WORLD TRADE ORGANIZATION

WT/DS114/R
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CANADA – PATENT PROTECTION OF PHARMACEUTICAL PRODUCTS

Complaint by the European Communities and their member States

Report of the panel (EXCERPTS[1])

I. INTRODUCTION

On 19 December 1997, the European Communities and their member States requested Canada to hold consultations pursuant to Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) and Article 64 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) regarding the protection of inventions in the area of pharmaceuticals under the relevant provisions of the Canadian implementing legislation (in particular the Patent Act) in relation to its obligations under the TRIPS Agreement (WT/DS114/1). No mutually satisfactory solution was reached in these consultations, held on 13 February 1998 and 12 June 1998. The European Communities and their member States requested the Dispute Settlement Body (DSB), in a communication dated 11 November 1998, to establish a panel to examine the matter (WT/DS114/5). At its meeting of 1 February 1999, the DSB agreed to establish a panel with standard terms of reference in accordance with Article 6 of the DSU. Australia, Brazil, Columbia, Cuba, India, Israel, Japan, Poland, Switzerland, Thailand and the United States reserved third party rights.

Terms of reference

"To examine, in the light of the relevant provisions of the covered agreements cited by the European Communities and their member States in document WT/DS114/5, the matter referred to the DSB by the European Communities and their member States in that document and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements."

Composition

Chairman: Mr. Robert Hudec
Members: Mr. Mihály Ficsor,
Mr. Jaime Sepúlveda

[1] Original text: 215 pages. This version prepared by Prof. D. Gervais for teaching purposes only. Footnote numbers etc. do not match original text. Claims under the GATT 1994 (esp. Art III:4) and procedural claims were purged from the text. Deletions are not shown.

II. FACTUAL ASPECTS

(a) Relevant Provisions of Canadian Patent Law

For the purposes of the case in hand, the main provisions of Canadian patent law which are of relevance to the case in hand stipulate the following:

> Patent Act, Section 55.2(1). "It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product."
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> Patent Act, Section 55.2(2). "It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires."
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> Patent Act, Section 55.2(3). "The Governor in Council may make regulations for the purposes of subsection (2), but any period provided for by the regulations must terminate immediately preceding the date on which the term of the patent expires."
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> Patent Act, Section 55.2(4). "The Governor in Council may make such regulations as the Governor in Council considers necessary for preventing the infringement of a patent by any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) or (2) including, without limiting the generality of the foregoing, regulations
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> > *(a)* respecting the conditions that must be fulfilled before a notice, certificate, permit or other document concerning any product to which a patent may relate may be issued to a patentee or other person under any Act of Parliament that regulates the manufacture, construction, use or sale of that product, in addition to any conditions provided for by or under that Act;
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> > *(b)* respecting the earliest date on which a notice, certificate, permit or other document referred to in paragraph *(a)* that is issued or to be issued to a person other than the patentee may take effect and respecting the manner in which that date is to be determined;
> >
> > *(c)* governing the resolution of disputes between a patentee or former patentee and any person who applies for a notice, certificate, permit or other document referred to in paragraph *(a)* as to the date on which that notice, certificate, permit or other document may be issued or take effect;
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> > *(d)* conferring rights of action in any court of competent jurisdiction with respect to any disputes referred to in paragraph *(c)* and respecting the remedies that may be sought in the court, the procedure of the court in the matter and the decisions and orders it may make; and
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> > *(e)* generally governing the issue of a notice, certificate, permit or other document referred to in paragraph *(a)* in circumstances where the issue of that notice, certificate, permit or other document might result directly or indirectly in the infringement of a patent."
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> Patent Act, Section 55.2(5). "In the event of any inconsistency or conflict between

(a) this section or any regulations made under this section, and
(b) any Act of Parliament or any regulations made thereunder,
this section or the regulations made under this section shall prevail to the extent of the inconsistency or conflict."

Patent Act, Section 55.2(6). "For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent."

Manufacturing and Storage of Patented Medicines Regulations. By virtue of these Regulations, "the applicable period referred to in subsection 55.2(2) of the *Patent Act* is the six month period immediately preceding the date on which the term of the patent expires."

(b) Canada's Regulatory Review System for Drugs

Under Canada's *Food and Drugs Act*, a "new drug" is defined in Section C.08.001 of the Food and Drug Regulations as a drug which contains a substance which has not been sold in Canada for a sufficient time and in sufficient quantity to establish its safety and efficacy. Thus, "newness" is not tied to novelty, and the category of "new drugs" includes both novel products (such as a drug that has had its novelty and utility recognized by the grant of a patent) as well as drugs that are not novel but are "new" in the sense that the particular version of the drug has not been previously marketed (as in the case of a competing or generic version of a drug that has the same properties as another version, whether patent-protected or not, that has been previously marketed).

Subject to the distinctions described below, the same requirements of the *Food and Drug Regulations* apply to the manufacture and control of the active ingredient and the dosage form of a drug regardless of whether the application for regulatory review relates to a patented or generic product. Both products are treated as a "new drug" because a generic is equivalent, not identical, to the patented drug it replicates. It contains the same active ingredient as the patented drug but its dosage formulation (including the filler, binding agent and coating) usually differs.

- The application contains details on the facilities, method of manufacture and controls to be used in the manufacture, preparation and packaging of the new drug, details of the tests applied to control the purity, stability and safety of the new drug, and evidence that all test batches of the new drug used in any studies included in the submission were manufactured and controlled in a manner that is representative of market production.

- The major difference between a submission for a new active substance (patented product) and a generic product is the data required to establish the safety of the new drug and its clinical effectiveness for the purpose and under the conditions of use recommended.

- For a new active substance, extensive pre-clinical testing is conducted, including pharmacological evaluation and toxicity testing (acute, subchronic, chronic toxicity, carcinogenicity and reproductive studies) in animals. Clinical studies range from early tolerability studies and pharmacokinetic studies to extensive trials in patients to establish clinical safety and efficacy.

- For a generic drug, evidence of clinical safety and effectiveness may be established by comparative studies with another, usually an innovator's (patented) product, i.e. the "Canadian Reference Product" identified in section C.08.001.1 of the Food and Drug Regulations. Pharmaceutical equivalence (identical amounts of active ingredients, in comparable dosage forms) and bioequivalence (therapeutic equivalence) based on pharmaceutical and, if

necessary, bioavailability (rate of absorption of the active ingredient in the human body) characteristics, must be demonstrated.

- Comparative bioavailability studies are normally conducted by measuring the level of the drug in the blood of healthy human volunteers with each "study subject" (i.e. volunteer) receiving both the original brand and the new generic brand on two separate occasions. The generic drug must be demonstrated to deliver the same amount of active ingredient at the same rate as the original brand. The number of volunteers required for a study depends on the characteristics of the drug product under study. On this basis the therapeutic effects of the two products should be the same since the effect of a drug depends on the levels of the medicinal ingredient(s) in the body.

- Some products may not be suitable for comparative bioavailability testing. In these cases, other methods, such as comparing the clinical or pharmacodynamic effects of the generic drug with the original brand, may be used. Generic drugs that are solutions and are administered by direct injection into the blood stream are not suitable for a comparative bioavailability study, because the rate and extent at which the medicinal ingredients enter the body are not dependent upon the formulation. Products applied topically to the skin may likewise not be suitable for comparative bioavailability testing.

- Additional information respecting safety and effectiveness of the generic drug may be required depending on the results of the evaluation of the above information.

The regulatory review procedure is time consuming. It may take from one to two-and-a-half years to complete. However, prior to this period, a generic manufacturer will have spent from two to four years in the development of its regulatory submission. Thus, the overall time required for a generic manufacturer to develop its submission and to complete the regulatory review process ranges from three to six-and-a-half years. After the development of its regulatory submission, the generic manufacturer will file an Abbreviated New Drug Submission ("ANDS") with Health Canada. The generic manufacturer files an ANDS because, typically, it is relying on comparative studies to a drug product that has proven to be safe and effective. An innovator, on the other hand, would file a New Drug Submission, since it must provide full pre-clinical and clinical data to establish the safety and efficacy of the drug in question. For an innovator, it takes approximately eight to 12 years to develop a drug and receive regulatory approval, which takes place during the 20-year patent term. The resulting period of market exclusivity under the current Canadian Patent Act varies from drug to drug. Estimated averages, at the time that the Act came into force, range from eight to ten years, according to the Pharmaceutical Manufacturers Association of Canada (PMAC), or 12 to 14 years, according to the Canadian Drug Manufacturers Association (CDMA).

III. FINDINGS AND RECOMMENDATIONS REQUESTED BY THE PARTIES

The European Communities and their member States requested the Panel to make the following rulings, findings and recommendations:

I. Section 55.2(2) and 55.2(3) of the Patent Act together with the Manufacturing and Storage of Patented Medicines Regulations

Article 28.1 together with Article 33 of the TRIPS Agreement

(a) That Canada, by allowing manufacturing and stockpiling of pharmaceutical products without the consent of the patent holder during the six months immediately prior to the expiration of the 20-year patent term by virtue of the provisions of Section 55.2(2) and 55.2(3) of the Patent Act together with the Manufacturing and Storage of Patented Medicines Regulations, violated its obligations under Article 28.1 together with Article 33 of the TRIPS Agreement.

Article 27.1 of the TRIPS Agreement

(b) That Canada, by treating patent holders in the field of pharmaceutical inventions by virtue of these provisions less favourably than inventions in all other fields of technology, violated its obligations under Article 27.1 of the TRIPS Agreement requiring patents to be available and patent rights enjoyable without discrimination as to the field of technology.

II. Section 55.2(1) of the Patent Act

Article 28.1 of the TRIPS Agreement

(c) That the provisions of Section 55.2(1) concerning activities related to the development and submission of information required to obtain marketing approval for pharmaceutical products carried out without the consent of the patent holder violated the provisions of Article 28.1 of the TRIPS Agreement.

Article 27.1 of the TRIPS Agreement

(d) That Canada, by treating patent holders in the field of pharmaceutical inventions by virtue of these provisions less favourably than inventions in all other fields of technology, violated its obligations under Article 27.1 of the TRIPS Agreement requiring patents to be available and patent rights enjoyable without discrimination as to the field of technology.

Canada requested the Panel to reject the complaints of the European Communities and their member States on the basis of the following findings:

Section 55.2(1) and 55.2(2) of the *Patent Act*

Section 55.2(1) and 55.2(2) of the *Patent Act* conform with Canada's obligations under the TRIPS Agreement, because:

(a) Each of these provisions is a "limited exception" to the exclusive rights conferred by a patent within the meaning of Article 30 of the TRIPS Agreement;

(b) Neither of these provisions discriminates, within the meaning of Article 27 of the TRIPS Agreement, as to the field of technology in which any relevant invention occurs or has occurred, because:

- the prohibition in Article 27.1 against discrimination on the basis of field of technology does not apply to allowable limited exceptions;

or, if the Panel were to find Article 27.1 applicable, because:

- the limited exceptions of Section 55.2(1) and 55.2(2) are not expressly related to any particular field of technology;

(c) Neither of these provisions reduces the minimum term of protection referred to in Article 33 of the TRIPS Agreement to a term that is less than that minimum.

The **European Communities and their member States**, in support of their claims, advanced information of the economic losses suffered by their pharmaceutical industry from the effects of Sections 55.2(1) and 55.2(2) of the Patent Act together with the Manufacturing and Storage of Patented Medicines Regulations. The European research-based pharmaceutical industry (EFPIA) had made an analysis of its alleged losses suffered in Canada, which exceeded the amount of C$ 100 million per year. This analysis was based on the conservative assumption that, while the operation of the provisions referred to above would allow copy manufacturers to market the product immediately upon patent expiry, in the absence of these provisions effective marketing would only be possible at the earliest two years after patent term expiry. The extrapolation was based on sales of the top 100 original pharmaceutical products sold in Canada between 1995 and 1997.

ARTICLE 30 OF THE TRIPS AGREEMENT

In respect of Article 30 of the TRIPS Agreement, the **European Communities and their member States** initially took the position that, while Canada, during the formal consultations under the DSU, had invoked Article 30 of the TRIPS Agreement to justify the measures at issue, it had done so in a rather summary and rudimentary manner. Therefore, the EC limited itself in its first written submission in this regard to stating that their view was that the Canadian measures could not be justified under Article 30, because the conditions set out in this provision were not met: the curtailment of patent rights under Canadian legislation did not constitute "limited exceptions to the exclusive rights conferred by a patent". Furthermore, the exceptions unreasonably conflicted with a normal exploitation of a patent and unreasonably prejudiced the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. In any event, a violation of Article 27.1 of the TRIPS Agreement could not be justified under Article 30.

Canada, in response, submitted that:

(1) Canada's exceptions to the exclusive rights conferred by a patent were "limited exceptions" within the meaning of *Article 30 of the TRIPS Agreement*, because they:

did not conflict in any mode or manner with the "normal exploitation" of a patent;

they did not prejudice, or if they did, they did not "unreasonably prejudice" the "legitimate interests" of a patentee taking account of the "legitimate interests" of third parties; and

the third party interests that the exceptions took account of were "legitimate interests" of relevant third parties.

(2)(a) the prohibition in *Article 27.1 of the TRIPS Agreement* against discrimination on the basis of field of technology did not apply to allowable limited exceptions;

(2)(b) in any event, Canada's limited exceptions to the exclusive rights conferred by a patent did not discriminate as to the field of technology in which an invention occurred, because they related to products that were subject to laws regulating the manufacture, construction, use or sale of a product and were not expressly related to any particular field of technology; and

(3) as regards *Article 33 of the TRIPS Agreement*, Canada's limited exceptions to the exclusive rights conferred by a patent did not reduce the term of protection accorded to a patent, because they did nothing to impair a patentee's right to exploit its patent for the full term of protection by working the patent for its private commercial advantage.

Canada argued that the essential question in these proceedings was whether the provisions of Section 55.2(1) and 55.2(2) were "limited exceptions to the exclusive rights conferred by a patent", within the meaning of Article 30 of the TRIPS Agreement. According to Canada, these two measures:

(a) were "limited exceptions" within the meaning of Article 30, since they allowed patent owners complete freedom to exploit their rights throughout the full term of patent protection, leaving the monopoly of commercial exploitation and the exclusivity of economic benefits unimpaired for the life of the patent;

(b) did not conflict with a normal exploitation of a patent or prejudice the legitimate interests of the patent owner, since they only affected the patent owner's commercial exploitation *after* the patent had expired;

(c) in any event, took into account Canada's national interest in measures conducive to social welfare and the achievement of a balance between rights and obligations, both of which were recognized objectives in Article 7 of the TRIPS Agreement; and

(d) in particular, as required by Article 30, took account of the legitimate interests of third parties, in that:

- they allowed potential competitors to compete freely with the patentee after the patent expired, consistent with the policy of full competition underlying the requirement of Article 29 that, in return for the grant of patent protection, patentees must disclose their inventions to the public; the provision of Article 33 that the exclusive rights be conferred for a specified term only; and the authorization in Article 40 of national measures to prevent abuse of intellectual property rights having an adverse effect on competition; and
- they sought to protect public health - a value recognized in Article 8.1 of the TRIPS Agreement - through promoting access to cost-effective generic medicines following patent expiry and, in this connection, they took into account the legitimate interests of individuals, private insurers and public sector entities that financed health care in maintaining access to affordable medicines.

According to Canada, Article 30 allowed uses that did not unreasonably conflict with a normal exploitation of the patent or unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. Canada submitted that Article 30 therefore authorized measures that limited exclusive rights, provided that no commercial exploitation - i.e. sales - took place during the patent term. Any other interpretation would:

- ignore the existence of the word "unreasonably" in Article 30 and, thereby, the fact that conflicts with normal exploitation and prejudice to the patent owner's interests *were* allowed;
- disregard the public policy principles inherent in Articles 29 and 33, which encouraged free and open competition with the patent owner immediately upon expiry of the patent; and
- as a consequence, where regulatory review delayed the entry of competing products on the market, promote the practice of enforcing patent rights within the patent term so as to extend the monopoly of the patent owner beyond the term, a policy which the European Communities and their member States had sought to have included in the Agreement, but which had *not* been so included, i.e. as the European Communities and their member States made plain in their first written submission, they sought to win through litigation the windfall period of protection that they could not secure by negotiation.

The extent or scope of the exceptions authorized by Article 30 were only restricted by the requirements that:

(a) they must be "limited";

(b) they must not "unreasonably conflict with a normal exploitation of the patent [...] taking account of the legitimate interests of third parties"; and

(c) they must not "[...] unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".

Canada argued that the exceptions created by subsections 55.2(1) and (2) of its *Patent Act* met each of the above requirements, for the following reasons.

- Canada's measures were "limited" within the ordinary meaning of that word.[2] The early working exception was restricted to the narrow circumstance where a third party made, constructed, used or sold a patented invention solely for purposes reasonably related to regulatory review. The stockpiling exception could only be used by the person who had relied on the first exception, and was limited to the last six months of the relevant patent. Neither measure affected commercial sales by the patent holder during the term or any other economic benefit of a patent, such as the profit that could be earned through licensing royalties or the sale of the right.

- Subsection 55.2(1) permitted a third party to use a patented invention without infringement liability only where the third party made, constructed, used or sold a patented invention solely for uses of the invention that were reasonably related to the development and submission of information required under any law that regulated the manufacture, construction, use or sale of a product to which the invention related. (The reference to selling the invention was necessitated by the fact that a generic drug manufacturer had to usually purchase the active ingredient for its product from a fine chemical producer. Other technical "transfers" made in the course of a regulatory review submission would include administration of the drug to test subjects and use of an outside laboratory for priority testing.)

- Subsection 55.2(2) permitted only the third party who made, constructed, used or sold a patented invention, in the manner contemplated by subsection 55.2(1), to make, construct or use the invention without infringement liability during the last six months of the patent term only for the purposes of the manufacture and storage of articles intended for sale after the date on which the term of the patent expired.

- The legitimate interests of a patent owner must, by definition[3], be interests that related to the rights and duties that the patent laws conferred or imposed, as the case might be, on persons who had developed or subsequently acquired a patentable invention. In other words, legitimate interests arose from the status of being a patent holder, not from the more general status of being a business person or a manufacturer. Thus, in return for disclosing an invention to the public and obtaining the grant of a patent, a patent holder had a legitimate interest in exploiting and enforcing for the duration of the term of protection the exclusive right to "work" the patent as a monopolist and to earn the economic returns that rewarded inventive activity and investment. After the term of protection expired, however, the interest in exploiting the invention could no longer be that of a monopolist. Instead, the interest was reduced to: (a) the right to compete on the open market; (b) any trademark interest in the

[2] According to *The New Shorter Oxford English Dictionary*, p. 1592, confined within definite limits; restricted in scope, extent, amount.

[3] "Legitimate: ... Conformable to law or rule; lawful, proper" (*New Shorter Oxford English Dictionary*, p. 1563)

brand name, which subsisted after patent expiry; (c) any right to prevent "passing off" at common law; and (d) any copyright interest in materials describing the product. None of these interests pertained to patent protection and none was affected by Canada's limited exceptions.

- Since the exceptions created by subsections 55.2(1) and 55.2(2) did not conflict with the normal exploitation of the patent during the term of protection, they did nothing to prejudice the legitimate interest of the patent owner in respect of the right to exploit the patent for the full duration of its term of protection. Similarly, since they did not impair a patentee's right to bring infringement proceedings at any time during the term of protection to restrain others from making any commercial sale of the patented invention, they did nothing to prejudice the patent owner's legitimate interest in prohibiting commercial exploitation during the term of protection.

- The interest that a patentee could have in restraining, during the term of protection, the activities that were sheltered from infringement liability by subsections 55.2(1) and 55.2(2) involved exploiting regulatory review laws which delayed the market entry of competitor products subject to those laws, in order to extend the patentee's monopoly beyond the term of protection specified by the patent law. As was apparent from their submission, it was that windfall period of protection that the European Communities and their member States asserted here. Such gratuitous distortion of the competitive market could not be said to be a legitimate interest. That interest could not be said to be legitimate, because by treaty and domestic law prescription, patents only conferred exclusive rights for a specified term. When the prescribed term expired, so did the exclusive rights. Accordingly, and notwithstanding the private economic advantage that would be obtained by doing so, a patentee could have no legitimate interest deriving from patent law in exercising its exclusive use and enforcement rights within the term of protection to achieve, through exploitation of regulatory review laws, a de facto extension of that term of protection beyond the prescribed period, thereby unilaterally altering the bargain between the patentee and society. In this respect, the interests of a patentee of a pharmaceutical invention could be no different from those of patentees in other fields of technology.

Section 55.2(1) and 55.2(2) took account of the legitimate interests of third parties

- If, however, a patentee's "normal exploitation" involved more than working the patent for commercial gain, or if the patentee's "legitimate interest" included exercising its exclusive rights during the term so as to extend the term unilaterally beyond the period specified by statute, neither the exploitation nor the interest was affected unreasonably by the disputed measures, "taking account of the legitimate interests of third parties".

- In this context, "third parties" had to be a reference to those who were adverse in interest to the patent owner. Persons not adverse in interest, such as licensees, were already covered by the protection that was extended to the patent owner. Consequently, "third parties" had to mean all those who, not having a property interest in the patent, had an interest in the availability, consumption, cost or production of regulated products that were subject to the protection of a patent. Thus "third parties" included society at large, individual and institutional consumers of such regulated products and would-be competitor producers of those products. In the particular case of pharmaceutical products, the "third parties" included the individual users of Canada's health care system and the public and private sector entities that paid for it.

- This reading of Article 30 was the one that gave proper effect to its terms in the context in which they were found. The TRIPS Agreement as a whole was framed so as to achieve balance between competing interests, and to ensure that the assertion of patent rights did not prevent the realization of other important societal objectives. As stated in the first

recital of its Preamble and in the objectives endorsed by its Article 7, the TRIPS Agreement was not intended to promote patent rights at the expense of legitimate trade, social and economic welfare, and the rights of others. In order to achieve the desired balance, these latter interests had been recognized in the reference in Article 30 to "third parties".

- The interests of these third parties were that the exclusive rights granted to patentees for a specified term of protection would be extinguished on the expiry of that term and that competitive conditions would thereafter govern the operation of the previously monopolized market for the regulated products at issue. The interest in the reinstatement of competition was not merely a "legitimate interest", it was a right which derived from the first principles of patent law. As stated in a report to Congress by the United States House of Representatives Committee on Energy and Commerce: "[T]he Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. That limited time should be a definite time and, thereafter, immediate competition should be encouraged."[4]

- Third parties therefore had an undeniably legitimate interest in measures which ensured that patent rights were not exercisable in a manner that effectively extended the term of protection sanctioned by statute, thereby giving the former patentee a gratuitous monopoly and restraining trade unreasonably in the post-expiry market.

- In this regard, it was significant that Articles 8.2 and 40 acknowledged that Members could invoke measures to control the abuse of patent rights by curtailing, whether by compulsory licence or revocation, the patent right for some or all of the remainder of its term of protection. Where such measures could be taken consistently with the Agreement to control the exercise of intellectual property rights that had an abusive or anti-competitive effect during the term specified for their protection, then *a fortiori* similar measures, which did not conflict with a normal exploitation of the patent, could also be taken consistently with the Agreement to prevent the anti-competitive effects of the patent after its term of protection had expired.

- The legitimacy of the third party interest in the adoption of measures like those enacted by Section 55.2 to counteract the post-expiry monopoly for regulated products was particularly pronounced in the cases of both users and payers of health care products. Public health was a value whose importance was recognized as a matter of principle in Article 8.1 of the TRIPS Agreement. Accordingly, the exercise of exclusive rights in respect of regulated health care products during the term of protection to extend the patentee's monopoly into the post-expiry market was of particular concern in the pharmaceutical products sector: "It is generally accepted that the scope and duration of the patent monopoly must be limited, because monopolies are inherently economically inefficient. A monopolist profits by reducing output below competitive levels and correspondingly raising the price, causing a "deadweight loss" to society. In the pharmaceutical context, outside the patent term, a monopoly would mean that the quantity of drugs available to society would be less than optimal, due to sales at prices considerably higher than marginal cost."[5]

- The cost of health care was a major concern for all WTO Member countries. A significant component of health care costs was the expense of drug therapies. Most Members, including both parties to this dispute, had taken positive measures to contain those costs, including direct price controls and incentives to encourage the use of generic drugs. The latter were particularly relevant here, since the creation of sophisticated and technical review requirements had meant that the only way to ensure a supply of generic drugs in the market as

[4] Harold C. Wegner. *Patent Law in Biotechnology, Chemicals & Pharmaceuticals* (2nd ed.), Stockton Press (N.Y.:1994), p. 475.

[5] Ben Hattenbach. "GATT, TRIPS and the Small American Inventor: an Evaluation of the Effort to Preserve Domestic Technological Innovation" (1995), 10 *Intellectual Property Journal* 61 at p. 95

soon after patent expiry as possible was through an exception to the patent monopoly for purposes related solely to the development of information required to obtain marketing authorization for competitive versions of a patented product.

- The use of generic medicines resulted in important economies for the public health care system, and so contributed to its viability and the protection of public health. In view of this, it was not surprising that Members had pursued a wide variety of measures to promote the use of generic drug products: "The actual level of growth of the generic market is becoming increasingly influenced by regulatory measures being introduced by governments and other payers for health care aimed either at forcing or encouraging the increased use of generic products. These measures have been introduced in response to the rising costs of health care in the major markets."[6]

- Measures that sought to control the costs of the health care system and to ensure access to needed drug therapies were obviously conducive to social welfare. As such, they could properly be adopted by Members pursuant to Article 30, as a means of achieving the balance contemplated by Article 7. In the post-expiry market, the interests of consumers and payers in ensuring access to less costly generic drugs were legitimate and important, while a patentee's interest in extending the period of monopoly was not one that was recognized in the TRIPS Agreement, let alone sanctioned as legitimate.

- The legitimacy of measures to promote the use of generic drug products as means of protecting public health was endorsed by the World Health Organization (WHO).

- Canada had introduced provisions into its *Patent Act* for compulsory licensing for the domestic manufacture of patented food and medicine products in 1923.[7] In 1969, the original compulsory licensing provisions had been expanded to allow the importation of the active ingredients for licensed patented drug products.[8] The Act had again been amended in 1987 to suspend the operation of a compulsory licence to prohibit the importation or the manufacture of the medicine for sale consumption in Canada for periods ranging from seven to ten years, measured from the date of the Notice of Compliance (marketing authorization) first issued in Canada on the medicine.[9] This compulsory licensing system was consistent with the international rules respecting intellectual property rights established by the *Paris Convention*.

- By providing competition for patented medicines during the term of protection, the compulsory licensing system had become an important policy tool for cost containment in Canada's public health care system during this period. It had been estimated that, during its currency, compulsory licensing saved Canadian consumers of prescription medicines and the third parties who might have paid for them many millions of dollars each year in health care costs by opening the market to competitively priced medicines *during* the period of patent protection.

- During the Uruguay Round, a major objective of many participants had been the elimination of the compulsory licensing provisions respecting patented foods and medicines in national intellectual property laws.

- In December 1991, the Dunkel [draft] text[10] of the TRIPS Agreement had been released in connection with the Uruguay Round. Canada, the United States and Mexico, who

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[6] Amanda Southworth, *Generic Pharmaceuticals* (1996 ed.), a Financial Times Management Report, p. 9

[7] S.C. 1923, Chap. 23, s. 17

[8] S.C. 1968-69, Chap. 49

[9] S.C. 1987, Chap. 41, adding sections 41.11 and 41.14. These amendments also established the Patented Medicines Price Review Board.

[10] MTN.TNC/W/FA, dated 20 December 1991.

were negotiating the *North American Free Trade Agreement* (NAFTA) at the time, all anticipated that the Dunkel text would become the new international standard for patent protection. Consequently, they had incorporated its substance, particularly as regards patents, into Chapter 17 of NAFTA.

- The Dunkel text restricted the ability of states to adopt compulsory licensing measures. Specifically, Article 31 confined their grant to particular individual circumstances or as a remedy for anti-competitive practices.[11]

- It had been anticipated that the TRIPS Agreement would come into force before NAFTA[12], which was scheduled to take effect on 1 January 1994.[13] Accordingly, the Government of Canada had, in June 1992, introduced the *Patent Act Amendment Act, 1992* (Bill C-91) in Parliament in order to ensure that Canada's patent law would conform with its international obligations when they came into force.

However, Bill C-91 also pursued other public policy objectives. One such objective was to find another policy tool to address cost containment in the health care system, to the extent permitted under Canada's new obligations. This objective had arisen out of the concern that expenditures on therapeutic drugs had been rising steadily for several years, and had been becoming very significant. In 1975, the annual cost had been $1.1 billion, but by 1992-93 it had risen to $8.6 billion. Consequently, the Government had determined that, while providing the level of patent protection contemplated by the international treaties, it should also enact measures to provide balance in the post-expiry market, as contemplated by Articles 7 and 30 of the TRIPS Agreement, to address the concern about the costs to the health care system that such enhanced protection would entail.

Australia also provided an overview of how it saw that national patent laws had developed over the years and, in doing so, advanced the following points:

- Contemporary patent law, exemplified by the wide range of standards established and affirmed by the TRIPS Agreement, was the product of centuries of steady evolution of law at the national level. The patent system had always aimed to define, safeguard and bound private patent rights so as to promote common benefits and the mutual advantage of the state, innovators and entrepreneurs, and the general public. The TRIPS Agreement established international minimum standards in areas of substantive intellectual property law that had hitherto been largely the province of national law making. One of the key interpretive questions in applying the TRIPS Agreement to the present case was therefore how existing municipal patent law should be taken into consideration.

- Obligations under the TRIPS Agreement should be interpreted according to the *Vienna Convention on the Law of Treaties* rather than by reference to any one national system, practice or tradition. However, given the absence of directly applicable international jurisprudence and any subsequent agreement between the relevant parties, it was appropriate to consider how patent law had developed at a national level and how it applied to the issues at stake, as this illustrated both the context of the provisions of the TRIPS Agreement in question, and the overall object and purpose of the TRIPS Agreement. The conferring of an exclusive private right, of fixed duration, in order to serve the broader public good, was a consistent feature of patent law, dating back, for example, to a 1474 statute prohibiting the

[11] In conjunction with Article 5A of the *Stockholm Act, 1967* of the *Paris Convention*, which was incorporated by reference in Article 2.1 of the Dunkel text

[12] However, the Uruguay Round was not concluded until the Marrakesh Agreement was signed, on 15 April 1994. The TRIPS Agreement did not come into effect (for developed countries) until 1 January 1996.

[13] NAFTA was concluded on 17 December 1992, but under Article 2203 would not come into effect until 1 January 1994: "This Agreement shall enter into force on January 1, 1994, on an exchange of notifications certifying the completion of necessary legal procedures."

manufacture in Venice[14] of any 'new and ingenious device' other than by its originator, so that more would "apply their genius, discover and build devices of great utility and benefit"; similarly, the English Statute of Monopolies of 1623 allowed limited-term exclusive rights for the "sole working or making of any manner of new manufacture".[15] Patents functioned, in effect, as a contract between the State and the inventor.

- The "balance of interests" noted in Article 7 of the TRIPS Agreement was found in this fundamental principle: an exclusive right to limit others' use of the invention was balanced by "consideration moving to the public", namely the making available of new technology for the benefit of the public and the full disclosure of the invention to the public. A new technology came into existence and was added to the common pool of knowledge; and the inventor, in exchange, had an exclusive limited opportunity to exploit the patent for financial reward. The TRIPS Agreement recognized that the need for this balance extended across borders, acknowledging the trade-distorting effects of insufficient or inappropriate protection of IP rights, and the impact of uneven or inconsistent forms of protection.

- A further important element of the patent system was that it was broad and comprehensive in reach. The patent system functioned to promote innovation and investment in new technologies, and did not generally operate as a means of regulating the use of such technologies (which was the subject of specific regulations, such as those governing health, safety and the environment). The patent system's overall public policy objectives would be compromised if the scope of patentable subject-matter were to be unduly restricted. These considerations were behind the general trend in patent law to define patentable inventions very broadly, and then to set out limited exceptions to this scope - such as exceptions based on *ordre public* or morality.[16] This trend towards comprehensiveness of subject-matter was reflected in Article 27.1 of the TRIPS Agreement, which provided that patent rights be "enjoyable without discrimination as to […] the field of technology".

Brazil could not agree with the reasoning of the European Communities and their member States that the subsections 55.2(1) and 55.2(2) of the Canadian Patent Act, laying down certain exceptions to the rights of patent holders, violated three provisions of the TRIPS Agreement, namely Article 27.1, Article 28.1 and Article 33, and that could not be justified under Article 30 of the Agreement. According to Brazil, *Article 30 served the purpose of striking a balance between private and public concerns* and Canada had made use of this provision without trespassing the limits established therein.

Brazil took the view that *the notion of balance was of paramount importance in the TRIPS Agreement*. On the one hand, there were the legitimate interests of the patent holders, the producers of technology who played an essential role in the process that led to economic development. The patent system could not be understood other than as a means of granting, for a limited period of time, adequate compensation for the investment made by inventors, as well as of providing an incentive for further research in the attempt to develop new creations. On the other hand, there was the consumer side, represented by the beneficiaries of these inventions, the society as a whole, whose interests were to be considered by governments. This relation was clearly depicted in Article 7 of the TRIPS Agreement.

According to Brazil, one possible way of achieving the balance in the case of patents could be *to avoid that the period of protection extended beyond the 20 years prescribed in Article 33 of the TRIPS Agreement*. As argued by the European Communities and their member States, in the absence of the measures provided for in the Canadian legislation, effective marketing would only be possible at the earliest two years after patent expiry. If it was true that there was no maximum term for patent protection prescribed in the TRIPS Agreement, it was also right to state that *Members were not*

[14] Patent statute of 1474, quoted in Mandich, *Venetian Patents (1450-1550)* (1948) 30 JPOS 166 at 1776-177
[15] Statute of Monopolies, 1623, 21 Jac. I c.3
[16] Article 27.2 of the TRIPS Agreement

obliged to extend protection to patents beyond the 20-year time-limit. As a consequence, *the Canadian legislation aimed at avoiding any de facto extension of the term of protection*, thus allowing the market to establish new and lower price levels for generic drugs, immediately after the expiry of the 20-year period. Furthermore, *the argument used by the EC when referring to economic losses incurred by right holders after expiry of the 20-year term of protection seemed to lack a sound legal basis, as no exclusive right - here translated into monopolistic revenue - could possibly be claimed under the TRIPS Agreement after the period of patent protection had expired*. Legitimizing any such claim would necessarily create a spillover effect regarding the patent holder's rights, when this de facto extension of the term of protection was not compulsory under the TRIPS Agreement - right on the contrary, one could contend that Canada was providing a fair implementation of the TRIPS Agreement by building a legal wall around the rights of the patent holder so that they did not spill over beyond the 20-year term. Conversely, the EC seemed to understand that Members had to apply, in practice, a minimum average period of 22 years of protection, from the filing date - or even a lengthier time-period (considering that Canada had referred to a period of three to six-and-a-half years instead of the minimum of two years referred to by the EC).[17] Clearly, this represented neither the spirit nor the letter of the TRIPS Agreement.

According to **India**, the central question before the Panel was therefore whether the provisions of Section 55.2(1) and 55.2(2) of the Canadian *Patent Act* were limited exceptions to the exclusive rights conferred by a patent within the meaning of Article 30 of the TRIPS Agreement. At issue was the question of balance in the TRIPS Agreement between exclusive rights conferred on the owner of a patent and recognized exceptions to those rights. Any tilting to the balance one way or the other would be a gross misinterpretation of the TRIPS Agreement and its objectives.

It was India's view that the exceptions in the Canadian *Patent Act* were legitimate exceptions within the meaning of Article 30. Any other interpretation of Article 30 would alter the delicate balance in the TRIPS Agreement between the rights conferred on the owner of the patent and the legitimate interests of all those other than the patent owner. India therefore urged the Panel to find that the disputed measures in this case fully conformed with Canada's obligations under the TRIPS Agreement. In doing so, the measures at issue should be examined in the light of Article 30 of the TRIPS Agreement as well as in the light of societal interests and public policy objectives.

Israel supported Canada's basic position in the dispute. Its view was that the provisions of the Canadian law at issue were essentially in compliance with the TRIPS Agreement and in particular with the Preamble and Articles 7, 8, 27, 28 and 30. The following arguments were put forward in this regard:

- The Preamble of the TRIPS Agreement underlined the need to promote effective protection of intellectual property rights while at the same time ensuring that the measures found in the Agreement did not become barriers to legitimate trade. Additionally, the Preamble recognized the public policy objectives of national systems, including developmental and technological objectives. The spirit of the TRIPS Agreement, effectively codifying the delicate balance of the rights and interests achieved throughout the multilateral negotiations, was found in its Article 7. It included achieving a balance of the rights and obligations which were conducive to promoting technological innovation, provided it was in a manner which was also conducive to social and economic welfare. Article 8 embodied the principle of the Agreement and stated, *inter alia*, that, in formulating their laws, Members could adopt laws to protect health and nutrition, provided that such measures were consistent with the Agreement. The fact that the objectives and principles set forth in Articles 7 and 8 appeared in the body of the Agreement, rather than having them set forth in the more general language of the Preamble, emphasized their importance and status for purposes of resolving disputes and should serve as primary tools for interpretation of the Agreement.

[17] See paragraph 4.21 above under (c).

- The central issue at the heart of this dispute was whether the challenged provisions of the Canadian Patent Law were limited exceptions to the exclusive rights conferred by a patent within the meaning of Article 30 of the Agreement. It was submitted that the high costs of a comprehensive health care system, due in large part to expenditures on therapeutic drugs, had motivated a large number of Members to include the principle regarding health and nutrition as set out in Article 8 of the Agreement. Without the exceptions found in the Agreement, patent owners would be able to charge monopoly prices for their drugs and hence raise the drug costs for additional years causing strain on already strained health budgets. Encouraging and promoting the sale of generic drugs following the expiry of the patent monopoly, as evidenced in a number of countries, including those found in the European Union, was consistent with the objectives of the Agreement.

- The Canadian law preserved the patentee's exclusive rights subject to reasonable limited exceptions as permitted by Article 30 of the Agreement. The limited exception of making preparations for the post-expiration period did not unreasonably prejudice the patentee's legitimate interests, taking into account the legitimate interests of third parties, and did not interfere with the patentee's exclusive right to commercialization of the invention during the full patent term. Thus, these limited exceptions did not interfere with the exclusive right to commercialize the invention during the entire patent term, including the exclusive right to sell or license the patented invention. Indeed, these exceptions did not allow for competitors to commercially exploit the patented invention during the life of the patent. The exceptions were limited and took into account the countervailing legitimate interests of patentees and society as a whole and related to activities which would have commercial value only after expiration of the entire patent term.

- Therefore, it was reasonable for Canada to recognize that delays inherent in regulatory approval processes could delay the availability of less expensive and more widely distributed generic drugs for the health and welfare of the Canadian public.

According to the **United States**, the dispute presented extremely important issues regarding core provisions of the TRIPS Agreement. The United States had chosen to participate as a third party in the dispute, because it had a substantial trade interest in the Canadian pharmaceutical market affected by the patent legislation challenged by the European Communities and their member States. In 1998, the United States had exported to Canada over US$1.3 billion in pharmaceutical products, and imported products worth US$648 million. The United States also had a broad systemic interest in the proper interpretation of the TRIPS provisions at issue.

In the view of the United States, the Panel should, in considering the two distinct exceptions under Canadian patent law to the exclusive rights conferred by a patent - both of which fell under Section 55.2 of the Canadian *Patent Act* – challenged by the European Communities and their member States, keep in mind the basic purposes of the patent system and the background of the regulated pharmaceutical industry. The United States identified these purposes and background as follows:

- Patent systems encouraged innovation by granting inventors certain exclusive rights for a limited period of time in exchange for disclosure of the invention. They provided incentives to invest in research and development by preventing competitors from free-riding off such investments, and thereby ensuring that inventors had an opportunity to recoup their investments. They also enlarged public knowledge through disclosure, which facilitated further improvements in the technology and public use of the invention after the patent expired.

- The pharmaceutical industry operated in a highly regulated market in which the interaction of stringent regulatory requirements, such as obtaining pre-market approval, with the patent system was complex and had important consequences. Regulatory authorities

> generally required that new pharmaceutical products be proven safe and effective before they could be commercially marketed. It commonly took many years for innovative pharmaceutical companies to satisfy these regulatory requirements for new drugs. The result was that an innovator company often suffered a significant reduction in the effective period of exclusive rights provided by the patent due to the inability of the company to market the product prior to its approval. On the other hand, the regulatory process for generic pharmaceuticals also took time to complete, and could delay effective competition with a pharmaceutical product coming off patent significantly beyond the time that it would normally take for a competitor to begin manufacturing and distribution. Governments maintaining these regulatory regimes for pharmaceuticals could seek to ensure that the regimes did not interfere with the incentives provided by the patent system for the creation of new pharmaceuticals, or with effective generic competition after the term of patent protection had ended.

The United States expressed the view that a properly crafted "pre-expiration testing"[18] exception was a reasonable exception to the exclusive rights that WTO Members were required to provide under Article 28 of the TRIPS Agreement, and was justified under Article 30 of the Agreement. By contrast, the United States did not believe that an exception to patent rights for "stockpiling"[19] could be similarly justified.

VII. FINDINGS

PRINCIPLES OF INTERPRETATION

The legal issues in this dispute primarily involve differences over interpretation of the key TRIPS provisions invoked by the parties, chiefly Articles 27.1, 30 and 33. The rules that govern the interpretation of WTO agreements are the rules of treaty interpretation stated in Articles 31 and 32 of the Vienna Convention.[20] The starting point is the rule of Article 31(1) which states:

> "A treaty is to be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."

The parties have submitted arguments on each of these elements, as well as further arguments based on subsequent practice by certain WTO Members, thus relying on Article 31(3)(b), which reads in relevant part as follows:

> "There shall be taken into account, together with the context: (a) […]; (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation."

The parties have also advanced arguments based on the negotiating history of the TRIPS provisions in dispute. Negotiating history falls within the category of "Supplementary Means of Interpretation" and is governed by the rule of Article 32 of the Vienna Convention, which provides as follows:

> "Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of Article 31, or to determine the meaning when the interpretation according to Article 31:
>
> (a) leaves the meaning ambiguous or obscure; or

[18] The United States used the term "pre-expiration testing" as shorthand for activities designed to develop information required for domestic regulatory purposes.

[19] The United States used the term "stockpiling" as shorthand for the manufacture and storage of patented products for sale after the patent expired.

[20] Vienna Convention on the Law of Treaties 1969, entered into force on 27 January 1980

(b) leads to a result which is manifestly absurd or unreasonable."

The Panel noted that, in the framework of the TRIPS Agreement, which incorporates certain provisions of the major pre-existing international instruments on intellectual property, the context to which the Panel may have recourse for purposes of interpretation of specific TRIPS provisions, in this case Articles 27 and 28, is not restricted to the text, Preamble and Annexes of the TRIPS Agreement itself, but also includes the provisions of the international instruments on intellectual property incorporated into the TRIPS Agreement, as well as any agreement between the parties relating to these agreements within the meaning of Article 31(2) of the Vienna Convention on the Law of Treaties. Thus, as the Panel will have occasion to elaborate further below, Article 9(2) of the Berne Convention for the Protection of Literary and Artistic Works (1971) (hereinafter referred to as the Berne Convention) is an important contextual element for the interpretation of Article 30 of the TRIPS Agreement.

As a consequence of the extended context that has to be taken into account when interpreting provisions of the TRIPS Agreement, the Panel, in considering the negotiating history of the TRIPS Agreement, concluded that interpretation may go beyond the negotiating history of the TRIPS Agreement proper and also inquire into that of the incorporated international instruments on intellectual property.

BURDEN OF PROOF

The legal issues in the present dispute turn primarily on questions of legal interpretation - the meaning of the TRIPS provisions under which the two provisions of Canada's Patent Act have been challenged. The basic facts pertaining to these issues of interpretation are essentially undisputed. However, a small number of factual issues have been raised with regard to the meaning of certain aspects of the Canadian law, and about the actual impact of that law in practice. Moreover, application of legal standards frequently involves mixed questions of law and fact, and disagreements over the application of such standards sometimes therefore involve disagreement over factual premises. To the extent that such factual disagreements do exist, rules pertaining to burden of proof are potentially relevant whenever the weight of the evidence does not permit conclusive judgements. As the Appellate Body put it in *United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India*[21]:

> "[...] it was up to India to present evidence and argument sufficient to establish a presumption that the transitional safeguard determination made by the United States was inconsistent with its obligations [...]. With this presumption thus established, it was then up to the United States to bring evidence and argument to rebut that presumption".[22]

Similarly in the present case, it was the Panel's view that the EC bears the burden to present evidence and argument sufficient to establish a prima facie case that Canada has violated Articles 27.1, 28.1 and 33 of the TRIPS Agreement. It would be up to Canada to advance sufficient argument and evidence to rebut such a prima facie case. Canada has, for all practical purposes, conceded the violation of Article 28, because it has resorted to the exception of Article 30 of the TRIPS Agreement in this case. Since Article 30 is an exception to the obligations of the TRIPS Agreement, it would be up to Canada to demonstrate that the provisions of Sections 55.2(1) and 55.2(2) comply with the criteria laid down in Article 30. It is on this basis that the Panel approached the analysis of the claims submitted to it.

[21] Document WT/DS33/AB/R, pp. 13-16 (adopted 23 May 1997).

[22] In other contexts the Appellate Body has used the terms "prima facie case" instead of "presumption" (see *EC - Measures Concerning Meat and Meat Products (Hormones),* WT/DS26/AB/R, paragraph 104).

SECTION 55.2(2) (THE STOCKPILING EXCEPTION)

(1) APPLICATION OF ARTICLE 28.1 AND ARTICLE 30 OF THE TRIPS AGREEMENT

The TRIPS Agreement contains two provisions authorizing exceptions to the exclusionary patent rights laid down in Article 28 - Articles 30 and 31. Of these two, Article 30 - the so-called limited exceptions provision – has been invoked by Canada in the present case.

Both parties agreed upon the basic structure of Article 30. Article 30 establishes three criteria that must be met in order to qualify for an exception: (1) the exception must be "limited"; (2) the exception must not "unreasonably conflict with normal exploitation of the patent"; (3) the exception must not "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties". The three conditions are cumulative, each being a separate and independent requirement that must be satisfied. Failure to comply with any one of the three conditions results in the Article 30 exception being disallowed.

The three conditions must, of course, be interpreted in relation to each other. Each of the three must be presumed to mean something different from the other two, or else there would be redundancy.[23] Normally, the order of listing can be read to suggest that an exception that complies with the first condition can nevertheless violate the second or third, and that one which complies with the first and second can still violate the third. The syntax of Article 30 supports the conclusion that an exception may be "limited" and yet fail to satisfy one or both of the other two conditions. The ordering further suggests that an exception that does not "unreasonably conflict with normal exploitation" could nonetheless "unreasonably prejudice the legitimate interests of the patent owner".[24]

Object and Purpose

Canada called attention to a number of other provisions of the TRIPS Agreement as relevant to the purpose and objective of Article 30. Primary attention[25] was given to Articles 7 and 8.1. In the view of Canada, Article 7 declares that one of the key goals of the TRIPS Agreement was a balance between the intellectual property rights created by the Agreement and other important socio-economic policies of WTO Member governments. Article 8 elaborates the socio-economic policies in question, with particular attention to health and nutritional policies. With respect to patent rights, Canada argued, these purposes call for a liberal interpretation of the three conditions stated in Article 30 of the Agreement, so that governments would have the necessary flexibility to adjust patent rights to maintain the desired balance with other important national policies.

The EC did not dispute the stated goal of achieving a balance within the intellectual property rights system between important national policies. But, in the view of the EC, Articles 7 and 8 are statements that describe the balancing of goals that had already taken place in negotiating the final texts of the TRIPS Agreement. According to the EC, to view Article 30 as an authorization for governments to "renegotiate" the overall balance of the Agreement would involve a double counting of such socio-economic policies. In particular, the EC pointed to the last phrase of Article 8.1 requiring that government measures to protect important socio-economic policies be consistent with the obligations of the TRIPS Agreement. The EC also referred to the provisions of first consideration

[23] See *United States - Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, p. 23 (adopted 20 May 1996).

[24] The report of the drafting committee for Article 9(2) of the Berne Convention, from which this text was derived, concluded that measures not in conflict with "normal exploitation" could nonetheless prejudice the "legitimate interests" of the copyright owner. The report is quoted in paragraph 7.72 below.

[25] Attention was also called to the text of the first recital in the Preamble to the TRIPS Agreement and to part of the text of Article 1.1. The Preamble text in question reads:

> "Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, *and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade*;" (emphasis added by Canada)

of the Preamble and Article 1.1 as demonstrating that the basic purpose of the TRIPS Agreement was to lay down minimum requirements for the protection and enforcement of intellectual property rights.

In the Panel's view, Article 30's very existence amounts to a recognition that the definition of patent rights contained in Article 28 would need certain adjustments. On the other hand, the three limiting conditions attached to Article 30 testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be equivalent to a renegotiation of the basic balance of the Agreement. Obviously, the exact scope of Article 30's authority will depend on the specific meaning given to its limiting conditions. The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes.

"Limited Exceptions"

Canada asserted that the word "limited" should be interpreted according to the conventional dictionary definition, such as "confined within definite limits", or "restricted in scope, extent, amount". Canada argued that the stockpiling exception in Section 55.2(2) is restricted in scope because it has only a limited impact on a patent owner's rights. The stockpiling exception, Canada noted, does not affect the patent owner's right to an exclusive market for "commercial" sales during the patent term, since the product that is manufactured and stockpiled during the final six months of the term cannot be sold in competition with the patent owner until the patent expires. By "commercial sales", Canada clearly meant sales to the ultimate consumer, because it acknowledged that sales of patented ingredients to producers engaged in authorized stockpiling is permitted. Thus, Canada was arguing that an exception is "limited" as long as the exclusive right to sell to the ultimate consumer[26] during the term of the patent is preserved. In addition, Canada also claimed that the exception is further limited by the six-month duration of the exception, and by the fact that it can be used only by persons that have made, constructed or used the invention under Section 55.2(1).

The EC interpreted the word "limited" to connote a narrow exception, one that could be described by words such as "narrow, small, minor, insignificant or restricted". The EC measured the "limited" quality of the proposed exception by reference to its impact on the exclusionary rights granted to the patent owner under Article 28.1. Applying that measure, the EC contended that the stockpiling exception is not "limited" because it takes away three of the five Article 28.1 rights - the rights to exclude "making", "using" and "importing". The EC argued that the impairment of three out of five basic rights is in itself extensive enough to be considered "not limited". The EC further contended that limitation of the exception to the last six months of the patent term does not constitute a limited impairment of rights when six months is taken as a percentage of the 20-year patent term, and especially not when taken as a percentage of the actual eight to 12-year period of effective market exclusivity enjoyed by most patented pharmaceuticals. In addition, the EC noted, there was no limitation on the quantities that could be produced during this period, nor any limitation on the markets in which such products could be sold. Finally, the EC pointed out that no royalty fees are due for such production, and that the patent holder does not even have a right to be informed of the use of the patent.

In considering how to approach the parties' conflicting positions regarding the meaning of the term "limited exceptions", the Panel was aware that the text of Article 30 has antecedents in the text of Article 9(2) of the Berne Convention. However, the words "limited exceptions" in Article 30 of the TRIPS Agreement are different from the corresponding words in Article 9(2) of the Berne Convention, which reads "in certain special cases".[27] The Panel examined the documented

[26] The term is used here to include purchasers in the distribution chain to the ultimate consumer.

[27] Article 9(2) of the Berne Convention reads: "It shall be a matter for legislation in the countries of the Union to permit the reproduction of [literary and artistic] works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author."

negotiating history of TRIPS Article 30 with respect to the reasons why negotiators may have chosen to use the term "limited exceptions" in place of "in special circumstances". The negotiating records show only that the term "limited exceptions" was employed very early in the drafting process, well before the decision to adopt a text modelled on Berne Article 9(2), but do not indicate why it was retained in the later draft texts modelled on Berne Article 9(2).

The Panel agreed with the EC that, as used in this context, the word "limited" has a narrower connotation than the rather broad definitions cited by Canada. Although the word itself can have both broad and narrow definitions, the narrower being indicated by examples such as "a mail train taking only a limited number of passengers"[28], the narrower definition is the more appropriate when the word "limited" is used as part of the phrase "limited exception". The word "exception" by itself connotes a limited derogation, one that does not undercut the body of rules from which it is made. When a treaty uses the term "limited exception", the word "limited" must be given a meaning separate from the limitation implicit in the word "exception" itself. The term "limited exception" must therefore be read to connote a narrow exception - one which makes only a small diminution of the rights in question.

The Panel agreed with the EC interpretation that "limited" is to be measured by the extent to which the exclusive rights of the patent owner have been curtailed. The full text of Article 30 refers to "limited exceptions to the exclusive rights conferred by a patent". In the absence of other indications, the Panel concluded that it would be justified in reading the text literally, focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact. In support of this conclusion, the Panel noted that the following two conditions of Article 30 ask more particularly about the economic impact of the exception, and provide two sets of standards by which such impact may be judged. The term "limited exceptions" is the only one of the three conditions in Article 30 under which the extent of the curtailment of rights as such is dealt with.

The Panel does not agree, however, with the EC's position that the curtailment of legal rights can be measured by simply counting the number of legal rights impaired by an exception. A very small act could well violate all five rights provided by Article 28.1 and yet leave each of the patent owner's rights intact for all useful purposes. To determine whether a particular exception constitutes a limited exception, the extent to which the patent owner's rights have been curtailed must be measured.

The Panel could not accept Canada's argument that the curtailment of the patent owner's legal rights is "limited" just so long as the exception preserves the exclusive right to sell to the ultimate consumer during the patent term. Implicit in the Canadian argument is a notion that the right to exclude sales to consumers during the patent term is the essential right conveyed by a patent, and that the rights to exclude "making" and "using" the patented product during the term of the patent are in some way secondary. The Panel does not find any support for creating such a hierarchy of patent rights within the TRIPS Agreement. If the right to exclude sales were all that really mattered, there would be no reason to add other rights to exclude "making" and "using". The fact that such rights were included in the TRIPS Agreement, as they are in most national patent laws, is strong evidence that they are considered a meaningful and independent part of the patent owner's rights.

In the Panel's view, the question of whether the stockpiling exception is a "limited" exception turns on the extent to which the patent owner's rights to exclude "making" and "using" the patented product have been curtailed. The right to exclude "making" and "using" provides protection, additional to that provided by the right to exclude sale, during the entire term of the patent by cutting off the supply of competing goods at the source and by preventing use of such products however obtained. With no limitations at all upon the quantity of production, the stockpiling exception removes that protection entirely during the last six months of the patent term, without regard to what other, subsequent, consequences it might have. By this effect alone, the stockpiling exception can be said to abrogate such rights entirely during the time it is in effect.

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[28] The *Shorter Oxford English Dictionary* at p. 1216

In view of Canada's emphasis on preserving commercial benefits *before* the expiration of the patent, the Panel also considered whether the market advantage gained by the patent owner in the months after expiration of the patent could also be considered a purpose of the patent owner's rights to exclude "making" and "using" during the term of the patent. In both theory and practice, the Panel concluded that such additional market benefits were within the purpose of these rights. In theory, the rights of the patent owner are generally viewed as a right to prevent competitive commercial activity by others, and manufacturing for commercial sale is a quintessential competitive commercial activity, whose character is not altered by a mere delay in the commercial reward. In practical terms, it must be recognized that enforcement of the right to exclude "making" and "using" during the patent term will necessarily give all patent owners, for all products, a short period of extended market exclusivity after the patent expires. The repeated enactment of such exclusionary rights with knowledge of their universal market effects can only be understood as an affirmation of the purpose to produce those market effects.

For both these reasons, the Panel concluded that the stockpiling exception of Section 55.2(2) constitutes a substantial curtailment of the exclusionary rights required to be granted to patent owners under Article 28.1 of the TRIPS Agreement.

Having concluded that the exception in Section 55.2(2) of the Canadian Patent Act does not satisfy the first condition of Article 30 of the TRIPS Agreement, the Panel therefore concluded that Section 55.2(2) is inconsistent with Canada's obligations under Article 28.1 of the Agreement. This conclusion, in turn, made it unnecessary to consider any of the other claims of inconsistency raised by the European Communities. Accordingly, the Panel did not consider the claims of inconsistency under the second and third conditions of Article 30, the claim of inconsistency with TRIPS Article 27.1, and the claim of inconsistency with Article 33.

SECTION 55.2(1) (THE REGULATORY REVIEW EXCEPTION)

(1) APPLICATION OF ARTICLE 28.1 AND ARTICLE 30 OF THE TRIPS AGREEMENT

(a) "Limited Exceptions"

Canada's arguments pertaining to the "limited" character of the regulatory review exception of Section 55.2(1) started from the same premises as its arguments with regard to the "limited" character of the stockpiling exception of Section 55.2(2). Canada again asserted that the regulatory review exception of Section 55.2(1) can be regarded as "limited" because the rights given to third parties do not deprive the patent holder of his right to exclude all other "commercial sales" of the patented product during the term of the patent. As noted above when discussing this argument in relation to Section 55.2(2), Canada evidently intended the term "commercial sales" to refer to sales to the ultimate consumer, rather than sales by suppliers of ingredients. As before, Canada was taking the position that an exception is "limited" as long as the exclusive right to sell to the ultimate consumer during the term of the patent is preserved.

In the case of the regulatory review exception, however, Canada added two further arguments based on the negotiating history of Article 30 and on the subsequent practices of certain WTO Members. Canada pointed out that in 1984 the United States had enacted a regulatory review exception similar to Section 55.2(1) of Canada's Patent Act, known as the "Bolar exemption".[29] Canada asserted that the United States "Bolar exemption" was well known during the negotiation of Article 30, and that governments were aware that the United States intended to secure an exception that would permit it to retain its "Bolar exemption". Canada further asserts that it was known that the United States agreed to

[29] The US statute in question is 35 United States Code, Section 271(e). The statute was passed to reverse a federal court decision ruling that infringing conduct for the purpose of making submissions for regulatory approval was not excused by the "scientific use" exemption in US patent law, and could thus be prohibited by the patent holder (*Roche Products Inc. v Bolar Pharmaceutical Co., Inc,* 733 F.2d 858 (C.A.F.C. 1984)).

the general language of Article 30 on the understanding that the provision would do so. Canada called attention to subsequent statements by United States officials stating that "[O]ur negotiators ensured that the TRIPS Agreement permits the Bolar exemption to be maintained."[30]

With regard to subsequent practice, Canada pointed out that after the conclusion of the TRIPS Agreement four other WTO Members (Argentina, Australia, Hungary and Israel) adopted legislation containing similar regulatory review exceptions, and that both Japan and Portugal adopted interpretations of existing patent law which confirmed exemptions for regulatory review submissions. Canada argued that these actions are subsequent practices by parties to the agreement, within the meaning of Article 31(3)(b) of the Vienna Convention, that confirm its interpretation that regulatory review exceptions are authorized by TRIPS Article 30.

In arguing that the regulatory review exception was not "limited", the EC again focused on the extent to which that exception diminishes the patent owner's rights of exclusivity required by Article 28.1 of the TRIPS Agreement. The EC pointed out that Section 55.2(1) permits third parties to perform all five of the activities which the patent owner may otherwise exclude under Article 28.1. The EC acknowledged that the permission to conduct these activities was subject to the condition that the final purchaser of the patented product has the intention to use the product for supplying information to regulatory authorities, but the EC argued that the terms of Section 55.2(1) allowed "wide-ranging activities by a wide range of operators" and "infringing acts of a significant extent".[31] The EC called particular attention to the fact that Section 55.2(1) authorizes the commercial sale of ingredients by fine chemical producers who often supply generic drug manufacturers with the ingredients needed to make test products. The EC also noted that regulatory requirements often require applicants or their suppliers to produce commercial quantities of drugs in order to demonstrate their ability to maintain the required level of quality at such production levels. The EC also stressed the fact that infringing activities are authorized at any time during the 20-year term of the patent. And finally, the EC called particular attention to the fact that Section 55.2(1) applied to regulatory submissions anywhere in the world, suggesting that the number and variety of such foreign regulatory procedures, as well as Canada's inability to supervise or influence them, would further enlarge the range of excluded activities permitted by this exception.

In the previous part of this Report dealing with the stockpiling exception of Section 55.2(2), the Panel concluded that the words "limited exception" express a requirement that the exception make only a narrow curtailment of the legal rights which Article 28.1 requires to be granted to patent owners, and that the measure of that curtailment was the extent to which the affected legal rights themselves had been impaired. As was made clear by our conclusions regarding the stockpiling exception, the Panel could not accept Canada's contention that an exception can be regarded as "limited" just so long as it preserves the patent owner's exclusive right to sell to the ultimate consumer during the patent term.

In the Panel's view, however, Canada's regulatory review exception is a "limited exception" within the meaning of TRIPS Article 30. It is "limited" because of the narrow scope of its curtailment of Article 28.1 rights. As long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded. Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner's rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of resulting final products.

The Panel found no basis for believing that activities seeking product approvals under foreign regulatory procedures would be any less subject to these limitations. There is no *a priori* basis to assume that the requirements of foreign regulatory procedures will require activities unrelated to

[30] First Submission of Canada, paragraph 105 and Exhibit 41, quoting letter of US Trade Representative Michael Kantor to Alfred B. Engelberg, 1 February 1996

[31] Oral Statement at First Meeting, paragraphs 67 and 68

legitimate objectives of product quality and safety, nor has the EC provided any evidence to that effect. Nor is there any reason to assume that Canadian law would apply the exception in cases where foreign requirements clearly had no regulatory purpose. Nor, finally, is there any reason to assume that it will be any more difficult to enforce the requirements of Canadian law when Canadian producers claim exceptions under foreign procedures. With regard to the latter point, the Panel concurred with Canada's point that the government is not normally expected to regulate the actual conduct of third parties in such cases. The enforcement of these conditions, as with other enforcement of patent rights, occurs by means of private infringement actions brought by the patent owner. The patent owner merely has to prove that the challenged conduct is inconsistent with the basic patent rights created by national law. Once that initial case is made, the burden will be on the party accused of infringement to prove its defence by establishing that its conduct with respect to foreign regulatory procedures was in compliance with the conditions of Section 55.2(1).

In reaching this conclusion, the Panel also considered Canada's additional arguments that both the negotiating history of Article 30 of the TRIPS Agreement and the subsequent practices of certain WTO Member governments supported the view that Article 30 was understood to permit regulatory review exceptions similar to Section 55.2(1). The Panel did not accord any weight to either of those arguments, however, because there was no documented evidence of the claimed negotiating understanding, and because the subsequent acts by individual countries did not constitute "practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation" within the meaning of Article 31.3(b) of the Vienna Convention.

A final objection to the Panel's general conclusion remains to be addressed. Although the point was raised only briefly in the parties' legal arguments, the Panel was compelled to acknowledge that the economic impact of the regulatory review exception could be considerable. According to information supplied by Canada itself, in the case of patented pharmaceutical products approximately three to six-and-a-half years are required for generic drug producers to develop and obtain regulatory approval for their products. If there were no regulatory review exception allowing competitors to apply for regulatory approval during the term of the patent, therefore, the patent owner would be able to extend its period of market exclusivity, de facto, for some part of that three to six-and-half year period, depending on how much, if any, of the development process could be performed during the term of the patent under other exceptions, such as the scientific or experimental use exception. The Panel believed it was necessary to ask whether measures having such a significant impact on the economic interests of patent owners could be called a "limited" exception to patent rights.

After analysing Article 30, the Panel was satisfied that it does in fact address the issue of economic impact, but only in the other two conditions contained in that Article. As will be seen in the analysis of these other conditions below, the other two conditions deal with the issue of economic impact, according to criteria that relate specifically to that issue. Viewing all three conditions as a whole, it is apparent that the first condition ("limited exception") is neither designed nor intended to address the issue of economic impact directly.

In sum, the Panel found that the regulatory review exception of Section 55.2(1) is a "limited exception" within the meaning of Article 30 of the TRIPS Agreement.

(b) "Normal Exploitation"

The second condition of Article 30 prohibits exceptions that "unreasonably conflict with a normal exploitation of the patent". Canada took the position that "exploitation" of the patent involves the extraction of commercial value from the patent by "working" the patent, either by selling the product in a market from which competitors are excluded, or by licensing others to do so, or by selling the patent rights outright. The European Communities also defined "exploitation" by referring to the

same three ways of "working" a patent.[32] The parties differed primarily on their interpretation of the term "normal".

The Panel considered that "exploitation" refers to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent. The term "normal" defines the kind of commercial activity Article 30 seeks to protect. The ordinary meaning of the word "normal" is found in the dictionary definition: "regular, usual, typical, ordinary, conventional".[33] As so defined, the term can be understood to refer either to an empirical conclusion about what is common within a relevant community, or to a normative standard of entitlement. The Panel concluded that the word "normal" was being used in Article 30 in a sense that combined the two meanings.

The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity. The specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices. Protection of all normal exploitation practices is a key element of the policy reflected in all patent laws. Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation, and the policy of those laws cannot be achieved unless patent owners are permitted to take effective advantage of that inducement once it has been defined.

Canada has raised the argument that market exclusivity occurring after the 20-year patent term expires should not be regarded as "normal". The Panel was unable to accept that as a categorical proposition. Some of the basic rights granted to all patent owners, and routinely exercised by all patent owners, will typically produce a certain period of market exclusivity after the expiration of a patent. For example, the separate right to prevent "making" the patented product during the term of the patent often prevents competitors from building an inventory needed to enter the market immediately upon expiration of a patent. There is nothing abnormal about that more or less brief period of market exclusivity after the patent has expired.

The Panel considered that Canada was on firmer ground, however, in arguing that the additional period of de facto market exclusivity created by using patent rights to preclude submissions for regulatory authorization should not be considered "normal". The additional period of market exclusivity in this situation is not a natural or normal consequence of enforcing patent rights. It is an unintended consequence of the conjunction of the patent laws with product regulatory laws, where the combination of patent rights with the time demands of the regulatory process gives a greater than normal period of market exclusivity to the enforcement of certain patent rights. It is likewise a form of exploitation that most patent owners do not in fact employ. For the vast majority of patented products, there is no marketing regulation of the kind covered by Section 55.2(1), and thus there is no possibility to extend patent exclusivity by delaying the marketing approval process for competitors.

The Panel could not agree with the EC's assertion that the mere existence of the patent owner's rights to exclude was a sufficient reason, by itself, for treating all gains derived from such rights as flowing from "normal exploitation".

In sum, the Panel found that the regulatory review exception of Section 55.2(1) does not conflict with a normal exploitation of patents, within the meaning of the second condition of Article 30 of the TRIPS Agreement. The fact that no conflict has been found makes it unnecessary to consider the question of whether, if a conflict were found, the conflict would be "unreasonable". Accordingly, it is also unnecessary to determine whether or not the final phrase of Article 30, calling for consideration

[32] EC Oral Statement at First Meeting, paragraph 70
[33] The New Shorter Oxford English Dictionary, p.1940

of the legitimate interests of third parties, does or does not apply to the determination of "unreasonable conflict" under the second condition of Article 30.

(c) "Legitimate Interests"

The third condition of Article 30 is the requirement that the proposed exception must not "unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties". Although Canada, as the party asserting the exception provided for in Article 30, bears the burden of proving compliance with the conditions of that exception, the order of proof is complicated by the fact that the condition involves proving a negative. One cannot demonstrate that no legitimate interest of the patent owner has been prejudiced until one knows what claims of legitimate interest can be made.

Definition of "legitimate interests"

The word "legitimate" is commonly defined as follows:

(a) Conformable to, sanctioned or authorized by, law or principle: lawful; justifiable; proper;

(b) Normal, regular, conformable to a recognized standard type.[34]

Although the European Communities' definition equating "legitimate interests" with a full respect of legal interests pursuant to Article 28.1 is within at least some of these definitions, the EC definition makes it difficult to make sense of the rest of the third condition of Article 30, in at least three respects. First, since by that definition every exception under Article 30 will be causing "prejudice" to some legal rights provided by Article 28 of the Agreement, that definition would reduce the first part of the third condition to a simple requirement that the proposed exception must not be "unreasonable". Such a requirement could certainly have been expressed more directly if that was what was meant. Second, a definition equating "legitimate interests" with legal interests makes no sense at all when applied to the final phrase of Article 30 referring to the "legitimate interests" of third parties. Third parties are by definition parties who have no legal right at all in being able to perform the tasks excluded by Article 28 patent rights. An exceptions clause permitting governments to take account of such third party legal interests would be permitting them to take account of nothing. And third, reading the third condition as a further protection of legal rights would render it essentially redundant in light of the very similar protection of legal rights in the first condition of Article 30 ("limited exception").

To make sense of the term "legitimate interests" in this context, that term must be defined in the way that it is often used in legal discourse - as a normative claim calling for protection of interests that are "justifiable" in the sense that they are supported by relevant public policies or other social norms. This is the sense of the word that often appears in statements such as "X has no legitimate interest in being able to do Y". We may take as an illustration one of the most widely adopted Article 30-type exceptions in national patent laws - the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement. It is often argued that this exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a "legitimate interest" in using the patent disclosure to support the advance of science and technology. While the Panel draws no conclusion about the correctness of any such national

[34] New Shorter Oxford Dictionary, page 1563

exceptions in terms of Article 30 of the TRIPS Agreement, it does adopt the general meaning of the term "legitimate interests" contained in legal analysis of this type.

The negotiating history of the TRIPS Agreement itself casts no further illumination on the meaning of the term "legitimate interests", but the negotiating history of Article 9(2) of the Berne Convention, from which the text of the third condition was clearly drawn, does tend to affirm the Panel's interpretation of that term. With regard to the TRIPS negotiations themselves, the meaning of several important drafting changes turns out to be equivocal upon closer examination. The negotiating records of the TRIPS Agreement itself show that the first drafts of the provision that was to become Article 30 contemplated authorizing "limited exceptions" that would be defined by an illustrative list of exceptions - private use, scientific use, prior use, a traditional exception for pharmacists, and the like. Eventually, this illustrative list approach was abandoned in favour of a more general authorization following the outlines of the present Article 30.

The text of the present, more general version of Article 30 of the TRIPS Agreement was obviously based on the text of Article 9(2) of the Berne Convention. Berne Article 9(2) deals with exceptions to the copyright holder's right to exclude reproduction of its copyrighted work without permission. The text of Berne Article 9(2) was not adopted into Article 30 of the TRIPS Agreement without change. Whereas the final condition in Berne Article 9(2) ("legitimate interests") simply refers to the legitimate interests of the author, the TRIPS negotiators added in Article 30 the instruction that account must be taken of "the legitimate interests of third parties". Absent further explanation in the records of the TRIPS negotiations, however, the Panel was not able to attach a substantive meaning to this change other than what is already obvious in the text itself, namely that the reference to the "legitimate interests of third parties" makes sense only if the term "legitimate interests" is construed as a concept broader than legal interests.

With regard to the meaning of Berne Article 9(2) itself, the Panel examined the drafting committee report that is usually cited as the most authoritative explanation of what Article 9(2) means. The drafting committee report states:

> "If it is considered that reproduction conflicts with the normal exploitation of the work, reproduction is not permitted at all. If it is considered that reproduction does not conflict with the normal exploitation of the work, the next step would be to consider whether it does not unreasonably prejudice the legitimate interests of the author. Only if such is not the case would it be possible in certain special cases to introduce a compulsory license, or to provide for use without payment. A practical example may be photocopying for various purposes. If it consists of producing a very large number of copies, it may not be permitted, as it conflicts with a normal exploitation of the work. If it implies a rather large number of copies for use in industrial undertakings, it may not unreasonably prejudice the legitimate interests of the author, provided that, according to national legislation, an equitable remuneration is paid. If a small number of copies is made, photocopying may be permitted without payment, particularly for individual or scientific use."[35]

In sum, after consideration of the ordinary meaning of the term "legitimate interests", as it is used in Article 30, the Panel was unable to accept the EC's interpretation of that term as referring to legal interests pursuant to Article 28.1. Accordingly, the Panel was unable to accept the primary EC argument with regard to the third condition of Article 30. It found that the EC argument based solely on the patent owner's legal rights pursuant to Article 28.1, without reference to any more particular normative claims of interest, did not raise a relevant claim of non-compliance with the third condition of Article 30.

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[35] Report on the Work of Main Committee I (Substantive Provisions of the Berne Convention: Articles 1 to 20), paragraph 85, in "Records of the Intellectual Property Conference of Stockholm, June 11-July 14, 1967", World Intellectual Property Organization (WIPO), Geneva, 1971, Vol. II, pp. 1145-1146.

Having reviewed the conformity of Section 55.2(1) with each of the three conditions for an exception under Article 30 of the TRIPS Agreement, the Panel concluded that Section 55.2(1) does satisfy all three conditions of Article 30, and thus is not inconsistent with Canada's obligations under Article 28.1 of the TRIPS Agreement.

(2) APPLICATION OF ARTICLE 27.1 OF THE TRIPS AGREEMENT

The EC claimed that Section 55.2(1) of the Canada Patent Act is also in conflict with the obligations under Article 27.1 of the TRIPS Agreement.

The EC argued that the anti-discrimination rule stated in the italicized language in the text of Article 27.1 above not only requires that the core patent rights made available under Article 28 be non-discriminatory, but also requires that any exceptions to those basic rights made under Articles 30 and 31 must be non-discriminatory as well. Canada advanced two defences to the EC's claim of an Article 27.1 violation. First, Canada argued that the non-discrimination rule of Article 27.1 does not apply to exceptions taken under Article 30. Second, Canada argued that Section 55.2(1) does not discriminate against pharmaceutical products.

(a) Applicability of Article 27.1 to Article 30 Exceptions

Canada took the position that Article 27.1's reference to "patent rights" that must be enjoyable without discrimination as to field of technology refers to the basic rights enumerated in Article 28.1 subject to any exceptions that might be made under Article 30. In other words, governments may discriminate when making the "limited" exceptions allowed under Article 30, but they may not discriminate as to patent rights as modified by such exceptions.

In support of this position, Canada argued that the scope of Article 30 would be reduced to insignificance if governments were required to treat all fields of technology the same, for if all exceptions had to apply to every product it would be far more difficult to meet the requirement that Article 30 exceptions be "limited". It would also be more difficult to target particular social problems, as are anticipated, according to Canada, by Articles 7 and 8 of the TRIPS Agreement. Conversely, Canada argued, requiring that exceptions be applied to all products would cause needless deprivation of patent rights for those products as to which full enforcement of patent rights causes no problem.

Canada acknowledged that there are certain textual difficulties with this position. It acknowledged that two of the primary purposes of Article 27.1 were to eliminate two types of discrimination that had been practised against pharmaceuticals and certain other products - either a denial of patentability for such products, or, if patents were granted, automatic compulsory licences permitting others to manufacture such products for a fee. Canada acknowledged that, in order to preclude discrimination as to compulsory licences, the non-discrimination rule of Article 27 was made applicable to Article 31 of the TRIPS Agreement, which grants a limited exception for compulsory licences under specified conditions. To defend its position, therefore, Canada was required to explain how Article 27.1 could apply to exceptions made under Article 31, but not to exceptions made under its neighbouring exception provision in Article 30. Canada argued that Article 31 was "mandatory" in character while Article 30 was "permissive," and that this distinction made it appropriate to apply the non-discrimination provision to the former but not the latter.

The Panel was unable to agree with Canada's contention that Article 27.1 did not apply to exceptions granted under Article 30. The text of the TRIPS Agreement offers no support for such an interpretation. Article 27.1 prohibits discrimination as to enjoyment of "patent rights" without qualifying that term. Article 30 exceptions are explicitly described as "exceptions to the exclusive rights conferred by a patent" and contain no indication that any exemption from non-discrimination rules is intended. A discriminatory exception that takes away enjoyment of a patent right is discrimination as much as is discrimination in the basic rights themselves. The acknowledged fact that the Article 31 exception for compulsory licences and government use is understood to be subject

to the non-discrimination rule of Article 27.1, without the need for any textual provision so providing, further strengthens the case for treating the non-discrimination rules as applicable to Article 30. Articles 30 and 31 are linked together by the opening words of Article 31 which define the scope of Article 31 in terms of exceptions not covered by Article 30.[36]

Nor was the Panel able to agree with the policy arguments in support of Canada's interpretation of Article 27. To begin with, it is not true that being able to discriminate against particular patents will make it possible to meet Article 30's requirement that the exception be "limited". An Article 30 exception cannot be made "limited" by limiting it to one field of technology, because the effects of each exception must be found to be "limited" when measured against each affected patent. Beyond that, it is not true that Article 27 requires all Article 30 exceptions to be applied to all products. Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than a frustration of purpose. It is quite plausible, as the EC argued, that the TRIPS Agreement would want to require governments to apply exceptions in a non-discriminatory manner, in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers.

The Panel concluded, therefore, that the anti-discrimination rule of Article 27.1 does apply to exceptions of the kind authorized by Article 30. We turn, accordingly, to the question of whether Section 55.2(1) of the Canadian Patent Act discriminates as to fields of technology.

(b) Discrimination as to the Field of Technology

In considering how to address the claims of discrimination, the Panel recalled that various claims of discrimination, *de jure* and de facto, have been the subject of legal rulings under GATT or the WTO.

With regard to the issue of *de jure* discrimination, the Panel concluded that the European Communities had not presented sufficient evidence to raise the issue in the face of Canada's formal declaration that the exception of Section 55.2(1) was not limited to pharmaceutical products. Absent other evidence, the words of the statute compelled the Panel to accept Canada's assurance that the exception was legally available to every product that was subject to marketing approval requirements. In reaching this conclusion, the Panel took note that its legal finding of conformity on this point was based on a finding as to the meaning of the Canadian law that was in turn based on Canada's representations as to the meaning of that law, and that this finding of conformity would no longer be warranted if, and to the extent that, Canada's representations as to the meaning of that law were to prove wrong.

The Panel then turned to the question of *de facto* discrimination. As noted above, de facto discrimination is a general term describing the legal conclusion that an ostensibly neutral measure transgresses a non-discrimination norm because its actual effect is to impose differentially disadvantageous consequences on certain parties, and because those differential effects are found to be wrong or unjustifiable. Two main issues figure in the application of that general concept in most legal systems. One is the question of de facto discriminatory effect - whether the actual effect of the measure is to impose differentially disadvantageous consequences on certain parties. The other, related to the justification for the disadvantageous effects, is the issue of purpose - not an inquiry into the subjective purposes of the officials responsible for the measure, but an inquiry into the objective

[36] Article 31 is titled "Other Use Without Authorization of the Rights Holder", and footnote 7 to Article 31 defines "other use" as "use" (derogations from exclusive patent rights) other than that allowed by Article 30.

characteristics of the measure from which one can infer the existence or non-existence of discriminatory objectives.

With regard to the first issue - the actual effects of the measure -, the EC had argued that, despite its potentially broad coverage of many industries, the exception created by Section 55.2(1) had "in effect" applied only to pharmaceutical patents. The Panel received no systematic information on the range of industries that have actually made use of Section 55.2(1). In the absence of such information, the critical question was whether there was some practical reason why the regulatory review exception would in reality work only to the disadvantage of producers of patented pharmaceutical products. The Panel asked the parties for an explanation of any practical considerations that would limit the scope of application of Section 55.2(1) to pharmaceutical products, but no such explanation was provided. The Panel concluded that the EC had not demonstrated that Section 55.2(1) had had a discriminatory effect limited to patented pharmaceutical products.

On the issue of discriminatory purpose, the EC had stressed on several occasions that, in the public discussion of Section 55.2(1), all relevant participants had been exclusively concerned with the impact of the measure on pharmaceutical products, with both support and opposition to the measure being argued in terms of that one dimension. Canada did not contest this characterization of the public debates.

The Panel did not find this evidence from the debates on Section 55.2(1) to be persuasive evidence of a discriminatory purpose. Indeed, it is a common desideratum in many legal systems that legislation apply its underlying principles as broadly as possible. So long as the broader application is not a sham, the legislation cannot be considered discriminatory.

In sum, the Panel found that the evidence in record before it did not raise a plausible claim of discrimination under Article 27.1 of the TRIPS Agreement. It was not proved that the legal scope of Section 55.2(1) was limited to pharmaceutical products, as would normally be required to raise a claim of *de jure* discrimination. Likewise, it was not proved that the adverse effects of Section 55.2(1) were limited to the pharmaceutical industry, or that the objective indications of purpose demonstrated a purpose to impose disadvantages on pharmaceutical patents in particular, as is often required to raise a claim of de facto discrimination. Having found that the record did not raise any of these basic elements of a discrimination claim, the Panel was able to find that Section 55.2(1) is not inconsistent with Canada's obligations under Article 27.1 of the TRIPS Agreement. Because the record did not present issues requiring any more precise interpretation of the term "discrimination" in Article 27.1, none was made.

VIII. CONCLUSIONS

In light of the findings above, the Panel has concluded as follows:

(1) Section 55.2(1) of Canada's *Patent Act* is not inconsistent with Canada's obligations under Article 27.1 and Article 28.1 of the TRIPS Agreement.

(2) Section 55.2(2) of Canada's *Patent Act* is not consistent with the requirements of Article 28.1 of the TRIPS Agreement.

Accordingly, the Panel recommends that the Dispute Settlement Body request that Canada bring Section 55.2(2) into conformity with Canada's obligations under the TRIPS Agreement.