

CANADA – PATENT PROTECTION OF PHARMACEUTICAL PRODUCTS

Complaint by the European Communities and their member States

Report of the panel

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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.

⁸ Document WT/DS33/AB/R, pp. 13-16 (adopted 23 May 1997).

⁹ 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).

7.19 The TRIPS Agreement contains two provisions authorizing exceptions to the exclusionary patent rights laid down in Article 28 - Articles 30 and 31.¹⁰ Of these two, Article 30 - the so-called limited exceptions provision – has been invoked by Canada in the present case. It reads as follows:

"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"¹¹; (3) the exception must not "unreasonably prejudice the legitimate interests of the patent owner, taking account of the

¹⁰ 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 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.

¹¹ 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.

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.¹² 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".¹³

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".²⁰ 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).²¹

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"²², 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.²³ 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.

¹⁶ EC Oral Statement at First Meeting, paragraph 52

¹⁷ EC Rebuttal, paragraph 59

¹⁸ Ibid, paragraph 60

¹⁹ First Submission of the European Communities, paragraph 23

²⁰ 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."

²¹ See Annex 6 to this Report for the various drafts of what became Article 30 discussed in the Uruguay Round Negotiating Group on TRIPS.

²² The Shorter Oxford English Dictionary at p. 1216

²³ The interpretation of the second and third conditions of Article 30 are explained under F(1)(b) and (c) below.

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 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.

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.³³

²⁶ First Submission of Canada, paragraphs 109-117

²⁷ See paragraph 7.13 above.

²⁸ First Submission of the European Communities at paragraphs 30 and 54

²⁹ Oral Statement at First Meeting, paragraphs 67 and 68

³⁰ *Ibid.* at paragraph 32

³¹ First Submission of the EC, paragraph 30

³² EC Oral Statement at First Meeting, paragraphs 64-69

³³ 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

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.³⁴

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

paragraph 6.8 above). Canada explicitly represented to the Panel that Section 55.2(1) did not permit commercial disposition 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.

³⁴ See paragraph 7.13 above.

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.³⁵ The European Communities also defined "exploitation" by referring to the same three ways of "working" a patent.³⁶ 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.³⁷ 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.³⁸ 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.³⁹ 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 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

³⁵ Canada's First Submission, paragraph 78

³⁶ EC Oral Statement at First Meeting, paragraph 70

³⁷ Canada's First Submission, paragraphs 78-79

³⁸ Canada, First Submission, paragraphs 81-86

³⁹ EC Second (Rebuttal) Submission, paragraphs 62-64, 80-81

of the word "normal" is found in the dictionary definition: "regular, usual, typical, ordinary, conventional".⁴⁰ 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 found the ultimate EC arguments here impossible to distinguish from the arguments it had made under that first condition.⁴¹

⁴⁰ The New Shorter Oxford English Dictionary, p.1940

⁴¹ 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)

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.

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 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.⁴⁸ Eventually, this illustrative list approach was abandoned in favour of a

⁴⁷ New Shorter Oxford Dictionary, page 1563

⁴⁸ 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.

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."⁴⁹

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 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."⁵⁰

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

⁴⁹ 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).

⁵⁰ 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.

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.⁵¹ 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".⁵²

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 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.⁵³

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

⁵¹ See paragraph 2.5 above.

⁵² 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.

⁵³ 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.

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.⁵⁴ 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 delayed marketing approval.⁵⁵ 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."⁵⁶

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

⁵⁴ 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.

⁵⁵ 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).

⁵⁶ Canada, First Submission, paragraph 86

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.⁵⁷ 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 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.

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 30.⁵⁸ Finally, the Panel could not agree with Canada's attempt to distinguish between Articles 30 and 31 on the basis of their mandatory/permissive

⁵⁸ 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.

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.

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.⁵⁹

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).⁶⁰ It also asserted that

⁵⁹ EC First Submission, paragraph 58

Section 55.2(1) was "in effect applied only to pharmaceutical products".⁶¹ 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.⁶²

7.97 Canada denied that the *de jure* scope of Section 55.2(1) is limited to pharmaceuticals.⁶³ 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 Section 55.2(1) limits its legal scope to patented pharmaceutical products.⁶⁴ 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.⁶⁵ 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

⁶⁰ EC First Submission, paragraph 51

⁶¹ EC First Submission, paragraph 57

⁶² EC Answers to Questions Asked by the Panel after the First Substantive Meeting, Answer to Question 16

⁶³ 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).

⁶⁴ *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]

⁶⁵ 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)

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,⁶⁶ 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.

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 products⁶⁷, 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

⁶⁶ EC Answers to Questions Asked by the Panel after the First Substantive Meeting, Answer to Question 16

⁶⁷ Questions Asked by the Panel after the First Substantive Meeting, Question 16

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) 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.⁶⁸