

**CANADA – PATENT PROTECTION OF PHARMACEUTICAL  
PRODUCTS**

*Complaint by the European Communities and their member States*

***Report of the panel***

The report of the Panel on Canada – Patent Protection of Pharmaceutical Products is being circulated to all Members, pursuant to the DSU. The report is being circulated as an unrestricted document from 17 March 2000 pursuant to the Procedures for the Circulation and Derestriction of WTO Documents (WT/L/160/Rev.1). Members are reminded that in accordance with the DSU only parties to the dispute may appeal a panel report, an appeal shall be limited to issues of law covered in the panel report and legal interpretations developed by the panel, and that there shall be no *ex parte* communications with the panel or Appellate Body concerning matters under consideration by the panel or Appellate Body.

Note by the Secretariat: This Panel Report shall be adopted by the Dispute Settlement Body (DSB) within 60 days after the date of its circulation unless a party to the dispute decides to appeal or the DSB decides by consensus not to adopt the report. If the Panel Report is appealed to the Appellate Body, it shall not be considered for adoption by the DSB until after the completion of the appeal. Information on the current status of the Panel Report is available from the WTO Secretariat.

## I. INTRODUCTION

1.1 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).<sup>1</sup> 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.

1.2 In document WT/DS114/6 of 29 March 1999, the DSB was informed of the terms of reference and the composition of the Panel. Due to the absence of agreement between the parties to the dispute on the composition of the Panel, the composition of the Panel was determined by the Director-General pursuant to Article 8.7 of the DSU.

### 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

1.3 The Panel heard the parties to the dispute on 9-10 June and 15 July 1999. The interim report was issued to the parties on 21 January 2000. Both parties requested the Panel to review parts of the interim report. While neither party requested in its comments on the interim report a further meeting with the Panel, Canada did request that it be granted an opportunity to comment on the submission of the European Communities. The Panel considered this request and decided to grant both parties the opportunity to comment upon the other's submission, informing them that these further comments should raise no issues not contained in the initial comments on the interim report.

## II. FACTUAL ASPECTS

### (a) Relevant Provisions of Canadian Patent Law

2.1 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 42. "Every patent granted under this Act shall contain the title or name of the invention, with reference to the specification, and shall, subject to this Act, grant

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<sup>1</sup> See Annex 1 to this Report.

to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction."

Patent Act, Section 44. "Subject to section 46, where an application for a patent is filed under this Act on or after October 1, 1989, the term limited for the duration of the patent is twenty years from the filing date."<sup>2</sup>

Patent Act, Section 55(1). "A person who infringes a patent is liable to the patentee and to all persons claiming under the patentee for all damages sustained by the patentee or by any such person, after the grant of the patent, by reason of the infringement."

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."

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."

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."

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

(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;

(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;

(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

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<sup>2</sup> Section 46 requires the payment of maintenance fees.

sought in the court, the procedure of the court in the matter and the decisions and orders it may make; and

(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."

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."

Patented Medicines (Notice of Compliance) Regulations. See under paragraph 2.7 below.

(b) Canada's Regulatory Review System for Drugs

2.2 Under Canada's Food and Drugs Act, the Therapeutic Products Programme (TPP) of the Federal Department of Health (Health Canada) is responsible, on behalf of the Minister of Health, to ensure that "new drugs" meet health and safety requirements.

2.3 A "new drug" is defined in Section C.08.001 of the Food and Drug Regulations<sup>3</sup> 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.<sup>4</sup> 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).

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<sup>3</sup> The full text of Part C.08 of the Regulations is reproduced in Annex 2 to this Report.

<sup>4</sup> According to the Federal Court of Appeal, in *Apotex Inc. v. Canada*, [1994] 1 F.C. 742 (appeal dismissed [1994] 3 S.C.R. 1100 (S.C.C.)), at p. 753, the process by which a "new drug" is approved for manufacture and sale in Canada can be summarized as follows:

"A "new drug" must undergo rigorous testing before it may be sold. The manufacturer of the drug must file a New Drug Submission ("NDS") with the [TPP] setting out, *inter alia*, the drug's qualities, ingredients and methods of manufacture and purification. The NDS also includes the results of the manufacturer's clinical studies supporting the drug's safety and effectiveness. All aspects of the NDS are examined by multidisciplinary teams of the Drugs Directorate of the [TPP]. A NOC [Notice of Compliance, i.e. marketing approval] will only issue if the drug is found to be both effective and safe for human use..."

2.4 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.

2.5 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.<sup>5</sup> 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).<sup>6</sup>

2.6 The delay involved in pre-market activities for a generic drug arises because, after first perceiving a market for a particular product, a generic manufacturer will then ordinarily seek an outside fine chemical producer to supply the active ingredient for the product, although sometimes manufacturing of the raw material is done internally or through a subsidiary. The technology involved in manufacturing fine chemicals requires different expertise and equipment from the manufacture of dosage forms (e.g., tablets).

- The fine chemical producer must attempt to develop a means to manufacture the active ingredient to the required degree of purity. Sometimes more than one producer will be asked by the generic manufacturer to develop a manufacturing process for the active ingredient, because not all will succeed in achieving the necessary purity. The generic manufacturer will do its own testing of the raw material samples sent by the fine chemical producer to satisfy itself that the purity is acceptable. On average, all this takes about one year, although it has, in some instances, taken much longer.
- Once a generic manufacturer has established a satisfactory source for the raw material, it will buy it as required from the fine chemical manufacturer. The generic manufacturer will then develop the formulation of the final dosage form.
- This involves mixing the raw material with the excipients (i.e., the inactive ingredients), typically consisting of inert filler, a binding agent and a coating of some kind. A testing model will be developed for establishing bioequivalence with the Canadian reference product to the satisfaction of Health Canada.
- The nature of this testing will vary depending on the new drug. Variables will include how many subjects (i.e., healthy volunteers) are to be used, how much of the drug is to be administered, whether a fed or a fasting study or both need to be done, how many samples will be taken of blood, urine, etc., and how they will be measured, and whether a comparative clinical trial (i.e., a trial comparing effectiveness in treating the condition with the Canadian Reference Product) must be done.
- Candidate formulations will be developed, manufactured in small batches, and then tested on subjects. This will be repeated if necessary until test results show that pharmaceutical equivalence can be established using a testing model satisfactory to Health Canada. The generic manufacturer must also include six months of stability data in its

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<sup>5</sup> See Annex 3 to this Report.

<sup>6</sup> Information package prepared jointly by Industry Canada and Health Canada to provide factual background information for the review of the Patent Act Amendment Act, 1992 (Bill C-91) by the House of Commons Committee on Industry, Government of Canada, February 1997.

submission, showing the formulation will not deteriorate prematurely. All this might take one to three years, in addition to the one year (approximately) needed for development of the raw material. Thus, the total pre-submission time necessary to develop a generic drug is two to four years.

2.7 Bill C-91, which resulted in the current Canadian Patent Act, led to a number of changes in the marketing and sale of patented drugs in Canada as well as the regulatory review process:

(i) ANDS reviews will lead to the grant of a Notice of Compliance in between 12 to 30 months, subject to litigation under the Patented Medicines (Notice of Compliance) Regulations enacted pursuant to section 55.2(4) of the Patent Act. The full text of these regulations can be found in Annex 4 to this Report. They "prohibit the issuance of Notices of Compliance in respect of 'patent-linked' drugs. A 'patent-linked' drug is one in respect of which both a Notice of Compliance and an unexpired patent have been issued. The patent may relate to either the medicine itself or the method of using the drug to treat an illness".<sup>7</sup> This prohibition against the issuance of Notices of Compliance in respect of "patent-linked" drugs means that the Minister of Health may not issue a Notice of Compliance to a party who is not the patent holder (i.e. to a generic drug manufacturer) where the patent holder alleges that marketing the medicine would infringe its patent. The procedure envisaged by the regulations is as follows:

- a patentee may submit a patent list to the Minister in respect of any drug that contains a "medicine", as defined in section 2 of the Regulations<sup>8</sup>;
- where a generic manufacturer files a submission for a Notice of Compliance in respect of a drug, and the submission compares the drug or refers to the drug of another manufacturer (the innovator) that has already been marketed in Canada pursuant to a Notice of Compliance, and concerning which the innovator has filed a patent list with the Minister, the generic manufacturer's ANDS must contain one or the other of two prescribed statements: (i) a statement that the generic manufacturer accepts that the Notice of Compliance will not issue until the patent expires, or (ii) an allegation that the innovator is not the owner or the exclusive licensee of the patent, that the patent has expired, that the patent is not valid, or that the generic manufacturer's marketing of the drug would not infringe any claim for the patented medicine itself or any claim for the use of the patented medicine<sup>9</sup>;
- if the generic manufacturer makes an allegation of the kind just described, it is obliged to serve a notice of the allegation on the innovator<sup>10</sup>;
- the innovator may then, within 45 days after being served with the notice of allegation, apply to a court for an order prohibiting the Minister from issuing the Notice of Compliance until the patent that is the subject of the allegation has expired<sup>11</sup>;

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<sup>7</sup> Federal Court of Appeal, in *Apotex Inc. v. Canada*, [1994] 1 F.C. 742 (appeal dismissed [1994] 3 S.C.R. 1100 (S.C.C.)), at p. 756.

<sup>8</sup> Section 4(1) of the Regulations

<sup>9</sup> Section 5(1) of the Regulations

<sup>10</sup> Section 5(3) of the Regulations

<sup>11</sup> Section 6(1) of the Regulations

- the Minister may not issue the Notice of Compliance during the 24-month period following receipt of the innovator's notice of application<sup>12</sup>, unless the application is finally dismissed by the court within that period.<sup>13</sup>

The normal practice is for Notices of Compliance to issue for generic drugs immediately upon patent expiry, at which time the drugs are available on the open market, except for provincial public assistance plans, which have their own acceptance processes (which range from one to 16 months).

(ii) Prior to the Patent Act Amendment Act, 1992 (Bill C-91), nothing prevented Notices of Compliance from being issued once all the safety and efficacy requirements were satisfied. "Prior to the proclamation of Bill C-91, a generic drug company could obtain a compulsory licence from the Commissioner of Patents authorizing it to advertise, manufacture and sell any drug in respect of which a Notice of Compliance had been issued. Although the generic drug company was required to pay royalties to the drug's innovator, it could sell the drug notwithstanding the innovator's patent rights. This arrangement was governed by subsection 39(4) of the *Patent Act*, R.S.C. 1985 [...]. Bill C-91 was drafted in order to protect innovator pharmaceutical companies' distribution and sales rights to patented drugs and represents a reversal of government policy adopted by Parliament in 1923 [...]. The immediate effects of Bill C-91 are well known. Section 3 of the Bill repealed the compulsory licensing provisions of the *Patent Act*, while section 12(1) extinguished all compulsory licences issued on or after December 20, 1991 [...]."<sup>14</sup>

### III. FINDINGS AND RECOMMENDATIONS REQUESTED BY THE PARTIES

3.1 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.

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<sup>12</sup> As originally promulgated, the Regulations prohibited the Minister from issuing the Notice of Compliance for a period of 30 months, but that period was reduced to 24 months by amendment in 1998 (SOR/98-166).

<sup>13</sup> Section 7(1)(e) and 7(4) of the Regulations

<sup>14</sup> Federal Court of Appeal, in *Apotex Inc. v. Canada*, [1994] 1 F.C. 742 (appeal dismissed [1994] 3 S.C.R. 1100 (S.C.C.)), at pp. 754-55.

**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.

**III. Article 64.1 of the TRIPS Agreement, Article XXIII of GATT 1994 and Article 3.8 of the DSU**

- (e) That the violations referred to under I. and II. above constituted prima facie nullification or impairment under Article 64.1 of the TRIPS Agreement, Article XXIII of GATT 1994 and Article 3.8 of the DSU.
- (f) That the DSB request Canada to bring its domestic legislation into conformity with its obligations under the TRIPS Agreement.

3.2 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.

**[Parties' arguments in Sections IV and V deleted from this version]**

## VI. INTERIM REVIEW

6.1 The Panel's interim report was sent to the parties on 21 January 2000. On 28 January 2000 both the European Communities and Canada requested the Panel to review precise aspects of the interim report, in accordance with Article 15.2 of the Dispute Settlement Understanding. Neither the EC nor Canada requested a further meeting with the Panel. Canada, however, requested an opportunity to comment on the comments submitted by the EC. The Panel decided that both parties should be given an opportunity to submit further comments strictly limited to each other's comments, to be submitted no later than 3 February 2000. On 2 February, both the EC and Canada submitted further comments.

6.2 The following is a description of the comments made at the interim review stage, and the Panel's responses, as required by Article 15.3 of the DSU.

6.3 The EC made four comments in its first submission. First, in what is now footnote 434 to what is now paragraph 7.97, the EC pointed out that the text of the footnote attributed to it a position concerning the meaning of Section 55.2(1) of Canada's Patent Act that it had never taken. The Panel revised the text of the footnote to remove the erroneous attribution and made a similar revision to what is now paragraph 7.95.

6.4 Second, in what is now paragraph 7.103, the EC pointed out that the Panel's description of the EC's characterization of the legislative proceedings leading to the enactment of Section 55.2(1) and 55.2(2) contained a qualification that was not part of the EC's characterization. The Panel revised the text to remove the qualification.

6.5 Third, the EC asked for clarification of several paragraphs of the interim report, but the paragraphs themselves were subsequently removed by the Panel in light of a clarification submitted by Canada, as described in paragraph 6.8 below. Removal of the paragraphs rendered the EC's question moot.

6.6 Fourth, the EC pointed out that the meaning of the final sentence of what is now paragraph 7.99 was unclear, and suggested a clearer form of expression. In its further comment responding to the EC comments, Canada objected to the wording of the correction suggested by the EC, which would have described Canada's representations about the meaning of the Canadian statute in question as an "undertaking". Canada pointed out that its Government was in no position to give undertakings about the eventual judicial interpretation of the statute, since it had no control over them. The Panel accepted the EC suggestion to clarify the sentence, and amended the paragraph accordingly, without describing Canada's representations as an "undertaking".

6.7 Canada submitted two comments in its first submission. First, in what is now paragraph 7.1, Canada objected to a paraphrase of Article 33 of the TRIPS Agreement which it believed might have unwanted legal significance. The Panel agreed to substitute a text tracking the exact words of Article 33.

6.8 Second, Canada called attention to the Panel's interpretation of a statement made by Canada to the Panel explaining the meaning of Section 55.2(1) with regard to commercial disposition of patented goods manufactured during the term of the patent in order to meet testing requirements of the regulatory review process. Canada clarified the intended meaning of its statement in a way that made the Panel's initial interpretation of that statement incorrect. In its further comment responding to Canada's comments, the EC disputed the interpretation of Section 55.2(1) represented by Canada in its corrected statement. The Panel found Canada's interpretation of Section 55.2(1) more persuasive than the EC's interpretation. Accordingly, the Panel withdrew from the Report its discussion of the issue of consistency with the TRIPS Agreement raised by its original interpretation of the Canadian

statement, and substituted footnote 404 to paragraph 7.45 below explaining how the issue had arisen and why the Panel had concluded that the Canadian law did not in fact present an issue of consistency with the TRIPS Agreement.

## VII. FINDINGS

### A. MEASURES AT ISSUE

7.1 At issue in this dispute is the conformity of two provisions of Canada's *Patent Act* with Canada's obligations under the *Agreement on Trade-Related Aspects of Intellectual Property Rights* ("the TRIPS Agreement"). The two provisions in dispute, Sections 55.2(1) and 55.2(2) of the Patent Act, create exceptions to the exclusive rights of patent owners. Under Article 28.1 of the TRIPS Agreement, patent owners shall have the right to exclude others from making, using, selling, offering for sale or importing the patented product during the term of the patent. According to Article 33 of the TRIPS Agreement, the term of protection available shall not end before the expiration of a period of 20 years counted from the filing date of the application against which the patent was granted. Sections 55.2(1) and 55.2(2) allow third parties to make, use or sell the patented product during the term of the patent without the consent of the patent owner in certain defined circumstances.

#### (1) SECTION 55.2(1): THE REGULATORY REVIEW EXCEPTION

7.2 Section 55.2(1) provides as follows:

"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."

Section 55.2(1) is known as the "regulatory review exception". It applies to patented products such as pharmaceuticals whose marketing is subject to government regulation in order to assure their safety or effectiveness. The purpose of the regulatory review exception is to permit potential competitors of the patent owner to obtain government marketing approval during the term of the patent, so that they will have regulatory permission to sell in competition with the patent owner by the date on which the patent expires. Without the regulatory review exception, the patent owner might be able to prevent potential competitors from using the patented product during the term of the patent to comply with testing requirements, so that competitors would have to wait until the patent expires before they could begin the process of obtaining marketing approval. This, in turn, would prevent potential competitors from entering the market for the additional time required to complete the regulatory approval process, in effect extending the patent owner's period of market exclusivity beyond the end of the term of the patent.

7.3 Because of the regulatory review exception's importance to the pharmaceutical industry, the operation of the exception with regard to new pharmaceuticals was explained in some detail by the parties. Information supplied by Canada in the proceedings before the Panel on the process of regulatory approval in Canada for patented and generic drugs can be found in paragraphs 2.2 to 2.7 above and Annexes 3 and 4 to this Report. The information has not been contested by the European Communities. Since patent applications are generally filed as quickly as possible after the invention has been made, actual marketing of the patented product is frequently delayed for a certain period of time because time is required for development of the product in commercial form, after which additional time is required to complete the testing required for government approval. According to the information supplied by Canada, the process of development of the drug and regulatory approval for new patented pharmaceuticals normally takes approximately eight to 12 years. The long

development and approval process means that, for most patented pharmaceuticals, the 20-year patent term results in an actual period of market exclusivity of only some 12 to eight years. After a pharmaceutical patent expires, it is common for other producers to enter the market supplying copies of the patented product at lower prices. These lower-priced copies, known as "generic" pharmaceuticals, often constitute a large part of the supply of pharmaceuticals in national markets. Generic pharmaceuticals must also comply with the government approval process. According to Canada's information, for generic producers the process of developing their version of the drug and obtaining regulatory approval takes approximately three to six-and-a-half years, with development taking some two to four years and the regulatory process itself one to two-and-a-half years. If none of the development process could be performed during the term of the patent, generic producers could be forced to wait the full three to six-and-a-half years after the patent expires before being able to enter the market in competition with the patent owner. To the extent that some development activity might be permitted, consistently with Article 30 of the TRIPS Agreement, under other exceptions such as the traditional exception for experimental use of the patented product, the delay in entering the market would be correspondingly less. The regulatory review exception in Section 55.2(1) would allow generic producers to complete both development and regulatory approval during the term of the patent, thus allowing them to enter the market as soon as the patent expires.

7.4 The structure of the generic pharmaceutical industry illustrates the actual operation of the regulatory review exception. Production of generic pharmaceuticals often involves a two-tier production arrangement. The firm that assembles and markets the final generic product often does not have the technological capacity/expertise or the commercial motivation to produce the so-called "active ingredient" - the chemical product that generates the desired medicinal effect. The active ingredient is thus often manufactured by a specialized producer of fine chemicals, and then sold to the generic producer which assembles the active ingredient with other agents to create the final product in a form that can be used by the ultimate consumer. In such cases, both producers must engage in conduct that, in the absence of a regulatory review exception, would be potentially infringing, if they are to satisfy the requirements of the regulatory review process – the fine chemical producer in developing, making and selling the necessary amounts of the active ingredient to the generic producer, and the generic producer in combining the various elements to make the final product and then demonstrating its safety, stability and effectiveness by appropriate tests.<sup>372</sup> The regulatory review exception applies to these activities of both producers.

7.5 To qualify for exemption under Section 55.2(1), such activities by either fine chemical producers or generic producers must be "solely for uses reasonably related to the development and submission of information required" by any law, Canadian or non-Canadian, that "regulates the manufacture, construction, use or sale of any product". In answer to a question from the Panel, Canada stated that, although Canadian marketing regulations for generic producers did not require production runs to demonstrate the applicant's ability to maintain quality production in commercial volumes<sup>373</sup>, the statute would allow either fine chemical manufacturers or generic producers to undertake such production runs if they were required by regulations in other countries.

7.6 With regard to the enforcement of these conditions, Canada explained that these exceptions were part of the general law of infringement, under which it is up to the patent owner to enforce his patent rights in a civil action for infringement.<sup>374</sup> Patent owners who believed that actions by generic producers did not comply with the requirements of Section 55.2(1) would have to bring an infringement action against such conduct.<sup>375</sup> Patent owners would merely be required to prove

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<sup>372</sup> The active ingredient may also be imported, for example from a producer located in a country where the product in question is not covered by patent protection.

<sup>373</sup> For the requirements under the Canadian marketing regulations, see Part C.08 of the Food and Drug Regulations, which Canada made available in the proceedings and which can be found in Annex 2 to this Report.

<sup>374</sup> See paragraph 4.20 above.

<sup>375</sup> Canada also called attention to the provisions of Section 55.2(4) of the Patent Act and the Patented Medicines (Notice of Compliance) Regulations, which establish a summary procedure that owners of a patent for a drug can use to

conduct inconsistent with the owner's exclusive patent rights, after which persons claiming the benefit of the Section 55.2(1) exemptions would then be required to prove their compliance with the conditions of that provision as a defence.

(2) *SECTION 55.2(2): THE STOCKPILING EXCEPTION*

7.7 Section 55.2(2) of the Patent Act, which is referred to as "the stockpiling exception", reads as follows:

"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."

The provision allows competitors to manufacture and stockpile patented goods during a certain period before the patent expires, but the goods cannot be sold until the patent expires. Without this exception, the patent owner's right to exclude any person from "making" or "using" the patented good would enable the patent owner to prevent all such stockpiling.

7.8 The exception created by Section 55.2(2) does not become effective until implementing regulations are issued. The only regulations issued to date under the stockpiling exception have been regulations making the exception operative with regard to pharmaceutical products. The period during which pharmaceutical products can be made and stockpiled is six months immediately prior to the expiration of the patent.

7.9 The text of Section 55.2(2) gives permission only to "make, construct or use" the patented product for purposes of stockpiling. In answer to a question from the Panel, however, Canada has taken the position that the exception will be construed also to allow the "sale" of patented ingredients that have been ordered by a producer who is stockpiling the final patented product - for example, with regard to pharmaceuticals, sales by fine chemical producers of active ingredients ordered by the generic producer.<sup>376</sup>

7.10 The stockpiling exception is available only to persons who have invoked the regulatory review exception in Section 55.2(1). This limitation has the effect of limiting the exception to products that are subject to the kind of government marketing regulations referred to in Section 55.2(1). As a practical matter, only persons who have actually obtained regulatory permission to market such regulated products would be able to benefit from the stockpiling exception, because there would be no commercial advantage in having a stock of goods on hand when the patent expires unless one also has regulatory permission to sell those goods as of that date. Conversely, the stockpiling exception does complement the competitive effects of the regulatory review exception. Without the additional permission to stockpile during the term of the patent, competitors who obtain regulatory permission to sell on the day the patent expires would still not be able to enter the market on that day, because they would first have to manufacture a sufficient stock of goods.

B. CLAIMS OF THE PARTIES

7.11 The EC asked the Panel to find that Sections 55.2(1) and 55.2(2) of Canada's Patent Act are inconsistent with Canada's obligations under Articles 27.1 and 28.1 of the TRIPS Agreement and, to

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prevent competitors seeking regulatory approval for a drug while comparing that drug with the patented drug from marketing their approved drug before the patent in question expires, if their drug infringes the patent or is covered by the patent claims but meets the conditions of Section 55.2(1).

<sup>376</sup> See footnote 49 above.

the extent that Section 55.2(2) violates Article 28.1, it is also inconsistent with Article 33 of the TRIPS Agreement.<sup>377</sup>

7.12 Canada argued that neither Section 55.2(1) nor Section 55.2(2) violate any of the three TRIPS provisions cited. With regard to the claimed violation of Article 28.1 of the TRIPS Agreement, Canada acknowledged that Sections 55.2(1) and 55.2(2) permit conduct that conflicts with the patent rights granted in accordance with Article 28.1, but Canada claimed that each of these two provisions is an exception authorized by Article 30 of the Agreement. With regard to the claimed violation of Article 27.1, Canada presented two defences: first, that Article 27.1 does not apply to measures authorized by Article 30 of the Agreement and second, that, even if Article 27.1 does apply to measures authorized by Article 30, the two provisions of the Patent Act in question do not discriminate in violation of Article 27.1. With regard to the claimed violation of Article 33, Canada maintained that Section 55.2(2) does not violate Article 33.

#### C. PRINCIPLES OF INTERPRETATION

7.13 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.<sup>378</sup> 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
- (b) leads to a result which is manifestly absurd or unreasonable."

7.14 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

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<sup>377</sup> On each occasion that the EC refers to its claim that Section 55.2(2) violates Article 28.1 of the TRIPS Agreement, the EC describes the violation as a violation of "Article 28.1 together with Article 33". The precise meaning of this linking terminology was not explained. The Panel concluded that it was required to deal with the claimed violation of Article 28.1 as a separate issue, and that it should defer considering the Article 33 claim, and the exact meaning of the "together with" linkage until that issue actually presented itself.

<sup>378</sup> Vienna Convention on the Law of Treaties 1969, entered into force on 27 January 1980

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.

7.15 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.

#### D. BURDEN OF PROOF

7.16 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*<sup>379</sup>:

"[...] 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".<sup>380</sup>

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.

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<sup>379</sup> Document WT/DS33/AB/R, pp. 13-16 (adopted 23 May 1997).

<sup>380</sup> 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).

E. SECTION 55.2(2) (THE STOCKPILING EXCEPTION)

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

(a) Introduction

7.17 The Panel began by considering the claims of violation concerning Section 55.2(2), the so-called stockpiling provision. It began by considering the EC claim that this measure was in violation of Article 28.1 of the TRIPS Agreement, and Canada's defence that the measure was an exception authorized by Article 30 of the Agreement.

7.18 Article 28.1 provides:

**"Rights Conferred**

1. A patent shall confer on its owner the following exclusive rights:
  - (a) Where the subject-matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling, or importing for these purposes that product;"

There was no dispute as to the meaning of Article 28.1 exclusive rights as they pertain to Section 55.2(2) of Canada's Patent Act. Canada acknowledged that the provisions of Section 55.2(2) permitting third parties to "make", "construct" or "use" the patented product during the term of the patent, without the patent owner's permission, would be a violation of Article 28.1 if not excused under Article 30 of the Agreement. The dispute on the claim of violation of Article 28.1 involved whether Section 55.2.(2) of the Patent Act complies with the conditions of Article 30.

7.19 The TRIPS Agreement contains two provisions authorizing exceptions to the exclusionary patent rights laid down in Article 28 - Articles 30 and 31.<sup>381</sup> Of these two, Article 30 - the so-called limited exceptions provision - has been invoked by Canada in the present case. It reads as follows:

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<sup>381</sup> The text of Article 31 reads as follows:

Article 31 - Other Use Without Authorization of the Right Holder: "Where the law of a Member allows for other use (footnote: "other use" refers to use other than that allowed under Article 30) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are

### "Exceptions to Rights Conferred"

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

7.20 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"<sup>382</sup>; (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.

7.21 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.<sup>383</sup> 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".<sup>384</sup>

7.22 Canada argued that Section 55.2(2) complies with each of the three conditions of Article 30. The European Communities argued that Section 55.2(2) fails to comply with any of the three

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- unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
  - (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
  - (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
  - (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
  - (l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
    - (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
    - (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
    - (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

<sup>382</sup> The parties disagreed over whether this second condition also includes the final phrase of Article 30 - "taking account of the legitimate interests of third parties". For reasons explained below, the Panel found it unnecessary to resolve this disagreement.

<sup>383</sup> See *United States - Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, p. 23 (adopted 20 May 1996).

<sup>384</sup> 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.

conditions. Both parties introduced their arguments with an analysis of the object and purpose of the TRIPS Agreement in this area, and then presented interpretations of the three Article 30 conditions in support of their positions.

(b) Object and Purpose

7.23 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<sup>385</sup> was given to Articles 7 and 8.1, which provide:

**"Article 7**

**Objectives**

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and *in a manner conducive to social and economic welfare, and to a balance of rights and obligations.*" (Italics added)

**"Article 8**

**Principles**

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."

7.24 In the view of Canada, the italicized text of Article 7 above 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.

7.25 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

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<sup>385</sup> 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)

Part of the Article 1.1 text referred to reads:

"Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal systems and practice."

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 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.

7.26 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.

(c) "Limited Exceptions"

7.27 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<sup>386</sup> 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).

7.28 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".<sup>387</sup> 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".<sup>388</sup> 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.<sup>389</sup> 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.<sup>390</sup>

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<sup>386</sup> The term is used here to include purchasers in the distribution chain to the ultimate consumer.

<sup>387</sup> EC Oral Statement at First Meeting, paragraph 52

<sup>388</sup> EC Rebuttal, paragraph 59

<sup>389</sup> Ibid, paragraph 60

<sup>390</sup> First Submission of the European Communities, paragraph 23

7.29 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".<sup>391</sup> The Panel examined the documented 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).<sup>392</sup>

7.30 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"<sup>393</sup>, 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.

7.31 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.<sup>394</sup> 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.

7.32 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.

7.33 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

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<sup>391</sup> 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."

<sup>392</sup> See Annex 6 to this Report for the various drafts of what became Article 30 discussed in the Uruguay Round Negotiating Group on TRIPS.

<sup>393</sup> The Shorter Oxford English Dictionary at p. 1216

<sup>394</sup> The interpretation of the second and third conditions of Article 30 are explained under F(1)(b) and (c) below.

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.

7.34 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.

7.35 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.

7.36 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. Without seeking to define exactly what level of curtailment would be disqualifying, it was clear to the Panel that an exception which results in a substantial curtailment of this dimension cannot be considered a "limited exception" within the meaning of Article 30 of the Agreement.

7.37 Neither of the two "limitations" upon the scope of the measure are sufficient to alter this conclusion. First, the fact that the exception can only be used by those persons who have utilized the regulatory review exception of Section 55.2(1) does limit the scope of the exception both to those persons and to products requiring regulatory approval. In regard to the limitation to such persons, the Panel considered this was not a real limitation since only persons who satisfy regulatory requirements would be entitled to market the product. In regard to the limitation to such products, the Panel considered that the fact that an exception does not apply at all to other products in no way changes its effect with regard to the criteria of Article 30. Each exception must be evaluated with regard to its impact on each affected patent, independently. Second, the fact that the exception applied only to the last six months of the patent term obviously does reduce its impact on all affected patented products, but the Panel agreed with the EC that six months was a commercially significant period of time, especially since there were no limits at all on the volume of production allowed, or the market destination of such production.

7.38 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.

F. SECTION 55.2(1) (THE REGULATORY REVIEW EXCEPTION)

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

7.39 Both parties agreed that, if the regulatory review exception of Section 55.2(1) met the conditions of Article 30 of the TRIPS Agreement, the acts permitted by that Section would not be in violation of Article 28.1 of the TRIPS Agreement. Canada argued that Section 55.2(1) complies with each of the three conditions of Article 30. The European Communities argued that Section 55.2(1) fails to comply with any of the three conditions. We now turn to the respective arguments for applying these three Article 30 conditions to Section 55.2(1).

(a) "Limited Exceptions"

7.40 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.

7.41 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".<sup>395</sup> 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 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."<sup>396</sup>

7.42 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.<sup>397</sup> Canada argued that these actions are subsequent practices by parties to the agreement,

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<sup>395</sup> First Submission of Canada, paragraph 25. 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)).

<sup>396</sup> First Submission of Canada, paragraph 105 and Exhibit 41, quoting letter of US Trade Representative Michael Kantor to Alfred B. Engelberg, 1 February 1996

<sup>397</sup> First Submission of Canada, paragraphs 109-117

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.<sup>398</sup>

7.43 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.<sup>399</sup> 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".<sup>400</sup> 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.<sup>401</sup> 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.<sup>402</sup> 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.<sup>403</sup>

7.44 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.

7.45 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.<sup>404</sup>

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<sup>398</sup> See paragraph 7.13 above.

<sup>399</sup> First Submission of the European Communities at paragraphs 30 and 54

<sup>400</sup> Oral Statement at First Meeting, paragraphs 67 and 68

<sup>401</sup> Ibid. at paragraph 32

<sup>402</sup> First Submission of the EC, paragraph 30

<sup>403</sup> EC Oral Statement at First Meeting, paragraphs 64-69

<sup>404</sup> In responding to a question asked by the Panel after the first meeting with the parties, Canada submitted an answer that indicated to the Panel that Section 55.2(1) would be interpreted by Canada to authorize the commercial disposition of patented products, manufactured during the term of the patent to meet regulatory review requirements, provided that they were sold after the patent in question had expired (see footnote 101 above). Although the parties themselves had not raised the issue of commercial disposition in such circumstances, this possible interpretation of Section 55.2(1) raised for the Panel the question whether a regulatory review exception authorizing such post-expiry commercial disposal could be considered "limited" within the meaning of Article 30 of the TRIPS Agreement. In its initial comments to the Panel's interim report, however, Canada corrected the Panel's interpretation of its earlier answer (see paragraph 6.8 above). Canada explicitly represented to the Panel that Section 55.2(1) did not permit commercial disposition

7.46 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 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).

7.47 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.<sup>405</sup>

7.48 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-a-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.

7.49 After analysing all three conditions stated in Article 30 of the TRIPS Agreement, the Panel was satisfied that Article 30 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

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of such products, even after the patent had expired, whether for export or domestic sales. Canada assured the Panel that all such commercial disposition would be considered an infringement of the patent on the ground that it would not be "reasonably related to the development or submission of information" required by regulatory review authorities. In its further comment responding to this Canadian comment (see paragraph 6.8 above), the EC disputed Canada's interpretation on the ground that actions taken after expiry of the patent "are perfectly free because the exclusive rights granted by the patent have ceased to exist". The Panel did not accept the EC position, finding no reason why a statute granting immunity from infringement liability could not make that immunity contingent on subsequent conduct. Moreover, given that the text of Section 55.2(1) does not deal explicitly with the issue of post-expiry sales, the Panel found Canada's interpretation of the statute's general language on this point to be the more likely interpretation. Accordingly, having found that Section 55.2(1) did not in fact present an issue of consistency with Article 30, the Panel did not pursue the issue further.

<sup>405</sup> See paragraph 7.13 above.

condition ("limited exception") is neither designed nor intended to address the issue of economic impact directly.

7.50 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"

7.51 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.<sup>406</sup> The European Communities also defined "exploitation" by referring to the same three ways of "working" a patent.<sup>407</sup> The parties differed primarily on their interpretation of the term "normal".

7.52 Canada's view of "normal exploitation" was implicit in its primary argument. Canada considered that the regulatory review exception of Section 55.2(1) does not conflict with "normal exploitation" because it does not conflict at all with the patent owner's exclusive marketing rights throughout the term of the patent.<sup>408</sup> To be sure, the value derived from the exercise of exclusive marketing rights during the term of the patent is the key ingredient in the exploitation of a patent. The issue in dispute, however, was whether the concept of "normal exploitation" *also* includes the additional period of market exclusivity that would be obtained, *after* the term of the patent, if patent rights could be used to prevent competitors from obtaining, or taking steps to obtain, marketing authorization during the term of the patent. By inference, Canada's assertion that "normal exploitation" is sufficiently safeguarded by protecting market exclusivity during the term of the patent amounted to an assertion that these post-expiration forms of market exclusivity should not be considered as normal exploitation. Although Canada did not explain this conclusion further in its arguments pertaining to the "normal exploitation" test, that same conclusion was also implicit in Canada's repeated assertion, in other contexts, that it had never been the intent of either the patent laws or the marketing authorization requirements, to permit themselves to be used by patent owners to create a period of de facto market exclusivity after the patent expires.<sup>409</sup> In other words, Canada argued, such patent extension had never been part of the bargain between patent owners and society, and consequently patent owners had no "legitimate interest" in such an extension.

7.53 The EC reply to Canada's definition of "normal exploitation" argued that Canada's focus on commercial sales during the term of the patent mistakenly treats a patent as establishing a right to sell, whereas in fact patent rights are rights to exclude several different kinds of behaviour. According to the EC's argument, Canada's definition of "normal exploitation" only took account of the patent owner's right to exclude sales by third parties during the term of the patent, and so failed to address the patent owner's other rights to exclude third parties from "making" or "using" the patented product during the term of the patent.<sup>410</sup> The EC's argument implied that "normal exploitation" should be defined in terms of the market exclusivity that arises from the exercise of all exclusionary rights, regardless of whether that market exclusivity arises during the patent term or after it. Since the rights to exclude "making" or "using" often lead to periods of de facto market exclusivity in the period after the patent expires, due respect for these particular patent rights must lead, in the EC's view, to the

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<sup>406</sup> Canada's First Submission, paragraph 78

<sup>407</sup> EC Oral Statement at First Meeting, paragraph 70

<sup>408</sup> Canada's First Submission, paragraphs 78-79

<sup>409</sup> Canada, First Submission, paragraphs 81-86

<sup>410</sup> EC Second (Rebuttal) Submission, paragraphs 62-64, 80-81

conclusion that post-expiration market exclusivity created by the exercise of such exclusionary rights must be part of the "normal exploitation" of a patent."

7.54 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".<sup>411</sup> 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.

7.55 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.

7.56 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.

7.57 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.

7.58 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 the Panel's view, the EC's argument contained no evidence or analysis addressed to the various meanings of "normal" - neither a demonstration that most patent owners extract the value of their patents in the manner barred by Section 55.2(1), nor an argument that the prohibited manner of exploitation was "normal" in the sense of being essential to the achievement of the goals of patent policy. To the contrary, the EC's focus on the exclusionary rights themselves merely restated the concern to protect Article 28 exclusionary rights as such. This is a concern already dealt with by the first condition of Article 30 ("limited exception") and the Panel

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<sup>411</sup> The New Shorter Oxford English Dictionary, p.1940

found the ultimate EC arguments here impossible to distinguish from the arguments it had made under that first condition.<sup>412</sup>

7.59 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 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"

7.60 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. Likewise, the weight of legitimate third party interests cannot be fully appraised until the legitimacy and weight of the patent owner's legitimate interests, if any, are defined. Accordingly, without disturbing the ultimate burden of proof, the Panel chose to analyse the issues presented by the third condition of Article 30 according to the logical sequence in which those issues became defined.

7.61 The ultimate issue with regard to the regulatory review exception's compliance with the third condition of Article 30 involved similar considerations to those arising under the second condition ("normal exploitation") - the fact that the exception would remove the additional period of de facto market exclusivity that patent owners could achieve if they were permitted to employ their rights to exclude "making" and "using" (and "selling") the patented product during the term of the patent to prevent potential competitors from preparing and/or applying for regulatory approval during the term of the patent. The issue was whether patent owners could claim a "legitimate interest" in the economic benefits that could be derived from such an additional period of de facto market exclusivity and, if so, whether the regulatory review exception "unreasonably prejudiced" that interest.

(i) *Primary EC claim of legitimate interest*

7.62 The European Communities argued that the regulatory review exception in Section 55.2(1) fails to satisfy the third condition of Article 30. The primary EC argument on this point rested on an interpretation that identified "legitimate interests" with legal interests. The EC asserted that the "legitimate interests" of the patent owner can only be the full enjoyment of his patent rights during the entire term of the patent.<sup>413</sup> Given that starting point, it followed that any exception to Article 28.1 rights would constitute "prejudice" to the legitimate interests of a patent owner. Consequently, the remainder of the EC's argument concentrated on whether the prejudice was "unreasonable", an issue which in turn focused on whether the "legitimate interests of third parties" outweighed the patent

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<sup>412</sup> Paragraph 82 of the EC's Second (Rebuttal) Submission argues as follows:

"By disregarding **all** patent rights stipulated by Article 28.1 of the TRIPS Agreement **during the entire patent term for a wide range of beneficiaries and for activities which are of a significant extent** if performed for Canadian regulatory requirements and perfectly outside the control and largely outside the knowledge of the Canadian authorities if performed to meet regulatory requirements in any other country, Section 55.2(1) of the Patent Act has to be considered to unreasonably conflict with a normal exploitation of the patent." (boldface in original)

<sup>413</sup> EC Oral Statement, First Meeting, paragraph 59; EC Second (Rebuttal) Submission, paragraph 67

owner's interests in full enjoyment of his legal rights. The EC first argued that the only relevant "third parties" for the purpose of Article 30 are the patent owner's competitors - in the case of pharmaceutical patents the generic drug producers, because they were the only parties with interests adverse to those of patent owners. According to the EC's view, the TRIPS Agreement constitutes a recognition that patent systems serve the interest of the society, including the multiple interests of its health policy. That being so, the patent rights granted by that Agreement, being a part of the balance of rights and obligations that governments have agreed to as beneficial, cannot be found to be adverse to, or in conflict with, the interests represented by general social welfare policy. And that, in turn, means that the only adverse third party interests to patent owners are the interests of those firms with whom they compete.

7.63 Then, following its position that "legitimate interests" are essentially legal interests, the EC went on to argue that the legitimate interests of competing producers are essentially the same as those of patent owners - that is, the full enjoyment of their legal rights. The legal rights of the patent owner's competitors, the EC argues, are the rights to make, use or sell the patented product on the day *after* the patent expires.<sup>414</sup> Such competitors, therefore, could have no "legitimate" interest in the rights granted by the regulatory review exception of Section 55.2(1), because they could have no legal right to "make" or "use" (or "sell") the patented product during the term of the patent.

7.64 Given these interpretations of the third condition of Article 30, the EC concluded: (1) that the impairment of the patent owner's Article 28 legal rights by the regulatory review exception amounts to "prejudice" to the patent owner's legitimate interests; and (2) that in the absence of any legitimate third party interest to the contrary, the abrogation of rights authorized by Section 55.2(1) is substantial enough to be characterized as "unreasonable".

7.65 Canada contested the two key parts of this EC argument - the EC's interpretation of the term "legitimate interests", and the EC's interpretation of the term "third parties".

7.66 Canada's interpretation of patent owners' "legitimate interests" departed from a base similar to the EC's focus on the patent owner's legal rights. Citing definitions of the word "legitimate" as "conformable to law, lawful, proper", Canada asserted that legitimate interests are those that "relate to the rights and duties that the patent laws confer or impose", and which "arise from the status of being a patent holder, not from the more general status of being a business person or manufacturer".<sup>415</sup> But the words "relate to" and "arise from" indicate that Canada was referring to something beyond the legal rights themselves. In explaining why the patent holder has no "legitimate interest" in the *de facto* extension of market exclusivity created by the regulatory review process, Canada's explanation rested not on an analysis of the legal rights of the patent owner, but on the norms (or policies) that Canada deduced from the patent laws that create those rights. Canada stated:

"[N]otwithstanding the private economic advantage that would be obtained by doing so, a patentee can 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 can be no different from those of patentees in other fields of technology."<sup>416</sup>

Canada's conclusion as to the "bargain" contained in the patent laws was a conclusion as to the underlying norms or policies of the patent laws. It tests the legitimacy of claims by their conformity to these norms - to be sure, norms based on the patent laws, but nonetheless a normative rather than

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<sup>414</sup> EC Oral Statement, First Meeting, paragraphs 72-74; EC Second (Rebuttal) Submission, paragraphs 68-70

<sup>415</sup> Canada, First Submission, paragraph 81

<sup>416</sup> Canada, First Submission, paragraph 86

legal definition of "legitimate". Thus, for Canada it is possible that the exercise of some legal rights in some circumstances are contrary to the policy norms of patent law, and that in such cases the patent owner has no "legitimate interest" in exercising those rights in those circumstances.

7.67 With regard to the EC's definition of the "third party interests" referred to in the last phrase of Article 30, Canada took the position that general societal interests, and particularly interests connected with health policy, were within the ambit of the term "third parties" and thus were entitled to consideration. In support of this position, Canada, together with several of the third party participants in this proceeding<sup>417</sup>, relied most heavily on the statements of objectives and principles stated in Articles 7 and 8.1 of the TRIPS Agreement.

(ii) *Definition of "legitimate interests"*

7.68 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.<sup>418</sup>

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").

7.69 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

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<sup>417</sup> The Panel uses the term "third party" here in the sense defined in Article 10 of the DSU, in contrast to the sense employed in Article 30 of the TRIPS Agreement, or the sense employed in Article 28 of that Agreement.

<sup>418</sup> New Shorter Oxford Dictionary, page 1563

such national 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.

7.70 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.<sup>419</sup> Eventually, this illustrative list approach was abandoned in favour of a more general authorization following the outlines of the present Article 30. The negotiating records of the TRIPS Agreement give no explanation of the reason for this decision.

7.71 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 Article 9(2) is as follows:

"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."<sup>420</sup>

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.

7.72 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

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<sup>419</sup> See document MTN.GNG/NG11/W/76 of 23 July 1990 - Status of Work in the Negotiating Group: Chairman's Report to the Group of Negotiations on Goods, Part III, Section 5, paragraph 2.2. The relevant text is quoted in Annex 6 to the present report.

<sup>420</sup> The text of Berne Article 9(2) also served as the model for three other exceptions clauses in the TRIPS Agreement - Articles 13, 17 and 26.2, providing respectively for similar exceptions from obligations on copyright, trademarks and industrial designs. Article 13 is a nearly identical copy of Berne Article 9(2). Like Article 30, both Articles 17 and 26.2 made small changes to the text of Berne Article 9(2).

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."<sup>421</sup>

The Panel recognized that the drafting committee's examples concern the area of copyright as opposed to patents, and that, even further, they deal with the situation as it was in 1967, and accordingly the Panel was reluctant to read too much into these examples as guides to the meaning of Article 30. But the Panel did find that the concepts of "normal exploitation" and "legitimate interests" underlying the three examples used by the drafting committee were consistent with the Panel's definitions of these concepts and of the differences between them.

7.73 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.

(iii) *Second claim of "legitimate interest"*

7.74 After reaching the previous conclusion concerning the EC's primary argument under the "legitimate interests" condition of Article 30, the Panel then directed its attention to another line of argument raised in statements made by the EC and by one third party. This second line of argument called attention to the fact that patent owners whose innovative products are subject to marketing approval requirements suffer a loss of economic benefits to the extent that delays in obtaining government approval prevent them from marketing their product during a substantial part of the patent term. According to information supplied by Canada, regulatory approval of new pharmaceuticals usually does not occur until approximately eight to 12 years after the patent application has been filed, due to the time needed to complete development of the product and the time needed to comply with the regulatory procedure itself.<sup>422</sup> The result in the case of pharmaceuticals, therefore, is that the innovative producer is in fact able to market its patented product in only the remaining eight to 12 years of the 20-year patent term, thus receiving an effective period of market exclusivity that is only 40-60 per cent of the period of exclusivity normally envisaged in a 20-year patent term. The EC argued that patent owners who suffer a reduction of effective market exclusivity from such delays should be entitled to impose the same type of delay in connection with corresponding regulatory requirements upon the market entry of competing products. According to the EC,

"[T]here exists no reason why the research based pharmaceutical enterprise is obliged to accept the economic consequence of patent term erosion because of marketing approval requirements which reduce their effective term of protection to 12-8 years while the copy producer should be entirely compensated for the economic consequence of the need of marketing approval for his generic product, and at the expense of the inventor and patent holder".<sup>423</sup>

Applied to the regulatory review exception, this argument called for the removal of such exceptions so that patent owners may use their exclusionary patent rights to prevent competitors from engaging

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<sup>421</sup> 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.

<sup>422</sup> See paragraph 2.5 above.

<sup>423</sup> Oral Statement, First Meeting, paragraph 74. See also EC Written Rebuttal, paragraphs 84-85. For a similar point made by Switzerland, see Third Party Submission by Switzerland, paragraph 37.

in product development and initiating the regulatory review process until the patent has expired. The result of removing the exception would be to allow patent owners to create a period of further, de facto market exclusivity after the expiration of the patent, for the length of time it would take competing producers to complete product development and obtain marketing approval.<sup>424</sup>

7.75 The normative claim being made in this second argument ultimately rested on a claim of equal treatment for all patent owners. The policy of the patent laws, the argument would run, is to give innovative producers the advantage of market exclusivity during the 20-year term of the patent. Although patent laws do not guarantee that patent owners will obtain economic benefits from this opportunity, most patent owners have at least the legal opportunity to market the patented product during all or virtually all this 20-year period of market exclusivity. Producers whose products are subject to regulatory approval requirements may be deprived of this opportunity for a substantial part of the 20-year period.

7.76 Under the Panel's interpretation of Article 30, this argument could be characterized as a claim of "legitimate interest" under the third condition of Article 30. It was distinct from the claim made under the second condition of Article 30 ("normal exploitation"), because it did not rest on a claim of interest in the "normal" means of extracting commercial benefits from a patent. Instead, it was a distinctive claim of interest, resting on a distinctive situation applicable only to patent owners affected by marketing approval requirements, asking for an additional means of exploitation, above and beyond "normal exploitation," to compensate for the distinctive disadvantage claimed to be suffered by this particular group of claimants.

7.77 The Panel therefore examined whether the claimed interest should be considered a "legitimate interest" within the meaning of Article 30. The primary issue was whether the normative basis of that claim rested on a widely recognized policy norm.

7.78 The type of normative claim put forward by the EC has been affirmed by a number of governments that have enacted *de jure* extensions of the patent term, primarily in the case of pharmaceutical products, to compensate for the de facto diminution of the normal period of market exclusivity due to delays in obtaining marketing approval. According to the information submitted to the Panel, such extensions have been enacted by the European Communities, Switzerland, the United States, Japan, Australia and Israel.<sup>425</sup> The EC and Switzerland have done so while at the same time allowing patent owners to continue to use their exclusionary rights to gain an additional, de facto extension of market exclusivity by preventing competitors from applying for regulatory approval during the term of the patent. The other countries that have enacted *de jure* patent term extensions have also, either by legislation or by judicial decision, created a regulatory review exception similar to Section 55.2(1), thereby eliminating the possibility of an additional de facto extension of market exclusivity.

7.79 This positive response to the claim for compensatory adjustment has not been universal, however. In addition to Canada, several countries have adopted, or are in the process of adopting, regulatory review exceptions similar to Section 55.2(1) of the Canadian Patent Act, thereby removing the de facto extension of market exclusivity, but these countries have not enacted, and are not planning to enact, any *de jure* extensions of the patent term for producers adversely affected by

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<sup>424</sup> The actual length of the additional period of de facto market exclusivity would depend on the time it would take competitors to complete the regulatory approval process from the day the patent expired. This would vary depending on whether and to what extent competitors would have been able to perform some of the development process during the patent term, which in turn would depend on the scope of other exceptions permitting use of the patented product without the consent of the patent owner, such as exceptions for scientific or experimental use of the product.

<sup>425</sup> The data on patent term extensions and regulatory review exceptions for the countries listed were supplied in replies to questions posed by the Panel to the parties and third parties in the proceeding. The questions posed by the Panel and the replies received can be found in Annex 5 to this report.

delayed marketing approval.<sup>426</sup> When regulatory review exceptions are enacted in this manner, they represent a decision not to restore any of the period of market exclusivity due to lost delays in obtaining marketing approval. Taken as a whole, these government decisions may represent either disagreement with the normative claim made by the EC in this proceeding, or they may simply represent a conclusion that such claims are outweighed by other equally legitimate interests.

7.80 In the present proceeding, Canada explicitly disputed the legitimacy of the claimed interest. As noted above, Canada appeared to interpret the term "legitimate interests" in accordance with the Panel's view of that term as a widely recognized normative standard. Canada asserted:

"[N]otwithstanding the private economic advantage that would be obtained by doing so, a patentee can 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 can be no different from those of patentees in other fields of technology."<sup>427</sup>

7.81 Canada's argument that all fields of technology must be treated the same implicitly rejected the EC's argument that those fields of technology affected by marketing approval requirements should be given certain additional marketing advantages in compensation. Canada was asked by the Panel to explain the distinction between its decision in Section 55.2(1) to remove the delay in obtaining marketing approval for competitive producers seeking to enter the market after the patent expires and its decision not to correct or compensate for the similar delay encountered by the patent owner himself. Canada responded that the *de facto* diminution of the market exclusivity for patent owners was an unavoidable consequence of the time required to ensure and to demonstrate the safety and efficacy of the product, whereas the delay imposed on competitors by use of the patent rights to block product development and initiation of the regulatory review process during the term of the patent was neither necessary to product safety nor otherwise an appropriate use of patent rights.<sup>428</sup> Canada's answer implied a further question as to the extent to which the marketing delays experienced by patent owners were in fact the result of government regulatory action, as opposed to the normal consequence of the necessary course of product development for products of this kind.

7.82 On balance, the Panel concluded that the interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognized that it could be regarded as a "legitimate interest" within the meaning of Article 30 of the TRIPS Agreement. Notwithstanding the number of governments that had responded positively to that claimed interest by granting compensatory patent term extensions, the issue itself was of relatively recent standing, and the community of governments was obviously still divided over the merits of such claims. Moreover, the Panel believed that it was significant that concerns about regulatory review exceptions in general, although well known at the time of the TRIPS negotiations, were apparently not clear enough, or compelling enough, to make their way explicitly into the recorded agenda of the TRIPS negotiations. The Panel believed that Article 30's "legitimate interests" concept should not be used to decide, through adjudication, a normative policy issue that is still obviously a matter of unresolved political debate.

7.83 Consequently, having considered the two claims of "legitimate interest" put forward by the EC, and having found that neither of these claimed interests can be considered "legitimate interests" within the meaning of the third condition of Article 30 of the TRIPS Agreement, the Panel concluded

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<sup>426</sup> See replies of Poland and Thailand to questions asked by the Panel to third parties. See First Submission of Canada, paragraphs 115, 116 (Hungary, Argentina).

<sup>427</sup> Canada, First Submission, paragraph 86

<sup>428</sup> Canada, Responses to Questions from the Panel to the Parties (at the first meeting), Question 14

that Canada had demonstrated to the Panel's satisfaction that Section 55.2(1) of Canada's Patent Act did not prejudice "legitimate interests" of affected patent owners within the meaning of Article 30.

(iv) *Conclusion with regard to compliance of Section 55.2(1) with Article 30*

7.84 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*

7.85 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. Article 27.1 provides:

**"Article 27  
Patentable Subject Matter**

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, *patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*" (emphasis added)

7.86 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. Thus, the EC concluded, Article 27.1 requires that the exception made by Section 55.2(1) must be non-discriminatory. The EC contended that Section 55.2(1) does not comply with the obligations of Article 27.1, because it is limited, both *de jure* and *de facto*, to pharmaceutical products alone, and thus discriminates by field of technology.

7.87 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. The Panel examined these two defences in order.

(a) Applicability of Article 27.1 to Article 30 Exceptions

7.88 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.

7.89 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.

7.90 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.

7.91 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.<sup>429</sup> Finally, the Panel could not agree with Canada's attempt to distinguish between Articles 30 and 31 on the basis of their mandatory/permissive character; both provisions permit exceptions to patent rights subject to certain mandatory conditions. Nor could the Panel understand how such a "mandatory/permissive" distinction, even if present, would logically support making the kind of distinction Canada was arguing. In the Panel's view, what was important was that in the rights available under national law, that is to say those resulting from the basic rights and any permissible exceptions to them, the forms of discrimination referred to in Article 27.1 should not be present.

7.92 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.

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<sup>429</sup> 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.

7.93 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

7.94 The primary TRIPS provisions that deal with discrimination, such as the national treatment and most-favoured-nation provisions of Articles 3 and 4, do not use the term "discrimination". They speak in more precise terms. The ordinary meaning of the word "discriminate" is potentially broader than these more specific definitions. It certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment. Discrimination may arise from explicitly different treatment, sometimes called "*de jure* discrimination", but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called "de facto discrimination". The standards by which the justification for differential treatment is measured are a subject of infinite complexity. "Discrimination" is a term to be avoided whenever more precise standards are available, and, when employed, it is a term to be interpreted with caution, and with care to add no more precision than the concept contains.

7.95 The European Communities acknowledged that the words of the regulatory review exception of Section 55.2(1) do not limit its application to pharmaceutical products. The terms of the exception protect potentially infringing conduct:

"solely for uses reasonably related to the development and submission of information required under any law [...] that regulates the manufacture, construction, use or sale of any product".

Applied literally, these words apply to any of a wide range of products that require regulatory approval for marketing. The EC itself mentioned agricultural chemicals, foodstuffs, cosmetics, automobiles, vessels and aircraft as products that often require regulatory approval.<sup>430</sup>

7.96 The EC pointed out, however, that pharmaceuticals were the only products mentioned in Canada's 1991 legislative debates on the enactment of Sections 55.2(1).<sup>431</sup> It also asserted that Section 55.2(1) was "in effect applied only to pharmaceuticals products".<sup>432</sup> These assertions led to two distinct allegations of discrimination. The first claim of discrimination was the claim that the legislative history's concentration on pharmaceuticals actually governs the legal scope of the measure, so that, as a matter of law, Section 55.2(1) applied only to pharmaceuticals. If that is so, it could be said that Section 55.2(1) imposes *de jure* discrimination against pharmaceuticals. The second claim of discrimination was the claim that, whatever the *de jure* scope of Section 55.2(1), the actual effects of Section 55.2(1) are limited to pharmaceutical producers, and these differential effects amount to a case of de facto discrimination.<sup>433</sup>

7.97 Canada denied that the *de jure* scope of Section 55.2(1) is limited to pharmaceuticals.<sup>434</sup> It pointed to the words of that provision making the exception available to "any product" for which marketing approval was needed. Canada did inform the Panel of a lower court decision, involving invocation of Section 55.2(1) by a producer of a medical device, holding that the legislative history of

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<sup>430</sup> EC First Submission, paragraph 58

<sup>431</sup> EC First Submission, paragraph 51

<sup>432</sup> EC First Submission, paragraph 57

<sup>433</sup> EC Answers to Questions Asked by the Panel after the First Substantive Meeting, Answer to Question 16

<sup>434</sup> Initially, the EC took the position that, while a wide list of other products from foodstuffs to aircraft were subject to regulatory review requirements in Canada and other countries, the legal scope of Section 55.2(1) was confined only to pharmaceuticals (EC First Submission, paragraph 58). Canada, however, has explicitly denied having conceded that point, and has reaffirmed without qualification that the legal scope of the statute is as broad as the words indicate (Canada, First Submission, paragraph 131; Oral Statement at Second Meeting, paragraph 30).

Section 55.2(1) limits its legal scope to patented pharmaceutical products.<sup>435</sup> That decision itself was reversed on appeal, however, but only on the ground that such a holding could not be made by summary procedure, reserving decision on the legal scope of the statute for determination at trial. No further developments in that case, or other relevant judicial interpretations of Section 55.2(1) were brought to the Panel's attention. With regard to the claim that the actual effects of Section 55.2(1) were limited to pharmaceutical producers, Canada pointed out that the legal decision referred to above did involve a producer of medical devices who had employed Section 55.2(1) as a defence to a claim of infringement.

7.98 In considering how to address these conflicting 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.<sup>436</sup> These rulings have addressed the question whether measures were in conflict with various GATT or WTO provisions prohibiting variously defined forms of discrimination. As the Appellate Body has repeatedly made clear, each of these rulings has necessarily been based on the precise legal text in issue, so that it is not possible to treat them as applications of a general concept of discrimination. Given the very broad range of issues that might be involved in defining the word "discrimination" in Article 27.1 of the TRIPS Agreement, the Panel decided that it would be better to defer attempting to define that term at the outset, but instead to determine which issues were raised by the record before the Panel, and to define the concept of discrimination to the extent necessary to resolve those issues.

7.99 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.

7.100 The Panel then turned to the question of *de facto* discrimination. Although the EC's response to the Panel's questions indicated that it did intend to raise the issue of *de facto* discrimination,<sup>437</sup> the EC did not propose a formal definition of *de facto* discrimination, nor did it submit a systematic exposition of the evidence satisfying the elements of such a concept. Australia and the United States, third parties in the proceedings, referred to previous GATT and WTO legal rulings treating *de facto* discrimination, but primarily for the purpose of suggesting the mirror image principle - that not all differential treatment is "discrimination". Canada did not associate itself with the Australian and United States positions. Notwithstanding the limited development of the arguments on the issue of *de facto* discrimination, the Panel concluded that its terms of reference required it to pursue that issue once raised, and accordingly the Panel proceeded to examine the claim of a *de facto* discrimination violation on the basis of its own examination of the record in the light of the concepts usually associated with claims of *de facto* discrimination.

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<sup>435</sup> *Visx, Inc. v. Nidek Co. et al.* (1997) 77 C.P.R. (3d) 286 (Fed.Ct. T.D.), appeal allowed, *Nidek Co. v. Visx, Inc.*, (1998) 77 C.P.R. (3d) 289 (Fed.Ct.App.) [Canada, Exhibit 59]

<sup>436</sup> See, e.g., *Japan — Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (adopted 1 November 1996); *European Communities - Regime for the Importation, Sale and Distribution of Bananas*, WT/DS27/AB/R (adopted 17 November 1997); *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R (adopted 15 February 1998); *United States - Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R (adopted 6 November 1998)

<sup>437</sup> EC Answers to Questions Asked by the Panel after the First Substantive Meeting, Answer to Question 16

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

7.102 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<sup>438</sup>, but no such explanation was provided. Nor was the Panel able to find such a practical reason from the information before it. The Panel concluded that the EC had not demonstrated that Section 55.2(1) had had a discriminatory effect limited to patented pharmaceutical products.

7.103 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.

7.104 The Panel did not find this evidence from the debates on Section 55.2(1) to be persuasive evidence of a discriminatory purpose. To be sure, such evidence makes it clear that the primary reason for passing the measure was its effect on promoting competition in the pharmaceutical sector. This is also evident from Canada's justification for the measure presented in this dispute settlement proceeding. But preoccupation with the effects of a statute in one area does not necessarily mean that the provisions applicable to other areas are a sham, or of no actual or potential importance. Individual problems are frequently the driving force behind legislative actions of broader scope. The broader scope of the measure usually reflects an important legal principle that rules being applied in the area of primary interest should also be applied to other areas where the same problem occurs. 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 the absence of any proof that the broader scope was a sham, it must be found that the evident concentration of public attention upon the effects of Section 55.2(1) on the pharmaceutical industry is not, by itself, evidence of a discriminatory purpose.

7.105 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)

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<sup>438</sup> Questions Asked by the Panel after the First Substantive Meeting, Question 16

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.<sup>439</sup>

## VIII. CONCLUSIONS

8.1 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.

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<sup>439</sup> On the record before the Panel, there was no occasion to consider the question raised by certain third parties -- whether measures that are limited to a particular area of technology - *de jure* or *de facto* - are necessarily "discriminatory" by virtue of that fact alone, or whether under certain circumstances they may be justified as special measures needed to restore equality of treatment to the area of technology in question. The Panel's decision regarding Section 55.2(1) did not touch upon that issue.