testing is allowed.¹⁷⁷

B. *Changing the Law by Action in the Diet*

To fully understand the plausibility of a legislative change effectuated by an action of the Diet requires at least a minimal understanding of the legislative process of Japan. Like the United States, the Japanese government has a similar separation of powers consisting of the legislative, executive, and judicial branches.¹⁷⁸ Of these, the Diet is clearly the

¹⁷² Judgment of the German Düsseldorf District Court, reported in 18 INT'L REV. INDUS. PROP. & COPYRIGHT 407 (1987).

¹⁷³ Judgment of the German Supreme Court, *Klinische Versuche*, GRUR 1996, 109, also reported in Kern, *supra* note 44.

¹⁷⁴ TAKENAKA, *supra* note 57, at 39-43.

¹⁷⁵ German Supreme Court Judgment, *supra* note 173.

¹⁷⁶ TAKENAKA, *supra* note 57, at 39-43.

¹⁷⁷ *Patent Troubles Give Drug Firms Headaches*, *supra* note 7, at 9.

¹⁷⁸ The law-making abilities of the Japanese government principally reside in the bicameral Diet, consisting of the House of Representatives (Shugi-in) and the House of Councillors (Sangi-in). A superior position is given the House of Representatives by the Constitution in that it can override a decision by the

legislative branch, while the courts are obviously the judicial branch, but what constitutes the executive branch is not as clear. The Constitution of Japan adopts a parliamentary system for the national government, which provides for a system wherein the Prime Minister (Naikaku Sori-daijin) is designated as the head of the Executive Cabinet by the Diet.¹⁷⁹ Under the Cabinet are the Prime Minister's office, the twelve statutory ministries, eight commissions, and twenty-four agencies.¹⁸⁰ The legislative process is heavily skewed toward legislative introduction by the Cabinet¹⁸¹ in which individual ministries (e.g., MHW) formulate their own agenda in order to be consistent with the Cabinet as a whole.¹⁸²

The ministry with the most interest in the law regarding experimental use is obviously the Ministry of Health and Welfare, which creates the pharmaceutical regulations and controls many aspects of the national health insurance.¹⁸³ One of the main sources of impetus behind new bills are questions raised in the course of routine work.¹⁸⁴ What this means is that many ideas for new bills come from a ministry identifying a problem through learning how the existing law affects its operations and goals for the future. This type of information can come from regional bodies which are charged with the actual enforcement of the law and from learning how the existing law is presently applied by the judiciary.¹⁸⁵ The importance of judicial interpretation of laws can thus form an important source of information from which a ministry can work to create new legislation to more closely tailor the law to the ministry's goals.

For the MHW to succeed in changing the law, it must perform a precarious balancing act. Japan's regulatory system, like many areas of Japanese culture, works by emphasizing close, informal contacts between

House of Councillors with a two-thirds majority in the case of a bill passage and with a simple majority in the case of a budget or treaty approval. TANAKA, *supra* note 162, at 38.

¹⁷⁹ *Id.* at 41.

¹⁸⁰ LAW AND THE LEGAL PROCESS IN JAPAN, *supra* note 163, at 354.

¹⁸¹ *Id.* at 368.

¹⁸² In fact, of the total number of bills introduced to the Diet from the 1st to the 100th session (the 100th session ending in 1985) amounted to 9,288 and of these 6,255 were submitted by the Cabinet. While the overall passage rate of bills submitted by the Cabinet hovers around 86%, those submitted by the House of Representatives have a passage rate of 25%, and those submitted by the House of Councillors have a passage rate of a mere 18%. Thus, with 85% of all laws passed being submitted by the Cabinet, introduction of a bill by the Cabinet carries a significant chance of becoming law. Therefore, it is appropriate to approach any realistic possibility of legislative change from the perspective of the relative importance that such a change would have in effectuating the goals of a ministry. *Id.* at 359.

¹⁸³ OTA REPORT, *supra* note 3, at 156.

¹⁸⁴ LAW AND THE LEGAL PROCESS IN JAPAN, *supra* note 163, at 364.

¹⁸⁵ *Id.*

the ministries and those whom they regulate.¹⁸⁶ As one commentator has noted, “[t]he close ties between the public and private sectors unite the interests of government and business, and portend harmful results for companies that challenge or ignore an agency’s guidance.”¹⁸⁷ The close ties between government agencies and those they regulate is represented by the *amakudari* system and could represent the largest impediment in changing the experimental use laws.¹⁸⁸ In many industries, the businessmen who deal with the ministries are themselves retired bureaucrats from those same agencies.¹⁸⁹ However, recently there has been new emphasis on procedure in these agencies and a move to dismantle the old *amakudari* system.¹⁹⁰

The move to dismantle the *amakudari* system was prompted by several incidences of impropriety, including a scandal involving the Ministry of Finance and Japan’s *jūsen*, or housing loan companies.¹⁹¹ Corruption scandals alone may not speed change, but these problems, combined with the economic situation of Japan, may.¹⁹² The unpredictable regulatory regime of Japan has induced many pharmaceutical companies to move their main manufacturing plants to other Asian countries.¹⁹³ Thus, the Japanese Diet, through the ministries, has acted “to stem the tide of financial and manufacturing corporations shifting their operations out of Japan by improving the transparency of the bureaucratic process.”¹⁹⁴ However, the close relationship between government and industry will surely die a slow death.¹⁹⁵ The close ties with industry are being pulled in opposite directions by the generic industry and those who manufacture name-brand pharmaceuticals. However, now it appears that the generic industry now has more support from the MHW.

The change in the law urged by the generic industry through the generic manufacturers’ organization, Iyakkyo, has support in both the

¹⁸⁶ Duck, *supra* note 149, at 1688.

¹⁸⁷ *Id.* at 1695.

¹⁸⁸ The *amakudari* system is best defined as a system wherein retiring Ministry bureaucrats become high-ranking executives in the companies they once regulated. *Id.* at 1696.

¹⁸⁹ *Id.* at 1696-1697.

¹⁹⁰ Curtis J. Milhaupt, *A Relational Theory of Japanese Corporate Governance: Contract, Culture, and the Rule of Law*, 37 HARV. INT’L L.J. 3, 58 (1996).

¹⁹¹ Duck, *supra* note 149, at 1699.

¹⁹² *Id.* at 1725.

¹⁹³ *Id.*

¹⁹⁴ *Id.* at 1763.

¹⁹⁵ For just in March 1995, the MHW formed a company called Genex Research Inc., with eight other companies whom it is supposed to regulate. Masato Ishizawa, *U.S., EU Patents Could Dominate Biotech Royalties*, NIKKEI WEEKLY, June 3, 1996, at 1, available in LEXIS, Asiapc Library, NIKKEI File.

MHW's goals of reducing health care as well as promoting more harmonized regulations.¹⁹⁶ The rising domestic health care expenditures, as well as foreign domination of major therapeutic markets, is forcing Japanese pharmaceutical companies to seek more global involvement.¹⁹⁷ As the Japanese firms seek internationalization, they typically seek a collaboration with a domestic company in the foreign country of interest. Historically these firms are highly reluctant to form collaborations with nations whose laws do not provide similar patent protection.¹⁹⁸ In this regard, a ban on experimental use may seem to be an advantage for a foreign company to collaborate with a Japanese company. But, the global call for harmonization, as well as rising health care costs, will likely drive the MHW to propose allowing experimental use.

Along with the enactment of the new Administrative Procedures Law in 1993,¹⁹⁹ other "recent developments portend a potentially fundamental shift in the Japanese legal environment."²⁰⁰ This shift is a move to create greater transparency between the government and industry.²⁰¹ One such instance of this change occurred in fall of 1996 when the MHW abolished the Pharmaceutical Affairs Bureau ("PAB").²⁰² The PAB's downfall was orchestrated by the *amakudari* system itself. By allowing the PAB to proceed with the dual functions of overseeing drug safety and also promoting the pharmaceutical industry, the Ministry created a disastrous mix. That disaster finally did happen when over 1,800 hemophiliacs became infected by HIV due to slack procedures and payoffs which allowed importation of non-heat-treated blood products to be used for transfusions.²⁰³ This incident was the main source of MHW's move to distance themselves from industry. One industry insider was noted as saying that "these drastic changes suggest an end to the cozy relationship between industry and government, and a move toward greater transparency."²⁰⁴

If truly this is the downfall of the *amakudari* system, then there is a strong likelihood that the MHW will suggest a change in the law to allow

¹⁹⁶ *Patent Troubles Give Drug Firms Headaches*, *supra* note 7, at 9.

¹⁹⁷ Poh-Lin Yeoh, *supra* note 133.

¹⁹⁸ OTA REPORT, *supra* note 3, at 86.

¹⁹⁹ *See generally* Duck, *supra* note 149.

²⁰⁰ Milhaupt, *supra* note 190, at 7.

²⁰¹ *See generally* Duck, *supra* note 149.

²⁰² *Japan's Drug Approval System to be Reformed*, *supra* note 130.

²⁰³ *Id.*

²⁰⁴ *Id.*

experimental use. Only the history of strong government support for industry likely stopped the MHW from instituting such a change before now. With the increased strength of the generic industry in Japan, as well as the decreased role industry will likely play in the policies of the MHW, combined with the need for lowering health care costs, the result is that the MHW is nearly required to accept the task of changing the law. The MHW can effectively lower one-third the cost of the national healthcare system by reducing pharmaceutical prices.²⁰⁵ This goal can be met while still allowing for a perfunctory recognition of the *amakudari* system. For the Ministry still may be reluctant to mandate that pharmaceutical firms implement severe price cuts on pharmaceuticals, which it has the power to do, and instead may feel more comfortable allowing earlier entry to the generic drugs while relying on generic drug entry as the reason for the price cuts. Additionally, the MHW will likely continue its pricing strategy on patented drugs, thus allowing for significant returns for pharmaceutical companies before generic entry.²⁰⁶ Moreover, the MHW is not likely to lend a sympathetic ear to an industry that basically wants the right to charge the government more for pharmaceuticals for an additional two to three years on top of the original patent grant. Therefore, the most likely source of change in the area of experimental use will be the MHW, guided primarily to its decision by simple economics.

V. CONCLUSION

Regardless of whether experimental use of patented pharmaceuticals is right for Japan, Japan nonetheless must give generic manufacturers some means of entering the market at patent expiration. Without generic drugs, the government of Japan faces a daunting task of paying more and more every year as the populace of Japan ages. While the government could effectively set a much lower price for pharmaceuticals, it has so far been reluctant to act so brazenly against strong industry pressure. A more likely

²⁰⁵ *Patent Troubles Give Drug Firms Headaches*, *supra* note 7, at 9.

²⁰⁶ Personal Interview with Dustin R. Klinger, importer of medical equipment to Japan (December 4, 1996). Mr. Klinger worked in Japan for several years for a medical device importer. His comments suggest that while medical devices are also required to meet certain regulatory criteria, the price set by NHI for insurance reimbursement is fully industry negotiated. His experience was that if the industry selling the device failed to reach a negotiated agreement with the Ministry on a price then the Ministry would merely set the price at approximately 5% less than what the industry asked. As Mr. Klinger indicated, this leads industry to present highly inflated cost data to the Ministry. He further states that it is not uncommon for industries in the medical field to expect upwards of a 300% profit on each product sold in Japan.

route for the MHW is to allow generic pharmaceuticals access to the market early enough to induce generic firms to commit to expanding and producing more low-cost drugs. The net result of earlier generic firm entry will require the name-brand drug makers to either follow suit or lose substantial market share. On the other hand, this does not alleviate the problem of the name-brand industry charging a very high price during the monopoly period. This too must be addressed to decrease healthcare costs for MHW. A compromise between the name-brand and generic firms is therefore necessary to keep the government from spending large sums of money on drugs that could be more cheaply produced and also to keep the name-brand pharmaceutical industry of Japan globally competitive.

The recent moves of the Japanese government to distance themselves from industry suggest that the MHW will propose a change to the existing law. However, with the number of suits pending on this issue in Japan, a High Court or possibly the Supreme Court may change the law before any action is taken by the legislature. One must ask what right do the name-brand pharmaceutical companies have to extend their patent right beyond the patent itself? Conversely, what right does a competitor have to be exempted from infringing activity, when what they are doing is preparing to commercially exploit a currently patented product? In all other fields where no regulatory approval is needed, no experimental marketing is allowed; so why should something similar be allowed in pharmaceuticals?

The answer to these tangled questions seems to be resolved by the SPC system of Europe. By allowing market exclusivity, but no other rights, the SPC system avoids the problems of experimental use being a loss of a patent holders' right to exclude. To fully embrace a system similar to the SPC system, the common practice must be for most drugs to receive SPC protection or go off patent early enough to allow effective generic competition to take place. Problems due to lack of harmonization of patent laws, as well as regulatory guidelines, cause serious problems for countries seeking foreign investment. With the economy of Japan relatively slow compared to the eighties, only positive foreign investment and foreign collaborations will ease the pain. But, when patent laws are perceived as weak or different, investment suffers. When speaking on Japan's patent law on this very point, Douglas McCormick stated:

A rosy glow has long suffused our vision of biotechnology in Japan: government support, public acceptance, highly

motivated researchers, the happy reports of American research executives with joint development agreements—it sounded ideal, a model and a challenge. So it was a shock to discover ... that the country may not be the land of tPA²⁰⁷ milk and recombinant²⁰⁸ honey.²⁰⁹

As Japan moves toward greater transparency between industry and government, this perception will no doubt change. Harmonizing the experimental use law of Japan with that of the other major pharmaceutical-producing nations is an effective first step.

²⁰⁷ tPA is short for Tissue Plasminogen Activator a known biotechnologically produced molecule useful for facilitating the dissolution of blood clots and currently sold and manufactured by Genentech, Inc.

²⁰⁸ Recombinant proteins are those which are produced by genetic manipulation, usually by placing the gene of interest into the appropriate expression vector for product expression. *See generally*, JAMES D. WATSON ET AL., *MOLECULAR BIOLOGY OF THE GENE* (4th ed. 1987).

²⁰⁹ OTA REPORT, *supra* note 3, at 149.

