12 The Pharmaceutical Industry in The Great White North and Land of the Rising Sun: A Comparison of Regulatory Data Protection in Canada and Japan

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Regulatory data protection (RDP) is gaining prominence as a category of intellectual property (IP) rights due to its significant economic implications. RDP is entrenched in key international IP agreements, however, countries have not consistently implemented it. While both Canada and Japan provide for RDP, the effectiveness and the level of protection vary considerably. This research serves a prospective role by analyzing the impact of impending developments resulting from mounting pressures to increase RDP from domestic and foreign stimuli in these two countries.

The Canadian approach, supported by a high level domestic appellate court, is to restrictively interpret the North American Free Trade Agreement's RDP provisions, which provide more specificity than those of the WTO's Trade-related Aspects of Intellectual Property Rights Agreement. This approach is consistent with the balance which Canadian courts and government continually seek to achieve in health-related areas of IP. This balance has generated a strong generic sector and condemnation from the innovative sector.

Japan, under the guise of a complex post-marketing approval re-examination period, provides for strong RDP and market exclusivity. The inertia of the Japanese innovative sector, coupled with the commitment at the political level, has resulted in a mandated study of the current RDP provisions with a view to increase protection. The existing balance of power between the Japanese innovative and generic sectors, and prevailing attitudes suggest that the proposed increase is a fait accompli.

1. Introduction

The pharmaceutical industry pits two rivalling sector against each other: (1) the innovator or brand name sector; and (2) the generic sector. Apart from the lucrative profits at stake, is the myriad of complex policy questions, running the gamut of ethics, human rights, health care, politics, social issues, as well as business and propriety rights. Unlike many technology-related industries where intellectual property (hereinafter "IP") rights alone are key, a complex regulatory infrastructure is also imposed on the pharmaceutical industry. The industry is not well understood, in part because of the complexity of drug regulation and that many aspects remain shrouded in secrecy from the public.

Research into the pharmaceutical industry's IP issues has tended to focus on patents and to a lesser extent trademarks. The important role of other categories of IP protection to the industry is increasingly being recognized and brought to the fore by leading scholars including Peter Drahos and John Braithwaite. (*1) Trevor Cook's, the well-respected U.K. IP solicitor, special report on regulatory data protection (hereinafter "RDP"), highlighted the growing importance of this often-neglected category of IP;

> As testing directed to securing regulatory approvals in such sectors becomes ever more expensive [*Footnote omitted*] and approvals more difficult to secure, the test data itself has become a valuable asset the protection of which is capable of conferring exclusivity reminiscent of more traditional intellectual property rights such as patents. (*2)

I was motivated to conduct research on RDP because it is emerging as a hot issue on the international front and it has significant economic implications. RDP also provides a unique opportunity to study the inter-relationship between IP rights and the regulatory infrastructure. Most importantly, there is a relative paucity of literature for key jurisdictions including Canada and Japan. Various experts, including Trevor Cook, have acknowledged the need for intensive analysis of these key jurisdictions. (*3) This paper aims to fill those gaps.

On the surface, the geography of the RDP regimes of the Great White North and Land of the Rising Sun are remarkably different. The level of protection and effectiveness of the Canadian and

(*) B.A., LL.B., J.D., BCL(Oxon)
(*1) Drahos and Braithwaite at 6.
(*2) Cook at 1.
(*3) Cook at 105.

Japanese regimes vary considerably. However, under the surface, both regimes have many similar geological features, which makes for an interesting comparison. Unfortunately, most North American and Asian researchers rarely have the opportunity to conduct primary research on RDP in both regions. Fortunately, the Japanese Institute of Intellectual Property generously made this possible by inviting me to conduct this research.

The growing international harmonization of IP systems and competition between innovative companies and generics, has led to both regimes facing stimuli either domestically and/or internationally to give stronger RDP to innovative companies. The Canadian regime is highly criticised for providing inadequate protection domestically by the innovative sector, and internationally as seen in recent United States Trade Representative (USTR) Annual Special 301 Reports. In contrast, the Japanese regime, though convoluted, is quite favourable to innovators. As a result of pressure from its innovative sector and a different philosophy towards IP protection, the Japanese government is now actively studying their regime with a view to extending the current RDP term.

I begin by outlining the case both for and against RDP. After that, I examine the impact of key international agreements such as the WTO TRIPS Agreement and the North American Free Trade Agreement, and provide a synopsis of the complex regulatory process. The majority of the paper critically evaluates the RDP regimes in Canada and Japan, and the implications for both the innovative and generic sectors as well as society at large. The complexities of both regimes are first demystified. Subsequently, the domestic and international stimuli which challenge them are placed in context with a view to discerning the optimum mix. The concluding sections for both countries speculate on the shape of things to come.

2. The Case for Regulatory Data Protection

According to the classic innovator view of RDP, subsequent applicants (typically they are generics, but could include other innovative competitors) should be precluded from relying either directly or indirectly on the data submitted to the regulator for approval of the innovator's reference product. Given the costs involved in generating such data, it is generally uneconomic for subsequent applicants to generate their own data. As such, a *de facto* right favouring the first applicant is conferred either as "exclusivity for a limited period, or more rarely in practice, no more than a right to remuneration during such period." (*4)

According to IP experts including Trevor Cook, Carlos Correa and Michael Blakeney, this view is being justified on the basis of equity and health policy. A recent study by the international federation representing innovative companies indicates that RDP has significant economic implications ranging in the hundreds of millions of dollars. (*5) This finding was confirmed by my interviews with Canadian and Japanese innovative companies and their associations. Innovative companies need RDP to recover their return on investment. It is an important incentive to support the R&D needed to develop drugs for tomorrow's diseases. Without RDP, generics will be 'free riding' on the backs of innovative companies' labour. According to Randall Marusyk, Chair of the Legal and Litigation Department of a leading Canadian pharmaceutical patent firm, "Innovative companies should not have to simply hand over their proprietary data to generics." (*6) With RDP, generics also benefit because ultimately there are more products available for them to market. RDP is most valuable where there may be no patent protection, or weak patent protection as with 'second generation' patents. Such situations give credence to innovative companies' opposition to a growing view that RDP should not extend beyond the period of patent protection.

3. The Case Against Regulatory Data Protection

Generics, developing countries, and many non-governmental organizations (NGOs) champion the case against RDP. In his extensive work on RDP for the South Centre, Carlos Correa discussed the public interest in promoting competition and preventing RDP from becoming the means of blocking the timely entrance of generics to off-patent drugs. (*7) The social cost to the developing world of delaying generics could be quite severe. RDP also increases the social, ethical, and economic costs of repetitive animal and human testing.

4. Regulatory Data Protection at the International Level

(a) TRIPS

Canada and Japan are parties to key international agreements, which inextricably shape their domestic policy. Article 39.3 of the World

(*4) Cook at 2.
(*5) IFPMA Review (Revised).
(*6) Interview with Randall Marusyk.
(*7) Correa at 6.

Trade Organization's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) (*8) was the first, and remains the most important, provision in a multilateral instrument dealing with RDP. During the controversial negotiations, many developing countries took the position that RDP was not an IP category and thus did not belong in the agreement. In contrast, RDP proponents including the Swiss argued that, "[it] embodies the central idea underlying IPR protection, namely that of the preservation of the exclusive commercial use of information created by investment of time, human and financial resources." (*9)

The literal interpretation of the expression 'undisclosed information', which is contained in the title to Section 7 of TRIPS, is misleading. What is protected is not undisclosed information, but rather "information disclosed selectively and under precise conditions." (*10) The term was used to avoid referring to an expression linked to any particular legal system. However, TRIPS leaves much unsaid about RDP. Not surprisingly, RDP varies considerably among WTO Members. It is controversial whether these permutations are consistent with the letter and spirit of TRIPS. For example, there is considerable divergence on the meaning of 'new chemical entity'. Is it an absolute (worldwide) or relative (local) standard? Does it cover 'second indication' pharmaceutical patents? Perhaps, the most difficult issue is whether government use of data submitted by an innovative company to determine bioequivalence of a generic is a 'commercial use'. If the commercial threshold is not met, the determination whether such use is unfair is unnecessary. According to Daniel Gervais's authoritative TRIPS drafting history and analysis, "This question was mentioned repeatedly during the negotiation." (*11) Those favouring a narrowly circumscribed RDP right, including Carlos Correa, argue that this type of government use is not commercial. (*12) The U.S. and other countries with strong innovative sectors argue to the contrary.

Another recurring issue is whether RDP confers exclusivity. Contrary to popular misconception, RDP is not a *sui generis* system, but rather is a category of IP pursuant to TRIPS Article 1.2. Using other categories of IP as an example, Carlos Correa demonstrates that it cannot be inferred that RDP requires exclusive rights. In addition, TRIPS is silent as to the period of protection, if any. Nonetheless, many countries such as the U.S. clearly confer a period of exclusivity. Jayashree Watal, former TRIPS negotiator for India, summed it up best, "In the end in the TRIPS text there is no clear obligation not to rely on the test data for the second or subsequent applicants nor a fixed duration of market exclusivity…This is a clear contrast to the corresponding provisions in NAFTA." (*13)

(b) NAFTA

The North American Free Trade Agreement (NAFTA) preceded TRIPS chronologically. However, several of NAFTA's IP provisions, including those on RDP, provide greater specificity than the corresponding ones in TRIPS. In part, this is because of the different interests at stake and that many of the negotiators were the same as those in the TRIPS negotiations which were quite mature at the time of NAFTA's signing. (*14) NAFTA Articles 1711(5), (6) and (7) protect the confidential information that companies must submit to governments to obtain marketing approval for new pharmaceutical products for a five-year period.

5. The Regulatory Process Explained

The introduction of pharmaceuticals, whether 'new' or generic versions, is governed by a maze of legislation, regulations and practice. The key Canadian legal instruments are the Food and Drugs Act, (*15) Food and Drug Regulations, (*16) Patent Act, (*17) and Patented Medicines (Notice of Compliance) Regulations. (*18) The Therapeutic Products Directorate (TPD), a division of Health Canada, is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. In Japan, the Pharmaceutical Affairs Law primarily controls the regulation of

(*8) Article 39.3 of TRIPS provides: "Members, when requiring as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."
(*9) Submission from the Swiss delegation in WTO document MTN.GNG/NG11/17 of 23 January 1990.
(*10) Gervais at 185.
(*11) Gervais at 188.
(*12) Correa at 28-30.
(*13) Watal at 199.
(*14) Interview with John Gero.
(*15) R.S., c. F-27 (Hereinafter "FDA").
(*16) C.R.C., c. 870 (Hereinafter "FDA Regulations").
(*17) R.S.C. 1985, c. P-4, as amended (Hereinafter "Patent Act").
(*18) SOR/93-133 (Hereinafter "NOC Regulations").

pharmaceutical drugs. The Pharmaceutical Affairs Bureau of the Ministry of Health, Labor and Welfare (MHLW) is the equivalent of the Canadian TPD. Like Canada, Japan utilizes various guidance documents to supplement its legislation.

In developed countries such as Canada and Japan, the 'new drug' approval process consists of four phases: Pre-Clinical; Clinical; New Drug Application Review; and Marketing. (*19) The new drug sponsor (an innovative company) submits an application to the regulator. The application must disclose confidential information to the regulator including detailed reports of safety tests and substantial evidence of the clinical effectiveness of the new product. If the regulator is satisfied with the safety and effectiveness of the drug, it may allow the drug to be marketed. In both countries there is a fast track or expedited mechanism for important new drugs. The drug approval process for generics, though still lengthy, is expedited and simplified through reliance on comparative bioavailability studies to establish safety and efficacy. Generic submissions are guided by various bioavailability guidelines.

6. Regulatory Data Protection in Canada

Canada's RDP regime is highly criticised, viewed with scepticism similar to its 'chequered history' in relation to pharmaceutical innovators. Allegedly, generics benefit from 'spring boarding' on the proprietary data of innovative companies during the period of protection. In the USTR 2003 Special 301 Report, Canada appeared in the 'watch list' category for, *inter alia*, not providing effective data exclusivity protection.

Subsection C.08.004.1 of the Food and Drug Regulations provides for RDP. Important litigation in Canada over this subsection has cast the spotlight on the RDP regime as highlighted in the 2001 USTR Special 301 Report. In the case of *Bayer Inc. v. The Attorney General of Canada and the Minister of Health, Apotex Inc. and Novopharm Limited intervening*, [1999] F.C.J. No. 826 (FCA) {Leave to the Supreme Court of Canada was dismissed}, there were two key issues before the Federal Court of Appeal (FCA): (1) does the generic approval system follow the regulations; and (2) are the regulations NAFTA compliant?

The main issue before the FCA was whether there is examination and reliance by the regulator on the confidential information originally filed by the innovator, when an innovator's competitor seeks approval of its product based on bioequivalence. The innovator (Bayer Inc.) argued that the regulator must explicitly or implicitly have examined and relied upon such confidential information in approving a product based on bioequivalence. Accordingly, Bayer Inc. argued that the regulator may not allow the generic to be marketed in Canada (i.e., the issuance of a Notice of Compliance (NOC)) earlier than five years after the date of issuance of the NOC to the innovator for its reference product. The FCA disagreed, reasoning that Bayer Inc.'s interpretation would invariably provide a minimum of five years of market protection to an innovator. The FCA also referred to the Regulatory Impact Analysis Statement as support for the view that the regulation's intent was that the confidential information filed by the innovator may or may not be examined and relied on by the government.

The other key issue the FCA considered was whether the regulation was consistent with Article 1711 of NAFTA. In summary, the FCA held that NAFTA Article 1711 only applies when the Minister relies upon confidential information or trade secrets. When the confidential information in the innovator's application is not relied upon, the NAFTA provision is thus inapplicable. If the innovator's interpretation of the regulation was accepted, an NOC for a generic version of a drug would not in practice be issued before five years after the NOC was issued for the innovator's reference product. According to Alice Tseng, a lawyer and pharmacist at a major Canadian law firm, "[s]uch an interpretation would have resulted in innovators receiving protection analogous to patent protection from non-patent legislation." (*20) This concern was central in the court's reasoning.

The issue is bubbling in the innovative sector's cauldron. At a 2002 Pharmaceutical Conference, Murray Elston, President of Canada's Research-Based Pharmaceutical Companies (RX&D) complained, "…Canada still lags behind other countries in terms of pharmaceutical patents because Canada does not have: effective data protection on research…" Since NAFTA is TRIPS plus with respect to RDP and the Canadian regime passed NAFTA muster it should also pass TRIPS scrutiny. However, the decision was from a Canadian domestic court. Only a decision from a WTO Panel or its Appellate Body can give finality.

In an attempt to solidify and possibly increase RDP protection, the issue is featured prominently in regional and bilateral negotiations involving the U.S. Canada is an active participant in one such negotiation, the ongoing Free Trade Area of the Americas (FTAA) negotiations. The U.S. sees the FTAA as an opportunity to ensure that Canada, and the developing countries involved, more fully

(*19) See Ramlall – Oxford Dissertation for a thorough explanation of the regulatory process. I am grateful to officials of Health Canada for shedding light on the Canadian regulatory regime.

(*20) Tseng.

implement their TRIPS - RDP obligations, and possibly achieve TRIPS plus RDP levels. The U.S. is concerned with Canada because many Canadian innovative companies are subsidiaries of American corporations. Canada is also a developed country with a strong reputation on the international stage. As such, the U.S.'s principal concern is that if Canada does not fully implement the U.S. version of TRIPS - RDP provisions, a negative precedent could be set for other countries, especially developing and least-developed countries (LDCs). This was a motivating factor behind the U.S. WTO challenge of Canada's term of protection for certain patents. The E.U. has similar concerns with Canada, which also motivated their WTO challenge of Canada's pharmaceutical patent regime. RDP is of particular importance in many developing countries, which until 2000 did not have to provide patent protection for pharmaceuticals. Some developing countries (e.g., India) still benefit until 2005 under the TRIPS Article 65.4 transitional provisions. When combined with often-ineffective enforcement of IP rights in these countries, there remains a large pool of pharmaceutical products with minimal IP protection.

The U.S. has gone further than 'naming and shaming' countries perceived to have insufficient RDP protection in their annual Special 301 Reports. For instance, in May 1996, the U.S. filed a WTO dispute challenging Argentina's RDP regime. Developing countries have been fighting back, publicly putting forth their views both collectively and individually on their interpretation of TRIPS Article 39.3. For instance, during WTO discussions on the access to medicines issue, a submission from various developing countries indicated that TRIPS "clearly avoids the treatment of undisclosed information as a "property" and does not require granting "exclusive" rights to the owner of the data." (*21)

With the ostensible resolution of the access to medicine issue (resulting from the August 30, 2003 decision of the WTO General Council), (*22) the U.S. may be more likely to reinvigorate its emphasis on RDP. They may perceive the international environment to be less precarious and the leverage of the developing world to be diminished. If this comes to fruition, Canada may very likely find itself once again an unwilling party brought before the WTO dispute settlement system.

7. Regulatory Data Protection in Japan

Although Japan has not recently been singled out internationally (for instance, in the USTR Special 301 annual reports) its IP regime has not been immune from criticism. Criticism of Japan's RDP regime has diminished in view of the growing recognition that Japan has one of the stronger RDP regimes favouring innovative companies. The Japanese regime is convoluted. (*23) According to Trevor Cook, Japan provides indirect and *de facto* RDP by "conferring in favour of the first application for approval a period of effective regulatory exclusivity tied to post-marketing surveillance obligations." (*24)

Article 14 of Japan's Pharmaceutical Affairs Law provides for RDP. Japan employs a system of re-evaluation of drugs whereby the efficacy and safety of a drug, which has already been approved, is reconsidered on the basis of the current status of medical and pharmaceutical sciences. The re-examination period varies depending on the type of drug. During the re-examination period, a new applicant must provide its own data that is equivalent and comparable to that submitted by the applicant for the reference product. The purpose of the re-examination period is to allow monitoring for safety of the original drug. In practice, it is easier for a generic to obtain approval after the re-examination period, although in theory the approval process is similar.

The Japan Pharmaceutical Manufacturers Association (JPMA) and its members have been pushing for an increase in RPD and to make the regime more straightforward. (*25) They are pushing to have the term of protection increased from the general period for most drugs (i.e., 6 years) to 10 years. The JPMA has been negotiating with the MHLW for over 10 years. According to information gathered during my interviews with the JPMA and several innovative companies, the current period of protection is too short to secure their return on investment. As a result, some new drugs are not being brought to the market. With increased RDP protection, generics would also benefit by having more drugs to copy. The momentum favouring the Japanese innovative sector is the considerable push in the E.U. to harmonize the term of RDP protection for all national registrations. Not surprisingly, the Japanese innovative sector would like the same competitive advantage.

(*21) WTO Document IP/C/W/296 of 19 June 2001 at paragraphs 39-40.

(*22) WTO Document WT/L/540 of 1 September 2003. See also WTO General Council Chairperson's statement of 30 August 2003.

(*23) I am grateful to the various Japanese academics and all of the other individuals who shared their knowledge with me during my interviews for helping me to discern the Japanese regime.

(*24) Cook at 113.

(*25) Interviews with the JPMA and various Japanese innovative companies.

On December 17, 2003 the European Parliament approved the E.U. Medicinal Products legislation which includes changes to RDP. It is known as the '8 + 2' rule in that "[e]ight years is given for data protection, with 10 years marketing protection, extendable to 11 years if the product is found to bring a significant clinical benefit in comparison with existing therapies." (*26) In effect, innovative companies will be given exclusive rights over data they submit for regulatory approval for eight years after the drug goes on the market. In the subsequent two years, the data is available for generic companies to start preparing and registering equivalents. European innovative and generic companies viewed the legislation as an acceptable compromise. This piece of legislation is now with the E.U.'s Council of Ministers for final approval. With these recent developments in Europe, the JPMA and its members are likely to have further leverage in pushing for increased protection.

During my interviews with the JPMA and its members I noted that while the E.U. may be one basis for comparison, both the U.S. and Canada currently provide only 5 years of RDP. While the innovative sector in these countries would no doubt like to see such an increase, there is no imminent likelihood of such changes. In response, the JPMA and its members downplayed a North American comparison. Instead, they noted that American and Canadian innovative companies have another weapon, unavailable to their Japanese counterparts, in their arsenal to stave off generics. That weapon is a virtual automatic stay of proceedings upon launching certain proceedings under the U.S. Hatch-Waxman Act and under the Canadian NOC Regulations. In the U.S. a 30-month stay is obtained, whereas in Canada it is a 24-month stay. The availability, and frequency at which these proceedings are brought, draw the ire of Canadian generics. The JPMA and its members would also be hesitant to draw a comparison with Canada since it does not offer patent term restoration (as does the U.S. and Japan) or Supplemental Protection Certificates, which have similar effect in the E.U.

Nonetheless, the JPMA and its members have successfully convinced the Japanese government to actively study this issue with a view towards increasing protection. On July 8, 2003 the Intellectual Property Headquarters released a detailed blue-print for Japan to become "an intellectual property-based nation." One of the items discussed was to consider the reinforcement of the protection of pharmaceutical test data,

Considering the reinforcement of the protection of pharmaceutical test data

From the viewpoint of ensuring the quality, effectiveness, and safety of a new pharmaceutical after it has been placed on the market, the test data to be submitted for obtaining approval for a new drug from the Ministry of Health, Labor and Welfare is subject to a re-examination period of six years, which effectively protects the data from being used later for filing an application for equivalent drugs (generics) in a simplified manner. By the end of FY 2005, the GOJ will consider strengthening protection of such data in order to protect intellectual property and increase the incentive for the development of new drugs from broad perspectives, including the possibility of making the term of protection 10 years.

(Ministry of Health, Labor and Welfare and Ministry of Economy, Trade and Industry) (*27)

It is likely that such an increase is *faite accompli* given the language of the document, prevailing attitudes towards generic companies in Japan, and the relative small market share of Japanese generics.

Publicly, Japanese generics have voiced relatively quiet opposition to the proposed strengthening of RDP. For instance, on June 2, 2003 the Japan Generic Pharmaceutical Research Group announced, "[t]he 10-year data protection requested by the JPMA is substantially a system for extending a patent term and is a movement of eliminating generics…" (*28) It is apparent that Japanese generics have not fought this proposed increase as vehemently as their counterparts in Canada or the U.S. would have done. The reality is that Japanese generics are mostly small or medium sized entities that are not well organized. Collectively they are also not economically significant to the Japanese economy as their counterparts in Canada. According to information gathered during my interview with a Japanese generic, the generic sector occupies only about 10 - 20% of the market share for pharmaceuticals post expiration of patent protection (including the period of patent term restoration). In contrast, according to the Canadian generic association, the national share of generic prescriptions for the 12-month period ending June 2003 was 40.4%.

This passive resistance by the Japanese generic sector may reflect a certain degree of pragmatism. The government has a remarkable pro innovative sector bias. Thus, Japanese generics

(*26) European Parliament UK Office – Latest News, December 17th, 2003.

(*27) "Strategic Program for the Creation, Protection and Exploitation of Intellectual Property" by the Intellectual Property Policy Headquarters, July 8, 2003.

(*28) JPMA deck (undated) provided during JPMA Interview.

accurately understand that there is little they can do to alter the course, which has been set for increasing RDP. The generic sector in Japan has many grave concerns of its own with the existing pharmaceutical regime. Perhaps, their strategy is to concentrate on their existing concerns in the hope that the government might address at least some of them in the final package of amendments. One key frustration is that generic pharmaceuticals containing previously approved active ingredients are listed only once per year (in July) by the Japan's National Health Insurance (NHI) system. In contrast, newly approved innovators' drugs are added to the NHI price list four times annually. Effectively, through this administrative practice, the timely entry of generics into the Japanese market is delayed. (*29)

Unlike their Canadian counterparts, Japanese generics do not flaunt their successes, instead choosing to maintain a low profile, because of their 'shy' corporate culture. This mitigates the potential influence that the sector can exert on the government. In time, the importance of the generic sector will rise. The government of Japan, like those in many other developed countries such as Canada, is faced with increasing pressure from a rapidly ageing population and the associated rising cost of health care. A more viable Japanese generic sector could possible provide a much needed reprieve. At the judicial level, the tide may be turning in the Japanese generics' favour. In a relatively recent landmark decision of the Japanese Supreme Court, Japanese generics scored an important victory over innovative companies. (*30)

8. Conclusion

RDP is becoming increasingly entrenched as a core category of IP rights. Clearly much has changed from the not so distant past, when the hotly contested question was whether to include RDP into the TRIPS Agreement during the Uruguay round of negotiations. The debate has progressed to what level of RDP is appropriate in the context of ensuring the 'right' balance between the rights of innovators and those of society to health at affordable prices.

While both Canada and Japan provide for RDP, the effectiveness and level of protection varies considerably. The strategic importance of studying Canada's RDP regime lay not only in the economic value of its market as a nation with a strong tradition of an emphasis on health care, but the precedent it could set for developing and LDC countries. Japan served as unique case study of a nation where its leaders, including the Prime Minister, see IP (and RDP in particular) as a critical tool to improve their international competitiveness and to promote national economic growth.

Despite the importance of RDP to the pharmaceutical industry in Canada and Japan, there has been surprisingly minimal discussion in the scholarly literature. This paper contributes to a better understanding of the current RDP regimes in Canada and Japan. It also serves a prospective role by analyzing the impact of impending developments. More importantly, the paper stimulates further discussion on what should be the appropriate levels of RDP in Canada and Japan in the face of mounting pressures to increase protection from domestic and foreign stimuli.

(*29) Interview with Norio Yamamoto.

(*30) Judgment of the Japanese Supreme Court, Date of Judgment, 1999.4.16, Case No. 1998 (Ju) No. 153. Translation by Sir Ernest Satow.

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