

## ATTACHMENT 1.1

### FIRST SUBMISSION OF THE UNITED STATES

(18 November 1999)

#### I. INTRODUCTION

1. This case is an exceedingly simple one. Articles 33 and 70 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) require all WTO members to provide a patent term of at least twenty years from the date of filing of the patent application. For a large group of patents, Canada applies a term that in many cases is shorter - calculated as seventeen years from the date that a patent is issued. A term of seventeen years from issuance is not the same as a term of twenty years from filing. For patent applications that are pending for less than three years before being issued, the seventeen year term is shorter. Thus, with respect to a large number of existing patents, Canada is in violation of the TRIPS Agreement because of its failure to provide an adequate patent term.

#### II. FACTUAL BACKGROUND

2. The facts of this case are straight-forward and uncontested. The Canadian Patent Act provides that the term of patents based on applications filed before October 1, 1989, is seventeen years from the date that the patent is issued. For patents based on applications filed on or after that date, the term is the TRIPS-minimum of twenty years from the filing date. Sections 44 and 45 of the Canadian Patent Act are unambiguous, and provide as follows:

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.

45. Subject to section 46, the term limited for the duration of every patent issued under this Act on the basis of an application filed before October 1, 1989 is seventeen years from the date on which the patent is issued.<sup>1</sup>

3. In general, the extent to which a patent term of seventeen years from issuance may be shorter than the TRIPS-required term of twenty years from filing varies from patent to patent. The gap depends entirely on the time that elapsed between the date of filing of a particular patent application and the date of issuance of the patent. As a matter of simple arithmetic, for *any* patent that was issued in less than three years from its date of filing, Canada's term of seventeen years from issuance is shorter than the TRIPS-mandated term of twenty years from filing. Canada is in violation of the TRIPS Agreement with respect to each and every one of these patents. If a patent takes exactly three years to be issued, there is no practical difference between the term provided by Canada and the term required by the TRIPS Agreement. If a patent took longer than three years to be issued, the seventeen-year term would actually be longer than required.

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<sup>1</sup> Canadian Patent Act, R.S.C., ch. P-4, §§ 44- 45 (1985) (Can.) (emphasis added) (Article 46 of the Canadian Patent Act, cross-referenced in the quoted articles, concerns the payment of maintenance fees for a patent).

4. During the consultations in this case, Canadian officials responded to written questions submitted by the United States and provided estimates of the number of patents affected by the provisions of the Canadian Patent Act at issue.<sup>2</sup> According to Canada, 169,966 patents were still in existence in June 1999 for which Canada provides a term of seventeen years from grant. Of these 169,966 existing patents with a term of seventeen years from grant, Canada estimated that 66,936 -- or 39.4% of them -- expire sooner than would be the case if Canada had provided a term of twenty years from filing. Historically, fifty percent (50%) of patent applications filed in Canada are from U.S. applicants. Thus, it appears that well over 33,000 U.S. patent holders are currently holding patents with a term less than that required under the TRIPS Agreement.

5. Indeed, for some U.S. right holders, Canada's delay in implementing its TRIPS obligations has already caused tremendous harm. As one example, a major pharmaceutical patent owned by Pfizer Inc on its anti-depressant drug "ZOLOFT" (sertraline hydrochloride) expired in August 1999, at the end of its term of seventeen years from issuance. Under a TRIPS-level term of twenty years from the date of filing, Pfizer's Canadian patent for ZOLOFT should not have expired until October 2000, fourteen months later.<sup>3</sup>

6. The patents affected by the inadequate Canadian patent term cover inventions in all fields of technology. Due to the significance of patent protection to the pharmaceutical industry, Canada's TRIPS violation has a particularly severe impact on the companies in this area. However, the thousands of patents affected by the Canadian deficiency cover inventions in fields as diverse as automotive technology, telecommunications, plastics, and computer-related technologies.<sup>4</sup>

7. Representatives of the Government of Canada have publicly acknowledged that Canada is obligated under the WTO to provide a term of at least twenty years from the date of filing for all patents. In a 1997 presentation to the Canadian House of Commons Standing Committee on Industry that was reviewing amendments to the Patent Act, Canada's Minister of Industry, the Honourable John Manley, stated that "We must give all patentees, pharmaceutical or otherwise, a minimum 20 year patent term."<sup>5</sup>

### III. PROCEDURAL BACKGROUND

8. The United States requested consultations in this case on May 6, 1999. The United States provided written questions to Canada on May 21, 1999. Consultations were held on June 11, 1999. These consultations focused on Canada's answers to the U.S. questions and the legal issue that is set forth in this submission. The consultations did not result in a resolution of the dispute. The United States first requested the establishment of a dispute settlement panel at the meeting of the Dispute Settlement Body on July 26, 1999. This Panel was established on September 22, 1999. The Panel was composed on October 22, 1999.

### IV. LEGAL ANALYSIS

9. Article 33 of the TRIPS Agreement describes the required term of patent protection under the Agreement. Article 70 governs the treatment of subject matter existing on the date of application of the TRIPS Agreement. By providing a term of protection for many existing patents of lesser duration

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<sup>2</sup> U.S. Questions to Canada, May 21, 1999 (US-Exhibit 1).

<sup>3</sup> Letter from Ian C. Read, Senior Vice President, Pfizer Pharmaceuticals, to GERALYN S. RITTER, Office of the U.S. Trade Representative (Oct. 15, 1999) (Exhibit US-2).

<sup>4</sup> Sample affected patents corresponding to the cited areas of technology are attached. (Exhibit US-3).

<sup>5</sup> Speaking Notes for the Honourable John Manley, Minister of Industry, to the House of Commons Standing Committee on Industry, Review of Bill C-91, 7 (Feb. 17, 1997) (available on Industry Canada web site, [www.ic.gc.ca](http://www.ic.gc.ca)) (emphasis added) (Exhibit US-4).

than required under Article 33, Canada is in violation of both of these provisions. An analysis of the text, context and object and purpose of Articles 33 and 70 supports this conclusion.<sup>6</sup>

10. Article 33 of the TRIPS Agreement is entitled “Term of Protection,” and provides that “The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.” By its plain terms, this Article obligates all WTO Members to grant a term of protection for patents that runs at least until twenty years after the filing date of the underlying application. The phrasing of the provision -- “shall not end before” -- also indicates that the twenty year term is a minimum term, rather than a maximum term, and that patent terms longer than twenty years from the date of filing are wholly consistent with the Agreement.

11. Article 70 of the Agreement is entitled “Existing Subject Matter,” and contains a number of transitional provisions. Article 70.2 specifically applies to “subject matter existing at the date of the application of the Agreement,” and provides in relevant part as follows:

Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. . . .

Read in accordance with its ordinary meaning, Article 70 means that the TRIPS Agreement gives rise to obligations – including the obligation to grant a patent term of at least twenty years from the date of filing – in respect of all patents (“subject matter”) existing on January 1, 1996, the date of application of the TRIPS Agreement to developed country Members of the WTO.<sup>7</sup>

12. The context, object and purpose of Articles 33 and 70.2 are consistent with the plain meaning of the terms of these Articles, and certainly do not contradict it. The TRIPS Agreement establishes minimum standards of protection of intellectual property rights. Article 1.1 provides that “Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.” Thus, WTO Members do not have the option of providing sub-standard protection in one area so long as they “compensate” by providing TRIPS-plus protection in another area.

13. Under Section 45 of the Canadian Patent Act, the term granted to patents issued on the basis of applications filed before October 1, 1989, is seventeen years from the date on which the patent is issued. For such patents that were issued in less than three years, the seventeen year term provided under Section 45 is shorter than the TRIPS-mandated term of twenty years from the date of filing. Thus, Canada is in violation of its TRIPS obligations under Articles 33 and 70.2 with respect to all patents filed before October 1, 1989, that took less than three years to issue, and that were still in existence on January 1, 1996.

14. The potential for Section 45 of the Canadian Patent Act to result in the grant of a sub-twenty year term is clear from the text of the statute. Although the application of this provision has in fact

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<sup>6</sup> As the Appellate Body stated in *India - Patent Protection for Pharmaceuticals and Agricultural Chemical Products*, WT/DS50/AB/R, p.17 (adopted Jan. 16, 1998), the obligations of the TRIPS Agreement should be analyzed in accordance with Article 31 of the Vienna Convention. *Cf. United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, p. 16-17 (adopted May 20, 1996). Article 31 of the Vienna Convention provides in part, “A treaty shall 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.”

<sup>7</sup> TRIPS, art. 65.

caused harm to U.S. right holders, the United States observes that the mere potential of the provision to result in the denial of a TRIPS-level patent term is sufficient to establish a violation of Articles 33 and 70.<sup>8</sup> Furthermore, in light of Canada's failure to properly implement these provisions, proof of actual trade damage is not required and nullification or impairment is presumed.<sup>9</sup> Finally, it is irrelevant whether, under certain conditions, Section 45 might result in the grant of a term of protection to certain right holders that is longer than required under TRIPS. Canada cannot rely upon its TRIPS-plus level treatment of some patentees to justify its denial of TRIPS-level treatment to other patentees.<sup>10</sup>

15. Under the Vienna Convention, "any subsequent practice" in the application of an Agreement may also establish "the agreement of the parties regarding its interpretation."<sup>11</sup> In this case, State practice of other developed-country WTO Members in applying Articles 33 and 70 of the TRIPS Agreement demonstrates the term of patent protection that other Members have viewed as legally required by the TRIPS Agreement.

16. In the United States, prior to the TRIPS Agreement, the term of a patent under U.S. law was seventeen years from the date of grant. To implement TRIPS, however, the United States amended its law to provide a term of seventeen years from the date of grant of the patent or twenty years from the effective filing date of the patent, whichever term is longer, for all patents in force (or that resulted from an application filed before) the date six months after the enactment of the U.S. implementing legislation.<sup>12</sup>

17. Other WTO members have also amended their laws to comply with these TRIPS provisions. In a 1994 amendment to its Patent Act, Australia increased its standard patent term from sixteen years from the date of filing to twenty years from the date of filing, effective July 1, 1995.<sup>13</sup> Moreover, Australia applied the twenty-year term not just to patents filed after the effective date, but also to all patents in force on the effective date. Similarly, Germany, Greece and New Zealand also amended their laws to implement the TRIPS obligation regarding a twenty year term for all existing patents.<sup>14</sup>

18. Portugal provides another example of correct - - if belated - - compliance with Articles 33 and 70. The United States requested dispute settlement consultations with Portugal under the WTO Dispute Settlement Understanding on April 30, 1996, regarding Portugal's failure to apply the provisions of Article 33 of TRIPS to all patents that were in force on January 1, 1996, and to all patents that were granted based on applications that were pending on January 1, 1996. On August 23, 1996, Portugal issued Decree-Law 141/96 confirming that all patents that were in force on

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<sup>8</sup> See United States -- Section 337 of the Tariff Act of 1930, BISD 36S/386, para. 5.13 (adopted Nov. 7, 1989).

<sup>9</sup> See Dispute Settlement Understanding, art. 3.8.

<sup>10</sup> See Section 337, at para. 5.14; see also TRIPS, art. 1.1.

<sup>11</sup> Vienna Convention, art. 31(3)(b).

<sup>12</sup> Uruguay Round Agreements Act ("URAA"), Pub. L. No. 103-465, § 532(a) (1994) (codified at 35 *see also* Statement of Administrative Action, 334 (1994) ("A further change in U.S. law incident to the change in how patent term is measured is required by virtue of the operation of Article 33, 70.2 and 70.4 of the TRIPS Agreement. Specifically, section 532(a) of the implementing bill amends section 154 to provide that the term of a patent in force on, or that results from an application filed before the date that is six months after the date of enactment of the URAA [Dec. 8, 1994] will be the greater of 17 years from the date of patent grant or 20 years from the date of filing of the application leading to the patent.") (Exhibit US-5).

<sup>13</sup> Patents (World Trade Organization Amendments) Act 1994, No. 154 of 1994, §§ 3-7 (Aust.) (Exhibit US-6).

<sup>14</sup> Law on the Extension of Industrial Property Rights, art. 6a (1995) (amended German law to extend term from 18 to 20 years for all East German patents that had not expired on December 31, 1995) (Germ.) (Exhibit US-7); Law No. 2359, art. 1 (15 November 1995) (Greece) (Exhibit US-8); Act to Amend the Patents Act 1953, Law No. 122, art. 18 (1994) (N.Z.) (Exhibit US-9).

January 1, 1996, and all patents granted after that date based on applications that were pending on January 1, 1996, will receive a term of protection that lasts either fifteen years from the date of grant of the patent or twenty years from the effective filing date of the patent, whichever term is longer.<sup>15</sup>

## V. CONCLUSION

19. The plain text of Articles 33 and 70 of the TRIPS Agreement requires Canada to grant a minimum patent term of twenty years from the date of filing to all existing patents. With respect to a large number of existing patents, Canada applies a shorter term. For these reasons, the United States respectfully requests the Panel to find that Canada is in violation of Articles 33 and 70 of the TRIPS Agreement, and to recommend that Canada bring its measures into conformity with its obligations under the TRIPS Agreement.

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<sup>15</sup> On October 3, 1996, the United States and Portugal notified the Dispute Settlement Body that this case had been resolved. WT/DS37/2, IP/D/3/Add.1 (8 Oct. 1996) (Exhibit US-10).

## ATTACHMENT 1.2

### ORAL STATEMENT OF THE UNITED STATES AT THE FIRST MEETING WITH THE PANEL

(20 December 1999)

1. Mr. Chairman, members of the Panel, it is an honor to appear before you to present the position of the United States in this important case. This case is extremely significant to U.S. patent holders, and presents important TRIPS issues. We very much appreciate the willingness of the members of the Panel to participate in hearing it. As you indicated in your statement Mr. Chairman, the Panel has read the first submission of the United States in this matter so I do not intend to repeat all of the arguments set forth in that submission.

2. The TRIPS provisions at issue in this case, Articles 33 and 70.2, are not complicated. They require Canada to provide a twenty year patent term to all patent holders. Canada's first submission goes to great lengths to avoid the plain language of Articles 33 and 70.2, and divert attention from the straight-forward nature of this case. The text of the Agreement, however, cannot be ignored. Article 33, in its entirety, states that "The term of protection shall not end before the expiration of a period of

3. What Canada's first submission actually does is establish the following key facts that are not in dispute and which are determinative of a violation of TRIPS:

- First, Section 45 of the Canadian Patent Act provides for a patent term of seventeen years from the date of issuance of the Patent.
- Second, as of January 1, 2000, there will be approximately 67,000 existing Canadian patents that will expire earlier than twenty years from the filing date.<sup>1</sup>

4. In light of this evidence, Canada not only has not rebutted the U.S. *prima facie* case, it has confirmed the facts that establish that case.

5. In its brief, Canada appears to rely in part on an impermissible averaging methodology to argue that the term of protection provided under Section 45 is "equivalent" to a term of twenty years from filing. The two terms are not equivalent, however, because under the seventeen year term, a very large number of individual Canadian patents received a term of less than twenty years from filing.

6. Canada's arguments about equivalence are apparently also based on its having had in place a series of procedures that allegedly would have permitted patent applicants to delay the grant of their patents. As we understand Canada's argument, a patent applicant back in the late 1980's or early 90's (years before TRIPS) should have obtained a twenty year term by asking a Canadian patent examiner to delay the examination -- even though the patent law and rules contained no provision entitling the applicant to such a delay -- or should have manipulated the system by actually abandoning or forfeiting his application and then reinstating it.

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<sup>1</sup> See Canada Exhibit 8, paras 19-20, and exhibits C and D to Canada Exhibit 8.

7. An analogous argument was made by Argentina, and rejected by the Panel, in *Argentina - Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items*.<sup>2</sup> In that dispute, the Panel observed that “[a] WTO Member cannot offer as a defence to a claim of violation of a WTO agreement, that its internal system provides for a remedy to such violation to certain individuals, . . . and that no violation of the WTO has therefore taken place.”<sup>3</sup> Canada’s argument here is even weaker than Argentina’s, in that the right to a twenty year term under TRIPS did not even exist at the time that right holders allegedly should have manipulated the procedural rules of the Canadian patent system to obtain twenty years. Moreover, the alleged practice of patent examiners to grant informal requests to slow down their processing of a patent application appears not to have been a legal right of the patent applicant, and was not published or available in written form.

8. In addition, Canada’s argument that applicants could and should have used these informal procedures to delay the date of grant of their patents would condone the very abuses which it claims justified its decision to amend its law in 1987. Canada asserts on the one hand that pre-1989 applicants should have sought delays in the application process by urging patent officers to delay the granting of their patents. Yet Canada also observes that such conduct was “manipulative” and disfavoured.

9. The United States has not argued that the term of protection required by Article 33 cannot be modified if an applicant fails to comply with reasonable procedures or formalities, such as the payment of maintenance fees. Article 62.1 authorizes Members to condition the acquisition and maintenance of intellectual property rights on compliance with reasonable procedures and formalities, but the second sentence of that paragraph specifies that the procedures and formalities must be consistent with the Agreement. Requiring that patent applicants choose between early protection for their invention and a full twenty-year term of protection cannot be considered “reasonable.” Article 62 has no relevance to this case, and does not excuse Canada from fulfilling its obligations under Articles 33 and 70.2.

10. Canada’s arguments with respect to Article 70.2 also fail. The text of Article 70.2 is key. A close textual analysis reveals the flaws in Canada’s interpretation of this provision. Article 70.2 states that except as otherwise provided in the Agreement, TRIPS “gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement.” A patent is a type of subject matter. Patents that existed at the date of application of the Agreement thus fall within the scope of Article 70.2. And Article 70.2 is quite clear: the Agreement “gives rise to obligations” in respect of such patents. The substantive obligation at issue is a twenty year patent term.

11. Canada makes much of the fact that the U.S. did not discuss in its written submission the phrase “unless otherwise provided” in Article 70.2. The phrase was not discussed, however, because it has no bearing on the legal issues involved in this case, and certainly does not have the effect described by Canada of essentially reading Article 70.2 out of the TRIPS Agreement. It refers, *inter alia*, to the second half of Article 70.2, which sets forth a different rule with respect to copyright, providing that Article 18 of the Berne Convention governs the protection of existing subject matter. When this phrase was added to Article 70.2 during the TRIPS negotiations, the Chairman of the TRIPS negotiating group reported the following: “In the first line [of Article 70.2], the initial phrase would be amended to read ‘Except as otherwise provided for in this Agreement . . .’ This would make it clear that, for example, Article 18 of Berne applies by virtue of Article 9.1.”<sup>4</sup>

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<sup>2</sup> WT/DS56/R (25 November 1997) at paras. 6.66 - 6.69.

<sup>3</sup> WT/DS56/R at para. 6.68, n. 198.

<sup>4</sup> 10 + 10 Meeting, Speaking Note for the Chairman (16 Dec. 1991).

12. The subsequent practice of WTO Members confirms the U.S. interpretation of Article 70.2. Under the Vienna Convention (Article 31(3)(b)) subsequent practice in the application of an Agreement may establish “the agreement of the parties regarding its interpretation.” In our written submission, we provided examples of our own practice, as well as that of other developed countries obligated to implement TRIPS in 1996, including Australia, Germany, Greece, New Zealand, and Portugal, all of which amended their laws to ensure that the term of patents in existence and protected in their territories did not end before a period of twenty years counted from the filing date of the application.

13. Article 70.1 of TRIPS does not mandate a different result. Article 70.1 provides that the TRIPS Agreement “does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.” The reference in Article 70.1 to “acts” refers to, *inter alia*, the acts Canada identifies in paragraph 116 of its first submission, as well as such acts as customs permitting entry of counterfeit or pirated goods prior to the date of application.

14. Let’s take a concrete example: TRIPS requires that countries provide all patentees with an exclusive right of “offering for sale.” Suppose a country did not provide that exclusive right back in 1993 and someone offered for sale a patented product without authorization. In 1993, it was not a violation of the patent law. Article 70.1 simply says that in implementing TRIPS, a country does not have to go back and provide a remedy against that person for his 1993 acts. The Agreement is not retroactive.

15. Canada is confusing the prospective application of TRIPS standards with “retroactivity.” Article 70.1 does not prevent the prospective application of these standards, including the standard governing the length of patent terms, to existing subject matter as mandated by Article 70.2.

16. Furthermore, Article 70 must be read as a whole. Article 70.1 cannot be interpreted without considering its relationship with the other paragraphs of Article 70. Canada argues that patents “issued prior to January 1, 1996 . . . are not subject to the obligations in the TRIPS Agreement.”<sup>5</sup> This interpretation of Article 70.1 leaves a glaring question unanswered: If all pre-1996 patents are not subject to TRIPS, what is the meaning of Article 70.2, particularly its reference to “subject matter existing at the date of application of this Agreement . . . and which is protected in that Member on the said date”? Canada gives this language no legal effect at all in violation of fundamental principles of treaty interpretation. Similarly, Canada’s reading of Article 70.1 would also imply that Articles 70.3, 70.4, 70.5, and 70.6 are meaningless or wholly redundant.

17. Finally, Canada’s interpretation would have far-reaching and devastating consequences for intellectual property right holders. Under this interpretation, every intellectual property right that existed before 1996 -- every patent, every copyright, every trademark, every industrial design and every geographical indication - - receives absolutely no protection under TRIPS. Accordingly, WTO members could today revoke for no reason all patents that were issued prior to January 1996, and remain in compliance with TRIPS. Or they could grant compulsory licenses on all pre-1996 patents without regard for any of the TRIPS conditions set out in Article 31. Such a dramatic undermining of the protection provided by the TRIPS Agreement is impossible to square with the text of Article 70, the subsequent practice of WTO members, and the negotiating history of the Agreement.

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<sup>5</sup> Canada First Submission, para. 113.



18. For all of these reasons, we urge this Panel to see this case for what it is, a straight-forward dispute with undisputed key facts. We respectfully request the Panel to reject Canada's attempts to obscure the real issues, and to find Canada in violation of Articles 33 and 70.2 of the TRIPS Agreement. Thank you.

### ATTACHMENT 1.3

#### RESPONSES OF THE UNITED STATES TO WRITTEN QUESTIONS FROM THE PANEL – FIRST MEETING

(7 January 2000)

#### I. REPLIES OF THE UNITED STATES TO QUESTIONS FROM THE PANEL ADDRESSED TO BOTH PARTIES

**Q.1 \*Article 62.2 provides that Members are to ensure that the procedures for granting intellectual property rights allow granting of the right "within a reasonable period of time so as to avoid unwarranted curtailment" of the protection period.**

- (a) **What would constitute an "unwarranted curtailment" of a patent protection term?**

The meaning of "unwarranted curtailment" cannot be determined in the abstract, and reasonableness may vary by situation. Certainly delay for its own sake should not be considered reasonable.

- (b) **Would an average pendency period for patents of approximately five years be considered a "reasonable period of time" which avoided "unwarranted curtailment" of a protection term? Why, or why not?**

An average pendency period of approximately five years may be considered unreasonable in the context of Article 62.2. Such an average pendency results in an average loss of full patent rights for approximately 1/4 of the potential term of a patent. While some loss of term due to pendency is inevitable, the loss of 1/4 of potential term may rise to the level of unreasonableness and constitute an "unwarranted curtailment of the period of protection."

**Q.2 What bearing, if any, do the general principles set out in paragraph 2 of Article 41 as incorporated in Article 62.4 have on arguments put forward in this dispute concerning delays in the grant of patents?**

Article 41.2 provides that procedures concerning the enforcement of intellectual property rights shall not be "unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays." The same standards apply to procedures concerning the acquisition of intellectual property rights. TRIPS, Article 62.4. These principles are highly relevant to Canada's defense in this case, and squarely reveal its weaknesses. One of Canada's arguments in this case appears to be that patent owners - several years before the TRIPS Agreement was completed - should have manipulated the old Act's procedures for obtaining a patent in order to delay the grant of the patent, solely for the purpose of extending the end-date of the term to which they were entitled under Canadian law. Canada thus would require patent applicants to have followed unnecessarily complicated procedures to obtain unwarranted delays in the grant of their patents, *i.e.* -- avoidable delays justified for no purpose other than mere delay. Besides conflicting with Article 62.4, the imposition of such avoidable delays appears also to conflict with the very provision cited by Canada

as the source of the delay, Section 30.2, which allows reinstatement of an abandoned patent application only where a delay “was not reasonably avoidable.”<sup>1</sup>

**Q.3 Why is the word "available" used in connection with the term of patent protection in Article 33 of the TRIPS Agreement but not in the provisions on the terms of protection of other intellectual property rights?**

The term “available” is used in connection with the duration of protection for industrial designs in Article 26 of the TRIPS Agreement and in connection with the term of patent protection in Article 33. It is not found in the articles dealing with the term of protection for copyrighted works (Article 12) or trademarks (Article 18). Each of these provisions, however, conveys the same essential meaning and sets forth the required minimum term of protection that applies to each type of intellectual property right. Canada emphasizes the unremarkable fact that patent owners can forfeit their patent rights (and thereby shorten their term) by failing to pay maintenance fees. By the same token, trademark owners can abandon their marks and have them cancelled for non-use. Neither of these possibilities undermines the basic requirements of Article 33 (which uses the term “available”) and Article 18 (which does not) to provide a certain defined minimum term of protection to right holders. Under Article 33, Canada is required to make available a term of patent protection that does not end before the expiration of a period of twenty years counted from the filing date. Under Article 70.2, that obligation is to be applied to patents that were in force on the date of application of the TRIPS Agreement for Canada. Canada does not provide a sound legal basis for such a term. Holders of a patent in force on January 1, 1996, have no legal right to a term that did not end before a date of twenty years from the date of filing. Such a term is not available under Canadian law for thousands of right holders.

**Q.4 Are you aware of any WTO Member that was obliged to apply the TRIPS Agreement as of 1 January 1996 and that does not apply a patent protection term of 20 years from the date of filing to all patents, including those patents that were in force and patent applications that were pending as of 1 January 1996?**

Other than Canada, the United States is not aware of any WTO Member that was obliged to apply the TRIPS Agreement as of 1 January 1996 and that does not apply a term of patent protection of twenty years from the date of filing to all patents, including those patents that were in force and patent applications that were pending as of 1 January 1996. As we noted in our first written submission, several of these countries -- including the United States -- had to amend their laws to apply the twenty year term to all existing patents and thereby meet their TRIPS obligation.

**Q.5 Do you believe that a system in which the patent term is calculated from the date of filing creates the same incentive to file a patent application promptly as a system in which the patent term is calculated from the date of grant?**

The two systems may not create exactly the same incentive to file a patent application promptly. The United States observes, however, that priority rights, in the event of other applicants for the same invention, provide the primary incentive for prompt filing in either system of term calculation.

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<sup>1</sup> Canadian Patent Act, R.S.C., ch. P-4, § 30.2 (1985).

**Q.6 Article 28 of the Vienna Convention on the Law of Treaties 1969 reads as follows:**

**"Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party."**

- (a) Does Article 28 belong to those provisions of the Vienna Convention which are part of customary international law?**

Yes. Article 28 of the Vienna Convention is part of customary international law.

- (b) Which paragraph(s) of Article 70 refer(s) to "any act or fact which took place...before the date of the entry into force of the treaty...?"**

Article 70.1 encompasses "any act or fact which took place...before the date of the entry into force of the treaty. . . ."

- (c) Which paragraph(s) of Article 70 refer(s) to "any situation which ceased to exist before the date of the entry into force of the treaty" or did not so cease to exist? Is the ongoing protection of an intellectual property right at the date of entry into force of a treaty, e.g. a patent that has been granted and which remains in force at that date, within the scope of "situation that ceased to exist"?**

To the extent that acts which occurred before TRIPS gave rise to situations which ceased to exist before TRIPS, Article 70.1 could be said to encompass such situations indirectly. The ongoing protection of an intellectual property right at the date of entry into force of a treaty, e.g. a patent that has been granted and which remains in force at the date, is not within the scope of a "situation that ceased to exist."

- (d) Assuming that the reply to question (a) is in the affirmative, does Article 70 represent a "contracting out" of this customary rule of international law or rather does it restate this rule?**

Article 70, particularly Article 70.1, merely restates this basic rule of international law. This interpretation is supported by the negotiating history of Article 70.1, the provisions of which were considered by some Members "too obvious to be necessary"<sup>2</sup>

**Q.7 Please provide an analysis of the meaning that should be attached to the various provisions of Article 70, in particular, explaining the meaning of paragraphs 2, 4 and 6 of Article 70. What is the relationship among the paragraphs of Article 70?**

Article 70.2

Article 70.2 states that except as otherwise provided in the Agreement, TRIPS "gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement." In the context of

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<sup>2</sup> "10 + 10 Meeting, 16 Dec. 1991: Speaking Note for the Chairman," 4. Attached as U.S. Exhibit 11.

this case, this provision means that Canada is obligated to apply the provisions of the TRIPS Agreement to all subject matter that existed and was still protected on January 1, 1996.

“Subject matter” in its ordinary meaning can be defined as “the ground, basis or source of something,” or “the subject or theme of a book, speech, etc., a topic.”<sup>3</sup> In the context of the TRIPS Agreement, “subject matter” is used to refer to such things as broadcasts that can be copyrighted (Article 14.3); signs that can be trademarked (Article 15.1); and inventions that can be patented (Articles 28.1, 31, and 34.1). In short, “subject matter” as used in the TRIPS Agreement generally refers to the matter that is or can be entitled to intellectual property protection. Indeed, this is exactly how Article 70.2 utilizes the term “subject matter”: It states that any subject matter that is either being protected or will meet the criteria for protection at the time of the applicability of the TRIPS Agreement is subject to the Agreement.

There is no substantive difference between the U.S. and Canadian views of the term subject matter. According to Canada, subject matter under Article 70.2 means “matter that is protectable by

<sup>4</sup> Thus, both Parties seem to agree that patented inventions are subject matter. Under the terms of Article 70.2, TRIPS “gives rise to obligations in respect of all” inventions (“subject matter”) existing on January 1, 1996, “and which [are] protected in that Member on the said date.” Accordingly, Canada is obligated to apply the provisions of Article 33 of TRIPS to all patented inventions (*ie.*, protected subject matter) that existed on January 1, 1996.

The second sentence of Article 70.2 sets out a different rule that governs copyright obligations with respect to existing works. It provides, *inter alia*, that such obligations “shall be solely determined under Article 18 of the Berne Convention.” Article 18.1 of Berne provides that “This Convention shall apply to all works which, at the moment of its coming into force, have not yet fallen into the public domain in the country of origin through the expiry of the term of protection.” According to the negotiating history of Article 70 prepared by Daniel Gervais, on which Canada relies so heavily, this provision may be called a “‘relative retroactivity provision,’ in that it applies to existing subject matter (thus affecting existing arrangements), but with some safeguards.”<sup>5</sup>

#### Article 70.4

Article 70.4 allows WTO members to limit liability for infringing acts to the payment of equitable remuneration when two conditions are satisfied: (1) the acts were commenced (or a significant investment was made) before TRIPS was accepted by the WTO Member in question, and (2) the acts became infringing under TRIPS. In this way, the Agreement allows WTO Members to balance the interests of intellectual property right holders and the interests of parties that may have engaged in acts which, prior to TRIPS were perfectly legal, yet became infringing under TRIPS.

Article 70.4 thus clearly contemplates that an act in respect of an invention could “become infringing” under TRIPS. If - as Canada argues - it has no obligations whatsoever with respect to intellectual property that existed before 1996,<sup>6</sup> then Article 70.4 is a nullity. This cannot be correct, and flies in the face of normal principles of treaty interpretation.

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<sup>3</sup> The New Shorter Oxford English Dictionary, 3119 (1993).

<sup>4</sup> First Oral Presentation of Canada, para. 67.

<sup>5</sup> Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 268 (1998) (parenthetical in original; emphasis added).

<sup>6</sup> First Written Submission of Canada, para. 113 (patents “issued prior to January 1, 1996 . . . are not subject to the obligations in the TRIPS Agreement.”).

## Article 70.6

This paragraph of Article 70 provides that Members are not obligated to apply the compulsory licensing disciplines of Article 31 of the Agreement, or to comply with the prohibition on discrimination by field of technology, with respect to compulsory licenses granted by the government before the date on which the TRIPS Agreement became known. This provision was important to some members that had relied on compulsory licensing in the past. Without it, under Article 70.2, the TRIPS disciplines in Article 31 would have applied to existing subject matter (including patentable inventions) as of 1996, and WTO Members would have had to ensure that all of their compulsory licenses were modified if necessary to comply with the requirements of Article 31. Under Canada's argument, that it has no obligations whatsoever with respect to patents that existed prior to 1996, Article 70.6 is wholly redundant.

## Relationship between all of the paragraphs in Article 70

Article 70.1 provides that TRIPS "does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question." Notably, the term used in Article 70.1 is "acts", not "subject matter." Reading Articles 70.1 and 70.2 together, it is evident that the Agreement does not give rise to obligations regarding acts that occurred before January 1, 1996, but it does give rise to obligations concerning subject matter that might have existed before January 1, 1996 (if that subject matter existed on January 1, 1996 and was protected on that date). Article 70.1 thus does not prevent the prospective application of TRIPS standards, including the standard governing the length of patent terms, to existing subject matter as mandated by Article 70.2.

Article 70.1 cannot be interpreted without considering its relationship with the other paragraphs of Article 70. Under Canada's reading advanced in its First Written Submission and First Oral Statement, Articles 70.2 and 70.4 are meaningless, and Article 70.6 is completely redundant. By contrast, under the U.S. interpretation described above and in our previous submissions, every provision of Article 70 is given effect, and the entire article is internally consistent and logical.

## **II. REPLIES TO QUESTIONS FROM THE PANEL TO THE UNITED STATES**

**Q.8 \*The last sentence of Article 1.1 states that Members shall be free to determine the "appropriate method" of implementing the provisions of the TRIPS Agreement within their own legal system and practice. How do you construe the term "appropriate method" as used in Article 1.1 of the TRIPS Agreement?**

The term "appropriate method" does not encompass a method that results in less protection than required under the Agreement. As the first part of Article 1.1 declares, "Members shall give effect to the provisions of this Agreement." The purpose of the last sentence of Article 1.1 is to make clear that Members have flexibility to implement their obligations within the context of their own domestic legal system. For example, implementing a particular TRIPS provision might require legislative changes in some WTO Members, while other Members might only have to amend their administrative regime. So long as the relevant obligation is indeed fully implemented and has a sound legal basis in a Member's legal regime, the precise method of implementation is left to the discretion of that Member.

If Canada's method of implementing a twenty-year patent term differed from that of the United States, but nevertheless provided to each and every patent applicant a sound legal basis for a minimum twenty-year term, there would be no issue under the TRIPS Agreement. Canada, however, has not provided a twenty year term by a different method; instead, for many patent holders, it has failed to provide a twenty year term at all.

**Q.9 \*Canada stated in paragraph 80 of its first written submission that the substantive equivalence of the two terms of protection under the old Act and the new Act appears to have been accepted by the parties to NAFTA, i.e. that NAFTA appears to recognize the substantive equivalence of the two methods of calculating the term. Please comment.**

Canada is incorrect in its assessment that the separation of two different patent terms in the NAFTA text with the word “or” necessarily implies that these two terms are equivalent. The text of NAFTA Article 1709(12) does not explicitly describe the two terms as being substantively equivalent. NAFTA allows the parties to that Agreement to choose which patent term they would provide, and thereby requires a lesser degree of harmonization among the parties regarding the length of patent terms than does the TRIPS Agreement.

Second, it is significant that TRIPS does not contain the same language as the NAFTA. Indeed, given the disparate practice among the negotiating countries in the calculation of patent term prior to conclusion of the TRIPS Agreement, the fact that the negotiators agreed on a single standard in Article 33, and did not include a choice among alternative terms, is significant. As described by Daniel Gervais,

“The question of the term of protection was a difficult subject during the negotiation, but right holders should welcome the harmonization made possible by the TRIPS Agreement. Previously, the term of protection was sometimes calculated from grant, and in other cases from filing. For reasons that included the different starting date of the calculation, the term varied from one country to another. The single standard chosen here is 20 years from filing.”<sup>7</sup>

**Q.10 If a Member put in place a system in which patent applicants were in complete control of the timing of the prosecution of their applications, and they were able to ensure that the term of protection did not expire less than 20 years from the date of filing, would that be sufficient for a Member to satisfy its ongoing obligation under Article 33 even if it had a much shorter term from grant?**

No. To take an extreme example, the hypothetical situation described in the question could arise in a Member with a patent term of one day from grant. In such a situation, the patent applicant would receive the exclusive rights related to a patent for only one day. The purpose of the requirements in Article 62.4 and 41.2 was to prevent such a situation. These obligations of the Agreement must be read together, not in isolation. The term of protection required to be provided in Article 33 presupposes reasonable procedures for the acquisition of patent rights, such that the requirement of a twenty year term of protection is not rendered a practical nullity.

**Q.11 \*How do you define the term "acts" in Article 70.1? Does the term "acts" in Article 70.1 include the administrative act of granting a patent by a patent office?**

See U.S. Response to Question 7, above, regarding Article 70.1. The New Shorter Oxford English Dictionary defines the term “acts” as “a thing done; a deed.”<sup>8</sup> This general meaning is consistent with the use of the term “acts” in other provisions of the TRIPS Agreement (*see* Articles 14, 22, 26, 28, 36, 37, 50, and 58). By its plain meaning, “acts” would include the administrative act of granting a patent by a patent office. The United States does not argue that Canada is in violation of its TRIPS obligations as a result of the failure of the Canadian Patent Office to grant to all patent holders prior to 1996 patents with a term of at least twenty years from filing. The

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<sup>7</sup> Gervais, 169 (emphasis added).

<sup>8</sup> New Shorter Oxford English Dictionary, 21.

“acts” of Canada’s Patent Office prior to 1996 are not at issue. Rather, Canada’s violation of the Agreement stems from its failure, since the date of application of the TRIPS Agreement, to extend the term of protection for existing patented inventions to at least twenty years from filing. This violation is unrelated to any pre-96 “act,” but is related only to the subject matter (protected inventions) that existed on 1-1-96. The rule in Article 70.1, that pre-1996 acts are not subject to the obligations in the Agreement does not imply that subject matter existing on January 1, 1996, is also not subject to the obligations of the Agreement.

**Q.12 \*(follow up question) In Article 58 the word "act" is used in connection with competent authorities. Is this broader than the definition you provided?**

No. *See* U.S. Response to Question 11. As stated by the U.S. representative during the first meeting of the Panel, the United States’ answers at that meeting to the Panel’s questions were preliminary. While the United States regrets the need to modify these answers, it retained its full rights to do so.

**Q.13 \*How do you define the term "subject matter" in Article 70.2?**

*See* U.S. Response to Question 7.

**Q.14 The Appellate Body stated in *Japan – Taxes on Alcoholic Beverages* that "the essence of subsequent practice in interpreting a treaty has been recognized as a 'concordant, common and consistent' sequence of acts...which is sufficient to establish a discernable pattern implying the agreement of the parties regarding its interpretation". Is the fact that six WTO Members, including the United States, amended their laws to provide a patent term of 20 years from the date of filing sufficient to support a claim that there was a "concordant, common and consistent sequence of acts"? In your response, please consider the matters raised in paragraphs 72 and 73 of Canada's first oral statement.**

*See* U.S. Response to Question 4. Concordant, common and consistent acts have indeed established a discernable pattern among WTO Members obligated to apply the TRIPS Agreement as of 1 January 1996 with regard to the interpretation of Articles 33 and 70.2. As discussed in the U.S. Response to Question 4, the United States is aware of no such WTO Member (except Canada) that fails to provide a patent term of twenty years from filing for all patents in existence on January 1, 1996. At least six of these WTO Members had to amend their law to provide such a term. Other WTO Members did not amend their law for the simple reason that they were already in compliance.

In its oral statement (paragraphs 72 and 73), Canada attempts to discount such subsequent practice by arguing that the circumstances of some of the countries that amended their laws were not the same as Canada’s. This point has no relevance. Regardless of what term those countries changed from, the key is that they all changed to a system that provided a minimum term of twenty years from the date of filing for all patents existing or pending on January 1, 1996. By contrast, under Canadian law, such a term does not apply to all patents existing or pending on January 1, 1996.

Furthermore, Canada discounts the example of Portugal, which in order to implement the TRIPS Agreement, issued Decree-Law 141/96 on August 23, 1996, to ensure that all patents will receive a term of protection that lasts either fifteen years from the date of grant or twenty years from the date of filing, whichever is longer. Canada argues that Portugal’s actions are not necessarily evidence of a common understanding of the meaning of the TRIPS provisions.<sup>9</sup> In making this

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<sup>9</sup> Oral Statement of Canada, para. 77.



argument, Canada has apparently chosen to ignore Portugal's own words in the communication sent to the Dispute Settlement Body:

Portugal and the United States further mutually confirm that, with respect to developed-country members, Article 70.2 of the TRIPS Agreement requires, among other things, that the provisions of Article 33 of the TRIPS Agreement be applied to all patents that were in force on 1 January 1996, and to all patents that are granted based on applications that were pending on 1 January 1996.<sup>10</sup>

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<sup>10</sup> *Portugal - Patent Protection under the Industrial Property Act: Notification of a Mutually Agreed Solution*, WT/DS37/2 (8 Oct. 1996). Attached as Exhibit 10 to U.S. First Submission.

## ATTACHMENT 1.4

### RESPONSES OF THE UNITED STATES TO WRITTEN QUESTIONS FROM CANADA – FIRST MEETING

(7 January 2000)

**Q.1 Would the United States please explain why it believes that the rule against retroactivity contained in TRIPS, Article 70.1 would not be available to Canada in respect of patents issued before the effective date of the Agreement?**

*See* U.S. Response to Panel Questions 7, 11 and 12.

**Q.2 Would the United States please explain why it believes that the rule in TRIPS, Art. 70.2, which requires retroactivity, would cover previously issued patents, since its wording only refers to “subject matter”?**

*See* U.S. Response to Panel Question 7.

**Q.3 Would the United States please describe what, if any, mandated statutory delays comparable to those in Canada’s old Act were available to patent applicants under United States patent legislation as it read prior to the Uruguay Round Agreements Act?**

The U.S. patent law, as it read prior to the Uruguay Round Agreements Act, did not contain any “mandated statutory delays,” nor were any added by the Uruguay Round Agreements Act. The U.S. patent law, however, did and does contain provisions similar to Section 30.2 of Canada’s old Act. *See* 35 U.S.C. §§ 111(4), 133 & 151. Each of these sections authorizes the Commissioner to reinstate abandoned applications if, in the case of Section 111(4), the failure to submit the required fee and oath within the prescribed period can be shown to the Commissioner’s satisfaction to have been unintentional or unavoidable, and, in the case of Sections 133 and 151, the failure to prosecute the application within six months of any office action or to pay the required issue fee, respectively, can be shown to the satisfaction of the Commissioner to have been unavoidable. The provisions, therefore, did not and do not provide an applicant with any “mandated statutory delay.”

Furthermore, the United States does not consider the term “mandated statutory delay” to be an accurate description of Section 30.2 or 73.2 of Canada’s old Act. There appears to be nothing “mandatory” about the delay possible in the situations described in those provisions. Such delay was hardly mandated in every instance; on the contrary, delays are clearly disfavoured. Under Section 30.2, an application can be reinstated only if a delay was “not reasonably avoidable.”<sup>1</sup>

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<sup>1</sup> Canadian Patent Act, R.S.C., ch. P-4, § 30.2 (1985).

**Q.4 Where a patent holder has finally forfeited its patent as a result of its failure to pay maintenance fees during the 20-year period counted from its application filing date, is the WTO Member, upon whose territory the application was made, in compliance with its TRIPS obligations? Assuming that a patent holder has the right, consistent with the Agreement, to reduce the 20-year period by failing to pay maintenance fees after the patent has issued, why would it not also have a right, consistent with the Agreement to reduce the period by taking steps to expedite the examination and allowance process, before the patent had issued?**

The WTO Member in the first hypothetical situation may be in compliance with its TRIPS obligations, depending, *inter alia*, on the amount of the maintenance fees and the procedures for paying them. The second question, however, misses the relevant issue in this case. The issue is not the patent holder's right to forfeit a portion of its patent term (which is undisputed), but rather the patent holder's right to a term of protection for the patent that does not end before a period of twenty years measured from the filing date. Under Canada's law, holders of valid patents on subject matter existing on January 1, 1996, are not provided with a legal right to such a term. Patent holders can hardly be said to forfeit something to which they never had a right in the first place.

**ATTACHMENT 1.5**

**REBUTTAL SUBMISSION OF THE UNITED STATES**

(14 January 2000)

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## I. INTRODUCTION

1. Under Section 45 of the Canadian Patent Act, the term of protection for patent applications filed before October 1, 1989 (“Old Act patents”), is seventeen years from the date the patent is granted. The TRIPS Agreement requires that Canada grant a term of protection that does not end before a period of twenty years from filing to all patented inventions in existence on January 1, 1996. Because a term of seventeen years from filing will often end before a term of twenty years from grant, this facial inconsistency between Section 45 and Articles 33 and 70.2 of the TRIPS Agreement warrants a finding by this Panel that Canada is in violation of its obligations under TRIPS.

2. Contrary to Canada’s assertion, a patent term of seventeen years from grant is not “equivalent” to a term of protection that expires twenty years from the date of filing. Moreover, under the Canadian patent law, a term of twenty years from filing currently is not available to all owners of patents that were in existence on January 1, 1996, nor was it available on a sound legal basis to all such patent owners at the time their applications were filed in Canada. Finally, pursuant to TRIPS Article 70, the requirements of the TRIPS Agreement, including the requirement to have a term of protection that does not end before a period of twenty years from filing, are applicable to all of Canada’s so-called Old Act patented inventions in existence today, regardless of whether Canada’s Patent Office had previously engaged in acts inconsistent with current TRIPS obligations.

## II. A TERM OF SEVENTEEN YEARS FROM GRANT IS NOT “EQUIVALENT” TO A TERM THAT EXPIRES TWENTY YEARS FROM THE DATE OF FILING

3. By Canada’s own admission, approximately 67,000 Canadian patents exist today with a term that will end before a period of twenty years from filing.<sup>1</sup> On January 1, 1996, the number was even higher: approximately 94,000 patents were in existence with terms that ended before twenty years from filing.<sup>2</sup> These key facts alone refute Canada’s first argument regarding the alleged “equivalency” of a term of seventeen years from grant and a term of twenty years from filing. For at least 94,000 patent owners, the patent term provided under Canadian law on January 1, 1996, would end before the period stipulated in TRIPS.

4. In an apparent attempt to diminish the legal significance of its admission regarding the tens of thousands of patents in existence with terms that will end before a period of twenty years from filing, Canada reads into Article 33 the concept of an “effective” period of protection, and reads out of Article 33 the literal text of the provision. In lieu of the plain language of Article 33, Canada bases its equivalency argument exclusively on what it variably calls the “effective” period of protection or the period of “exclusive privilege and property rights.”<sup>3</sup> According to Canada, it has satisfied Article 33 because its “effective” period of protection under a term of seventeen years from grant is at least as long as the average “effective” period of protection under its regime of twenty years from filing (because of an average five-year pendency period for patents). Two fatal flaws exist in this equivalency argument.

### A. REGARDLESS OF THE PERIOD OF “EFFECTIVE PROTECTION” PROVIDED BY CANADA, UNDER ARTICLE 33, THE TERM OF PROTECTION SHALL NOT END BEFORE THE EXPIRATION OF TWENTY YEARS FROM THE FILING DATE

5. The text of TRIPS Article 33 does not refer to the “effective” period of protection, or the period of “exclusive privilege and property rights,” but rather to the date that the term of protection is

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<sup>1</sup> First Submission of Canada, para. 45 (citing 66,936 such patents).

<sup>2</sup> First Submission of Canada, para. 43 (citing 93,937 such patents).

<sup>3</sup> See, e.g., First Submission of Canada, paras. 68 and 74; First Oral Presentation of Canada, para. 13.

to end.<sup>4</sup> In violation of the Appellate Body's repeated direction to give primary significance to the words of the Agreement,<sup>5</sup> Canada would read the plain language of TRIPS Article 33 right out of the Agreement, and substitute the concept of "effective protection" for the existing text.

6. Canada would have this Panel find -- in direct contradiction with the plain language of TRIPS Article 33 -- that a system under which a term of protection may (and often does) end before a period of twenty years from filing nevertheless does not violate Article 33. There is no basis in the TRIPS Agreement for such a finding. The plain language of Article 33 must govern the resolution of this dispute.

7. In interpreting the WTO agreements, the Appellate Body and previous panels have consistently looked to the *Vienna Convention on the Law of Treaties* for guidance and clarification.<sup>6</sup> Article 31(1) of this Convention states:

A treaty shall 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.

Thus, the text of an agreement is often the best expression of the intentions of the parties.<sup>7</sup> In the words of the Appellate Body, "The proper interpretation of [a provision] is, first of all, a textual

8. Canada has sought to avoid and modify the clear language of Article 33 by relying on Article 62.<sup>9</sup> Article 62.2 contains a separate obligation -- that of ensuring that the period of protection is not unjustifiably curtailed by unreasonable procedures. Article 62.2 addresses the issue of the commencement of the term of protection, and does not address the expiration date of the period of protection. Article 33 of course must be considered in context, and that context includes Article 62.2 of TRIPS; however, Article 62.2 does not warrant attributing a meaning to Article 33 that conflicts with its explicit terms. Canada is incorrect in its assertion that, because of the average five-year pendency period of New Act patents with a term of twenty years from filing, fifteen years of "effective protection" is all that is required under Article 33. Article 33 means what it says. Under Article 33, regardless of the period of "effective protection", the term of a patent shall not end before a period of twenty years from its filing date.

#### B. CANADA'S EQUIVALENCE ARGUMENT RESTS ON AN IMPERMISSIBLE AVERAGING METHODOLOGY BETWEEN EFFECTIVE PERIODS OF PROTECTION

9. The second fundamental flaw in Canada's equivalency argument is that it relies on the normal or average period of "effective" protection or "exclusive privilege and property rights" that

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<sup>4</sup> TRIPS Article 33 provides that "The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date."

<sup>5</sup> See, e.g., Appellate Body report on *Japan - Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (adopted on November 1, 1996), at 9-10 ("See also, e.g., Appellate Body report on *United States - Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R (adopted May 20, 1996), at 16-17 ("*United States - Reformulated Gas*"); panel report on *United States - Reformulated Gas*, WT/DS2/R (adopted May 20, 1996), para. 6.7.

<sup>6</sup> See Sources cited *supra*, note 5.

<sup>7</sup> Ian Brownlie, *Principles of Public International Law* (4<sup>th</sup> ed.), at 627. See also Appellate Body report on *Japan - Alcoholic Beverages*, at 11-12.

<sup>8</sup> Appellate Body report on *Japan - Alcoholic Beverages*, at 19.

<sup>9</sup> First Oral Presentation of Canada, paras. 18-19.

Canada currently provides to New Act patentees. Throughout its First Written and Oral Statements, Canada repeatedly and explicitly justifies the period of protection under its seventeen-years-from-grant patents by comparing it to the “normal or average” period of “effective” protection under its twenty-years-from-filing patents.<sup>10</sup>

10. Canada uses the averaging methodology in two ways. First, it claims that since five years is the “normal or average” pendency period for New Act patent applications, the effective term of protection under a regime of twenty years from filing would “normally” be an “average” of fifteen years, which is less than the seventeen year period provided under the Old Act.<sup>11</sup> Canada also uses the averaging methodology to make the opposite comparison -- *ie.*, to assert that the “average” two to four year pendency period for its Old Act patents makes these patents “equivalent to and in fact . . . longer than the normal or average” period of “effective” protection required by the TRIPS Agreement.<sup>12</sup> Canada’s reliance, however, on average pendency periods of Old Act and New Act patents inevitably means that its analysis fails to take into account those patents with pendency periods outside the average. Every Old Act patent that pended for less than three years before being issued by Canada has a term that ends before a period of twenty years from the date of filing. Canada admits this fact,<sup>13</sup> yet insists on using this averaging methodology to justify its claim of equivalency.

11. The United States has already noted that such averaging methodology is inappropriate. Indeed, as explained by the panel in *United States - Section 337 of the Tariff Act of 1930*:

The Panel rejected any notion of balancing more favourable treatment of some imported products against less favourable treatment of other imported products. If this notion were accepted, it would entitle a contracting party to derogate from the no less favourable treatment obligation in one case, or indeed in respect of one contracting party, on the ground that it accords more favourable treatment in some other case, or to another contracting party. Such an interpretation would lead to great uncertainty about the conditions of competition between imported and domestic products and thus defeat the purposes of Article III.<sup>14</sup>

12. After the Panel in this case pointed out the inconsistency of an averaging methodology with the Panel Report in the *Section 337* case,<sup>15</sup> Canada appears to have shifted its argument slightly. In its answer to the Panel’s question, Canada departs from its previous references to “normal or average” pendency times, and cites only the fact that the majority of New Act patents (89%) confer a lesser period of “exclusive privilege and property rights” than patents with a term of seventeen years from grant.<sup>16</sup> While Canada’s excessively long examination period for New Act patents is not at issue in this dispute, it can hardly provide justification for Canada’s failure to provide a TRIPS-consistent term to all Old Act patentees. More importantly, this argument is still inconsistent with the principles set forth in the *Section 337* case. Under the principles of the *Section 337* report, even the “mere

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<sup>10</sup> First Submission of Canada, para. 81 (“normal or average”). *See also* First Submission of Canada, paras. 76 (“normal or average”)-77; First Oral Presentation of Canada, para. 21 (“normal or average”); and Canada’s Response to Panel Question 22, at 38-39.

<sup>11</sup> First Submission of Canada, paras. 76 (“normal or average”) -77(noting that “any particular case” may diverge from the average), 81 (“normal or average”). *See also* First Oral Presentation of Canada, para. 21 (“normal or average”); Canada’s Response to Panel Question 22, at 39.

<sup>12</sup> First Submission of Canada, paras. 72-73, 81. *See also* Canada’s Response to Panel Question 16, at 32.

<sup>13</sup> First Submission of Canada, para. 64.

<sup>14</sup> *GATT panel report on United States - Section 337 of the Tariff Act of 1930*, BISD 36S/386 (adopted November 7, 1989), para. 5.13 (“*United States - Section 337*”).

<sup>15</sup> Panel Question 21.

<sup>16</sup> Canada’s Response to Panel Question 21, at 37.

potential” of a measure to deny rights under the Agreement would result in a violation.<sup>17</sup> Far beyond having the mere potential to deny rights to patent holders under Article 33 of TRIPS, Canada’s system actually has denied such rights, on January 1, 1996, to approximately 94,000 patent holders, and today denies them to almost 64,000 patent holders. These patentees cannot be dismissed as “exceptional” as Canada attempts to do in its response to the Panel’s Question on this point.

### **III. THE RIGHT TO A TERM OF PROTECTION THAT DID NOT END PRIOR TO THE EXPIRATION OF THE TWENTY-YEAR PERIOD FROM THE FILING DATE WAS NOT “AVAILABLE” TO ALL OLD ACT PATENT APPLICANTS**

13. Somewhat inconsistently with its argument that a twenty-year term of protection is actually provided to Old Act patentees, Canada also argues that such a term was at least available to them because of the possibility of manipulating the pendency periods of applications that resulted in such patents. Canada does not dispute the fact that a term of protection of twenty years from filing is not available now to all Old Act patentees. Furthermore, such a term was not available on a sound legal basis to all such patent applicants in the past. Finally, Old Act patentees cannot be said to have voluntarily chosen to forfeit their rights to a TRIPS-level term of protection during a time when TRIPS rights did not exist, and when obtaining such a term would have required many applicants to forego a portion of the early years of protection to which they were entitled under the Old Act.

A. FOR OLD ACT APPLICANTS, A PATENT TERM THAT DID NOT END BEFORE TWENTY YEARS FROM FILING HAS NEVER BEEN AVAILABLE ON A SOUND LEGAL BASIS IN CANADA

14. Canadian law provides no sound legal basis for patent applicants that filed applications before October 1, 1989, to obtain a term of protection that did not end before a period of twenty years from the filing date. Neither of the provisions of law cited by Canada -- Sections 30(1) and 73 of the Old Act -- provided such a basis.

15. According to Canada, an Old Act applicant could obtain a term of twenty years from filing by actually abandoning its patent application not once, but twice. Then, after twice abandoning its application for a maximum period of time, and having it reinstated, the applicant could forfeit that application, wait a maximum period of time, and then reinstate it a third time. By means of such a tortured and highly non-transparent process, Canada argues that it has satisfied its TRIPS obligation to provide a patent term that does not end before twenty years from filing.<sup>18</sup>

16. Section 30(2) of the Old Act does not provide a sound legal basis for the procedure outlined by Canada -- repeatedly abandoning and reinstating a patent application for purposes of delay. Section 30(2) of the Old Act declares in no uncertain terms that the reinstatement of an abandoned patent application would only be permitted if a delay “was not reasonably avoidable.”<sup>19</sup> Far from providing a legally guaranteed right to delay a patent application, Canadian law explicitly prohibits use of the abandonment and reinstatement procedure described by Canada where a delay was reasonably avoidable.

17. In response, Canada essentially argues that its patent examiners routinely ignore the mandatory provisions of Section 30(2), asserting that its Patent Commissioner is unaware of reinstatement ever having been refused.<sup>20</sup> Regardless of the practices of Canada’s patent examiners,

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<sup>17</sup> *United States - Section 337*, para. 5.14.

<sup>18</sup> First Oral Presentation of Canada, paras. 43-44.

<sup>19</sup> Canadian Patent Act, R.S.C., ch. P-4, § 30(2) (1985). Canada Exhibit 16.

<sup>20</sup> First Oral Presentation of Canada, para. 47. Canada then hedges by concluding that if a reinstatement was disallowed, an applicant could simply have reapplied. Canada thus states the obvious, that a



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patent applicant could repeatedly file and abandon a patent application forever, thereby ensuring that a patent is never granted. The availability of such a procedure, however, is of no relevance to the term of protection.

<sup>21</sup> WT/DS50/AB/R (adopted January 16, 1998).

<sup>22</sup> *Id.*, paras. 67-71.

<sup>23</sup> *Id.*, paras. 69-70.

<sup>24</sup> Canada's Response to Panel Question 24(c), at 44.

21. Furthermore, under Canada's Old Act, patent applicants whose applications would ordinarily be issued in less than three years would have had access to a TRIPS-level term of protection only if they were willing to forfeit a portion of the early years of patent protection to which they were entitled under the Old Act. In other words, under the Old Act, Canada attached conditions to the supposedly available term of twenty-years-from-filing that for many patent owners would have resulted in a lesser "effective" period of protection. For instance, a patent applicant with a two-year pendency period would be entitled under TRIPS to an "effective" period of protection of eighteen years. Whereas under Canada's Old Act, to obtain the TRIPS-level of protection, the applicant would have had to prolong the pendency period of its patent for an additional year, and thereby forfeit one year of effective protection. Many applicants would not have made this choice, and should not have had to forego any portion of the patent term merely to obtain a term that does not end before twenty years from filing.

22. Articles 41.2 and 62.4 of the Agreement provide important guidance on this issue. The highly complicated procedure described by Canada would have imposed significant unnecessary costs on many patent owners, in violation of the basic TRIPS requirement that procedures for the acquisition of patent rights not be unnecessarily complicated or costly, or entail unwarranted delays. Reading Article 33 in context with Articles 41.2 and 62.4 of the Agreement, it is apparent that Canada's alleged system of making available a term of protection of twenty years from filing is wholly inadequate to comply with its obligations.

#### **IV. UNDER TRIPS ARTICLE 70.2, PATENTED INVENTIONS THAT EXISTED ON JANUARY 1, 1996, ARE ENTITLED TO A TERM OF PROTECTION OF AT LEAST TWENTY YEARS FROM FILING**

23. The text, context, object and purpose of Article 70.1, as well as its negotiating history, and the subsequent practice of WTO Members demonstrate that pre-1996 "acts" do not absolve Members from the obligation to provide TRIPS-level intellectual property protection – including a patent term of twenty years from filing – to all subject matter existing on January 1, 1996. The United States has previously set forth in detail its position regarding the proper interpretation of TRIPS Article 70 in paragraphs 10-17 of its First Oral Statement and its Response to Panel Questions 7 and 11-14. Rather than repeating those arguments, the United States will primarily address in this submission the new arguments raised by Canada, particularly in its response to Panel Questions 6 and 7.

A. THE EXEMPTION FOR PRE-1996 ACTS IN ARTICLE 70.1 HAS NO RELEVANCE TO THE REQUIREMENT TO APPLY TRIPS OBLIGATIONS TO EXISTING SUBJECT MATTER UNDER ARTICLE 70.2.

24. It is important to note that, despite the focus during these proceedings on the definition of the terms "acts" and "subject matter" in Articles 70.1 and 70.2, the United States sees little difference between the Parties regarding these definitions. Rather, the essence of this dispute stems from the differing conclusions that the Parties draw from these definitions.

25. According to both Parties, the term "acts" can include both administrative and legislative acts of governments as well as acts of right holders and third parties. Such pre-1996 acts could include the "act" of granting a patent, revoking a patent, infringing a patent or granting a compulsory license on a patent. These acts themselves are not subject to the obligations in the TRIPS Agreement.

26. The positions of Canada and the United States differ primarily with respect to the implications of this definition of "acts." The mere fact that Canada engaged in pre-1996 acts that denied TRIPS-level protection to certain subject matter, does not mean that Canada is forever exempted from applying TRIPS obligations to such subject matter. In the context of patented inventions, the fact that Canada denied a term of twenty years from filing before TRIPS does not

mean that Canada is forever exempted from the obligation to grant a TRIPS-level patent term to such inventions that existed on January 1, 1996.

27. Of course, pre-1996 legislative and administrative acts (and infringing acts by third parties) could have negatively affected the rights of patent holders, and could have been inconsistent with TRIPS-standards. Such acts themselves are not actionable under TRIPS. The subject matter to which the acts applied, however, can be eligible for TRIPS-level protection after January 1, 1996. Article 70.1 does not prevent the prospective application of TRIPS standards, including the standard governing the term of protection, to existing subject matter as mandated by Article 70.2.

28. Articles 70.1 and 70.2 are separate provisions that address distinct situations. Canada argues that the United States has interpreted TRIPS Articles 70.1 in a way that renders it “meaningless,” and fails to “resolve” the “apparent conflict” between Articles 70.1 and 70.2.<sup>25</sup> In the view of the United States, however, there is no conflict -- apparent or otherwise -- between Article 70.1 and Article 70.2. The “conflict” between these two provisions is apparent only to Canada, and results from Canada’s strained reading of those provisions. Furthermore, Article 70.1 is not at all meaningless, but merely has no relevance in the specific factual circumstances of this case. Indeed, as we have set forth in our previous submissions, it is Canada’s interpretation of Article 70.1 that would render large portions of Article 70 meaningless or redundant.

29. Canada argues that there must be “compelling reasons presented by the U.S.” to “override the language of the TRIPS Agreement, including Article 70.1. Article 70.1 is simply not relevant to this particular dispute because the United States is not challenging Canada’s pre-1996 acts. Again, the irrelevance of Article 70.1 to this dispute does not imply that Article 70.1 is without meaning and we have demonstrated in detail in our submissions why our interpretation of Article 70.1 and 70.2 is logical and consistent with the text, context, object and purpose of Article 70, the negotiating history of that provision, and the subsequent practice of WTO Members.<sup>26</sup> The United States, however, does not seek to “override” any

30. In sum, the United States does not argue that Canada is in violation of its TRIPS obligations as a result of the failure of the Canadian Patent Office to grant, before 1996, patents with a term of at least twenty years from filing. The “acts” of Canada’s Patent Office prior to 1996 are not at issue, and indeed, are not subject to TRIPS obligations. Rather, Canada’s violation of the Agreement stems from its failure, since the date of application of the TRIPS Agreement, to provide a term of protection for existing patented inventions of at least twenty years from filing. This violation is unrelated to any pre-1996 “act,” but is related only to the subject matter (protected inventions) that existed on January 1, 1996. The rule in Article 70.1 that pre-1996 acts are not subject to the obligations in the Agreement does not imply that subject matter existing on January 1, 1996, is also not subject to the obligations of the Agreement.

B. THERE IS NO BASIS IN TRIPS FOR CANADA’S ARGUMENT THAT ARTICLE 70.2 REQUIRES COMPLIANCE WITH ONLY SOME, BUT NOT ALL, OF THE OBLIGATIONS IN THE TRIPS AGREEMENT, WITH RESPECT TO EXISTING SUBJECT MATTER

31. In response to U.S. arguments in its Oral Statement of 20 December that Canada’s interpretation of Articles 70.1 and 70.2 would render meaningless other aspects of Article 70, Canada has clarified that Article 70.2 would apply at least with respect to TRIPS rights under Articles 27.1, 28 and 31(h). For example, in response to Panel Question 7, Canada made the following statements:

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<sup>25</sup> Canada Response to Panel Question 7, at 25, 27.

<sup>26</sup> Canada Response to Panel Question 7, at 25 (third paragraph).

In the result Canada also understands that, *by virtue of paragraph 2 of Article 70*, subject matter which is ‘novel, inventive and useful’, which was invented and protected before the application date and which continued to be protected as of that date, *would be entitled to protection by the patent vehicle pursuant to Article 27.1 and to the conveyance of the exclusive benefits, even if enhanced by TRIPS, bestowed by virtue of Article 28.*<sup>27</sup>

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Patentable subject matter under Article 70.2 would include the obligations set out under Article 28 to confer certain exclusive rights on a patent owner, and the right to be paid remuneration under Article 31(h) where a Member sanctioned a use unauthorized by a right holder for patentable subject matter.<sup>28</sup>

32. It is significant that Canada concedes that pre-1996 acts do not preclude the application of the obligations in Articles 27.1, 28 and 31(h) to existing subject matter. Thus, for example, Canada would apparently agree that if it granted a patent on an invention in 1993, and if Canadian law provided only four of the five exclusive rights outlined in Article 28, Article 70.2 would imply that Canada must grant, as of January 1, 1996, the fifth exclusive right to that patentee.

33. Where Canada and the United States continue to differ is whether Article 70.2 requires Canada also to apply the TRIPS obligation to provide a patent term of twenty years from filing to inventions which enjoy patent protection on January 1, 1996. While Canada agrees that WTO Members are obliged by Article 70.2 to provide TRIPS protections under Articles 27.1, 28, and 31(h) to subject matter existing on January 1, 1996, Canada argues that the term of protection applicable to such subject matter is not covered by Article 70.2. Canada has not and cannot explain why the TRIPS obligation involving the term of protection may be properly excluded under Article 70.1 while other TRIPS obligations, such as the provision of exclusive rights in Article 28, are not.

34. In elaborating its theory of Article 70.2, Canada places great weight on the argument that a “patent” is not “subject matter.”<sup>29</sup> The Parties do not appear to be in dispute that existing inventions (which may already be patented) are subject matter within the meaning of Article 70.2. Thus, Canada’s distinction is without any significance in this case. Patented inventions that existed on January 1, 1996, are entitled to TRIPS-level protection. Such TRIPS-level protection includes the rights provided for in Articles 27.1, 28, and 31 of the TRIPS Agreement, as well as a term of protection that does not expire before twenty years from filing, as provided in Article 33.

## V. CONCLUSION

35. Accordingly, the United States respectfully requests the Panel to find that Canada is not in compliance with Articles 33 and 70.2 of the TRIPS Agreement, and respectfully requests that the Panel recommend that Canada bring its law into conformity with these provisions.

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<sup>27</sup> Canada Response to Panel Question 7, at 22 (second full paragraph) (emphasis supplied).

<sup>28</sup> Canada Response to Panel Question 7, at 28 (first full paragraph).

<sup>29</sup> Canada response to Panel question 7 at 26 (second paragraph).

## ATTACHMENT 1.6

### ORAL STATEMENT OF THE UNITED STATES AT THE SECOND MEETING WITH THE PANEL

(25 January 2000)

#### I. INTRODUCTION

1. Mr. Chairman, Members of the Panel, Representatives of the Government of Canada, and members of the Secretariat: On behalf of the United States delegation, I would like to first thank the Panel and the Secretariat Staff for your time and continued effort in this case.

2. Despite Canada's claims to the contrary, and its attempts to make it otherwise, this case remains "an exceedingly simple one."

3. The text of TRIPS Article 33 is unequivocally clear:

The term of protection available [for patents] shall not end before the expiration of a period of twenty years counted from the filing date.

Yet, Canada admits that the terms of protection for forty percent of its Old Act patents that are presently in existence will end before the expiration of a period of twenty years counted from their respective filing dates.<sup>1</sup> The terms of these patents are therefore inconsistent with the express obligation of Article 33.

4. The text of TRIPS Article 70.2 is equally unambiguous:

Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date . . .

Many of Canada's Old Act patents were still valid at the time the TRIPS Agreement became applicable for Canada on January 1, 1996. This is uncontested. Thus, the "Agreement gives rise to obligations in respect of" the inventions protected by these Old Act patents. One such obligation is that of Article 33: Canada must provide terms of protection that "shall not end before the expiration of twenty years counted from the filing date" for all such Old Act patents.

5. And because Canada does not meet this obligation for forty percent of its existing Old Act patents, Canada is therefore in *prima facie* violation of Articles 33 and 70.2 of the TRIPS Agreement. It is really just that simple.

#### II. REBUTTALS TO CANADA'S ARTICLE 33 DEFENSES

##### Equivalency

6. Canada has offered two defenses related to Article 33 of TRIPS. First, Canada claims that even if a term of seventeen years from grant does in fact end prior to the expiration of twenty years

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<sup>1</sup> First Submission of Canada, para. 45.

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<sup>2</sup> Second Submission of Canada, para. 3.

<sup>3</sup> Appellate Body report on *United States - Standard for Reformulated and Conventional Gasoline*, WT/DS2/AB/R (adopted May 20, 1996), at 17.

<sup>4</sup> Rebuttal Submission of the United States, paras. 9 & 10.

<sup>5</sup> See GATT panel report on *United States - Section 337 of the Tariff Act of 1930*, BISD 36S/386 (adopted November 7, 1989), para. 5.13.

<sup>6</sup> Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 169 (1998).

<sup>7</sup> First Oral Presentation of Canada, para. 55.

### Availability

11. In addition to its “equivalency” argument, Canada also claims that it is not in violation of Article 33 because a term of twenty years from filing was “available” to patent holders by means of delay tactics in patent application prosecution. By not “taking advantage of” these delay tactics, Canada argues, the applicants essentially “waived” their right to a patent term of twenty years from filing.<sup>8</sup> This argument too has fundamental flaws.

12. First of all, it is uncontested that all Old Act patents were based on patent applications filed prior to October 1, 1989. It is similarly uncontested that the obligation to provide a patent term of twenty years from filing did not arise for Canada until the TRIPS Agreement became applicable on January 1, 1996. Thus, it was impossible for Old Act applicants to have knowingly waived their rights under TRIPS to a term of twenty years from filing. Moreover, since certain Old Act applicants – whose patents would be granted in less than three years – would have had to forego a period of effective protection in order to obtain a term that did not end before twenty years from filing, the “choice” that Canada made available to patent applicants was hardly that contemplated by Article 33.

13. In support of its position that a patent term of twenty years from filing was available to Old Act applicants, Canada repeatedly points out that sixty percent of Old Act patents have terms that exceed twenty years from filing. This statistic, however, proves nothing about the availability of a term of twenty years from filing to all Old Act applicants. It is just as significant that forty percent of Old Act patents have terms that end before twenty years from filing.

14. Second, the incredibly convoluted delaying tactics described by Canada – twice abandoning an application and then reinstating it each time, and then forfeiting the application and restoring it again – have no sound legal basis. Following the Appellate Body’s guidance in the *India - Patent Protection* case,<sup>9</sup> the United States – in paragraphs 14 to 28 of our rebuttal submission – examined the relevant provisions of the Old Act as they relate to such delay tactics. In doing so, we noted that there is no legally guaranteed right for an applicant to use such tactics to obtain a patent term of twenty years from filing. Section 30(2) of Canada’s Old Act permitted the reinstatement of abandoned applications if “the failure to complete or prosecute the application within the time specified was not reasonably avoidable.”<sup>10</sup> In other words, a patent applicant that had abandoned an application had no legal right to reinstate that application if the applicant engaged in reasonably avoidable delays. The fact that the Chairman of Canada’s Patent Appeals Board is aware of no cases of delays being refused is of no legal consequence, and does not change the plain text of the Canadian law.

15. Canada attempts to bolster its argument regarding these delay tactics by asserting that “similar<sup>11</sup> This comparison only highlights the weakness in Canada’s argument. The U.S. patent law does contain a rule similar to Section 30(2) of Canada’s Old Act. Like Canada’s Section 30(2), the U.S. provision is not available to anyone for the asking. Rather, it provides that patent applications can be reinstated only where a delay was “unavoidable”. Furthermore, under U.S. law, patent applicants need not engage in any delaying tactics to obtain a patent term that does not end before twenty years from filing. Rather, all applicants and current patent owners have a legal right to such a term under U.S. law – even where they chose not to repeatedly abandon and forfeit their patent applications.

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<sup>8</sup> Second Submission of Canada, para. 29.

<sup>9</sup> See Appellate Body report in *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (adopted January 16, 1998), paras. 66, 69, and 70.

<sup>10</sup> Canadian Patent Act, R.S.C., ch P-4, section 30(2) (1985). Canada Exhibit 16.

<sup>11</sup> Second Submission of Canada, para. 33.

16. Finally, it is interesting to note the inconsistency between Canada's argument regarding the "availability" of a twenty-year patent term with Canada's argument that such a term is actually provided under Canadian law. One might wonder why, if the two terms were indeed "equivalent," an Old Act patent applicant would have to delay the date of grant to obtain a twenty year term. The obvious answer is that a term of twenty years from filing is not in fact provided under Section 45 of the Canadian Patent Act.

### III. REBUTTALS TO CANADA'S ARTICLE 70 DEFENSE

17. Canada's final defense in this case rests upon Article 70. Article 70.2, by its terms, requires WTO developed-country Members to apply the obligations of the TRIPS Agreement - - all of the obligations of the TRIPS Agreement - - to inventions that were patented on January 1, 1996. Article 70.1 does not diminish this requirement or provide otherwise. By contrast, Canada's interpretation of Article 70.2 of TRIPS is inconsistent with the text of that provision, its context, object and purpose, its negotiating history, as well as the subsequent practice of every other WTO developed-country Member.

18. The text of Article 70.2 is the key to its interpretation. The plain language of this provision indicates that the obligations of the TRIPS Agreement apply to all "subject matter" existing on January 1, 1996, "which is protected" on that date. An invention is subject matter. A patent is a form of intellectual property protection. In short then, Article 70.2 requires the obligations of TRIPS to be applied to existing patented inventions.

19. Canada attempts to cloud the interpretation of this straight-forward provision by placing great weight on the distinction between a patent and the subject matter protected by a patent. This distinction has no effect on the interpretation of Article 70.2. Quite simply, the TRIPS obligations must be applied to patented inventions. Along the same lines, Canada appears to argue in its Second Submission that "patented subject matter" is not "subject matter."<sup>12</sup> Given that Article 70.2 applies to "subject matter . . . that is protected," Canada's distinction again has no significance.

20. Apart from these irrelevant semantic distinctions under Article 70.2, Canada's Article 70 defense rests on a sweeping interpretation of Article 70.1. As described in the Rebuttal Submission of the United States, Article 70.1 applies to all "acts" which occurred before the date of application of TRIPS to Canada. Such acts can be those of private parties or acts of government authorities. In our previous submissions, the United States has provided numerous examples of the acts covered by Article 70.1 and the effect of that provision.<sup>13</sup>

21. In the context of this case, Article 70.1 means that Canada is not today in violation of the TRIPS Agreement for its failure to make available, before 1996, patent terms of twenty years from filing to all applicants. The U.S. is not arguing that Canada's physical acts of granting patents with terms of seventeen year from grant back in the early 1990's violate TRIPS. This concept may seem obvious - - and indeed, to many TRIPS negotiators, it was. As noted in the U.S. Answer to Panel Question 6.d., during the TRIPS negotiations, some countries thought Article 70.1 stated a concept "too obvious" to be included in the Agreement. The negotiating history does not support Canada's position that Article 70.1 in effect represents a sweeping and complex exemption from the provisions of Article 70.2.

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<sup>12</sup> Second Submission of Canada, para. 51.

<sup>13</sup> *E.g.*, First Oral Statement of the United States, para. 14, U.S. Response to Panel Question 11, Rebuttal Submission of the United States, para. 25.



22. The United States' complaint before this Panel is not based on any pre-1996 act of any Canadian authority. Rather, it is based on Canada's failure, as of January 1, 1996, to apply prospectively the obligations of TRIPS to all patented subject matter that existed on January 1, 1996. Article 70.1 has no effect on this particular case, and no relevance to it.

23. More specifically, the mere fact that Canada engaged in pre-1996 acts that denied TRIPS-level protection to certain subject matter, does not mean that Canada is forever exempted from applying TRIPS obligations to such subject matter. In the context of patented inventions, Canada's failure prior to 1996 to make available to all applicants a term of twenty years from filing, does not mean that Canada is excused from the obligation to grant a TRIPS-level patent term to patented inventions that existed on January 1, 1996.

24. Canada's contrary interpretation of Article 70.1 is unsupported by the context, object and purpose of Article 70. In this regard, Canada first attempted to convince this Panel that all the obligations of TRIPS do not apply to patents granted prior to January 1, 1996. To quote Canada's First Submission: "patents issued prior to January 1, 1996 are not subject to the obligations in the <sup>14</sup> Such a far-reaching interpretation of Article 70.1 would make several of the other provisions of Article 70 redundant or meaningless. It would also completely eviscerate the protection provided by the TRIPS Agreement for thousands of existing patent holders, with the result that the legal effect and the benefits of the TRIPS Agreement would not be felt for years into the future. This was not the intent of the negotiators of the Agreement, and is not consistent with the detailed negotiations that accompanied the drafting of Articles 70.2, 70.4 and 70.6.

25. Presumably to avoid such an extreme result, Canada subsequently narrowed its argument, and now distinguishes between some of the obligations in the TRIPS Agreement that would apply to existing subject matter, and other obligations (such as patent term) that allegedly do not. There is no textual basis in Article 70.1 or 70.2 for Canada's attempt to distinguish between the obligations in TRIPS that will apply to existing subject matter. The obligations in Articles 27, 28 and 31 of TRIPS cannot be distinguished from the obligation in Article 33. Under Article 70.2, Canada must apply all TRIPS obligations to all inventions that were protected on January 1, 1996.

26. In its Second Submission, Canada attempted to support its distinction between the various obligations of TRIPS by citing little more than the fact that the obligation concerning the exclusive rights conveyed by a patent and the obligation concerning the term of a patent appear in different articles of the Agreement. This argument ignores the fact that other patent obligations also are not merged into one provision, but are set forth in separate articles. Furthermore, there is no indication that the drafters of the Agreement intended to limit the application of Article 70.2 merely by the organization of the patent obligations in TRIPS into separate articles.

### **Subsequent Practice**

27. On a final note, the United States must re-emphasize the highly significant fact that among all WTO developed-country members (except Canada), there appears to be complete uniformity of practice regarding the interpretation of Articles 33, 70.1 and 70.2. Canada has provided no evidence rebutting the evidence provided in the U.S. First Submission on this point. On the key issue in dispute - - whether a patent term of at least twenty years from filing must be available for all patents in force on January 1, 1996 - - every other developed country member of the WTO agrees that it must. Given the importance of subsequent practice as a guide to interpretation of the treaty provisions under Article 31(3)(b) of the Vienna Convention, this consensus among other WTO members cannot be dismissed.

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<sup>14</sup> First Written Presentation of Canada, para. 113.

#### **IV. CONCLUSION**

28. For all of these reasons, the United States respectfully requests that the Panel find that Canada is in violation of its obligations under Articles 33 and 70 of the TRIPS Agreement, and recommend that Canada bring its law into compliance with these provisions.

**ATTACHMENT 1.7**

**RESPONSES OF THE UNITED STATES TO WRITTEN QUESTIONS FROM THE PANEL –  
SECOND MEETING**

(3 February 2000)

**B. AVAILABILITY (ARTICLE 33)**

**Q.32 Does the TRIPS Agreement permit Members to give patent applicants a choice between either obtaining protection early, or obtaining a term of protection that expires twenty years from the filing date?**

No. The Agreement mandates that the term of protection available must not end before the expiration of twenty years from the filing date. The Agreement also mandates that patents be granted "within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection", and that procedures for the acquisition of patent rights may not be unnecessarily complicated or costly, or entail unwarranted delays. The text of the Agreement does not support the notion that a Member can ignore one obligation simply by fulfilling another.<sup>1</sup> These obligations are not "either-or" choices. A Member cannot condition its compliance with one TRIPS obligation on a patent applicant's willingness to forfeit its rights under another TRIPS provision.

**Q.33 If Article 70.2 rendered Article 33 applicable to inventions under protection in developed country Members on 1 January 1996, would it require those Members to make available on that date a term of protection for existing patents that did not expire before the end of 20 years from their respective filing dates or would it be sufficient that that term was available at the time that the patent application was filed?**

The text of Articles 70.2 and 33 indicates that it would not be sufficient for a WTO Member to provide a term of twenty years from filing only at the time that a patent application was filed. Essentially, such a scenario would read into Article 70.2 an exception that does not exist in the text. The terms of Article 70.2 are unqualified on this point, and require developed country Members to comply with the TRIPS obligations in respect of inventions under protection on 1 January 1996. In this case, it is undisputed that on 1 January 1996, Canada did not make available to all patent owners a term of protection that did not end before twenty years from filing. ON 1 January 1996, an Old Act patent owner whose patent would expire sooner than twenty years from filing had no recourse under Canadian law. (Moreover, notwithstanding the premise of this hypothetical question, Canada also did not make this term available on a sound legal basis for every one of its Old Act patent applicants at any time prior to 1 January 1996.)

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<sup>1</sup> See, e.g., *GATT panel report on United States – Section 337 of the Tariff Act of 1930*, BISD 36S/386 (adopted November 7, 1989), para. 5.13.

**Q.34 How can those applicants whose patents were granted before the date of application of the Agreement be said to have chosen to forego a later term when the TRIPS Agreement had not even been applied?**

Those applicants whose patents were granted before the date of application of the Agreement cannot be said to have chosen to forego a later term when the TRIPS Agreement had not even been applied. To have "chosen to forego a later term" necessarily implies that Old Act applicants knowingly made the decision to waive their right to this later term prior to the granting of their patents. Logically, one cannot waive a right that did not exist. The right to a term of twenty years from filing did not (and does not) exist for Old Act applicants under Canadian law, and did not exist under the TRIPS Agreement until its date of application to Canada on 1 January 1996.

**ATTACHMENT 2.1**

**FIRST SUBMISSION OF CANADA**

(2 December 1999)

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## I. INTRODUCTION

1. In these proceedings the United States of America (US) challenges the conformity of the provisions of the Canadian *Patent Act* (Act) respecting the duration of the term of protection accorded to certain Canadian patents with the minimum standard for that term prescribed by Article 33 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (variously referred to as: TRIPS, the Agreement or the TRIPS Agreement).

2. The US notes that the term of protection granted to patents issued on the basis of patent applications filed before October 1, 1989 is defined, pursuant to section 45 of the Act, to be seventeen years from the date on which such a patent is issued. On this basis the US advances the allegation that this provision of Canadian patent law is inconsistent with Canada's obligations under the TRIPS Agreement, including but not necessarily limited to Articles 33, 65 and 70.<sup>1</sup>

3. The US position is based on a narrow and incomplete analysis of the relevant provisions of Canadian law and practice as well as of the relevant terms of the Agreement.

4. In reply Canada denies that there is merit in the US allegation and confirms that its patent law and practice respecting the term of protection accorded to Canadian patents issued on the basis of patent applications filed before October 1, 1989 are consistent with the obligations imposed by the TRIPS Agreement and more specifically are consistent and conform with the minimum standard required by Article 33 as well as with the transitional or application rules set out in Articles 65 and 70 of the Agreement.

5. It is Canada's submission that the provisions of section 45 of the Act are consistent, and in conformity, with the TRIPS Agreement and more specifically with the referenced Articles because:

- (a) the term of the exclusive privilege and property right available under a "section 45" patent is equivalent or superior to and consistent with the term of the exclusive privilege and property right conferred by a patent where the term of protection available does not, as required by Article 33, end before the expiration of a period of twenty years counted from the filing date;
- (b) in prescribing a term of protection that is measured from the date of the grant of a patent, section 45 does not provide, or otherwise require, that the term of protection conferred shall end before the expiration of the twenty year period measured from the filing date of the patent application;
- (c) the events or circumstances which may operate to limit the period of the term of protection of a section 45 patent to less than twenty years measured from the filing date are events or circumstances that are within the private decision making capacity and strategic control of the applicant; and,
- (d) in any event, "section 45" patents which were issued under an act of grant executed before the application date of the TRIPS Agreement are exempt from the obligations of the Agreement by virtue of the express exception set out in paragraph 1 of Article 70 and, more particularly, neither the retroactive application provisions of the

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<sup>1</sup> Letter from Ambassador Rita D. Hayes of the US to Ambassador John M. Weekes of Canada; dated May 6, 1999. Reproduced as Exhibit No. 1.

Agreement set out in paragraph 2 of Article 70 nor the term of protection prescribed in Article 33 have any application to such patents.

## II. FACTS

### A. TREATY PROVISIONS

6. Under the heading of “*Term of Protection*” Article 33 of TRIPS provides that:

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date [of a patent application].

7. The scope of this obligation is further addressed in paragraphs 1 and 2 of Article 62. Those two paragraphs stipulate that:

1. Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part II, compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this Agreement.

2. Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

8. Each Member’s obligation to implement the standards prescribed by the TRIPS Agreement arises by virtue of both the provisions of paragraph 4 of Article XVI of the Agreement Establishing the World Trade Organization (WTO) and the provisions of paragraph 1 of Article 1 of the TRIPS Agreement. In their material parts these two paragraphs provide, respectively, that:

Each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements.

Members shall give effect to the provisions of this Agreement...Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.<sup>2</sup>

9. As a substantive annex to the Agreement Establishing the WTO the TRIPS Agreement entered into force on January 1, 1995. However, by virtue of its one year moratorium on the obligation to implement, paragraph 1 of Article 65 delayed the “date of application” for the TRIPS Agreement in Canada and other developed Member states until January 1, 1996. Specifically paragraph 1 of the Article provides that:

Subject to the provisions of paragraphs 2, 3 and 4 [which are not relevant here], no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

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<sup>2</sup> The Appellate Body endorsed the application of this rule respecting Member discretion in implementing their TRIPS obligations in: *India – Patent Protection For Pharmaceutical And Agricultural Chemical Products (AB-1997-5)*, (WT/DS50/AB/R) (December 19, 1997) at paragraph 59 and following, beginning at page 22.

10. The obligations both to implement and to implement by a date certain are, despite their positive expression, nevertheless subject to the caveats or special application rules which, under the heading “*Protection of Existing Subject Matter*”, are set out in Article 70.

11. Most of these special application or transitional rules are narrowly or specifically focussed and seek to address specific, anomalous or ambiguous circumstances that the treaty negotiators expected to arise on the application date of the Agreement.

12. However the rules set out in paragraphs 1 and 2 of the Article are rules of general application. The first, the paragraph 1 rule gives specific effect within the TRIPS context to the presumption of international law<sup>3</sup> as well as of the municipal law of many Member states against the retroactive application of new law which would affect vested property or contractual rights subsisting on the coming into force of the new law.

13. The rule against the retroactive application of its obligations is set out in the opening paragraph of Article 70 and specifies that:

This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.

14. By its own terms, the second–or the paragraph 2–rule operates subject to the other provisions of the Agreement. In its material part it provides that:

Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement.

#### B. TERM OF PROTECTION PROVISIONS IN CANADIAN PATENT LAW

15. Current Canadian patent legislation contains two provisions, which originally came into force on October 1, 1989, that define the term of protection to be accorded to a successful applicant for patent protection.

16. The two provisions are distinguishable on the basis of the filing date of a patent application, by their references to different commencement dates for measuring the running of the term of protection and by their specification of different lengths of the period for which protection will continue after the happening of the commencement date.

17. Following their recent, essentially editorial, amendment by the *Intellectual Property Law Improvement Act*<sup>4</sup> of 1993, the two provisions now specify that:

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<sup>3</sup> The presumption has been codified in Article 28 of the *Vienna Convention on the Law of Treaties* which provides that:

Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party.

<sup>4</sup> S.C. 1993, ch. 15, s. 42. Reproduced in relevant part as Exhibit No. 2. These amendments came into force on October 1, 1996.



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.

45. Subject to section 46, the term limited for the duration of every patent issued under this Act on the basis of an application filed before October 1, 1989 is seventeen years from the date on which the patent is issued.

18. Section 46 provides for the payment of annual fees—“maintenance fees”—to maintain the rights accorded by the patent once granted. It also provides that where such fees are not paid within the time prescribed, the patent shall be deemed to have expired at the end of that prescribed time. Specifically section 46 states that:

46.(1) A patentee of a patent issued by the Patent Office under this Act after the coming into force of this section shall, to maintain the rights accorded by the patent, pay to the Commissioner such fees, in respect of such periods, as may be prescribed.

(2) Where the fees payable under subsection (1) are not paid within the time provided by the regulations, the term limited for the duration of the patent shall be deemed to have expired at the end of that time.<sup>5</sup>

#### C. LEGISLATIVE CONTEXT AND HISTORY

19. The substance of sections 44 and 45 was, together with a large number of other proposed amendments to the *Patent Act*, first introduced in Parliament on November 6, 1986 in Bill C-22. Although still more commonly referred to as Bill C-22, the Bill was enacted and became law under the title of *An Act to amend the Patent Act and to provide for certain matters in relation thereto*<sup>6</sup> (variously referred to as: Bill C-22; or, the Bill) on November 17, 1987.

20. In Bill C-22 the provisions at issue were drafted to reflect their then prospective application. Numbered as sections 46 and 47 within clause 16 of the Bill they provided that:

46. Subject to section 48, the term limited for the duration of every patent issued by the Patent Office under this Act the application for which patent was filed after the coming into force of this section shall be twenty years from the date of the filing of the application in Canada.

47. Subject to section 48, the term limited for the duration of every patent issued by the Patent Office under this Act the application for which patent is filed on or after August 1, 1935 and before the coming into force of this section shall be seventeen years from the date on which the patent is issued.<sup>7</sup>

21. Section 48 in Bill C-22 was equivalent to what, in the current version of the Act, is section 46. But for some variation in the lapsing provision in subsection (2), section 48 is substantively identical to section 46.

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<sup>5</sup> S.C. 1993, ch. 15, s. 43. Reproduced in Exhibit No. 2.

<sup>6</sup> S.C. 1987, ch. 41, ss. 46, 47. Reproduced in relevant part as Exhibit No. 3.

<sup>7</sup> The reference to August 1, 1935 alludes to the effective date of the term of protection provision in the prior version of the *Patent Act* which, to harmonize the Canadian with the US term, had originally introduced the ‘seventeen year from the date of grant’ term into Canadian patent law. R.S.C. 1970, Ch. P-4. Section 48 introduced the seventeen year term. Reproduced in part as Exhibit 4.

48.(1) A patentee of a patent issued by the Patent Office under this Act after the coming into force of this section shall, to maintain the rights accorded by the patent, pay to the Commissioner such fees, in respect of such periods, as may be prescribed.

(2) Where the fees payable by a patentee in respect of a period prescribed for the purposes of subsection (1) are not paid before the expiration of that period, the term limited for the duration of the patent shall be deemed to have lapsed on the expiration of such further period as may be prescribed.<sup>8</sup>

22. Two principal rationales underlay the introduction and enactment of Bill C-22.

23. The first involved the Canadian Government's resolve to respond to international dissatisfaction with the open-ended nature of the provisions in Canadian patent legislation which allowed for the compulsory licensing of patented inventions relating to the use, preparation or production of foods and medicines.<sup>9</sup> (Amongst other matters, the resulting amendments considerably curtailed the period during which such compulsory licences were allowed to operate.<sup>10</sup>)

24. The second involved the Government's decisions to ratify the *Patent Cooperation Treaty*, to switch to a "first to file" from a "first to invent" system of patent protection and, more generally, to modernize domestic patent laws, administrative procedures and practices.<sup>11, 12</sup>

25. While the desire to modernize the Canadian patent system was one, it was not the only, reason which lay behind the changes to the commencement date and length of the term of protection provisions of the then contemporary patent legislation. Another and important rationale for these changes reflected "the desire to prevent patent applicants from manipulating the patent application system by deliberately delaying the grant of their patent in order to delay the date of expiry...".<sup>13</sup>

26. In commenting on the effect of a "twenty year from filing" term in his book, *Intellectual Property Law Copyright Patents Trade Marks*, Professor David Vaver gives some comparative perspective to this further rationale for change when he observes that:

The present monopoly period [twenty years from filing] is effectively less than twenty years. ... Before [1 October] 1989, patents lasted seventeen years from date of grant, which could be long after the date of application because of delays in the PO [Patent Office]. Some delays were unavoidable. Others were deliberately caused by applicants intent on prolonging their monopoly.<sup>14</sup>

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<sup>8</sup> S.C. 1987, ch. 41, s. 48. Reproduced in Exhibit No. 3.

<sup>9</sup> See, for instance, David J. French. "Patent Law Reform in Canada", *Canadian Intellectual Property Review*, Vol.4, no. 2, 337. Reproduced as Exhibit No. 5.

<sup>10</sup> See: Exhibit No. 3, section 41.11 set out in clause 15.

<sup>11</sup> Department of Consumer and Corporate Affairs, *News Release*, June 27, 1986. Reproduced as Exhibit No. 6.

<sup>12</sup> Roger T. Hughes et al. *Hughes and Woodley On Patents*, (Butterworths: Toronto, 1984), Loose leaf service updated as of April 1999, pages 315 to 315-5. Reproduced in relevant part as Exhibit No. 7.

<sup>13</sup> Affidavit of Peter J. Davies, Chairman of the Patent Appeal Board of the Canadian Patent Office, Paragraph 3. Reproduced in its entirety as Exhibit No. 8. Hereafter cited as: Davies affidavit.

<sup>14</sup> David Vaver, *Intellectual Property Law-Copyright-Patents-Trade-marks*, (Irwin Law; Concord [Ontario], 1997) at page 114, footnote 2. Reproduced in relevant part as Exhibit No. 9.

27. The Bill C-22 amendments were introduced and published on November 6, 1986 and just over a year later became law, as noted above, on November 17, 1987. However, for a variety of reasons associated with the need to devise and draft complementary regulations, to attend to other transitional issues as well as to give the intellectual property community time to adjust to the new system, most of the “modernizing” amendments, including the amendments relating to the term of protection, were not brought into force until October 1, 1989. Thus both Government and affected parties had three years notice of the change in regime in which to make transitional arrangements.

28. The reference in sections 44 and 45 to a threshold application date clearly served some of the transitional purposes required to effect the change from a system using a “seventeen year from grant” term to another using a “twenty year from filing” term. It did not, however, provide a mechanism for converting from one system to the other.

29. In this circumstance Bill C-22 included an additional transitional provision that specified the law that would apply to pre-threshold date applications. The rule was set out in section 27 of the Bill and provided that:

27. Applications for patents filed before the coming into force of the provisions of this Act referred to in subsection 31(1) [which included the seventeen year term provision] shall be dealt with and disposed of in accordance with the *Patent Act* as it read immediately before the coming into force of those provisions.<sup>15</sup>

30. The law applicable to such applications is generally referred to as the “Old Act”.

#### D. THE PROSECUTION OF PATENT APPLICATIONS IN CANADA

31. In contrast to copyright and trade-mark property rights, which arise spontaneously upon either the creation of the “work”, in the case of copyright, or the association in commerce of a mark with “wares”, in the case of trade-marks; patent rights do not arise until the State or its agent—in Canada, the Commissioner of Patents or a patent examiner—is satisfied that the invention claimed meets the statutory criteria of being new, inventive and useful.

32. Where satisfied that an invention is new, inventive and useful, the Commissioner will confirm these qualities by granting and issuing “letters patent”<sup>16</sup> to the inventor (or its assignee). The Commissioner, through one of the examiners in the Patent Office, satisfies him or her self of the novelty, creativity and utility of the claims in a patent application through a process of examination and dialogue with the applicant.<sup>17</sup>

#### E. OLD ACT APPLICATIONS

33. As a consequence of the transitional rule set out in section 27 of Bill C-22, section 45 or Old Act applications continue to be evaluated on a “first to invent” basis and to be examined in accordance with the other rules governing Old Act applications.<sup>18</sup>

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<sup>15</sup> See: Exhibit No. 3, clause 27 of the Bill became section 27 when enacted as part of the amending Act.

<sup>16</sup> Peter D. Rosenberg. *Patent Law Fundamentals*, (Second Edition), (Clark Boardman: New York, 1989), Vol. 5 at pages 1-5/6. Reproduced in relevant part as Exhibit No. 10. And see: Harold G. Fox. *Canadian Patent Law and Practice*, (Fourth Edition), (Carswell; Toronto, 1969) at 163. Reproduced in part as Exhibit No. 11. Roger T. Hughes. *Op. cit.*, at page 315. David Vaver. *Op. cit.*, at page 113.

<sup>17</sup> Davies affidavit, paragraph 8.

<sup>18</sup> Davies affidavit, paragraphs 5 and 7.

34. The Old Act application process, like the new, begins with the filing of an application for the issuance of letters patent granting the applicant an exclusive privilege or property right in respect of the invention claimed in the application. Subject to the applicant withdrawing or abandoning an application, the process culminates in the performance of one of two statutory acts. Thus at the end of the process the Commissioner will act to either: refuse the application and give notice of the refusal to the applicant by registered letter (Old Act, section 40<sup>19</sup>); or, under his or her signature and the seal of the Patent Office, execute the grant of the patent (Old Act, section 43<sup>20</sup>).

35. The “dialogue” that occurs between the date of filing and the performance of either statutory act of “grant” or “refusal” would typically begin where, after having “searched” the application—meaning examining the claims against prior art literature and other matters affecting patentability, the examiner issues a report to the applicant informing it of any deficiencies in the claims or scope of the claims advanced in the application as well as of any inconsistencies in the application with the requirements of the Old Act or Rules.<sup>21</sup> Following the issuance of the examiner’s report the applicant is accorded a six month period in which to respond to any issues raised by the examination.

36. The prosecution of an Old Act application and its period of pendency before the Patent Office was, and continues to be, under the procedural control of the applicant. Thus by controlling the speed of the “dialogue” through the several means described in the quotation that follows, the applicant is able to accelerate or, as Professor Vaver notes, retard the prosecution of its application according to its own strategic interest in the timing and longevity of the protection it receives from the patenting process.<sup>22</sup>

37. The principal means for controlling the pace of the “dialogue” and application process have been described by the Chairman of the Patent Appeal Board of the Canadian Patent Office. The most direct of these methods is for the applicant to simply approach the examiner and ask that the examination be postponed to a later date.<sup>23</sup> The Chairman describes this and the other methods of influencing the pace of the prosecution process as follows:

Many means exist that allow an applicant to slow down the prosecution of an old Act application. These include the following:

- i) An applicant can achieve a delay in processing simply by asking the patent examiner. In my personal experience, I am unaware of any such request being refused.
- ii) One simple means for delaying an application is for an applicant to wait until the end of each time limit imposed upon the applicant to take a specified action. For example, an applicant can wait until the end of the six month period for responding to each report issued by the examiner and until the end of the six-month period for paying the final fee due before a patent is granted.
- iii) An applicant can also choose to not respond to an examiner’s report within the six month period following issuance of the report. This has the consequence that

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<sup>19</sup> *Patent Act*, R.S.C. 1985, c. P.-4; c. 33 (3<sup>rd</sup> Supp.). Reproduced in relevant part in Exhibit 12.

<sup>20</sup> See: Exhibit 12, section 43.

<sup>21</sup> Davies affidavit, paragraph 8.

<sup>22</sup> Davies affidavit, paragraphs 3, 4 and 9.

<sup>23</sup> Davies affidavit, subparagraph 10.i).

the application will be treated as abandoned; however, an abandoned application can be reinstated within twelve months.

iv) An applicant can further choose to not pay the final fee within the six month period following the Office notice requiring payment. This has the consequence that the application will be treated as forfeited; however, a forfeited application can be restored within six months.

v) Prior to October 1, 1996 there was a provision in the Patent Rules that permitted an applicant, upon payment of a fee, to postpone the date of issue of a patent by up to 10 weeks.

In a similar manner an applicant can accelerate the prosecution of an old Act application, for example, by making a request to advance an application for examination out of its routine order and paying a fee; by asking the patent examiner to speedup processing of the application; or simply by responding immediately to examiners' reports or other requirements of the Office.<sup>24</sup>

38. Those who Professor Vaver has described as being "intent on prolonging their monopoly" by exploiting these various opportunities to delay the processing of an Old Act application, were able to do so without prejudice to the security of their inventions.

39. The security of the invention was attributable to two features of the Old Act system. First, and in contrast to "new Act" applications which become open to public inspection no later than eighteen months after their filing dates<sup>25</sup>, Old Act applications are only opened for public inspection once the patent issues. Second, under the Old Act "first to invent" system, disputes as to the entitlement to patent protection are resolved through conflict proceedings<sup>26</sup> which, on their conclusion, award the patent right to the first to invent.

40. Thus, while the application is in the Patent Office and unless disclosed by the applicant, the contents of the application, which is to say the invention, remain secret and protectable under the laws of trade secrecy for the entire period during which the application is being prosecuted. (Moreover, where thought to be advantageous, the applicant could withdraw or abandon its application and continue to rely on trade secrecy protection indefinitely because the Patent Office never discloses the contents of an Old Act application which has been withdrawn, abandoned or refused.)<sup>27</sup>

#### F. OLD ACT PATENTS – STATISTICS

41. An examination of the records of the Canadian Patent Office relating to patents issued against applications filed prior to October 1, 1989 and that still existed when TRIPS took effect in Canada<sup>28</sup> reveals that a substantial number of Old Act applications had been prosecuted pursuant to a schedule

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<sup>24</sup> Davies affidavit, paragraphs 10 and 11.

<sup>25</sup> See: Exhibit 12, section 10 and S.C. 1993, c.15, s. 28.

<sup>26</sup> These are "contested" proceedings within the Patent Office in which competing applicants for patents respecting an invention file affidavit evidence to establish their respective "invention dates". Davies affidavit, paragraphs 2 and 7.

<sup>27</sup> Davies affidavit, paragraph 6.

<sup>28</sup> For reasons related to application filing date data entry problems, the date used for the examination was actually October 1, 1996. However, given the number of patents issued in Canada on an annual basis, the Patent Office is satisfied that the October 1 statistics are a reliable surrogate for the statistics that would have been applicable on January 1, 1996 had the data been available. Davies affidavit, paragraphs 13 and 15.

that, when viewed from the perspective of the application filing date, prolonged the duration of the period of protection available to the applicant.

42. More particularly the records show that, as of the surrogate TRIPS application date, 142,494 or just over 60 per cent of the Old Act patents then in existence (236,431) had terms that would not, assuming that annual maintenance fees are paid, expire until, or until well after, the expiry of the twenty year period following their application dates. In a very large number of these cases, the expiry dates will be 2 to 5 years after the expiry of the twenty year period.<sup>29</sup>

43. The obvious corollary of the foregoing is that, as of the surrogate TRIPS application date, 93,937 or just under 40 per cent of the Old Act patents then in existence had terms that will, assuming the payment of annual maintenance fees, expire in less than the twenty year period measured from their application dates. In 84 per cent of these cases, the patent will expire in the course of the nineteenth year following the application date. (In these “nineteenth” year expiry cases, 52 per cent will expire in the last half of the year, while the remaining 32 per cent will expire in the first half.)<sup>30</sup>

44. A supplementary examination of the records of the Patent Office, but one conducted in relation to Old Act patents which will still be in force on January 1, 2000, reveals a foreseeably similar result. Thus of the 169,966 Old Act patents that will, subject to the continued payment of annual maintenance fees, then still be in existence, 103,030 or just over 60 per cent will not expire until, or until well after, the expiry of the twenty year period following their respective application dates.<sup>31</sup>

45. Correlatively, 66,936 or just under 40 per cent of the Old Act patents still in force on January 1, 2000 will, again subject to the payment of the annual maintenance fees, expire in less than a twenty year period measured from their respective application dates. In 77 per cent of these cases, the patent will expire in the course of the nineteenth year following the application date. (In these “nineteenth” year expiry cases, 55 per cent will expire in the last half of the year, while the remaining 22 per cent will expire in the first half.)<sup>32</sup>

#### G. NEW ACT APPLICATIONS

46. When Bill C-22 introduced the “first to file” system and redefined the commencement date of the term of protection it eliminated an applicant’s capacity to delay the prosecution process so as to extend the period during which it could enjoy protection. In so doing it also effectively reversed any incentive or licence to delay which had been inherent in the Old Act system.

47. The incentive to delay was reversed by the facts that the new term of protection ran from the application filing date (section 44) and the application would become open to public inspection no later than eighteen months after the date of filing (section 10) irrespective of whether the patent had been “examined” and issued. The incentive to delay was further diluted by the fact that an application does not, under the New Act, enter the “examination” queue until the applicant requests “examination” and pays the associated fees (section 35). Originally the Bill C-22 *Patent Rules* provided that this request had to be made within seven years of the application date. The rule has since been changed to reduce the period to five years (section 96).<sup>33</sup>

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<sup>29</sup> Davies affidavit, paragraphs 14 to 17.

<sup>30</sup> Davies affidavit, paragraphs 14 to 17.

<sup>31</sup> Davies affidavit, paragraphs 18 to 22.

<sup>32</sup> Davies affidavit, paragraphs 18 to 22.

<sup>33</sup> Davies affidavit, paragraph 26.

48. The combined effect of these New Act rules is that the measurement of the term limited for the duration of the patent begins to run before the patent is issued so as to grant the applicant an exclusive privilege and property right in the invention. Accordingly, and in contrast to the Old Act system, the period during which an applicant can expect to benefit from trade secrecy and enjoy the privilege of exclusivity for the exploitation of its invention is being inexorably reduced throughout the entire period during which the application for protection is being prosecuted and examined.

49. The changes introduced by Bill C-22 did, however, also preserve the capacity of an applicant to exercise substantial control over the application prosecution process. It did so by virtue of two of its provisions. First, it did so by giving the applicant the freedom to determine when, within a specified period—first seven, now five years—after it had filed its application, it filed or would file its subsequent “request for examination”. Second, it preserved the capacity to control by preserving the rule which, on the payment of a fee, allows an applicant to advance its position in the queue for examination.

50. In addition to preserving measures which allowed applicants to exercise substantial control over the prosecution process, Bill C-22 also introduced new rules relating to maintenance fees which, in effect, gave successful applicants, whether under the Old Act or the New, control over the expiry date of their patents.

51. The new rules respecting “maintenance fees” have this effect because they make the longevity of the patent term of the exclusive privilege and property right accorded to a patentee for its invention contingent upon the payment of annual fees which, when not paid within the prescribed time, result in the deemed expiry of the patent.

#### H. NEW ACT PATENTS – STATISTICS

52. An examination of the records of the Canadian Patent Office relating to applications filed in Canada on or after October 1, 1989 reveals that, as of November 1, 1999, there have been 285,678 new Act applications filed since the new Act came into force. Of these new Act applications, 125,406 (approximately 43 per cent) have, since filing, requested examination. On average the period between the date of filing and the date of the request for examination for these 125,406 applications has been twenty seven and one half months.

53. The same exercise, when focussed on patents that have actually issued against New Act applications, reveals that 40,847 New Act patents have been granted by the Patent Office since the coming into force date of the New Act (October 1, 1989). The average pendency period, being the period between the application filing date and the date of grant, for this subset of New Act applications which have been processed through to grant, has been approximately sixty months or five years.<sup>34</sup>

54. The sixty month total has three components. Its first component involves the period of time between the filing date and the date on which the applicant makes the request and pays the fee for “examination”. On average the delay between these two dates has, over the last ten years, been approximately fifteen months. Subject to the applicant asking that its application be advanced in the queue and the payment of maintenance fees, the second component involves the time spent waiting in the queue for an available examiner. Over the last ten years the queue has averaged approximately twenty four months. The last component involves the time spent in “examination” itself. Arithmetic says that this period has averaged approximately twenty months.<sup>35</sup>

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<sup>34</sup> Davies affidavit, paragraph 29.

<sup>35</sup> Davies affidavit, paragraph 29.

55. Thus just as an Old Act applicant could, by its own conduct, control and **prolong** the duration of its term of protection when measured from the application filing date where it so wished, under the New Act an applicant can, by its own conduct, control and **abbreviate** a substantial part of the period by which the term of its exclusive privilege and property right will be reduced by the examination process.

### III. POINTS IN ISSUE

56. The issue in these proceedings is whether certain Canadian patents which:

- (1) were issued against applications filed before October 1, 1989;
- (2) existed on January 1, 1996; still exist: and
- (3) have a term of protection that, when measured from their respective application filing dates, will end before the expiration of a period of twenty years;

are consistent and in conformity with Canada's obligations under the TRIPS Agreement.

### IV. SUBMISSIONS

#### A. THE ROOT CAUSE OF THE MATTERS IN DISPUTE

57. The issue in dispute arises out of the fact that section 45 of the Canadian *Patent Act* uses a formula for specifying the term of protection to be accorded to successful patent applicants which is different from and, for the purposes of judging its compliance with TRIPS standards, cannot be directly compared to or converted into, the formula for specifying the term employed in and prescribed by Article 33 of the TRIPS Agreement.

58. The TRIPS formula specifies that: "The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date." Similarly section 44 of the Canadian *Patent Act* prescribes that, for patents issued on or after October 1, 1989, "the term limited for the duration of the patent is twenty years from the filing date.". If more definite than the TRIPS formula, section 44 is easily assessed against and is clearly in conformity with the standard prescribed by Article 33. It gives rise to no issues in these proceedings.

59. The section 45 formula however makes no reference to the application filing date. And that fact lies at the heart of this dispute.

60. Instead of using the filing date as the commencement date of the term during which protection shall be available, Section 45 provides that "the term limited for the duration of every patent issued...on the basis of an application filed before October 1, 1989 is seventeen years from the date on which the patent issued."

61. The difficulty in comparing or converting the protection available under the section 45 formula with that available under the TRIPS formula arises out of the disjunction between the various steps in the patent application process.

62. Typically, there are three discrete steps in the patenting process. First, the applicant files its application with a patent office authority. Second, through a process of examination and dialogue with the applicant, the patent authority satisfies itself as to whether or not the invention is new,



inventive and useful. Third, where the patent authority is satisfied that the invention is new, inventive and useful, it grants the patent; where, alternatively, it is not so satisfied, it refuses to grant the patent.

63. It is obvious that in this sequence of events the date of application and the date of grant will be separated in time. Furthermore, because of the variability of the examination process, the temporal distance between the two dates may be quite considerable. As of November 1999, there were, for example, about 1,000 patent applications which had been filed in Canada before October 1, 1989 and against which no patent has yet issued.<sup>36</sup>

64. As a result of the considerable variability of the temporal separation between the application and granting dates, a patent bearing a face term of seventeen years from grant may, when measured from its application filing date, have an “alternative” term of protection that is shorter than, equal to or longer than the twenty year period referred to in Article 33.

65. The US contends that when the “alternative” term of a seventeen year from grant patent is less than twenty years, a Member’s law that confers a seventeen year term from grant is not in conformity with the Article 33 standard and the Member has an obligation to amend its law to extend the term to a full twenty years from the application date so as to bring both the law and the patents at issue into conformity with the TRIPS standard.

66. Canada disagrees. It submits that there are good reasons for disputing, and denying, the validity of both:

- (a) the US proposition that the terms of protection of the patents here in issue are not consistent with TRIPS; as well as
- (b) the US proposition that the TRIPS Agreement requires that both the enabling law be changed and that the terms of protection of the patents at issue be extended.

#### B. THE TERM OF EXCLUSIVITY PRIVILEGE UNDER SECTION 45 AND ARTICLE 33 IS EQUIVALENT

67. One of the reasons to deny the validity of the US propositions is that Article 33 does not stand alone within the TRIPS Agreement but must be read in conjunction with the complementary term of protection provisions in paragraph 2 of Article 62.

68. The latter provisions specify that the granting or registration procedures of Members shall not operate so as to produce an “unwarranted curtailment” of the term of protection afforded to rights holders. Accordingly, Article 33 cannot be understood as intending to provide a minimum of twenty full years of protection for the exclusive privilege and property rights which a patent confers.

69. In this light Article 33 is properly characterized as a substantive, not a merely technical, rule. This emerges clearly from the conjoint reading of: the “*Desiring*” and paragraph (b) of the first “*Recognizing*” recitals which introduce the substance of the TRIPS Agreement and respectively read

...taking into account the need to promote effective and adequate protection of intellectual property rights,

*Recognizing* ...the need for new rules and disciplines concerning...(b) the provision of adequate standards and principles concerning the availability, scope and use of...intellectual property rights;

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<sup>36</sup> Davies affidavit, paragraph 23.

with the “unwarranted curtailment” language of paragraph 2 of Article 62, which in its turn and relevant part reads

Members shall ensure that the procedures for grant or registration, ..., permit the granting or registration of the right within a reasonable period of time so as to avoid **unwarranted curtailment** of the period of protection.

70. Consequently when evaluating the conformity of a Member’s domestic law with its TRIPS obligations under Article 33 it is necessary, not merely convenient, to scrutinize the substance, “effectiveness” and “adequacy” of both the domestic law and the TRIPS obligation.

71. When the substantive, “effective” and “adequacy” content of section 45 and Article 33 is so scrutinized, it is immediately apparent that the periods of protection extended to the holders of exclusive rights under the two term of protection formulas are equivalent. And where one term is substantively or “effectively” equivalent to, or as in the case of section 45, better than the other, the two are by definition consistent with one another within the context of the reasonableness and unwarranted curtailment standards articulated in paragraph 2 of Article 62.

72. Earlier analysis has demonstrated that, when measured from the application filing date, the term of protection accorded to a section 45 patent is variable upwards from its face term of seventeen years. The variability is attributable to the fact that, at least in Canada, it normally took the patent authority two to four years to complete the examination process.<sup>37</sup>

73. However while the “alternate” term of protection may vary according to the length of the examination process, the seventeen year term during which a successful applicant will enjoy the exclusive privilege and property right conferred by a patent is **constant** at seventeen years.

74. In systems such as the system contemplated by TRIPS where the term of protection is related to the date of application rather than to the date of grant but where the exclusive privilege and property right that flow from the patent run from the date of grant, the period during which a successful applicant will enjoy the exclusive privilege and property right conferred by the patent is **not** constant. Consequently in practice that period will be variably **eroded** by the time required to complete the examination and granting process.

75. The fact that under the TRIPS formula the period of exclusivity will be **eroded** by the granting process is recognized by paragraph 2 of Article 62 which, in seeking to impose a reasonable limit on the degree of erosion, nevertheless sanctions the reduction in the exclusivity period when it requires that:

...Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid **unwarranted curtailment** of the period of protection. (Emphasis added)

76. Where in the normal course it takes, as it currently does in Canada in respect of New Act patents, five years to complete the examination process for a patent whose term is related to its application filing date, the period of exclusivity will be reduced accordingly.<sup>38</sup> Since the five year examination period is the normal or average examination period, it must, in Canada’s submission, be

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<sup>37</sup> Davies affidavit, paragraph 8 and see as well the numbers of patents that have issued more than three years after their application filing dates.

<sup>38</sup> Davies affidavit, paragraph 29.

viewed as being ‘a reasonable period which avoids any unwarranted curtailment of the period of

77. In the result, where, as in the case of section 44 patents, the term limited for the duration of the patent is set at twenty years from its filing date, the period during which a successful applicant will enjoy the exclusive privilege and property right conferred by a patent once issued will, in the normal course, be fifteen years. (It may, of course, provide either more or less protection depending on the length of the examination process in any particular case.)

78. Thus where the section 45 class of term provision provides for a guaranteed seventeen year term of substantive or “effective” protection for the exclusive rights conferred by a patent and the other, the TRIPS, class of term provision provides a variable term of substantive or “effective” protection for those rights that is normally fifteen years, the two provisions can be said to be substantively or “effectively” equivalent.

79. Canada submits that the two classes are, in both fact and practice, equivalent when measured against any of the referenced standards.

80. In this respect it bears noting, that the substantive equivalence of the protection offered by the two classes of term provision appears to have been accepted by the Parties to the North American Free Trade Agreement (NAFTA) when they agreed to, and adopted, a term of protection provision which provides that:

Each party shall provide a term of protection for patents of at least twenty years from the date of filing or seventeen years from the date of grant. A Party may extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes.<sup>39</sup>

81. Canada submits that where the constant period of substantive or “effective” protection for the exclusive rights conferred by a section 45 patent is equivalent to and in fact is routinely two years longer than the normal or average, variable period of substantive or “effective” protection resulting from the joint operation of Articles 33 and 62 of the TRIPS Agreement, the term of protection defined by section 45 can be fairly said to be, and is, consistent with the minimum standard prescribed by TRIPS.

82. Canada submits as well that since its two methods of determining the term of protection provide equivalent periods of substantive or “effective” protection, in deciding to maintain the two provisions in the course of implementing its TRIPS obligations, it acted within the scope of the freedom afforded Members under paragraph 1 of Article 1 “...to determine the appropriate method of implementing the provisions of [the] Agreement within their own legal system and practice.”

83. Canada further submits that the fact of the substantive or “effective” equivalency and consistency of its law and practice, whether under section 44 or section 45, with the standard articulated by Article 33 is, **by itself**, sufficient to dispose of the US complaint.

C. SECTION 45 DOES NOT NOW, NOR DID IT EVER, REQUIRE THAT THE TERM OF PROTECTION END BEFORE THE EXPIRY OF A PERIOD OF TWENTY YEARS COUNTED FROM THE FILING DATE

84. A further reason to deny the validity of the US propositions is based upon the non-restrictive nature of the term of protection prescribed by section 45 which in its material part provides that “the

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<sup>39</sup> NAFTA, Article 1709, paragraph 12. Reproduced as Exhibit No. 13.

term limited for the duration of every patent issued...on the basis of an application filed before October 1, 1989 is seventeen years from the date on which the patent is issued.”.

85. Section 45 makes no reference to the application filing date. It therefore makes no prescription as to when the term of protection it grants may end in relation to the filing date. More particularly, section 45 does not prescribe that the term of protection shall end before the expiration of the twenty year period counted from the filing date.

86. The mere fact that section 45 does not specify that the term of protection shall not end before the expiry of the period referred to in Article 33 neither means nor implies that the section, or its substantive or “effective” content, is inconsistent with the standard prescribed by TRIPS. The Agreement neither proposes nor imposes specific forms or formula for fulfilling the substantive or “effective” obligations of Members.

87. Paragraph 1 of Article 1 confirms this where, in its last sentence it unambiguously states that: “Members shall be **free** to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and **practice**.” (Emphasis added).

88. There is therefore no obligation to implement or respond to the provisions of the Agreement according to any specific or predetermined formula. Consequently it can only be the substance, “effectiveness” or “adequacy” of a Member’s legal system and **practice** that will be determinative of questions of compliance or non-compliance with its obligations under the Treaty.

89. In the presence of this freedom to implement within a Member’s own legal system and practice, the issue in this dispute can be reduced to whether or not section 45 makes a term of protection which “shall not end before the expiration of a period of twenty years counted from the filing date” universally available to successful applicants for patent protection.

90. The evidence of the practice relating to the administration of Old Act patent applications makes it clear that a twenty year period measured from the application filing date was and continues to be available to any applicant for a patent to which section 45 applies.

91. It is equally clear from the evidence drawn from the records of the Patent Office that as many as forty per cent of Old Act applicants chose not to take advantage of the delays available within the application process to ensure themselves a term of protection that would not end before the expiration of a period of twenty years counted from their application filing dates.

92. The obligation in Article 33 however only requires that the term be available. It does not require that it be imposed contrary to the revealed preference or strategic choice of an applicant.

93. It is material here in discussing the availability of a ‘twenty year from filing’ term of protection to make reference to the fact that, not only could and can an applicant, by its own conduct, control and prolong the prosecution process to extend its term of protection but it could and can as well, by its own conduct, truncate its substantive or “effective” term of protection at any time during the life of that protection, by simply refusing, or choosing not, to pay its annual maintenance fees.

94. It is similarly material to recognize that the provisions of domestic or municipal law that give rise to this unilateral power to terminate a patent term before its statutory or, more significantly in the context of these proceedings, its treaty, course has run, is a power that is recognized and condoned by paragraph 1 of Article 62 of the TRIPS Agreement. Thus, contrary to the apparent mechanistic nature of the rule in Article 33 and of the assumption underlying the US allegation of non-conformity, TRIPS contemplates that the substantive term of protection conferred on a patentee may, at the

instance of the patentee, terminate at any time during the twenty year period counted from the filing date.

95. This is so by virtue of paragraph 1 of Article 62 which stipulates that:

Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part II [which includes the provisions relating to patents] compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this Agreement.

96. Where a Member may adopt measures which impose conditions on the maintenance of the substantive rights conferred by a patent, Article 33 cannot be said to establish an inflexible, mechanical formula for measuring the term of protection which imposes a minimum fixed term on the longevity of the exclusive privileges and property rights conferred by a patent. If it were otherwise then Article 33 would contradict paragraph 1 of Article 62 and unwarrantably curtail the discretion which that paragraph unambiguously extends to Members.

97. There are many reasons associated with the commercial or technological value of a patent why a patentee might refuse, or choose not, to pay its annual maintenance fees and thus **unilaterally** terminate the substantive or “effective” term of protection conferred on the patentee by virtue of either an Old Act or a New Act patent before that term had run its course under either the prescription of the TRIPS Agreement or the domestic law formula of protection.

98. Similarly, there are many reasons associated with the commercial or technological value of a patent why an Old Act applicant might have preferred to have chosen, or seen a strategic advantage for itself in choosing, to obtain the exclusive private property rights conferred by a patent as soon as possible and in so doing, choosing also to forego the opportunity to obtain a term of protection that would not end before the expiry of a twenty year period measured from its application filing date.

99. This is reflected in the fact that any applicant filing before October 1989 who prosecuted its application without regard to the pace of the process would have known that, at a minimum, it would obtain full protection of its exclusive privilege and property right for the seventeen year period running from the granting date. And if they so pursued their application, they did so knowing that if they wished a longer term measured from their application filing date they could have acted to delay the prosecution of their application to achieve that result.

100. However where an applicant has made those choices it cannot later be heard to complain of its choices and seek to reverse them in order to obtain the windfall benefit of having its term of protection retroactively extended. As the United States Court of Appeal, Federal Circuit observed in a case involving circumstances that are similar to those here in issue:

Abbott’s argument that it should not be bound by the earlier filing date because it received no benefit from the divisional application is not persuasive. The district court found that Abbott chose to designate its patent as divisional in order to receive the potential benefits associated with the earlier filing date. Abbott’s choice to do so cannot be disregarded simply because it subsequently found that the later filing date would be more advantageous. Abbott must accept the consequences as well as the potential benefits of the divisional status of [its] application.<sup>40</sup>

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<sup>40</sup> *Abbott Laboratories v. Novopharm Limited and Geneva Pharmaceuticals, Inc.* 104 F.3d 1305 (Fed. Cir. 1997) at 1308. The trial court expressed exactly the same view. See: *Abbott Laboratories v. Novopharm Limited and Geneva Pharmaceuticals, Inc.*, 1996 WL 131498 (N.D. Ill) at \*4. Both reproduced as Exhibit No. 14.

101. So too here.

102. The evidence drawn from the records of the Patent Office further shows that just over sixty per cent of all Old Act applicants saw and continue to see the benefit of taking advantage of the availability of terms of protection that would not end before the expiration of the twenty year period measured from their respective application filing dates.

103. The evidence of this fact becomes particularly revealing when, as appears in the bar chart graphics annexed as Exhibit E to the Davies affidavit, the duration of the term of protection statistics are organized in relation to the portfolios of Old Act patents relating to pharmaceutical inventions that are held by a variety of individual corporate patentees.

104. The chart graphics use the TRIPS twenty year from filing date standard as their “ground zero” or datum level and depict the negative and positive deviations from this standard in respect of each Old Act patent in the several portfolios. The chart graphics clearly demonstrate that the managers of the various patent portfolios managed their respective application strategies in a manner that would, in a commanding majority of cases, provide terms of protection that were and are well in excess of the minimum term prescribed by Article 33.

105. The evidence then shows that while a minority of Old Act applicants did not act to prolong the length of the term of protection they would receive when measured from the filing date, the majority did obtain terms of protection that equalled or considerably exceeded the minimum term prescribed by TRIPS.

106. This comparative evidence of choice and predominance in respect of the length of patent terms emerges more demonstrably from the statistics relating to the pharmaceutical patents held in individual corporate portfolios. In most of these instances, only the smallest minority of the patents in the portfolio carried terms which, when viewed from their respective filing dates, would end before the expiry of the twenty year period referred to in Article 33.

107. The US has not alleged and there is otherwise no evidence that shows that any Old Act applicant that sought a term of protection that was at least equal to a twenty year period measured from its application filing date, was refused a term that met the minimum Article 33 standard. All of the evidence is to the contrary. In the words of the Chairman of the Patent Appeal Board:

An applicant can achieve a delay in processing simply by asking the patent examiner. In my personal experience, I am unaware of any such request being refused.<sup>41</sup>

108. On the strength of this evidence, Canada submits that its Old Act or section 45 system made the minimum twenty year from date of filing term of protection available both in law and in **practice** to every Old Act applicant. And Canada did so without exception.

109. In the result, and given the factual availability in Canadian law and **practice** of the term of protection referred to in Article 33, Canada reiterates its submission that, in deciding to maintain both the section 44 and the section 45 methods for the specification of the term of protection in the course of implementing its TRIPS obligations, it acted within the scope of the freedom afforded Members under paragraph 1 of Article 1 “...to determine the appropriate method of implementing the provisions of [the] Agreement within their own legal system and practice.”

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<sup>41</sup> Davies affidavit, subparagraph 10.i). Mr. Davies tenure with the Canadian Patent Office exceeds 33 years (Davies affidavit, paragraph 1).

110. In summary conclusion, here again Canada submits that the fact that the term of protection referred to in Article 33 was available under the Canadian law and practice relating to section 45 patents is, by itself, sufficient to dispose of the US complaint.

D. ARTICLE 70

111. Canada has demonstrated that the substantive or “effective” term of protection accorded by section 45 is equivalent or superior to and consistent with the substantive or “effective” term contemplated by and available under the Article 33 obligation. Canada has, as well, demonstrated that under the law and practice relating to section 45 the term of protection contemplated by Article 33 was available without exception to every Old Act applicant.

112. Canada further submits that, notwithstanding the substantive or “effective” equivalency with, and the practical availability of, the term of protection contemplated by Article 33 under Canadian law and practice, the Article 33 obligation does not apply retroactively to patents granted by the Commissioner of Patents prior to January 1, 1996.

113. Old Act patents issued prior to January 1, 1996 were granted by the administrative act of the Commissioner of Patents and are not subject to the obligations in the TRIPS Agreement by virtue of the express language of paragraph 1 of Article 70 which, for ease of reference, is reproduced here in its entirety:

This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.

114. Read in the context of paragraph 1 the word “act” is not qualified as referring to any particular type or class of act. The only limitation contained in the paragraph is the temporal one which restricts the application of the paragraph to acts which occur before the date of application of the Agreement for the Member in question.

115. In contrast to its use in paragraph 1 of Article 70, wherever the word “act” is used elsewhere in the TRIPS text, its application and meaning is specifically limited or qualified by the context of its use or modifying references which are associated with its use.

116. “Act” or “acts” is, for example, qualified in: Article 22.2(b) to refer to ‘acts of unfair competition’; Articles 26.1, 28.1(a) and (b), 36, 41.1 and 70.4 to refer to acts of infringement, potential infringement or unauthorized use; Article 37 and its heading to refer to acts not requiring the authorization of the right holder; Article 50.7 to refer to acts or omissions of a right holder in relation to provisional measures; and, in Article 58 to refer to acts of competent authorities in relation to the execution of border measures.

117. It is obvious from this pattern of use that had the TRIPS negotiators intended to limit the meaning of “acts” in paragraph 1 of Article 70 to a specific meaning such as “acts of infringement” they would have done so, just as they did in Articles 26.1, 28.1(a) and (b), 36, 41.1 and 70.4. That they did not use such words of modification argues that it was deliberate and they did not intend a limited or qualified meaning.

118. There is, as the Chairman of the Negotiating Group on TRIPS notes in his forward to Daniel Gervais’s book on the TRIPS Agreement<sup>42</sup>, no authoritative negotiating history or formal record of

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<sup>42</sup> Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, (Sweet & Maxwell: London, 1998). Forward by Lars Arnell page vii at page viii. See too the Preface by Gervais himself at page ix. Reproduced in pertinent part as Exhibit No. 15.

the TRIPS negotiation available to assist those involved in the application and interpretation of the Agreement in determining the meaning or intended meaning of the Agreement. Daniel Gervais's history and analysis, however, provides a useful substitute for a more formal record of the deliberations of the negotiators.

119. In the passages of Dr. Gervais's analysis commenting on Article 70 he explains the rule in paragraph 1 of the Article in the following terms:

The first rule is simple: **acts** (including infringing acts) that occurred before the date of application of the Agreement...to a Member do not give rise to obligations for the Member on the territory of which those acts occurred. ***This is non-retroactivity. ... There are no exceptions to the first rule in Article 70.***<sup>43</sup> (Bold emphasis in the original. Bold, italicized emphasis added.)

120. Thus both the textual evidence and expert commentary lead to the conclusion that the word "acts" as used in paragraph 1 of Article 70 has a broader meaning than the US implies in its sparsely expounded analysis.

121. The US relies solely on paragraph 2 of Article 70 to establish its allegation that Article 33 must be applied to Old Act patents which existed on the date of application of TRIPS for Canada. Paragraph 2 of Article 70 provides, in material part, that:

**Except as otherwise provided for in this Agreement**, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. (Emphasis added)

122. In its self-described "exceedingly simple" analysis of this case the US has failed to take any account of the "Except as otherwise provided for in this Agreement" words which introduce paragraph 2 of Article 70. In ignoring these words, the US also fails to take any account of the rule in paragraph 1 of Article 70 which Dr. Gervais has described as a "simple" rule respecting non-retroactivity and from which he says "there are no exceptions."

123. In the *India – Patent Protection* case, a case relied on by the US in its first written submission, the Appellate Body, citing paragraph 2 of Article 19 of the *WTO Understanding on Rules and Procedures Governing the Settlement of Disputes (1994)* (Understanding),<sup>44</sup> noted in the sentence immediately following the passage cited by the US, that in interpreting a treaty it is **not** appropriate to read into a treaty words or concepts that are not there, so as to lend meaning and context to the Agreement. In the words of the Appellate Body:

The duty of a treaty interpreter is to examine the words of the treaty to determine the intention of the parties. This should be done in accordance with the principles of treaty interpretation set out in Article 31 of the *Vienna Convention*. But these principles of interpretation neither

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<sup>43</sup> Gervais, 268.

<sup>44</sup> Article 19, paragraph 2 provides that:

In accordance with paragraph 2 of Article 3, in their findings and recommendations, the panel and Appellate Body **cannot add to or diminish** the rights and obligations provided in the covered agreements. (Emphasis added)



require nor condone the imputation into the treaty of words that are not there or the importation into a treaty of concepts that were not intended.<sup>45</sup>

124. The obvious corollary of this rule against the **adding of words and concepts** to a treaty is that ‘the principles of interpretation neither require nor condone the **subtraction of words or concepts** from a treaty’ simply because it suits the interpreter’s purposes.

125. The idea that subtraction of words and concepts is no more acceptable than the idea of addition of words and concepts, is an idea that is not simply applicable to the Panel and Appellate Body jurisdiction to make recommendations as was the case where the Appellate Body made reference to paragraph 2 of Article 19 of the Understanding in the *India – Patent Protection* case. It is also an idea that operates, as a general rule of the Understanding, to discipline the Dispute Settlement Body itself. This general rule is set out in paragraph 2 of Article 3 which provides that:

The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. **Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements.** (Emphasis added)

126. In the presence of these rules of construction Canada notes that on its plain language paragraph 1 of Article 70 is a proviso ‘otherwise set out in the Agreement’ which trumps the selected passage of the application provision upon which the US relies and which immediately follows both the rule in paragraph 1 and the words of exception which introduce the provisions of paragraph 2 that the US contends are applicable to this case.

127. Canada also notes that WTO jurisprudence is unequivocal in holding that the onus lies on the complaining party to establish a *prima facie* case of non-compliance. In the *United States – Woven Wool Shirts* case the Appellate Body expressed this principle as follows:

...a party claiming a violation of a provision of the *WTO Agreement* by another Member must assert and prove its claim. ... India did so in this case. And, with India having done so, the onus then shifted to the United States to bring forward evidence and argument to disprove the claim. This, the United States was not able to do...<sup>46</sup>

128. Canada further notes that under Article 28 of the *Vienna Convention on the Law of Treaties* (Convention) there is a codified presumption against the retroactive application of treaty obligations which applies “Unless a different intention appears from the treaty or is otherwise established...”. In its reliance on a selective portion of paragraph 2 of Article 70 the US has not shown any “different intention”, nor has it “otherwise established” a contrary intention to the TRIPS codification of the Convention rule against the retroactive application of treaty provisions to matters that pre-date its coming into effect.

129. It is, therefore, Canada’s position that the US legal analysis supporting its allegation that the obligation in Article 33 applies to section 45 patents does not establish a *prima facie* case of non-compliance.

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<sup>45</sup> *India – Patent Protection For Pharmaceutical And Agricultural Chemical Products (AB-1997-5)*, (WT/DS50/AB/R) (December 19, 1997) at pages 17-18.

<sup>46</sup> *United States – Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, (WT/DS33/AB/R), (adopted: 23 May 1997) at pages 16-17.

130. It does not do so because that analysis relies solely on a **selected part** of paragraph 2 of Article 70 and fails to take any account of either the opening subordinating phrase of that paragraph or of the scope and application of the obviously related general rule against the retroactive application of the Agreement set out in the immediately preceding provisions of paragraph 1 of Article 70.

E. CONCLUSION

131. In summary it is Canada's position that:

- (a) the substantive or "effective" term of protection available under section 45 of the *Patent Act* is equivalent or superior to and consistent with the substantive or "effective" term of protection described by Articles 33 and 62 and does not therefore breach any TRIPS obligation;
- (b) the minimum term of protection described by Article 33 is and has, without exception, been available under the Canadian law and practice relating to section 45 patents; and,
- (c) the US has failed to establish that Article 33 has retroactive application to patents issued against applications filed prior to October 1, 1989 and granted by the Commissioner of Patents prior to January 1, 1996.

V. DISPOSITION REQUESTED

132. Canada requests that the Panel established to examine this matter and to make such findings as will assist the Dispute Settlement Body in making its recommendations or making its rulings in respect of the conformity of section 45 of the *Patent Act* with Canada's treaty obligations, find that:

- (a) the term of patent protection available under section 45 is equivalent or superior to and is consistent and in conformity with the term of patent protection described by Article 33;
- (b) the minimum term of protection described by Article 33 is and has been available, without exception, under the Canadian law and practice relating to section 45 patents;
- (c) by virtue of paragraph 1 of Article 70, Article 33 does not have retroactive application to patents granted by the Commissioner of Patents prior to January 1, 1996; and,

on the basis of those findings, conclude that section 45 of Canada's *Patent Act* conforms with its obligations under the TRIPS Agreement.

## ATTACHMENT 2.2

### ORAL STATEMENT OF CANADA AT THE FIRST MEETING WITH THE PANEL

(20 December 1999)

#### I. INTRODUCTION

1. Mr. Chairman and members of the panel, my name is Ted Thompson and it is my privilege to present Canada's oral argument today. With me are my colleagues, Mr. Rob Sutherland-Brown and Mr. Reagan Walker who may assist me in presenting Canada's case. The other members of the Canadian delegation are: Catherine Dickson and Mark Wigmore.

#### II. BACKGROUND

2. On January 1, 1995, Canada and the United States as founding Members of the WTO, assumed important new treaty obligations. Canada treats these obligations seriously. Included are the obligations flowing from the Agreement on Trade Related Aspects of Intellectual Property Rights. As you know, its application date in respect to Canada was January 1, 1996. TRIPS imposes a number of new disciplines which are intended, among other things described in the recitals, to promote adequate protection of intellectual property rights. It also (in sub paragraph C of the recitals) recognised the need to take into account differences in national legal systems. Indeed, Art. 1.1 makes specific provision for this.

3. TRIPS while concerned with protecting private intellectual property rights recognises that this has to be achieved in a wider universe. And so, we find in the statements of Objectives and Principles set out in Arts. 7 and 8 that the protection and enforcement of these private rights must be achieved "in a manner conducive to social and economic welfare and to a balance of rights and obligations" and as well permitting Members to formulate laws which "promote the public interest in sectors of vital importance to their socio-economic and technological development provided the measures are consistent with the provisions of this Agreement".

4. In Canada's view, these words are not idle platitudes; they are to be given force and meaning. Interpreting an important Agreement such as TRIPS is not a mechanical exercise, rather it requires a careful examination of the rights actually intended to be protected and a balancing of those rights within the context of the agreement's explicit allowances for dissimilar legal systems and the broader interests of society.

5. I know the panel will bear these overarching considerations in mind as it considers Canada's response to the U.S. complaint that Canada's patent term protection measures are not fully compliant with the obligation articulated in Art. 33.

6. In presenting its oral argument, Canada of course relies on its first written submission which it is confident has been carefully read. To the extent Canada makes references to legal authorities or other supplementary materials, in the course of its oral presentation, they will be suitably identified in the written version of this presentation.

7. Canada will present argument on three issues. The first two are independent stand-alone arguments. They present Canada's position that the impugned measure, which we are calling for convenience a "section 45 patent", is compliant with TRIPS.

8. First, Canada states the “period of protection” when properly construed afforded by a s.45 patent is equivalent or superior to the period of protection contemplated by Art. 33.

9. Second, Canada states a period of 20 years from filing in the terms of Art. 33 was “available” to all applicants for s.45 patents without exception. This availability is demonstrable and rooted to a “sound legal basis” to use the standard approved by the Appellate Body in the India - Patent Protection case.

10. Canada’s third and final argument is that the U.S. in alleging Canada’s term of patent protection is non-compliant failed to establish a prima facie case that the obligation set out in Art. 33 has retroactive application to s.45 patents which exist as a result of acts which occurred before the date of application of the Agreement to Canada. Canada will also comment on the introduction of so called “subsequent practice” evidence by the U.S.

11. With your permission, I will now turn to Canada’s first argument, which is elaborated, in our first written submission at paragraphs 67 to 83.

### III. ARGUMENT 1

12. In considering this argument, I would ask you to consider a basic question in respect of Art. 33. That is: What is “the term of protection”?

13. The answer to this question is fundamental to resolving the issue in dispute. The U.S. would have you accept that a period of protection that does not end before 20 years from filing - means a patent is guaranteed 20 years of protection. But this in Canada’s submission is clearly not the case. The Agreement does not provide for 20 years of effective patent protection.

14. The very name of this dispute, Canada - Term of Patent Protection, suggests this conclusion. The inviolate condition precedent to a term of protection under Art. 33 is a patent. This obvious statement has real meaning. Understanding and applying it will have a direct result on the success of Canada’s first argument.

15. Art. 33 is part of Section 5 of TRIPS which is entitled - Patents. Art. 33 in turn is titled Term of Protection. The term of protection is therefore directly related to the existence of a patent.

16. A patent does not exist until it is issued. That being said, it is evident that there is a period of time between the date of filing and the issuance of a patent, which does not benefit from the Art. 33 “term of protection” because very simply, there is no patent to protect during that interregnum.

17. This period of time will vary depending on the particular circumstances. It follows that a “patent term of protection” as contemplated by Art. 33 is not as the U.S. argues a fixed minimum period of 20 years, but a variable period of less than 20 years depending on the date of issue in relation to the date of filing. This fact was observed by Prof. Vaver as noted in paragraph 26 of Canada’s first written submission.

18. The negotiators were also aware of this result as is plain from Art. 62.2 which suggests process time should be completed in a reasonable time - “so as to avoid unwarranted curtailment of

19. It is clear from the plain language of Art. 62.2 that the period of protection is known and accepted to be curtailed by the procedures necessary for grant or registration. The term of protection must *a fortiori* be a variable period of less than 20 years measured from the filing date. In commenting on Art. 62.2, Dr. Gervais writes in his book at page 239, “Curtailed could also refer to

a general diminution of the value of the protection, however, and thus include delaying in an unwarranted (“unjustifiable”) fashion the beginning of the period of protection which may affect the

20. How does this variable period inscribed in Art. 33 compare with the definite period of 17 years guaranteed by s.45?

21. The Chairman of Canada’s Patent Appeal Board has said in paragraph 29 of his affidavit (Exhibit 8) that in Canada the normal or average period to process a “new Act” or s.44 patent application is 60 months or 5 years. This leaves an average period of 15 years for the term of protection contemplated by Art. 33, which will vary, up or down depending on circumstances. (Here refer to Exhibit F to Davies Affidavit)

22. Under the old Act regime, there is a minimum 17 year term of protection, which follows whatever the process time is from the date of filing. The old Act term of protection is clearly equivalent. A guaranteed period of protection of 17 years measured against a variable term ranging up or down from 15 years depending on circumstances is in fact superior to the TRIPS standard.

23. It is important to recall that the ability to control the process period is very much in the hands of the applicant. I will describe this in more detail in a moment in presenting Canada’s 2<sup>nd</sup> argument. However, as noted in paragraph 80 of Canada’s first written submission, the U.S. appears to have recognised the equivalency of the two terms as one of the parties to NAFTA. In Art. 1709.12 of NAFTA, the parties have approved two separate terms as acceptable; namely 20 years from filing or disjunctively 17 years from grant. Either term is acceptable, to the U.S. under NAFTA.

24. In paragraph 81 of its first written submission, Canada summarizes its argument on this issue. It notes that the term of real or effective protection under the 20 years from filing formula is variable depending on the process time. Accordingly, it does not lend itself to a simple arithmetic or mechanical application with an axiomatic result as suggested by the U.S. in paragraph 3 of its first written submission.

25. The U.S. argues that thousands of US. patentees have suffered harm as a result of time deficient 17 year patents (see for example paragraphs 4,5,6 of its first written submission). Canada says that this allegation is without foundation.

26. Again, under the s.44 patent regime, Canada has demonstrated that in Canada the average or normal period of effective protection is 15 years, that is 20 years from filing less processing time, whereas s.45 patents have a fixed 17 year patent term. The U.S. argument holds that a s.45 patent holder who chose to have his patent issue in less than three years from filing is entitled as of right to a commercial windfall, because of a subsequent configuration of patent term protection it wants applied retroactively. Notwithstanding, the period of effective protection is two years longer than the normal period to be expected under the new system, the applicant is entitled to even more protection because the process time, a period that is offered no protection under Art. 33, presents an arithmetical advantage. Canada, as I understand the U.S. position, must now give effect to some notional or artificial advantage that confers no real benefit under the new system and disavows the original bargain with society without conferring any balancing benefits.

27. This, with respect, is inconsistent with the stated objects and principles of the Agreement. It is to require that someone who is receiving substantively more under the old system than normally available under the new, be given yet more. To what end? So that Pfizer to use the U.S. example can extend its term of exclusivity for 14 months and enjoy windfall sales. Someone has to pay and the additional costs will be imposed on the Canadian consumer. Competitive manufacturers who have made plans and investments based on one system of laws will have to be told we retroactively changed the rules. This can only result in marketplace disruptions even if compensation is paid. This

will not promote competition, trade, innovation, socio-economic development or the transfer and dissemination of technology. You will search in vain for such benefits flowing from the U.S. position.

28. Such a result can only flow from a narrow and selective reading of the agreement and does not achieve protection in the language of TRIPS Art. 7, “ in a manner conducive to social and economic welfare and to a balance of rights and obligations”.

29. Giving support to such a mechanical application of Art. 33 will serve the ends of windfall profits and undermine the broader principles of the WTO to “promote the public interest”. No reasonable expectations or legitimate interests of patent holders will be prejudiced by accepting and recognising the equivalency of these two systems. A s.45 patent holder has 17 years of full effective protection. There are no accrued rights associated with these patents that would be adversely affected by refusing to adopt the gratuitous windfall position advanced by the U.S. Giving effect to the U.S. position will disrupt commercial investment and visit increased costs on Canadian consumers.

#### **IV. ARGUMENT 2**

30. Canada’s second argument supplies an independent reason for denying the U.S. complaint. (It is detailed in paragraphs 84 to 110 of Canada first written submission) It is also complementary of its first argument.

31. Like the first argument, it arises from a plain reading of the language of Art. 33.

32. Art. 33 states simply “the term of protection available” shall not end ...etc.

33. Available means something capable of being used, at hand or obtainable. S.45 is of course silent about a filing date although that is what starts the process to obtain a patent. Is or was 20 years from filing available under the old Act system? Peter Davies the Chairman of Canada’s Patent Appeal Board and a man of 33 years experience in the field says it was and that it was available without exception.

34. In his affidavit (Exhibit 8) at paragraph 10(i) he says an applicant can achieve a process delay simply by asking. He is unaware of a delay ever being refused. The time was there for the asking.

35. Neither s.45 nor any other law or requirement of Canada purports to limit or restrict the period of protection available to less than 20 years from filing. As a matter of Canadian law and practice it is available for the asking. It may be argued perhaps that applicants couldn’t make informed choices because it wasn’t an issue before 1986 when Canada tabled Bill C-22. What is true on all the evidence is that if somebody wanted to delay the issuance of their grant, they could. The time was there for the asking in almost unlimited amounts if you consider the more than 1000 s.45 patent applications, which are still pending.

36. The Appellate Body in India - Patent Protection had the opportunity to consider what standard a member must meet under Art. 1.1 of TRIPS. By way of reminder Mr. Chairman, you will recall that s.5 of India’s Patent Act prohibited issuing patents for certain pharmaceutical and agricultural chemical products. India, relying on the Art. 1.1 freedom to determine the appropriate method of implementing the provisions of the Agreement within its own legal system and practice purported to meet the obligations of Art. 70.8 of TRIPS by issuing “administrative instructions” by which applications for patents in respect of the prohibited products could be filed with filing dates assigned to them.

37. At paragraph 59 of its report, the Appellate Body affirmed a Member could rely on Art. 1.1 in meeting its obligations but concluded at paragraphs 70 and 71 of the report that India's administrative instructions did not provide a sound legal basis for preserving the novelty of inventions and priority of applications as of the relevant filing dates and accordingly the measure was inconsistent with Art. 70.8(a) of TRIPS.

38. Earlier in its reasons, the Appellate Body at paragraphs 56 and 57 affirmed the legal test established in the Panel report under appeal namely that "means" employed to meet an obligation under TRIPS must provide a "sound legal basis" to protect or preserve the right or interest in question.

39. The obligation set out in Art. 33 is to make available a term of protection that does not end before 20 years measured from the filing date. As I will explain in a moment, it is Canada's position that it has provided a legal mechanism in its laws through which an applicant can obtain 20 years from filing. And therefore Canada has provided a "sound legal basis" for such a term of protection.

40. S.45 patent term protection is not described in language that is similar to the language employed in Art. 33. S.45, unlike India's Patent Act, does not purport to prohibit or limit a benefit available under TRIPS.

41. The evidence of Mr. Davies (Exhibit 8) is unequivocal that the 20 years from filing date was available and he describes how patent applicants could exercise control over the pendency period between filing and grant in paragraphs 9, 10 and 11 of his affidavit.

42. It is clear that the obligation under Art. 33 is to make the period available. It does not require a member to impose that period against the revealed preference of the applicant. Under the Patent Act and its accompanying rules, the applicant could exercise control. The applicant could do so informally, simply by asking, or alternatively the applicant could take advantage of statutorily mandated delays for perfecting applications and other essential procedural steps.

43. Consistent with the analysis in the India-Patent Protection dispute Canada submits that the time periods established by statute for an applicant to prosecute its application provides the "means" by which Canada makes the term of protection available and the fact they are statutory rights establishes the "sound legal basis". Under Canada's Patent Act, unlike the administrative instructions to India's officials, Canadian officials are not required to ignore statutory provisions, but to give effect to them. Under s.30 (1) of the old Act, which is being distributed to you now, there are two time frames established for completing certain acts under penalty of an application being deemed abandoned, the first is 12 months to complete an application after filing and the second is 6 months to prosecute the application after notice that an examiner has taken action. Under s.30 (2), an applicant is provided a period of 12 months to apply to have an abandoned application reinstated. When each of these process delays are added, together, that is; 12 months to complete the application plus where one fails to do so a further 12 months to have it reinstated plus 6 months to prosecute the application plus, where one fails to so prosecute, a further 12 months for re-instatement, it can be seen that s.30 alone permits delays of 42 months or 3.5 years available to any applicant who chooses to take advantage of the provisions. (Canada Exhibit 16)

44. A second statutory delay is found in s.73 of the old Act. That section provides a period of up to 6 months to pay the prescribed fees in a notice of allowance on penalty of forfeiture. A forfeited application may be restored within 6 months from incurrence on payment of the prescribed fees. This makes a further year of delay available from the filing date. When one adds the delays from filing available under s.30 and s.73 to the 17 year patent term protection from grant, the total amounts to a statutorily available term of 21.5 years from date of filing. Of course none of these delays take account of the time required for a patent examiner to complete an examination or the potential for multiple additional delays to provide requested information to an examiner during that process.

45. There is a difference between the delays provided in s.30 and s.73 of the old Patent Act. Under the latter section reinstatement is automatic on payment of the prescribed fees; however, under s.30 (2) the applicant must satisfy the Commissioner the reason for the delay was not reasonably avoidable. This discretion not to allow reinstatement does not undermine the “sound legal basis” of the statutory scheme for several reasons.

46. First, as we have noted in Canada’s first written submission at paragraph 95, pursuant to Art. 62.1 of TRIPS, Members may require compliance with reasonable procedures to maintain intellectual property rights. That is exactly what the discretion in s.30 (2) provides.

47. Second, as Mr. Davies affidavit (Exhibit 8) affirms at paragraph 10(iii) an abandoned application can be reinstated. A search of Canadian jurisprudence reveals there has never been a challenge based on reinstatement being disallowed under s.30 (2) of the old Act. Mr. Davies has sworn he is unaware of any delay being refused. Finally, the consequence of a refusal if there ever was one is only that the process would have to be recommenced with a new application. This results in further delay, which is presumably what the applicant desired.

48. In light of the continued secrecy protection and the “first to invent” regime for resolving conflicting claims the applicant/inventor’s rights are at no risk. You will recall that under the old Act, trade secrets are protected indefinitely until a patent is issued; and that conflicting claims are resolved in favour of the first to invent.

49. Accordingly, under the old Act regime, a bona fide inventor was at no risk during the period his application for patent was pending or abandoned. Applicants were vested with the right to expedite, delay or let the process proceed at its natural pace. These rights, being those of the applicant, were exercised according to their interest and not the Canadian government. Indeed, Mr. Davies at paragraph 23 of his affidavit has identified approximately 1000 old Act applications that are still pending.

50. The U.S. complaint, while it embraces all patent subject matter is driven by elements of the pharmaceutical industry. The U.S. admits as much in its first written submission at paragraphs 5 and 6 by using Pfizer Inc. as an example. Pfizer sued Canada unsuccessfully, earlier this year, in an attempt to have its “Zoloff” patent extended. Bristol-Myers Squibb has orchestrated media campaigns encouraging other s.45 patent holders to demand the type of extensions that the U.S. alleges are required by TRIPS. To date, none have been forthcoming.

51. If we examine the s.45 patent portfolios of some major drug manufacturers, the availability of terms as long or longer than twenty years from filing is manifest. Mr. Davies has appended graphic depictions of this as Exhibit E to his affidavit. I will not take you through all of them but have chosen three as illustrative, Pfizer Canada Inc., Bristol-Myers Squibb and Merck Frosst Canada (Exhibit E at page 10, 4 and 8 respectively). The graphs show the term of protection for the portfolio of s.45 patents in relation to 20 years from filing which equals 0. (Here use overhead depiction and describe)

52. Although the right to extend s.45 patents beyond 20 years from filing has not always been exercised, it is plainly apparent that it is obtainable or available if desired.

53. The U.S. has also led evidence in addition to Zoloff of ten other non-pharmaceutical s.45 patents, which according to their argument are term deficient. The ten selected patents were issued on December 28, 1998. There were in fact 500 s.45 patents issued on that date; 77% had terms greater than 20 years from filing which in Canada’s submission is further confirmatory evidence of the availability of such a term. (Canada Exhibit 17)



54. It is unambiguously the case that an applicant relying solely on statutorily mandated delays can arrange its affairs so as to obtain 20 years of protection from the filing date under the old Act regime. Those that did not received the right to their exclusive patents early and can exploit them for a full 17 years. As in the Abbott case referred to in paragraph 100 of Canada's first written submission, those who made that choice must accept both the benefits and the consequences. Pfizer, for example, through the U.S. complaint is asking the WTO to give it the full benefit of both regimes even though it had no legitimate right to both terms when it decided to have its patent issue.

55. Before turning to Canada's final argument, it is useful to consider the underlying purpose of Art. 33. Dr. Gervais at page 169 of his book, indicates the goal was to achieve harmonization of the term of protection among member states. Canada has provided the twenty year from filing formulation since 1989. Dr. Gervais also made the following observation:

“During the negotiation, attempts were made to extend protection for certain products the marketing of which is often delayed by regulatory approval processes, notably pharmaceuticals. No such provision is included in the final version”.

56. Statutory mandated delays aside, the complexity of the approval process alone caused such delays that consideration to extending the 20 year term was debated and given some recognition in Art. 62.2.

57. It is apparent that for the pharmaceutical companies who are driving this complaint it may well have required extra effort to expedite their s.45 applications in order to avoid a delayed term of protection which would not start before three years after the date of filing.

#### **V. ARGUMENT 3, ART. 70 - (PARAGRAPHS 111 TO 130 CANADA'S FIRST WRITTEN SUBMISSION)**

58. In order to found a complaint of non compliance, the U.S. must at a minimum establish a prima facie case that Art. 33 has application to s.45 patents. In Canada's submission, the U.S. has failed this threshold standard.

59. Art. 28 of the Vienna Convention is directly relevant here. It raises a presumption against the retroactive application of treaties in relation to any act or fact or situation, which ceased to exist before the date a treaty, comes into force. “Unless a different intention appears from the treaty or is otherwise established”. Because of their obvious potential to negatively impact on accrued rights and interests, Canada submits that retroactive provisions, where there is any doubt as to their scope or meaning, should be construed narrowly.

60. To meet this challenge to demonstrate a treaty obligation has retroactive application, the U.S. has chosen to rely on a selective passage in Art. 70.2 without reference to its context. That is just not good enough.

61. Canada readily concedes that presenting a coherent, consistent and complete interpretative rationale for Art. 70 and each of its paragraphs is a daunting task. In light of Canada's first two arguments, it is a task this panel may not have to undertake. But that does not relieve the U.S. of its evidential burden.

62. As the Appellate Body wrote in Brazil-Desiccated Coconut:

“Absent a contrary intention, a treaty cannot apply to acts or facts which took place, or situations which ceased to exist, before the date of entry into force”. (Brazil-Measures Affecting Desiccated Coconut WT/DS22/AB/R, 21 February 1997 at page 15)

63. The legal analysis in U.S. first written submission does not even attempt to address the clear affirmation of Art. 28 of the Vienna Convention expressed in Art. 70.1. In fact, it does not acknowledge the paragraph in any way.

64. Art. 70.1 is brief and bears repeating in its complete text:

“This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the member in question”.

65. In Canada’s submission, it is for the U.S. to demonstrate that this clear and unambiguous language has no application to s.45 patents issued before January 1, 1996. Canada notes that the act of filing an application is necessary to trigger the time period in Art. 33 and the administrative act of issuing a patent is necessary to trigger the term of patent protection that may occur in the course of that time period.

66. In paragraph 11 of its first submission, the U.S. without explanation, discussion or analysis equates patents with “subject matter”. Let us consider Art 70.2 for a moment; it commences with the following words:

“Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement”.

67. In TRIPS as is clear from the sub-heading of Art. 27 patents are not subject matter. Some subject matter is patentable; that is capable of being patented but the patent itself is not subject matter. A patent is a grant of an exclusive right for a specific period of time by a government, it is not the subject matter of that grant. The expression “subject matter” clearly refers to matter that is protectable by intellectual property rights and not the vehicle through which they are protected.

68. The U.S. theory of Art. 33 applying to s.45 patents is therefore both incomplete and misconstrued.

69. There is one further argument advanced by the U.S. that Canada will address at this time.

### **Argument on Subsequent Practice**

70. In the U.S. first written submission at paragraph 15, it is alleged that the subsequent practice of certain WTO Members has established the general agreement of all Members with the American interpretation of TRIPS, Arts. 33 and 70.

71. Canada submits that subsequent practice is a rule of evidence and not a canon of interpretation. As Lord McNair has described, it:

...subsequent practice of the parties is not so much a principle of interpretation as a rule of evidence. “It is a question of the probative value of the practice of the parties as indicative of

72. It is necessary to examine the U.S. evidence in order to see what it proves. In Canada’s submission, that evidence falls well short of establishing the agreement of all WTO Members with the American interpretation. For such an agreement to be established, evidence of a common

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<sup>1</sup> Lord McNair. *The Law of Treaties*. Oxford (Clarendon Press:1961), p. 427

understanding as to the application of these provisions in the same, or at least, similar, circumstances, would be required. The rule is described in the Encyclopaedia of Public International Law Vol. 2 at page 1421 in these words:

“Subsequent practice must be more or less uniform and accepted by the parties in order to furnish a valid means of treaty interpretation.”

73. In paragraph 17 of its first written submission the U.S. lists five WTO Members who allegedly amended their laws to comply with the mentioned TRIPS provisions in the same way as the US did: Australia, Germany, Greece, New Zealand and Portugal. But the circumstances in these Members was not the same, or even similar, to Canada’s disputed measure.

74. Each of the first three countries mentioned had, prior to TRIPS, a term from filing system. Because that system fell short of 20 years protection, – 15 years from filing for Greece; 16 years from filing for Australia, and 18 years from filing for Germany; each of these was deficient in terms of the 20 years from filing obligation of TRIPS, Art. 33. Apparently uniquely, New Zealand established that; “S.30 (3) The term of every patent shall be 20 years from the date of the patent” (U.S. first submission Exhibit 9 page 59).

75. Canada’s term from filing system was already at the level of 20 years of protection at the time the TRIPS Agreement took effect and had been at that same level ever since the relevant provisions of Bill C-22 came into force, i.e. on 1 October 1989. This fact is not in issue in this dispute.

76. The U.S. offers no evidence of the existence of a subsequent practice establishing an agreed application of the Agreement to term-from-grant patents.

77. The only WTO Member having a term-from-grant system, that is mentioned by the U.S. as agreeing with the American interpretation, is Portugal. However, it is obvious that Portugal did not amend its legislation of its own volition.

78. Whereas the other WTO Members mentioned by the U.S. all passed legislation in 1994 or 1995, in anticipation of their TRIPS obligations. Portugal did not do so until much later. And this was only because the U.S. initiated a WTO Panel proceeding against them. When a country amends its legislation and applies a provision of a treaty in order to resolve a trade dispute, it is **not** necessarily evidence of a common understanding of the meaning of the provision. Indeed, it is only the exceptional case that is settled solely on the basis that one party has decided the other was right in its position. (Canada notes, with some curiosity, that the U.S. initiated its complaint against Portugal in 1996 but has waited until 1999 to commence a similar complaint against Canada).

79. The reality is that the U.S. is alone in its interpretation of how Arts. 33 and 70 apply to term-from-grant systems. It is also the case that the U.S. has no evidence to demonstrate its legal system and practice or any of the Members it identifies are in any way similar to Canada’s. The international law commentators and the WTO Appellate Body alike are agreed that a unilateral interpretation by one of the parties to a treaty does not establish a subsequent practice so as to be binding on other parties. The Appellate Body in Japan-Taxes on Alcoholic Beverages put it in the following terms:

“...the essence of subsequent practice in interpreting a treaty has been recognized as a ‘concordant, common and consistent’ sequence of acts or pronouncements which is sufficient to establish a discernible pattern implying the agreement of the parties regarding its interpretation. **An isolated act is generally not sufficient to establish subsequent practice...** (emphasis added)”

80. Canada submits that the U.S. has submitted no subsequent practice evidence capable of assisting the Panel in interpreting the relevant provisions of the TRIPS Agreement.

## **VI. CONCLUSION**

81. In summary, Canada asserts that the U.S. has failed to meet the evidentiary burden to establish that Art. 33 has application to Canada's s.45 patent regime. Even assuming Art. 33 is applicable, a term of protection as described in that paragraph has always been available under both of Canada's patent regimes. As well, the guaranteed term of protection of 17 years from grant prescribed by s.45 is equivalent to the variable term of effective protection which arises under the Art. 33 formulation.

82. That concludes Canada's first oral submission and we appreciate the close attention you have given our remarks.

### ATTACHMENT 2.3

#### RESPONSES OF CANADA TO WRITTEN QUESTIONS FROM THE PANEL – FIRST MEETING

(7 January 2000)

#### I. REPLIES OF CANADA TO QUESTIONS FROM THE PANEL ADDRESSED TO BOTH PARTIES

**Q.1 \*Article 62.2 provides that Members are to ensure that the procedures for granting intellectual property rights allow granting of the right "within a reasonable period of time so as to avoid unwarranted curtailment" of the protection period.**

**(a) What would constitute an "unwarranted curtailment" of a patent protection term?**

In answering this and associated questions Canada believes that it is critical to bear in mind that Article 62 of TRIPS is specifically concerned with giving the treaty's sanction to the erosion of nominal terms of protection which occur where the term begins on the application filing date but the intellectual property right at issue is subject to reasonable pre-registration or pre-granting procedures that have the effect of curtailing the actual length of the term of protection accorded to the rights holder.

The Article is therefore relevant to the term of protection accorded to patents governed by section 44 of the Canadian *Patent Act* (Act) but not to patents governed by section 45 of the Act. The United States of America (US), the complaining party in this dispute, has neither challenged nor otherwise put in issue, any attribute of section 44 patents or the system by which they are granted.

With these considerations in mind Canada would begin its answer to this specific question by observing that "unwarranted" means "unauthorized, unjustified" and that "curtailment" means "cut short, deprive of".<sup>1</sup> Taken together in the phrase "unwarranted curtailment", the two words would therefore mean: An unauthorized or unjustified cutting short of something, in this case, the period of protection associated with a patent. The phrase expresses an ordinal concept which, like the analogous ordinal concepts of "unreasonableness" and "undueness", must take its meaning from the facts and circumstances that are relevant in the context of its use. In other words "unwarranted curtailment" is a question of fact to be determined in the particular circumstances in which the curtailment occurs.

Thus to know what may constitute "unwarranted curtailment" treaty interpreters must, in the context of the "reasonable procedures and formalities that Members may require as prerequisites" for the application, approval, granting and maintenance of patents, examine the procedures and formalities in issue and decide: whether they are "authorized", in the current context, by statutory or regulatory provisions of a Member or, where they flow from administrative practices and rules, whether they are justified by the nature and purpose of the application-approval and granting processes.

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<sup>1</sup> *The Concise Oxford Dictionary of Current English, Seventh Edition, (Oxford: The Clarendon Press, 1982).*

In this regard treaty interpreters will need to take into account the function of the procedures at issue, the resources available to perform those functions, reasonable administrative response times to fulfill those functions, variations in demand for the applicable administrative services, the conduct and degrees of freedom given to an applicant in the prosecution of its application as well as the level of user satisfaction with the patent granting system.

It is Canada's view that in drafting paragraphs 1 and 2 of Article 62 the TRIPS negotiators understood that the patent application and examination process is a variable exercise that will depend on the simplicity or complexity of the invention claimed, the sophistication of the field of technology in which it occurs as well as on the relationship between the invention claimed and other inventions in that field of technology (prior art). They therefore also understood that the duration of the process would itself be variable and so could not be defined by, or confined to, a single, specific cardinal period of time.

Accordingly, in seeking to impose some reasonable limitation on a Member's freedom to condition the acquisition or maintenance of intellectual property rights on compliance with reasonable procedures and formalities, the TRIPS negotiators deliberately chose the flexible, ordinal standard of "unwarranted curtailment" to discipline curtailment of the period of effective protection that might be caused by delays in the application-approval and granting process which were neither authorized by law nor justified by the nature of the substance of the approval-granting process.

In the result there is no unique, universally applicable definition of what may constitute "unwarranted curtailment" of the period of protection referred to in paragraph 2 of Article 62. Accordingly, in an "authorized" system where the rules are "justified" by the nature of the patent granting process and the need of the granting authority to be satisfied in respect of the novelty, inventiveness and utility of the invention claimed, the "warrantedness" of the amount of curtailment associated with the process will always be a question of fact.

**(b) Would an average pendency period for patents of approximately five years be considered a "reasonable period of time" which avoided "unwarranted curtailment" of a protection term? Why, or why not?**

As noted in the answer to the question in paragraph (a), the "reasonableness" or "warrantedness" of any particular pendency period related to a particular patent application will always be a question of fact to be determined on the basis of the particular system used to process applications, the circumstances relating to the particular application, the particular invention claimed and the conduct of the applicant in the prosecution of that particular application.

In view of the foregoing, some may argue that "average pendency" periods may not be looked at for the purposes of TRIPS treaty analysis and interpretation. While this may in fact be a valid criticism where a dispute is focussed on a particular patent application, it is doubtful that it has any similar force where a dispute has a systemic focus on or, as in these proceedings, may or can be related to the particular system used to process and grant patents in respect of claims to patentability.

That said, as a general or "average" matter, in Canada's view the answer to the first of these two questions is, at least in respect of section 44 patents<sup>2</sup>: yes

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<sup>2</sup> As explained in paragraphs 49 and 54 of Canada's First (Written) Submission New Act (section 44) applications will not proceed to examination until the applicant files a request, and pays the fee, for examination. This introduces a new element in the approval process which, while under the obvious control of the applicant, introduces a statutory delay in the approval process - one that has averaged 15 months for granted patents and 27 odd months for those not yet granted, which was not present in the Old Act procedure - which

In answer to the second, the "Why, or why not", of these two questions is grounded in the fact that, as suggested in paragraphs 54 and 76 of the Canada's First (Written) Submission, and given the expert resources that Canada has made available for the conduct of the patent application approval and granting process, in the normal course - a course that has been processing some 285,678 patent applications<sup>3</sup> over the last ten years - the average pendency period has been sixty months, or five years. Consequently, for being an average pendency period achieved by an adequately staffed, professional patent-granting organization which follows examination and granting procedures that mirror international practice standards and, like other patent granting authorities, is subject to application prosecution decisions which are in the control of applicants, Canada's five year pendency period for New Act patents must be accepted as being a "reasonable" pendency period.

As such, a five year pendency period for (New Act) patents issued pursuant to Canadian or any analogous national law must be accepted as being pendency periods that are "reasonable period[s] of time" which avoid "unwarranted curtailment of the period of protection" bestowed on successful applicants for the exclusive privileges and property rights which are conferred by a patent.

In conclusion Canada would note again, as it did when it responded orally to this question when originally posed by the Panel, that it is aware of no coherent body of evidence which suggests that the beneficiaries of the Canadian patent system are dissatisfied with the timeliness with which patent applications are processed by the Canadian granting authority.

Where the users or beneficiaries of the system are not dissatisfied with the time taken to process and grant a patent in response to an application it is difficult, if not impossible, to argue or conclude that the effective term of protection which results from the process of approval and grant has been or is being "unwarrantedly curtailed".

**Q.2 What bearing, if any, do the general principles set out in paragraph 2 of Article 41 as incorporated in Article 62.4 have on arguments put forward in this dispute concerning delays in the grant of patents?**

The US, the party of adverse interest in these proceedings, has not complained of or otherwise put in issue the "fairness, equity, complexity, costliness, timeliness or delay characteristics" of the procedures for the examination, approval and granting of patents in Canada. Consequently in Canada's view the principles articulated in paragraph 2 of Article 41 which, by virtue of paragraph 4 of Article 62, are to govern the "[p]rocedures concerning the acquisition and maintenance of intellectual property [in this case, patent] rights" have no direct bearing on the "arguments put forward in this dispute concerning delays in the grant of patents".

In making the foregoing observation Canada does not suggest that the principles of fairness and equity articulated in paragraph 2 of Article 41 are irrelevant to Canadian or other Member entity's legal and administrative procedures governing the application for, examination, approval and granting of domestic patents. They clearly must be a part of, and relevant within, any rules-based system which is governed by the fundamental principles of the rule of law.

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typically took 2 to 4 years or an average of 3 years to complete. Thus for Old Act patents Canada would be more comfortable with saying that on average, the reasonable pendency period for an Old Act application would have been 2 to 4, or, when averaged, 3 years.

<sup>3</sup> Affidavit of Peter J. Davies, Chairman of the Patent Appeal Board of the Canadian Patent Office, Paragraph 28. Reproduced in its entirety as Exhibit No. 8 to Canada's First (Written) Submission. Hereafter cited as: Davies affidavit.

In this respect Canada would note that all Canadian federal law is subject to the standards of fairness, equity and non-arbitrariness articulated by the *Canadian Charter of Rights and Freedoms*, the *Canadian Bill of Rights* as well as the complementary quasi-constitutional common law rules governing procedural fairness. The rules governing the application for, the examination, approval and granting of patent rights are subject to these standards and have not been successfully challenged on any of the "unfairness", "equitable" or "procedural fairness" grounds guaranteed by those constitutional laws.

The fact that there is no such evidence supports Canada's conclusion that there is no "unwarranted curtailment" of the period of protection available under section 44 of the Canadian New Act patent law and that the resulting fifteen years of patent protection offered by the New Act's "first to file" system is both reasonable and compliant with the minimum standards required by TRIPS.<sup>4</sup>

Since, under a "first to invent" system, the examination process takes place prior to the commencement of the period of protection accorded to the exclusive privilege and property rights conferred by a patent, the application of these principles to the "curtailment" analysis have little relevance to the amount of effective protection offered to patentees under the Old Act system governing section 45 patents. Subject to the payment of maintenance fees, the latter term, of course, remains constant at seventeen years.<sup>5</sup>

That said the application of those principles to a "first to file" system is, of course, critical to the exercise of judging the compliance, comparability, equivalence and consistency of a "first to file" system's effective period of protection with that provided by a "first to invent" system of patentability.

### **Q.3 Why is the word "available" used in connection with the term of patent protection in Article 33 of the TRIPS Agreement but not in the provisions on the terms of protection of other intellectual property rights?**

In Canada's view the notion or concept of "availability" is, where not explicit as in Articles 26 (Industrial Designs) and 33 (Patents), inherent in all the "term of protection" provisions found within sections 1, 2 and 4 to 6 inclusive of Part II of the TRIPS Agreement.

Canada takes this view because, although each was, in Canada's understanding, negotiated separately, each reflects or reproduces in some measure the concepts or language used in the other term of protection provisions. Thus all of the term of protection provisions use a formula that first requires or implies the availability of a term of protection, and, second, specifies an open-ended limit on the duration or, what is perhaps a less precise measure, the ending of the term referred to.

Specifically and in the sequencing of the Agreement: the **Copyright** term provision (Article 12) provides that, "...such term shall be no less than 50 years from the end of [a variety of commencement dates]..."; the **Trademarks** provision (Article 18) provides that, "...registration...shall be for a term of no less than seven years."; there is no term provision for **Geographical Indications**; the **Industrial Designs** provision (Article 26) provides that, "The duration of protection available shall amount to at least 10 years."; the **Patents** provision (Article 33) specifies that, "The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date."; last, the **Layout-Designs** provisions use two formula (paragraphs 1 and 2 of Article 38), the first specifies the term where registration is a precondition to protection and requires that "...the term...shall not end before the expiration of a period of 10 years counted from the date of filing an

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<sup>4</sup> See: Paragraphs 76 and 77 of Canada's First (Written) Submission.

<sup>5</sup> See: Paragraph 73 of Canada's First (Written) Submission.



application for registration..." and the second specifies that, where registration is not a required prerequisite, the design "...shall be protected for a term of no less than 10 years from the date of the first commercial exploitation...".

All these provisions therefore require, assume or imply "availability" of a term of protection for the right at issue. They also require, in the course of defining the term of protection, that it be a minimum or open-ended term insofar as each provision makes use of some variant of "no less than", "at least", or "not end before".

In these circumstances what is of interest in this dispute is not the use of the word (or concept of) "available", but rather how the concepts of "availability" and "open-endedness" work in conjunction with paragraphs 1 and 2 of Article 62. The latter, as noted in paragraphs 74 to 76 of Canada's First (Written) Submission and the answers to question 1(a) and (b) above, sanction the erosion of the period of protection. They, of course, sanction erosion of the term by acknowledging the right of Members to "condition the acquisition or maintenance of intellectual property rights on compliance with reasonable procedures and formalities so long as those procedures and formalities do not result in an 'unwarranted curtailment' of the period of protection elsewhere prescribed in the Agreement".

As is clear from the face of the provision, paragraph 2 of Article 62 only applies to sanction the erosion of the term of protection otherwise specified by the Agreement where the right in issue is subject to the "right being granted or registered". The interplay between availability, open-endedness and prerequisite procedures therefore only has significance in the cases of trademarks, certain layout-designs and patents.

Where, as in the case of Trademarks and one class of layout-design, the term provision uses the "no less than" open-ended formula, the formula can only be understood as describing an absolute minimum term which will run from the date of the registration of the mark or design. Accordingly, the paragraph 2 provisions of Article 62 cannot operate to permit the erosion of the term of protection to a period that is less than the absolute minimum specified by the applicable term provision.

However, where, as in the case of the Patent and paragraph 38.1 Layout-Design provisions, the open-ended formulas provide that the term of protection "shall not end before the expiration of" a specified period of years counted from a filing date of an application and are not, therefore, referable to the date that the protection is recognized by registration or bestowed by grant, it is clear that the right only arises on registration or grant and, hence, the "effective" term that is defined by the "not ending before a specified date" formula may, without violating TRIPS, be less than the number of years referred to in the formula for describing the period during, **but not for**, which protection of the exclusive privileges and property rights must be **available**.

Thus in these latter two cases, those involving patents and paragraph 38.1 Layout-Designs, the minimum term is not an **absolute** minimum, but rather is a **variable** minimum which runs its variable course within the specified period but will vary within that period according to the time that lapses between the date of filing for recognition of the right and the date on which the right is recognized by the act of grant or registration, as the case may be.

**Q.4 Are you aware of any WTO Member that was obliged to apply the TRIPS Agreement as of 1 January 1996 and that does not apply a patent protection term of 20 years from the date of filing to all patents, including those patents that were in force and patent applications that were pending as of 1 January 1996?**

Canada is concerned that the question as posed, appears to suggest that, notwithstanding the Article 1.1 licence to determine the appropriate method of implementing their TRIPS obligations, Members have an obligation to "apply a patent protection term of 20 years from the date of filing".

Canada does not share this view, believing that the scope of the Article 33 obligation is limited to ensuring that "The term of protection **available** shall not end before the expiration of a period of twenty years counted from the filing date.". (Emphasis added) The concept of availability is critical to the proper interpretation of Article 33 because paragraph 2 of Article 62 clearly contemplates that rights granting and registration procedures will **curtail** any period of protection where, while the period is measured from an application filing date, the right does not arise until some subsequent time when the right claimed is either registered or granted such that the "effective" term of protection is **less** than the period referred to in the formula used to define how the term of protection is to be measured.

Against that background, Canada is aware of two WTO Member jurisdictions where the Member has not adopted, or has not exclusively adopted, a term of protection provision that explicitly uses the TRIPS reference to a "term of 20 years from the date of filing".

First, and on the evidence led by the US<sup>6</sup>, it would appear to Canada that New Zealand law, as amended in December 1994, provides that: "The term of every patent shall be twenty years from the date of the patent." Thus although this formula may exceed the minimum required by TRIPS, it does not apply a "term of 20 years from the date of filing". Accordingly, unless subject to special definitions that are not available in the US exhibit, the quoted language would appear to include every patent issued pursuant to New Zealand law whether before or after January 1, 1996. It would thus also appear to embrace patents issued after January 1, 1996 on the basis of an application filed before that date.

Second, as noted in paragraphs 17 and 20 of Canada's First (Written) Submission, Canadian patent law contains two term of protection provisions one of which - section 44 - uses the TRIPS style formula to provide that;

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.

and the second of which - section 45 - provides that;

45. Subject to section 46, the term limited for the duration of every patent issued under this Act on the basis of an application filed before October 1, 1989 is seventeen years from the date on which the patent is issued.

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<sup>6</sup> See: US Exhibit 9.

For the independent reasons advanced in paragraphs 57 through 83 and, subsequently, in paragraphs 84 through 110 of Canada's First (Written) Submission, Canada takes the view and submits that the term of protection prescribed by section 45 on the basis of "first to invent" patent applications filed before October 1, 1989 makes a twenty year from filing term **available** and is equivalent, comparable, consistent, harmonious and compliant with the term of protection required to be accorded to "first to file" applications by the TRIPS Agreement and as is prescribed by the undisputedly TRIPS compliant provisions of section 44 of the Canadian legislation.

Further, for the reasons referred to in the preceding paragraph Canada does not concede, as assumed by the question, that it was obliged to apply the TRIPS Agreement to provide a term of protection measured from the patent application filing date where, such of its patents that were not so measured, are **available** for a twenty year from filing term and are substantively equivalent, comparable and in harmony with the variable terms of protection that are available under the formula of protection defined by Article 33 of the Agreement.

As noted in the introduction to this answer, it is Canada's position that the obligation set out in Article 33 is an obligation to ensure that "The term of protection **available** shall not end before the expiration of a period of twenty years counted from the filing date." (Emphasis added) By virtue of the freedom conferred on Members by paragraph 1 of Article 1 "to determine the appropriate method of implementing the provisions of [the] Agreement", Members are not required to implement this or any other obligation by the adoption of any particular form of words or formula of measurement so long as, as a matter of substance, the specified term is, as it is under section 45, **available** on a "sound legal basis" under the law and practice of the implementing Member.<sup>7</sup>

**Q.5 Do you believe that a system in which the patent term is calculated from the date of filing creates the same incentive to file a patent application promptly as a system in which the patent term is calculated from the date of grant?**

Canada has discussed or adverted to the incentives inherent in both of the "first to invent" and "first to file" systems for awarding patents in paragraphs 36, 38 to 40 and 46 to 48 of its First (Written) Submission. In those paragraphs it made the point that the difference in incentive between a "first to invent" and a "first to file" system related to the speed with which the application, once filed, would be prosecuted by the applicant. The calculation of the term of protection thus is more likely to influence the speed of the prosecution of a patent application than it may influence the alacrity with which the application is itself filed.

In a "first to invent" system where the patent term of protection runs from the date of issuance of the patent and the inventor's "secret" is protected by non-disclosure and trade secrecy laws prior to grant, there is little if any systemic incentive to prosecute the application expeditiously. There may, of course, be very substantial commercial or other self-serving strategic reasons that might negate and reverse the absence of any such incentive in the application and granting system and so motivate the applicant to prosecute its application with speed.

In contrast, in a "first to file" system where the term of protection runs from the date of the filing of the application, where the amount of protection is eroded by the granting process and where the contents of the application may be required to be made publicly known well before the patent issues and so expose the invention to potentially infringing uses by third parties, the incentive to prosecute an application expeditiously would appear to be considerably stronger. However, here too there may be very compelling commercial - read financing, manufacturing, distributional and marketing - as well as regulatory - read marketing approval, reasons which may negate and reverse

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<sup>7</sup> See: Paragraphs 37 to 39 of Canada's First Oral Presentation and the Appellate Body jurisprudence cited and referred to in those paragraphs.

the incentive to prosecute an application vigorously and so make the applicant indifferent to the speed with which its application is processed.

While as a general matter it may be fair to say that the systemic incentives in the two systems operate in different directions insofar as the speed of the processing of the application may be concerned, it is less clear that the system used for the measurement of the term of protection has a similarly divergent influence on the promptness of the act of filing itself.

This may be the case because, while a "first to file" system may seem to encourage early filing so as to make the "first filer" the winner in a patent entitlement dispute with another inventor (or the patent office), if the other inventor (or the patent office) establishes that another invention constitutes "prior art" the patent is unlikely to issue to or, if issued, have any continued longevity for the benefit of, the "first to file" applicant.

In this sense the risk that may appear to be negated by a "first to file" system may be illusory. This may be so because in both the "first to file" and the "first to invent" systems the incentive to file, as opposed to prosecute, promptly is ordinarily related to the risk that someone else may "invent" the same or substantially or obviously the same subject matter and so defeat the claim to exclusivity whether through a claim to be the "first to invent" or through an assertion of lack of novelty or inventiveness notwithstanding a "first to file" date.

Undoubtedly a "first to file" system that allegedly ignores "first to invent" considerations creates some incentive to file quickly, however a prior "unfiled" invention, if it exists, will, for undermining the novelty and inventiveness criteria of the claimed invention, ordinarily operate to defeat the patentability of the "first filed" claimed invention. In view of the foregoing it would appear to be uncertain whether or not one can fairly conclude that a "first to file" system creates a greater incentive to file a patent application promptly as compared to a "first to invent" system.

**Q.6 Article 28 of the Vienna Convention on the Law of Treaties 1969 reads as follows:**

**"Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party."**

**(a) Does Article 28 belong to those provisions of the Vienna Convention which are part of customary international law?**

Canada believes that a strong case can be made for the proposition that Article 28 of the *Vienna Convention on the Law of Treaties* (the Convention) has entered into the realm of "customary international law". It bases its view on the criteria required to promote a treaty norm into a customary rule of law that are set out in *North Sea Continental Shelf (Federal Republic of Germany v. Denmark)*, [1969] I.C.J. p. 4, the leading case on this issue. After sounding a cautionary note to the effect that such a conversion "...is not lightly to be regarded as having been attained"<sup>8</sup>, the International Court of Justice went on to say that the following three criteria would be required to demonstrate that such a result had been achieved and that the treaty norm at issue had indeed matured into a customary rule of international law.

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<sup>8</sup> *North Sea Continental Shelf* at paragraph 71. Reproduced as Exhibit No. 20

The first of these criteria requires that "...the provision concerned should, at all events potentially, be of a fundamentally norm-creating character such as could be regarded as forming the basis of a general rule of law".<sup>9</sup> The second requires that the norm at issue enjoy extensive and virtually uniform application in State practice so as to show a general recognition that a rule of law or legal obligation is involved.<sup>10</sup> Thirdly the Court suggested that, as a matter of *opinio juris*, "Not only must the acts concerned amount to settled practice, they must also be such, or be carried out in such a way, as to be evidence of a belief that this practice is rendered obligatory by the existence of a rule of law requiring it."<sup>11</sup>

In Canada's view the facts that: analogous rules expressing the presumption against the retroactive application of new law to subsisting vested rights and obligations exist in the municipal law of many, if not most, modern states; the rule has, as a rule of general application, been recreated within Article 70 of the TRIPS Agreement; and, that the Convention rule has, at least twice, been referred to and applied by the Appellate Body<sup>12</sup>, all argue that the three criteria of: creating a fundamental norm; being widely endorsed by State practice; and, State practice being confirmed by statutory and international tribunal recognition, are met by the treatment accorded Article 28 of the Convention.

This conclusion is strongly supported by the additional fact that the Appellate Body has, in the Bananas case, described Article 28 as stating "a general principle of international law".<sup>13</sup>

**(b) Which paragraph(s) of Article 70 refer(s) to "any act or fact which took place...before the date of the entry into force of the treaty...?"**

Although obviously drawn directly from Article 28, Canada believes that the reference to the "date of the entry into force of the treaty" is not entirely apt in the circumstances of this case. This is so because in the TRIPS context "the date of the entry into force" being January 1, 1995<sup>14</sup> has a particular or special meaning and is distinct from "the date of application of the [or this] Agreement for the Member in question" being, *inter alia*, January 1, 1996 for most developed country Members. Within TRIPS, the latter date serves the function of a coming into force date for a particular or particular class of Member as opposed to the date which is elsewhere normally referred to as "the date of the entry into force".

The dichotomy does have significance within TRIPS because, as paragraphs 8 and 9 of Article 70 make clear, some provisions trigger obligations from the "entry into force date" while most - but not all - others use the date of application as the applicable triggering date. However, Canada has sought to avoid confusion by reading the reference as being a reference to the "date of application of the Agreement for the Member in question" and would, in this light, answer the question as follows.

Paragraph 1 explicitly refers to "acts which occurred before the date of application of the Agreement for the Member in question". As such it would, but for its reference to "the date of application" rather than the "date of entry into force", appear to restate the substance of what Article 28 of the Convention has to say about "acts which took place before the coming into force" date of a treaty.

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<sup>9</sup> *North Sea Continental Shelf* at paragraph 72.

<sup>10</sup> *North Sea Continental Shelf* at paragraph 74.

<sup>11</sup> *North Sea Continental Shelf* at paragraph 77.

<sup>12</sup> *Brazil – Measures Affecting Desiccated Coconut*, WT/DS22/AB/R (21 February 1997) at page 15. *European Communities – Regime for Bananas*, WT/DS27/AB/R paragraph 235 and following.

<sup>13</sup> *European Communities – Regime for Bananas*, paragraph 235.

<sup>14</sup> See: Paragraph 1 of Article 65 and the footnote, footnote \*\*, to that paragraph.

Paragraph 2, in referring to "subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date", would appear to be addressed to "facts" which existed before the date of application but continued as of that date. It may not, therefore, fall within the ambit of this branch of the question.

Paragraph 3 by its reference to an intellectual property right that had entered into the public domain before "the date of application of this Agreement for the Member in question", would clearly appear to refer to "facts" which occurred before the referenced date and were not continuing as of that date. However, the paragraph could also be more accurately characterized as addressing a "situation which ceased to exist before the date of the entry into force of the treaty".

Paragraph 4, like paragraph 1, also makes explicit reference to "acts". However, it limits the universe of relevant "acts" to those that occurred "before the date of acceptance of the WTO Agreement by that Member". Given that paragraph 1 of Article XIV of the *Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations* (Final Act) gave contracting-party Members two years from the date of the Final Act (April 15, 1994) to "accept" the Agreement, the date of acceptance may fall on either side of the date of application. In the result this provision may or may not address "acts" which occurred before the date of application of the TRIPS Agreement. (However, since the acts referred to in the paragraph are embodied in subject matter that exists on the application date, this paragraph also has a hybrid character and could also be said to apply to a "situation which had not ceased to exist" on the coming into force of the Agreement.)

Paragraph 5 refers to purchases of originals or copies of certain copyrighted materials which occurred before "the date of application of this Agreement for the Member in question". It would, therefore, appear to fall within the branch of the question which is concerned with references to "acts". However to the extent which the "works" purchased may remain in the channels of commerce, this provision too would appear to have a hybrid character and, therefore, could also refer to a "situation that continues to exist".

Paragraph 6 refers, by implication, to administrative "acts" of Member governments which granted compulsory licences to third parties without the authorization of the rights holder. However, here again as with paragraph 4, the paragraph only addresses a limited subset of such "acts" insofar as the granting "act" had to have taken place before the date on which the TRIPS Agreement became known before the Member may rely on the "grand-fathering" exception created by the paragraph to save an otherwise offending "compulsory licence". (The date the "Agreement became known" is generally accepted to be a reference to the date of the "publication" of the Dunkel text of the Agreement, that date being December 20, 1991.)

Paragraph 7 refers to applications for intellectual property right protection that were pending on "the date of application of this Agreement for the Member in question". It would, therefore, appear to address "facts" - application filings - which occurred before but had not been acted upon by the date of application. In this sense, the paragraph may more accurately be described as addressing a continuing situation rather than an "act" or a "fact".

Finally, paragraphs 8 and 9 refer to "facts" - patent protection for pharmaceutical and agricultural chemical products - or perhaps "situations" that did not exist "as of the entry into force date of the WTO Agreement" in the law of the Member in question and impose certain interim obligations on such Members in respect of the products referred to. That said, because these two paragraphs in essence are concerned with the creation of new obligations, albeit of a transitional nature, they do not appear to fit well within Article 70 which is predominantly concerned with the transition rules that will govern the application of obligations specified elsewhere in the Agreement.

They therefore may not be intended to make any reference to "the acts, facts or situations that have ceased to exist" which are at the heart of Article 28 of the Convention.

- (c) **Which paragraph(s) of Article 70 refer(s) to "any situation which ceased to exist before the date of the entry into force of the treaty" or did not so cease to exist? Is the ongoing protection of an intellectual property right at the date of entry into force of a treaty, e.g. a patent that has been granted and which remains in force at that date, within the scope of "situation that ceased to exist"?**

The answer to the first branch of this question has already been partially canvassed by the answers to the questions in 6(b). As noted in those answers, paragraph 3, although it may be characterized as addressing "facts", is probably more clearly concerned with elaborating a clarifying transitional rule that denies the treaty's application to situations - the presence of subsisting intellectual property rights - which had ceased to exist as of the application date of the Agreement for the Member on whose territory the situation had once existed.

Similarly, but in response to the second branch of this question, a number of the provisions of Article 70 have, as noted in the answers to the questions in 6(b), a hybrid character. Thus while they may be characterized as addressing some "act" as is the case in paragraphs 4, 5 and 6, that "act" can be or is related to a "fact" or "situation" which, in intellectual property law, could have continuing significance. This relationship exists, for instance, in paragraph 4 where the "act" in question is embodied in protected subject matter which may continue to be protected after the application date and may therefore give rise to infringement liability. The same may, with appropriate technical modifications, be true in respect of the "acts" implicitly referred to in paragraphs 5 and 6.

In summary of the answers to the first two branches of this question, Canada is of the view that, with the exception of paragraph 3 of Article 70 - which itself is at least slightly ambiguous - the drafting of the paragraphs of Article 70 as well as the of the included references to the fact situations which the drafting seems to have contemplated, is sufficiently opaque or illusive to defeat clear and unambiguous characterization of any of those paragraphs as clearly belonging solely to one particular class of category of exempt subject matter referred to in Article 28 of the Convention.

In consideration of the third branch of this question Canada is of the view that patents which were, before the application date of the Agreement, issued in respect of particular subject matter that continued to exist as protected subject matter on the application date for the Member in question cannot be easily dismissed as being "within the scope of a 'situation that ceased to exist'."

Canada holds this view because, in its understanding of the TRIPS Agreement, the Agreement draws distinctions between: the vehicle which conveys an intellectual property right; the act, where an act is so required, which triggers the recognition of the right; and, the subject matter which attracts both the right and the protection that is to be made available to the right holder.

Thus, as in this dispute, Canada understands that the Agreement imposes three essential elements in respect of intellectual property rights. First it requires that a vehicle of protection - in this dispute, a patent - be available pursuant to Article 27 to protect qualified "subject matter" - in this dispute, an invention which is novel, inventive and useful. Second, it requires that protection of the rights at issue be available for the period specified by the formula prescribed by the Agreement for the definition or measurement of that period - in this dispute, the period referred to in Article 33. And, third, it requires that the subject matter shall be accorded a bundle of exclusive benefits - in this dispute, the rights set out in Article 28.

In the result Canada also understands that, by virtue of paragraph 2 of Article 70, subject matter which is "novel, inventive and useful", which was invented and protected before the application date and which continued to be protected as of that date, would be entitled to protection by

the patent vehicle pursuant to Article 27.1 and to the conveyance of the exclusive benefits, even if enhanced by TRIPS, bestowed by virtue of Article 28.

Dissimilarly Canada does not understand, and it would take issue with the proposition, that the patent, as the vehicle of the pre-existing and continuing protection, is itself "existing subject-matter" within the meaning of paragraph 2 of Article 70. Unlike the subject matter of protection which is the creation of an "inventor" and subsists indefinitely, the patent, as the vehicle of protection, flows from two "acts" - the act of application and the act of grant - both of which pre-date and were fully executed before the application date of the Agreement and respectively ask for or consummate a time-limited bargain between the inventor and the State (and the third parties it represents) as of the discrete moment in time when each "act" is executed.

There is nothing in the "subject matter" language of paragraph 2 of Article 70 which suggests that the time-limited bargain consummated by the "act" of grant is a bargain that has been or was intended to be disturbed by the obligations agreed to within TRIPS. Similarly, there is nothing in the "subject matter" language of paragraph 2 of Article 70 which suggests that the saving language of paragraph 1 of Article 70 does not apply to preserve the bargain here at issue. However, there is, in contrast, language in paragraph 2 of Article 70 which strongly suggests that its "subject matter" provisions will not apply where the Agreement makes an alternative provision as it does, for pertinent example, in paragraph 1 of Article 70.

That paragraph 2 language introduces the whole of the paragraph and reads: "Except as otherwise provided for in this Agreement..." In Canada's view paragraph 1 of Article 70 provides otherwise.

**(d) Assuming that the reply to question (a) is in the affirmative, does Article 70 represent a "contracting out" of this customary rule of international law or rather does it restate this rule?**

As set out in the answer to question 6(a) Canada believes that a strong case can be made for the proposition that Article 28 of the Convention has matured into a "customary rule of international law".

That noted, Canada also believes that at least the first three paragraphs of Article 70 of the TRIPS Agreement recreate or restate the rule in Article 28 of the Convention and do not "contract out" of its substance. Canada has formed this belief because, in its view, in drafting Article 70 of the Agreement the TRIPS negotiators in effect unbundled the "acts, facts and situations which ceased to exist" trilogy set out in the Vienna Convention.

They did so, apparently, in order to distinguish between and provide separately for the application or transitional rules which would be applicable to each category of circumstance included in the Convention trilogy. In so doing, however, they made some modifications to the "acts, facts and situations" language of the Convention to reflect the nomenclature and substance of intellectual property law and practice. The TRIPS recasting of the Convention trilogy is set out in paragraphs 1, 2 and 3 of Article 70.

First, paragraph 1 recreates the Convention rule against the retroactive application of new rules to existing **acts** when, for TRIPS application purposes, it provides that:

This Agreement **does not give rise** to obligations in respect of **acts** which occurred before the date of application of the Agreement for the Member in question. (Emphasis added)



Second, paragraph 2 expresses a "contrary intention" to the Convention rule respecting the retroactive application of new rules to existing **facts** or factual circumstances, which the TRIPS negotiators refer to as "existing subject matter which is protected or protectable on the application date" of the Agreement. For TRIPS purposes however the contrary intention is, itself, subject to exception since, for those purposes, it provides that:

**Except as otherwise provided** for in this Agreement, this Agreement **gives rise** to obligations in respect of **all subject matter existing** at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. (Emphasis added)

Third, paragraph 3 recreates the Convention rule against the retroactive application of new rules to **situations which ceased to exist** before the entry into force date of the treaty. The TRIPS negotiators describe these situations as being those where intellectual property "subject matter" has fallen into the public domain (and, therefore, has ceased to be protected). Specifically and for the purposes of the TRIPS Agreement, paragraph 3 provides that:

There shall be **no obligation to restore** protection to subject matter which on the date of application of this Agreement for the Member in question has **fallen into the public domain**. (Emphasis added)

**Q.7 Please provide an analysis of the meaning that should be attached to the various provisions of Article 70, in particular, explaining the meaning of paragraphs 2, 4 and 6 of Article 70. What is the relationship among the paragraphs of Article 70?**

In responding to this question Canada notes that it is the US that has chosen to rely on a selective passage of Article 70.2 to establish its claim. In Canada's view the burden of establishing the applicability of Article 33 to Canada's impugned measure is for the US. In raising Article 70 as the essential link to the applicability of Article 33 the burden to present a rational explanation of that article remains with the US. Canada's view of the appropriate analysis of the meaning that should be attached to the various provisions of Article 70 will address some of the positions advanced to date by the US in its representations to the Panel.

In its first oral statement the US asserts at paragraph 16 that Canada's reading of Article 70.1 renders much of the rest of Article 70 "meaningless or wholly redundant". Canada disagrees, but even if that were the case, that does not justify reading Article 70.1 in such a way as to render it meaningless for the reasons set out in paragraphs 122 to 126 of Canada's First (Written) Submission of December 2nd, 1999, which speak to the applicable rules of treaty interpretation.

It is Canada's position that to the extent Article 70 imposes obligations on Members or grants benefits to existing subject matter it should be read narrowly where there is any uncertainty as to its scope or applicability. In any event Article 70 can not be read to override the clear language of Article 70.1 in the absence of compelling reasons presented by the US.

Article 70 arises under TRIPS Part VII, Institutional Arrangements: Final Provisions. Article 70.2 is concerned with the protection of existing subject matter. In respect to patents, which is the only class of intellectual property at issue in this dispute, patentable subject matter is defined under Article 27. That article is the first of eight within TRIPS that make up Section 5: Patents.

Subject to the exceptions described in paragraphs 2 and 3 of Article 27, patents are available for any inventions, whether products or processes, which meet the qualifying criteria of "novelty, inventiveness and utility". Article 28 provides that a patent shall confer on its owner certain exclusive rights. Article 31 authorises certain uses without authorization of the right holder and in so doing

refers expressly to "other use of the subject matter of a patent". Accordingly, the subject matter referred to in Article 70.2 as it relates to patentable subject matter is as defined in Article 27 and does not, as contended by the US, include a patent itself.

In Canada's view Article 70.2 is a provision which "Except as otherwise provided for in this Agreement" gives rise to obligations to all existing subject matter (inventions in this case) at the date of application of this Agreement and which is protected as of that date or which meet, or comes subsequently to meet, the criteria for protection under the terms of this Agreement.

Patentable subject matter is defined under Article 27, that is products or processes which are new, involve an inventive step and are capable of industrial application. Therefore, any invention which meets or is capable of meeting the criteria set out in Article 27 and which existed on the application date of the Agreement is entitled to the benefit of the obligations under the Agreement except, of course, as otherwise provided. The exception is not limited to exceptions which are described in Article 70.2 as argued by the US in paragraph.11 of its first oral submission. The exception expressly refers to the whole Agreement and not just paragraph 70.2. Nor does the quote cited by the US in the noted paragraph support its thesis because the example given in the quote of an exception contained in Art 70.2 is unambiguously illustrative in nature and in no way suggests exceptions are limited in the manner contended for by the US.

It is apparent that the language employed in Articles 70.1 and 2 is similar. Namely, "this Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement..."and "This Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement...". In Canada's submission the apparent conflict between these two paragraphs is for the US, as the party relying on the provisions, to resolve. That is the US must ensure both paragraphs have meaning and its failure to do so should result in its complaint being dismissed.

One interpretation that is open that results in Canada's section 45 patents not being subject to the Agreement is to recognise that the act of filing an application for a section 45 patent and the administrative act of issuing such a patent are essential to initiating a term of protection under Article 33. In the event that either of these acts occurred before the date of application of the Agreement no obligations in respect of the term of protection accorded to the patent arise under the Agreement.

In this respect Canada notes that by implication the US appears to accept that an administrative act is included within the scope of Article 70.1. At paragraph 13 of its first oral statement the US, submits that acts of customs officials permitting entry of counterfeit or pirated goods prior to the date of application of the Agreement are within the scope of acts not subject to obligations under the Agreement.

In Canada's view there are no legal distinctions between the administrative character of these official acts of customs and patent officials. Canada further notes that in Article 70.6 an administrative act is given express recognition as excluding the application of Article 31 for Members "where authorization for such use was granted by the government before the date this Agreement became known". This formulation in Article 70.6 is consistent with the administrative act of issuing a patent being found within the scope of Article 70.1.

This interpretation of Article 70.1, that is excluding section 45 patents from the obligation under Article 33, does not, in the words of the US, imply that other paragraphs of Article 70 are meaningless or wholly redundant. Patentable subject matter under Article 70.2 would include the obligations set out under Article 28 to confer certain exclusive rights on a patent owner, and the right to be paid remuneration under Article 31 (h) where a Member sanctioned a use unauthorised by the right holder for patentable subject matter. These examples are not intended to be exhaustive but

illustrate that there is a rational resolution of the apparent conflict between paragraphs 1 and 2 of Article 70 and which results in section 45 patents not being subject to Article 33.

The question further asks for direct comment on the meaning of paragraphs 4 and 6 of Article 70 and which the US also claimed in its oral statement were rendered redundant by its inaccurate characterization of Canada's statement in relation to Article 70.1.

The transitional rule in Article 70.4 is clearly intended to apply in circumstances in which TRIPS requires a Member to protect subject matter that the Member did not previously protect, and has no application to the circumstances here. Article 70.2 gives rise to certain obligations in respect to the subject matter at issue but not in respect of patents. Where for example there was a field of technology not previously protected under the laws of a developed Member, and the TRIPS Agreement now requires it be protected, implementing legislation would be required to provide for the issuance of patents for existing inventions (subject matter) in that field of technology.

It may be that persons were using inventions in that field of technology prior to the application date of the Agreement. The transitional rule in Article 70.4 applies to acts which were not infringing at that time but which subsequently became infringing once, as in Canada's example, patents in the field of technology are issued in accordance with the implementing legislation.

Article 70.6 represents another exception available to Members in respect to existing subject matter. It is in effect a grand-fathering clause which protects pre-existing compulsory licences granted by the government before the date this Agreement became known.

Canada agrees with the assertion of the US in paragraph 14 of its oral statement that the Agreement is not retroactive, at least it is not in respect of concluded, pre-application date acts. This is consistent with international law as expressed in Article 28 of the Vienna Convention and Article 70.1. which provides that the Agreement has no application to "acts" which occurred prior to the application date of the Agreement.

At paragraph 17 of its oral statement the US makes the rather extravagant claim that if section 45 patents are excluded from the Agreement then all forms of intellectual property that existed prior to the application date would receive "absolutely no protection under TRIPS" and then advances "*in terrorem*" arguments that Members could revoke, for no reason at all, patents issued before January 1996 and still remain in compliance with TRIPS.

Such statements without more do little to enlighten the understanding of the obligations set out in Article 70. The scope of the word "acts" in Article 70.1 as suggested by Canada does not, for example, exclude the results of creative acts from the obligations which arise under Article 70.2 as implied by the US. The act of creation within the contemplation of TRIPS results in subject matter. The product is not itself an "act". Inventing something may be an act but the resulting invention is subject matter and not an act. TRIPS obligations apply to subject matter and not acts. Article 70.1 on the other hand applies to acts but not to subject matter.

In Canada's view the relationships that exist between the various paragraphs of Article 70 broadly exceed the issues that need to be decided in this complaint. As noted in response to question 6 (d) it appears that paragraphs 1, 2 and 3 of Article 70 could be said to reflect the "acts" "facts" and "situations which ceased to exist" set out in Article 28 of the Vienna Convention.

Article 70 is concerned with the protection of existing subject matter. Paragraphs 1, 2 and 3 describe generally what obligations the Agreement does and does not give rise to. Paragraphs 4, 5, 6 and 7 describe certain special situations of application.

Finally paragraphs 8 and 9 of Article 70 are concerned with what has come to be referred to as "mail box" provisions requiring a Member to make special provision for certain pharmaceutical and agricultural chemical products where patent protection was not available prior to the entry into force of the WTO Agreement. These latter two transitional provisions do not appear to contain any particular relationship to the other paragraphs of Article 70 beyond providing "protection for existing subject matter" which, of course, is consistent with the general purpose of the Article.

## II. REPLIES TO QUESTIONS FROM THE PANEL TO CANADA

### **Q.15 \*Concerning the interpretation of "appropriate method" in Article 1.1, do you believe that, had a new Act not been implemented in Canada in 1989, the old Act would have been an appropriate method to comply with the TRIPS Agreement?**

This is, clearly, a "counterfactual" speculative question. Canada's 1994 decisions relating to its implementation of its TRIPS obligations were necessarily conditioned on the state and scope of its then existing laws and practices and their degree of compliance or consistency with its then impending TRIPS Treaty obligations.

However, based on the discussion and elaboration of the legislative context and history of the 1989 amendments to Canada's patent laws which is set out in paragraphs 22 to 30 of Canada's First (Written) Submission, one might, as a matter of reasoned speculation, conclude from the reasons that led Canada to introduce those far reaching amendments in 1986 that, had it not made those amendments, it would, in the interests of modernizing its patent legislation and administrative practice and in switching to a "first to file" from a "first to invent" system, probably have, in the further interest of achieving the harmony in patenting systems desired by the TRIPS negotiators, decided to make similar amendments to its patent laws, within its TRIPS implementing legislation.

Notwithstanding this informed speculation, it is germane to note that since the protection provided to patents and patentees under the Old Act - being the legislation that would have been in force in 1994 had the 1986 amendments not been made - is, and was in 1994, substantively equivalent to the protection prescribed by the TRIPS Agreement.<sup>15</sup> It is similarly germane to note that under section 45 of the Old Act the term of protection **available** to patentees was, when measured from the TRIPS filing date perspective, then as it is now, more certain than and equal or superior to the variable minimum term prescribed by TRIPS.

All of which is to say that, since the equivalency and availability arguments would have been available to Canada in 1994 when it was drafting and enacting its TRIPS implementing legislation, it could then, given the Article 1.1 freedom to chose an appropriate method of implementation, have chosen not to amend its term of patent protection statutory provisions and still have fulfilled its TRIPS patent term obligations.

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<sup>15</sup> As noted in paragraph 80 of Canada's First (Written) Submission, NAFTA would appear to recognize and, by recognition, endorse the equivalence here under discussion.

**Q.16 \*You stated that the average pendency period, described as the period between the filing date and the date of grant, is approximately 60 months or five years for those applications that were filed after 1 October 1989 and for which patents were granted. For those patents that were filed prior to 1 October 1989:**

- (a) please confirm that the average pendency period was two to four years (paragraph 72 of your First Submission); and**

As requested Canada confirms that the average pendency period in respect of patent applications filed prior to October 1, 1989 has, historically, been two to four years as stated in paragraph 72 of its First (Written) Submission. This fact is set out in paragraph 8 of the Davies affidavit - Exhibit 8 to Canada's First (Written) Submission - and can be further confirmed by reference to Exhibit B to that affidavit.

In confirming this fact Canada would go on to note that the difference between the average pendency period under the Old Act - two to four years - and the average pendency period under the New Act - five years - is, on an average basis, explained by the provisions in the New Act which hold an application in abeyance until the applicant fulfils its obligation to file a request, and pay the fee, for examination.

As discussed in paragraphs 53 and 54 of Canada's First (Written) Submission, although applicants are given five years from their filing date in which to meet these requirements, they have, on an average basis, filed their request and paid the fee for examination fifteen months after filing their applications, in the case of patents which have issued; or, twenty seven odd months, in the case of patents that have not yet issued. The fifteen or twenty seven month periods are, roughly speaking, equal to the difference between the New Act and the Old Act pendency periods.

- (b) what were the shortest and longest pendency periods for those Section 45 patents that have been granted?**

By reference to the same data base used to calculate the number of patents that might have been affected by the term of protection obligations defined by Article 33, the Chairman of the Canadian Patent Appeal Board reports that: the shortest pendency period for a section 45 patent which has been granted is: 2.76 months.

By reference to the same data, the longest pendency period for a section 45 patent which has been granted is reported as having been: 493.08 months (or 41 odd years).<sup>16</sup>

**Q.17 \*Is the term "term of protection" as used in Article 33 synonymous with a period of "exclusive privilege and property rights" as used in your First Submission? Please explain why or why not.**

No. As used in reference to Article 33, (and as they would also be used in an analysis of paragraph 1 of Article 38) the two terms are not synonymous.

As explained in paragraphs 74 to 78 of Canada's First (Written) Submission and more extensively canvassed in the answer to Question 3 set out above, the two terms differ for the following reason. The term of protection referred to in Article 33 defines the period during which protection **shall be available** but during which the "exclusive privilege and property rights" conferred

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<sup>16</sup> See: E-mail message from Peter Davies, the Chairman of the Patent Appeal Board to Rob Sutherland-Brown dated January 4, 2000 and reproduced as Exhibit No. 21.

by a patent **may not yet exist** because, by virtue of the operation of the granting procedures sanctioned by paragraphs 1 and 2 of Article 62, the patent conferring the exclusive privilege and property rights associated with a patent once granted, **has not been granted**, notwithstanding that the period of nominal protection, as measured from the filing date of the patent application, has already begun to run.

**Q.18 \*In your first oral statement, you seemed to imply that in a first-to-file patent system, where four or five years elapsed before a patent was granted, the period of protection of that patent would be 16 or 15 years. However, does the period of protection run from the date of filing, rather than the date of grant, so that the period of effective protection is 20 years?**

In Canada's first oral statement it did indeed say - throughout paragraphs 13 to 26 - that the effective term of protection under the combined operation of Article 33 and paragraph 2 of Article 62 would invariably be less than the period referred to in Article 33 as being the minimum period during which the term of protection must run. However, as explained in the answer to Questions 17 and 3 as well as in paragraphs 74 to 78 of Canada's First (Written) Submission, the period of "effective" protection **can only begin to run once the patent** (or other intellectual property right which is subject to prerequisite granting or registration procedures) **is in fact granted** or registered, as the case may be.

If a patent has not issued, it attracts no exclusive privilege or property right. Accordingly where the defined period of protection begins to run before the right is granted, the defined period cannot confer and does not define "a period of effective protection" for the period defined. Because of the separation in time between the date of application and date of grant, the period of "effective" protection will, as a practical matter, always be less than a period that is defined to commence before the granting, or other formal recognition, of the right.

**Q.19 \*(follow up to previous question). If, during the, say, five years that a patent is pending in Canada, the applicant can sell the claimed product in Canada, why would it be willing to act so as to delay the grant, given that it could be at risk if it were to operate in the market prior to grant? Would it not wish to receive the grant of patent as soon as possible?**

While it is indeed possible for a patent applicant to sell its invention in the market prior to the date of grant, it is unlikely that a typical applicant would do so because, as the question notes, it would risk losing its opportunity to eventually obtain or thereafter maintain the exclusive right to exploit the invention. (The fact that the absence of any exclusive right would probably have a negative effect on the price that such an applicant could obtain for its invention or the product of its invention, may also operate to discourage such pre-grant selling.)

As to the second branch of the question, Canada would note that the question will almost invariably be a question of fact. There are any number of factors which may influence an applicant's behaviour or decisions in both seeking patent protection itself and in prosecuting its application for protection once it has made the decision to do so. The applicant's decisions in this respect are very subjective and it is not therefore possible on a prospective basis to elaborate a theory or to identify any particular factor which will explain the conduct of any given applicant in making a decision to accelerate or retard the filing or prosecution of a patent application.

Some of the factors that commonly influence these decisions include: whether or not the applicant can or is ready to manufacture; where it cannot or is not, whether the applicant can licence its invention to a third party; whether the applicant has or has located the financial resources to exploit the invention; whether the applicant has or has not arranged for the marketing and/or distribution of

its invention; and, where the invention or the product of the invention is regulated, whether or not it has, or can expect to obtain, marketing approval from the competent authorities.

**Q.20 \*You state in paragraph 72 of your First Submission that it took two to four years to complete the "examination process" for Section 45 patents and in paragraph 76 that it took five years to complete the "examination process" under the new Act. Please confirm that the term "examination process" as used in paragraphs 72 and 76 covers the period between the filing date and the date of grant. (Note that you use the term "examination" elsewhere to describe the period during which the patent office examines the patent application).**

Canada confirms that in both paragraphs 72 and 76 of its First (Written) Submission it has used the phrase "examination process" as a term of art to describe the period - often referred as the pendency period - between the application filing date and the date of grant.

Canada acknowledges that it has, in several places in its submissions, used the word "examination" to describe either: the activity of the patent authority in "examining" the patentability of the claims in an application, or the period during which that activity takes place.

The different terms or references are intended to contrast the "shorter" actual or *per se* "examination" activity with the "longer" "examination process" which includes all pre-grant activities or delays, being: the period before a request for "examination" is made (New Act only); the time spent in the pending queue awaiting "examination"; the "examination" period itself; and, the delay period between the notice of approval and the actual grant.

Canada trusts that the appropriate or intended meaning of either term will be clear in the context of use and, where that is not the case, Canada would be pleased to clarify its use or intended meaning in such instances.

**Q.21 It is argued that whereas the protection term in respect of patents granted under Section 45 may be longer or shorter than 20 years from filing, that this provision is consistent with Article 33 because the average term is in excess of 20 years from filing. How do you reconcile this fact with the Panel's finding in *United States—Section 337 of the Tariff Act of 1930* that "an element of more favourable treatment would only be relevant if it would always accompany and offset and element of different treatment" and its rejection of "any notion of balancing more favourable treatment...against less favourable treatment"?**

This question would appear to reflect the assertions of the US<sup>17</sup> that Canada's arguments are based upon "an impermissible averaging methodology". This misapprehends Canada's arguments which do not rely on any such "averaging methodology". Moreover they do not assert that when allegedly term-deficient section 45 patents are added together with those having surplus term and are then appropriately divided, the resulting average term is greater than the term referred to in Article 33 and is, therefore, consistent with the TRIPS standard.

Nor do Canada's arguments assert that, for TRIPS interpretative purposes, the "more favourable treatment" accorded to surplus term section 45 patents otherwise compensates for the alleged deficiency in the term granted to so called "term-deficient" section 45 patents.

Canada's arguments as set out, respectively, in paragraphs 67 to 83 and paragraphs 84 to 110 advance two independent, albeit mutually reinforcing, propositions which: first assert the equivalency of the terms of protection available under the two filing and term measurement systems; and, second, assert the availability of the TRIPS twenty year from filing term under section 45 and other provisions

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<sup>17</sup>.See: Paragraph 14 of its First (Written) Submission and paragraph 5 of its (First) Oral Statement.

of the Old Act, notwithstanding that under the Old Act the term or period of protection granted ran, by virtue of the statute, from the date of grant.

The first proposition, in summary characterization, argues that while Old Act (section 45) patents confer a guaranteed, constant seventeen years of protection for the "exclusive privilege and property rights" conferred by a patent measured from the date of the grant of the patent, New Act (unambiguously TRIPS compliant section 44) patents confer a variable period of protection for the "exclusive privilege and property rights" conferred by a patent which variable period has, in 89 per cent<sup>18</sup> of those instances where a section 44 patent has been issued, conferred seventeen or fewer years of protection for those "exclusive privileges and property rights". (For the purposes of this type of analysis, Canada considers that, where the term of "effective" protection under one patent granting system is variable, it is inappropriate to restrict or limit its equivalency comparison to a system using a fixed term of "effective" protection by referring only to the exceptional, upper-limit results achievable under the variable term regime.)

As noted generally elsewhere above and specifically in paragraph 77 of Canada's First (Written) Submission this curtailment from the term referred to in Article 33 occurs because the "examination process" has, under the aegis of Article 62, eroded the period of protection defined by the term measurement criteria set out in Article 33. In the result to two systems produce equivalent, comparable, harmonious and consistent terms of protection for the "exclusive privileges and property rights" that are here at issue.

Second, and again in summary characterization, Canada has argued that, while the section 45 patent term provision guarantees seventeen years of protection from the date of grant for the "exclusive privileges and property rights" conferred by a patent, when viewed from the perspective of the patent application filing date, it also makes a twenty year from filing date term available, without exception, to any patent applicant wishing to view and obtain protection on that basis. The second argument concludes with the proposition that, since the twenty year term from filing was available to any applicant who sought it, where an applicant did not seek to obtain the twenty year term it would itself be responsible for the deficiency and could not later complain of the deficiency.

Given the substance of these two arguments and the difference between them and what was at issue in the *Section 337* case which has been cited by the US and quoted in the question, Canada does not agree that the referenced jurisprudence has any pertinence or application to this dispute or the agreed facts from which it arises.

**Q.22 \*You argue that the term of protection under the old Act and the new Act are equivalent. You also argue that the United States has failed to establish a prima facie case that Article 33 has retroactive application. In order to clarify these arguments, could you indicate whether, in your view, if the old Act provided a much shorter term of protection, say 10 years from grant, such a provision would comply with the TRIPS Agreement, because the TRIPS Agreement lacked retroactive application?**

In its oral response to this question Canada suggested that in order for a ten year from grant term to be equivalent to the term defined by Articles 33 and 62 of TRIPS, the granting procedures applicable to New Act patents would need to involve 10 years of delay. This, in Canada's initial view, appeared to lack balance and justification given the nature and purpose of the granting procedures.

Canada continues to hold this view. It would however elaborate on its verbal response by noting that if the term set out in section 45 were 10, not 17, years and all other provisions of both the

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<sup>18</sup> See: Exhibit F to Davies Affidavit.



Old and New Acts remained constant as they now are, then both the "equivalency" and the "availability" arguments and analyses would fail.

The "equivalency" argument and analysis would fail because the constant period of protection for the "exclusive privilege and property rights" offered by the hypothetical section 45 ten year guaranteed term - being ten not seventeen years - would fall far short of and clearly not exceed the normal fifteen years of "effective" protection afforded to those exclusive privileges and rights by the term of protection formula prescribed by the conjoint reading of Articles 33 and 62.

Similarly, the "availability" argument and analysis would fail because the statutory provisions which are catalogued in paragraph 43 of Canada's First Oral Presentation and which provide a "sound legal basis" for an applicant's ability to prosecute its application without any rights-defeating penalty for at least 42 months after filing its application would, when added to the guaranteed base hypothetical term of ten years from grant, only result in a total of thirteen and one half years of protection being available to an applicant. This clearly contrasts unfavourably with the twenty and one half years of protection that are available to applicants when the same calculation is made in respect of a system using a seventeen year from grant base term.)

As the Panel knows it is Canada's position that, while the US has not made out its interpretative case respecting the application of paragraph 2 of Article 70 to the application of Article 33 to Canada's section 45 patents, the US's spare analysis of, and attempt to apply, that paragraph in this dispute is irrelevant in the face of the undisputed facts that underlie the dispute. It is irrelevant or redundant for two reasons. It lacks relevance because, first, on a substantive basis, the "effective" protection available under section 45 is equivalent to the "effective" protection available under the TRIPS system of term measurement. Second, it lacks relevance, because, pursuant to an undeniably sound statutory - that is, legal - basis, a twenty year from date of application term of protection was available to any Old Act applicant that sought to measure and obtain its term of protection on that basis.

In sum, therefore, because section 45 is, for reasons of equivalency and availability, TRIPS compliant, no change in Canadian law is required. Of course, where no change in law is required (or made), there is no need to provide for or, as in this case, apply a transitional rule, such as the rule in paragraph 2 of Article 70, to regulate the transition from one set of laws to another. Where there is no need, there is irrelevance and, as in this case, redundancy.

Against this background of irrelevancy and redundancy of the application of Article 70 in these proceedings, Canada would address the Panel's hypothetical question by noting that, where both the "equivalency" and the "availability" arguments and analyses have no application, the relevancy of Article 70 would acquire life.

Were it to so spring to life and become a determinative factor, and Canada does not concede that it does or has (except in the face of the hypothetical character of the question put), then Canada would again observe, as it has at paragraphs 126 to 129 of its First (Written) Submission and paragraphs 58 to 68 of its First Oral Presentation, that, as suggested in the answers to questions 6 and 7 elaborated above: paragraph 2 of Article 70 has no application to patents *per se*, since patents are not within the meaning of the "subject matter" referred to within that paragraph; and, paragraph 2 of Article 70 being, by its own terms subject to other provisions of the Agreement, cannot and does not operate to usurp the saving provisions respecting pre-application date "acts", such as the act of filing a patent application and the subsequent act of granting the patent, that are explicitly protected by paragraph 1 of Article 70.

**Q.23 You indicated in paragraph 7 of your first oral statement that your first two arguments were independent and stand-alone. Which is your principal argument and which is the alternative? Is the third argument independent of, or complementary to, the first two?**

In Canada's First Oral Presentation it presented three principal arguments as well as a fourth, attacking the sufficiency of the US evidence respecting "subsequent practice". Although within the context of these proceedings the principal arguments are related, each is independent and not subordinate to another.

Nor is any one of the principal arguments alternative to the others in the sense that if one fails, then the second or third comes into play as a subsequent "fall back" argument of lesser force than any of its predecessors in a sequenced hierarchy. This is so because each establishes an independent rationale for the Panel to dismiss the US complaint.

The first two arguments, which are admittedly complementary and mutually reinforcing, rather than merely "related", advance reasons, as matters of fact and the substantive municipal law of Canada as well as of the substantive treaty law of the TRIPS Agreement, explaining why the substance of section 45 of the Canadian *Patent Act* is consistent with TRIPS obligations and standards. The substance of section 45 does so for two reasons.

The first reason is that, as a matter of substance, section 45 provides for equivalent "effective" protection for the "exclusive privileges and property rights" it confers as compared to the "effective" protection accorded to those privileges and rights by a patent that is issued under an undeniably TRIPS compliant system. The second is that, again as a matter of substance, the Old Act law includes provisions for ensuring that the term of protection available pursuant to section 45 is not required to end before the expiration of a period of twenty years counted from the filing date of the patent application.

The third argument advanced in Canada's First Oral Presentation presented independent argument as to why the US had failed to make out a prima facie case that the transitional rule set out in paragraph 2 of Article 70 applied to "acts" of application and grant that pre-dated the application of TRIPS for Canada.

The third argument contends that paragraph 2 of Article 70 is limited in its application to "subject matter" of intellectual property protection and thus has no application to patents and the other "vehicles" of such protection. It also contends that, since by its own terms, the paragraph is subject to the other provisions of the TRIPS Agreement, it did not, nor did the US establish that it did, have any application to "acts" that pre-dated the application of the Agreement and were, for that non-retroactive reason, saved by the substance of paragraph 1 of Article 70.

In addition to the three principal arguments, Canada's fourth argument challenges the "subsequent practice" evidence led by the US and demonstrates that that evidence was deficient because the practice referred to did not arise out of circumstances that were the same as, or even closely similar to, the circumstances that prevail in Canada in respect of the substance of the protection afforded under section 45.

**Q.24 \*You argue that an applicant can obtain a patent protection term of 20 years from the date of filing under Section 45 by controlling the prosecution process which is "within the private decision making capacity and strategic control" of the applicant.**

- (a) How could patent applicants whose applications had been examined prior to the entry into force of Bill C-22 on 17 November 1987 obtain a patent protection term of 20 years from the date of filing?**

The substance of the Old Act patent rules and system had, prior to 1987 (or, perhaps more accurately, prior to 1989 when the 1986 proposed amendments were brought into force), been in place since the Old Act had last been consolidated in 1952. Therefore at any time after 1952 any applicant who had been interested in obtaining a term of protection which, when measured from the applicant's filing date, equalled or exceeded twenty years from that date could have obtained the desired term in the same manner as described in paragraph 10 of the Davies affidavit, paragraphs 36 to 38 of Canada's First (Written) Submission and paragraphs 33 to 49 of Canada's First Oral Presentation.

It may be implicit in this question that before the New Act amendments or the TRIPS obligations were law or became known, this possibility would have been irrelevant. No one would have organized their patent interests in a way that would have delayed the earliest possible grant of the patent sought. All the evidence contradicts this hypothesis.

The evidence, both that which relates to the whole universe of patent applicants and that which relates to pharmaceutical patent applicants, shows that sixty per cent of all applicants filing applications before October 1, 1989 and an overwhelming majority of pharmaceutical applicants filing applications before October 1, 1989, managed their applications or otherwise behaved so as to obtain patent terms that, when measured from the application filing date, exceeded the twenty year period counted from the applicable application filing date.

- (b) What remedies, if any, would an applicant be able to invoke in case of an unauthorized use by a third party prior to the grant of a patent?**

Typically speaking "first to invent" patent granting systems do not provide pre-grant remedies to those who, pre-grant, are merely "applicants" for rights that, until granted, have not come into existence. In this situation there is no exclusive right in existence which would support the concept of "unauthorized use".

Such systems do, however, typically preserve the confidentiality of the contents of the application. Accordingly, any Old Act "first to file" applicant would enjoy any remedy it would otherwise at law enjoy to protect its own commercial or inventive confidences. In the normal case such recourse would be available under the common law of trade secrecy.

- (c) If a patent applicant might suffer prejudice prior to the grant of its patent, why would it not be in its best interest to obtain a speedy examination?**

The risk of prejudice to a patent applicant's anticipation or expectation of obtaining a monopoly right for its invention before the grant of an anticipated patent, is always present. It is, as suggested in the answers to questions 5 and 19 without doubt one of the factors that may influence a patent applicant to accelerate either the filing or the prosecution of an application. However, as particularly noted in the answer to question 19 there are many factors at play that may reverse what appears to be an obvious motivation to obtain patent protection as soon as possible. There are however a large number of compelling reasons why a patent applicant might chose to retard its filing or its prosecution of a patent application.

Unfortunately, it has not proven easy to elaborate a coherent or straightforward theory to reliably explain, on an anticipatory basis, why or why not patent applicants may chose to behave in one manner or another or to identify one or more factors as being predominant motivators in what are, in final analysis, private, individual decisions by each applicant.

**Q.25 Is it not the responsibility and obligation of the government to provide a patent term ending at least 20 years from the date of filing, especially in light of the fact that Article 33 provides that the term of patent protection available "shall" not end before the expiration of a period of twenty years counted from the filing date?**

No. It is, as set out as a matter of fact in paragraph 8 of Canada's First (Written) Submission the responsibility and obligation of each Member to implement its treaty obligations. Thus, in the context of this dispute and the obligation described by Article 33, it is the responsibility and obligation of each Member to ensure that "The term of protection available [in respect of patents] shall not end before the expiration of a period of twenty years counted from the filing date [of the patent application].".

Given the freedom granted by paragraph 1 of Article 1 of TRIPS, this obligation does not extend to requiring that a Member implement its obligations in the manner suggested by the question. This is particularly the case where, as in the case of Article 33, its facial obligation is refined and modified by the provisions of paragraph 2 of Article 62 which explicitly authorize the reasonable or "warranted" curtailment of the term defined by Article 33.

In this respect and in light of the last branch of this question, Canada notes that the word "shall" in Article 33 refers to the expiry date of the patent and not to the obligation of Members to make available a term of protection that "shall not end before the expiration" of the period referred to.

Thus the obligation set out in Article 33 is not a responsibility or obligation for Members to adopt laws that force patent applicants to pursue their applications or pay their maintenance fees in a manner which is contrary to their own perceived best commercial or other interests. As the US conceded in an oral response to a question put by Canada, where a patentee determines that it is not in its continued interest, commercial or otherwise, to "maintain" its patent, it may, without jeopardising its host Member's compliance with its TRIPS obligations, cease to pay those fees and so trigger the deemed expiry of its patent before it TRIPS term has run. Similarly, it can, within statutory limits, control when its period of effective protection will commence in relation to the date it chooses to file its application.

**Q.26 You refer to potential statutory delays in paragraphs 43 and 44 of your first oral statement. Are these the type of delays which are to be minimized under Article 62.2? If so, how is it reasonable to require an applicant to rely on tactics entailing exploitation of such delays to obtain a term of protection consistent with Article 33 when they are discouraged by Article 62.2 and 62.4?**

In Canada's view the answer to the first branch of this question is: no. The delays permitted under Canadian patent legislation are delays that are designed to ensure that, from the users point of view, the administration of the patent-granting system is fair, equitable, non-arbitrary and does not impose the "unreasonable time-limits" referred to in paragraph 2 of Article 41.

The statutory provisions at issue are in essence rules which allow an applicant for a benefit granted by the State to pursue its application and arrange its affairs in relation to that application in accordance with its own best interests, perceived or real.

From this "own best interest" perspective, it is important in Canada's view to bear in mind that under Canadian law any patent applicant whose perceived "own best interest" was or would be to accelerate the processing of its application has, within its own control and power, the capacity to request the acceleration of its patent application.<sup>19</sup>

Against the background of the foregoing Canada would suggest that there is nothing improper or untoward in allowing an applicant for a benefit to be granted by the State to take advantage of the rules governing the granting of that benefit. Governmental benefit programmes and systems are not unlike the private sector credit system. Thus, if the creditor or governmental programme allows one sixty days to settle an account or take some defined step, there is no shame, penalty or allegation of abuse that can fairly be attached where the account is not paid, or the defined step is not taken, until the sixtieth day.

**Q.27 \*Given that, in your first oral statement at paragraph 67, you state that "subject matter" in Article 70.2 does not refer to patents, but rather to "matter that is protectable by intellectual property rights", please explain what Article 70.2 means.**

Within the context of the TRIPS Agreement "subject matter" would appear to have a "term of art" meaning as appears from its use in Articles 14.3, 15 heading, 27 heading, 28(1)(a), 28(1)(b), 31, 34, and 44. (An exceptional use occurs in paragraphs 3 and 4 of Article 40, where the phrase is used to refer to what is being discussed therein, as opposed to the work, mark, indication, industrial design, invention or layout-design that is subject to intellectual property protection.)

For a full discussion of the meaning to be attached to "subject matter" and the operation and meaning of paragraph 2 of Article 70, please see the answers to questions 6 and 7.

**Q.28 What does Article 70.2 refer to in the phrase "subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date". Does it include an invention under patent on the date of application of the Agreement?**

In Canada's view patentable subject matter are qualifying inventions and not the patents issued to such inventions. For a full discussion of this issue and related matters please refer to the answers to questions 6 and 7.

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<sup>19</sup> See: Paragraph 11 of the Davies affidavit and paragraph 37 of Canada's First (Written) Submission.

## ATTACHMENT 2.4

### REBUTTAL SUBMISSION OF CANADA

(14 January 2000)

#### I. INTRODUCTION

1. Having considered the representations advanced by the United States of America (US) in its First Submission filed on November 18, 1999, in its Oral Statement to the Panel at its First Meeting on December 20, 1999 as well as in its Responses to Questions Posed to the Parties by the Panel and by Canada filed on January 14, 2000, Canada is confirmed in its view that the US has failed to establish a *prima facie* case that the term of protection provisions of section 45 of Canada's *Patent Act* (Act) do not comply with the obligations which the US contends are imposed under Article 33 by virtue of the transitional provisions of paragraph 2 of Article 70 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (variously referred to as: TRIPS, the Agreement or the TRIPS Agreement).

2. Furthermore, even if the US had established a *prima facie* case that the Article 33 obligation applied to certain section 45 patents by virtue of the transitional provisions of paragraph 2 of Article 70, which Canada denies and does not concede, it has either misconstrued or simply ignored and, therefore, failed to rebut or otherwise discredit Canada's arguments respecting "equivalency" and "availability" which render the application of paragraph 2 of Article 70 irrelevant or redundant in these proceedings.

3. Briefly put those arguments<sup>1</sup> have, without reasoned contradiction, established that:

- (a) the guaranteed seventeen years of substantive patent protection extended to the "exclusive privilege and property rights" conferred by a section 45 patent are substantively equivalent and comparable to and, therefore, consistent and harmonious with the substantive patent protection of that privilege and those rights which is conferred by the variable term of protection available under the term of protection measurement formula defined by the conjoint provisions of Article 33 and paragraph 2 of Article 62 of the TRIPS Agreement; and,
- (b) the term of protection **available** under section 45 was (and is<sup>2</sup>), by virtue of the statutory procedures and legal practices applicable to the prosecution of Old Act patent applications, **available**, without exception and on a sound legal basis, for a term that, as specified by Article 33, would not end before the expiration of a period of twenty years counted from the application filing date, notwithstanding that the formal statutory term under the Old Act is defined to run for seventeen years measured from the date the patent was issued.

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<sup>1</sup> The arguments are, respectively, elaborated in paragraphs 67 to 83 and 84 to 110 of Canada's First (Written) Submission and in paragraphs 12 to 29 and 30 to 59 of Canada's First Oral Presentation. They are also further amplified, where relevant, in many of Canada's Responses to Questions Posed to the Parties by the Panel.

<sup>2</sup> There are approximately 1,000 Old Act applications still outstanding. See: Davies Affidavit at paragraph 23.

4. The balance of these rebuttal submissions will address certain arguments advanced by the US in its various submissions to the Panel and demonstrate why the US has failed to establish a *prima facie* case in support of its complaint.

## II. THE FAILURE OF THE US COMPLAINT

5. The US complaint is based on two propositions:

- (a) its first premise is that by virtue of Article 33 of TRIPS, all WTO Members are required to provide or grant a term of protection for patents that runs at least until twenty years after the application filing date;
- (b) its second premise is that by virtue of paragraph 2 of Article 70, all patents existing at the date of application of TRIPS for the Member in question and which were protected as of that date, are entitled to a term of protection equal to the term described in Article 33.

As set forth in the paragraphs that follow and as is clear from the evolution of the US submissions and the points that have been conceded within those submissions, neither premise is accurate. Accordingly, neither sustains the US complaint.

### The Failure of the First Premise – The TRIPS Term is Variable

6. In its initial articulation of this complaint the US alleged that "By its plain terms [Article 33] obligates all WTO Members to **grant** a term of protection for patents that **runs at least until twenty years after the filing date** of the underlying application.". It went on to allege that "The phrasing of the provision...also indicates that the **twenty year term is a minimum term....**".<sup>3</sup> (**Bold face** added for emphasis)

7. It reiterated this position in the second articulation of its complaint where it stated that: "They [being Articles 33 and 70.2] require Canada to provide a twenty year patent term to all patent holders." In support of this proposition the US inaccurately quoted Article 33 as providing that: "The term of protection shall not end before the expiration of a period of twenty years counted from the filing date."<sup>4</sup>

8. To critical effect, this rendition of Article 33 omits the word **available** from the specification or definition of the obligation which, in its authentic version, reads: "The term of protection **available** shall not end before the expiration of a period of twenty years counted from the filing date."<sup>5</sup> (**Bold face** added for emphasis)

9. The US again advanced the "twenty year minimum term" hypothesis in its third articulation of its position where, in its answer to the third Question posed to both Parties by the Panel, it characterized the basic requirement of Article 33 to be "to provide a certain defined minimum term of protection to rights holders."<sup>6</sup>

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<sup>3</sup> Paragraph 10 of the First Submission of the United States, at page 3.

<sup>4</sup> Paragraph 2 of the Oral Statement of the United States, at page 1.

<sup>5</sup> TRIPS, Article 33.

<sup>6</sup> Answer 3, Responses of the United States to Questions Posed to the Parties by the Panel.

10. As the Panel is aware, in Canada's view Article 33 cannot be read in isolation from other Articles of the Agreement and, most particularly, cannot be read in isolation from or as ignoring Article 62, paragraph 2 of which **recognizes and sanctions** the fact that the term referred to in Article 33 will be **eroded by the operation of reasonable procedures which, *inter alia*, are prerequisite to the granting of a patent.**<sup>7</sup>

11. Notwithstanding the US assertion referred to above in paragraph 10 and notwithstanding that in paragraph 9 of its Oral Statement, the US contended that "Article 62 has no relevance to this case...", elsewhere in its responses to the Panel questions it now concedes that, by virtue of the operation of paragraph 2 of Article 62, "...some loss of term due to pendency is **inevitable ...**"<sup>8</sup> (**Bold face** added for emphasis)

12. In making this concession, the US admits that Article 33 **does not require** Members "to provide a certain defined minimum term of protection to rights holders."

13. Further, where in its answer to paragraph (a) of the Panel's first question to both Parties, the US states that "The meaning of unwarranted curtailment cannot be determined in the abstract, and reasonableness may vary by situation.", it concedes that not only will the term referred to in Article 33 be inevitably eroded and thus be less than that twenty year term, but also that the amount of inevitable erosion will be **variable**.

14. A Member's compliance with the Article 33 obligation cannot, therefore, be determined by a simple, arithmetic comparison.

15. The US admissions that the term referred to in Article 33 will inevitably be eroded and that the inevitable erosion will vary in accordance with the circumstances defining the reasonableness of the procedures referred to in Article 62, jointly and severally admit by necessary implication that the first premise advanced in support of the US complaint is fallacious and cannot be sustained in the face of the unequivocal clarity of the relevant provisions of the Agreement.

#### **The Failure of the First Premise – The TRIPS Term is Available**

16. The first premise of the US complaint also fails for the additional reason that it does not take account of the uncontested fact that under Canadian law and practice respecting Old Act patents, a term of protection at least equal to (and frequently in excess of) a period of twenty years counted from the filing date of an underlying patent application was (and continues to be) **available**, without either exception or discrimination, to any Old Act applicant who wished to count and obtain a term of protection on that basis.

17. As a matter of public record, just over sixty per cent of all such Old Act applicants obtained or will obtain such equal or superior terms of protection. Such terms, therefore, were (or will be), as

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<sup>7</sup> The US would appear to share this view since, in reference to Articles 33, 62.4 and 41.2, it states in its answer to the 10<sup>th</sup> question posed by the Panel that: "These obligations of the Agreement must be read together, not in isolation. The term of protection required to be provided in Article 33 presupposes reasonable procedures for the acquisition of patent rights, such that the requirement of a twenty year term....is not rendered a practical nullity."

<sup>8</sup> See: Lines 3 and 4 of the US Response to Question 1(b). See too the US response to Question 10 referred to in footnote 6. The US had previously noted this "variability", but only in relation to its analysis of the alleged term-deficiency of section 45 patents, see: Paragraph 3 of its First Submission.



Article 33 requires, unequivocally **available** to any applicant who chose to similarly order their affairs under section 45 and the other relevant provisions of the Old Act.

18. The US has, by necessary implication, conceded the fact of "availability" where it argues<sup>9</sup> that the twenty year and twenty year plus terms that have been or will be granted under section 45 do not compensate for the terms that, notwithstanding their substantive equivalency with the effective patent term protection offered by the conjunctive provisions of Articles 33 and 62, did or do not meet the twenty year from filing date standard.

19. Similarly, in focussing its allegations of TRIPS non-compliance on the forty per cent of section 45 applicants who obtained a term of protection which was less than the nominal term referred to in Article 33<sup>10</sup>, it concedes by necessary implication that the twenty year or twenty year plus term was nevertheless "available" as demonstrated by the results obtained by the remaining sixty per cent of all section 45 applicants.

20. In other words, since there is nothing in the Canadian "availability" measures which discriminates between applicants or applications, what was obtained in respect of sixty per cent of the section 45 applications was "available" for one hundred per cent of the section 45 applications.

21. Notwithstanding these admissions by necessary implication, the US has subsequently sought to impugn the propriety or TRIPS relevance of the Canadian measures which made the twenty year term from application filing date available to any Old Act applicant who sought to view and obtain its protection on that basis.<sup>11</sup>

22. Thus in its answer to the second question posed by the Panel to both Parties, the US is critical of the provisions of Canadian law that allowed patent applicants to delay both the commencement date and, as a result, the end date of their term of full, substantive patent protection. It condemns those measures as being "unnecessarily complicated procedures".

23. Canada disagrees. The procedures at issue are, as described in Canada's answer to the Panel's Question 26, designed to ensure that, from an applicant's point of view, the rules of the patent-granting system would, as contemplated and required by Articles 41.2 and 62.4, be >fair, equitable, non-arbitrary and free of "unreasonable time limits".

24. As admitted in the US answer to the third question posed by Canada, A...US patent law ...did and does contain provisions similar to Section 30.2 (*sic*) of Canada's Old Act. (In the description which follows, the US answer makes clear that its system also contains a rule similar to the rule in Section 73 of the Old Act but for the fact that, unlike the Canadian provisions which operate as of right, the US provisions are subject to the Commissioner's discretion.)

25. Canada has tabled the applicable procedural rules as Exhibit 16. Contrary to the allegations in paragraphs 6 and 7 of the First Oral Statement of the US, the applicable rules speak to legal rights albeit one is, like all the analogous rules in US law, subject to the discretion of the Commissioner of Patents and they have, at all material times been available in a written, published form as integral parts of the Old Act and Rules.

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<sup>9</sup> See: Paragraph 14 of the First Submission of the US.

<sup>10</sup> See: Paragraph 4 of the First Submission of the US.

<sup>11</sup> See: Paragraphs 6 and 7 of the Oral Statement of the US as well as the US answer to the second question posed by the Panel to both Parties.

26. The procedural stipulations and rules, if awkwardly drafted, are simple and straightforward. At their most complicated, they require as does US law the applicant-petitioner to satisfy the Commissioner of Patents that its failure to prosecute its application within the specified time "was not reasonably avoidable". Why this requirement might be "unnecessarily complicated" for an applicant who would have first hand knowledge of the reasons why it could not complete its prosecution within the specified time, is unclear to Canada.

27. Furthermore, the US alleges, in its answer to the Panel's second question, that >Canada required applicants to follow such "unnecessarily complicated procedures to obtain unwarranted delays in the grant of their patents, *i.e.* avoidable delays justified for no purpose other than mere delay."

28. Canada denies this speculative allegation. Further, contrary to the companion allegations set out in the same answer that Canada "imposed" such delays on applicants, Canada reiterates the fact that the procedural rules in question were designed to ensure fairness and equity in the granting process. As such they established rules that offered relief from the otherwise arbitrary time limits set out in the statute or regulations for the completion of certain steps in the patent application process. They were **available** to, not "**imposed**" on, applicants. It is inescapable from the face of the rules themselves that they were, at the instance that is, on the "petition" or "application" of the applicant, available to any applicant wishing to obtain the relief provided for by the rules.

29. Moreover, although designed and enacted in the interests of fairness and equity, the rules could also be used to obtain a delay in the commencement and end dates of full patent protection in the interests of practical commercial or regulatory reasons which might supplant the incentive to obtain patent protection as soon as possible.<sup>12</sup>

30. An excellent example of one of the reasons an applicant might wish to shift its patent protection forward in time is described by the Chairman of the 10 + 10 Meeting when he reported on the concerns some TRIPS negotiators had about "...the normal period of delay between the filing of a pharmaceutical patent application and the obtaining of approval for marketing the pharmaceutical... [being]...something over 10 years."<sup>13</sup>

31. Clearly, where the start and end date of the full patent protection to be conferred on a pharmaceutical invention can be moved forward in time to more closely coincide with the date of regulatory approval for the marketing of the product, the forward shift in time will reduce the erosion of the exclusive patent rights, not to mention their value, which would otherwise result from the regulatory approval process.

32. In view of the foregoing, Canada submits that neither the propriety nor the relevance of the Canadian rules and practices respecting relieving delays in the patent application prosecution process can be dismissed as being improper in or irrelevant to an analysis of the availability of a twenty year from filing date term of protection under section 45 of the Old Act. The fact that similar rules exist under US patent legislation argues that it is not open to the US to impugn their propriety. The fact that they can and did operate to make a twenty year from filing date term available under a term from grant system confirms that they are not irrelevant.

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<sup>12</sup> See: Canada's answers to Panel Questions 5 and 19.

<sup>13</sup> See: US Exhibit No. 11 at page 4.

33. In the result under this, the "availability", branch of the analysis respecting the failure of the first premise of the US complaint, it can be shown to fail for two reasons. It fails first because it has, by necessary implication, admitted that a twenty year from filing date term of protection was **available** under the Canadian law and practice relating to section 45 patents.

34. It fails second because it has not established that the procedural mechanisms which ensured **availability** are improper or irrelevant either: to the assessment of Canada's compliance with its TRIPS obligations; or, to the related determination as to whether or not, under the test articulated by the Appellate Body in the *India B Patent Protection* case<sup>14</sup>, those mechanisms provided a "sound legal basis" for the **availability** of the term of protection here at issue.

35. In this latter regard Canada notes that in the *India B Patent Protection* case the Appellate Body endorsed a Member's Article 1.1 freedom to determine the appropriate method of implementing its TRIPS obligations within its own legal system and practice.<sup>15</sup> However it also went on to decide that, if implementation was by "practice" it had to have a "sound legal basis" which "would survive legal challenge".<sup>16</sup>

36. Canada submits that its "availability" measures, whether grounded in the formal legal rules disclosed in Exhibit 16 respecting the Old Act or in the informal practices of examiners referred to in Exhibit 8<sup>17</sup> that existed in the shadow of those formal rules, are consistent with this standard.

37. Canada makes this rebuttal submission on the basis that all of the delays that may have been granted pursuant to either the formal or informal rules although once, are no longer, exposed to legal challenge.

38. This is so because, first, the period roughly being October 1979 to April 1992 in which such decisions could have had any impact on the term of protection here at issue has long since expired. Second it is so because, as emerges clearly from the undisputed evidence in the Davies affidavit, no request for delay was ever refused. And, third, it is so because the procedural rules permitting challenges of such decisions, require that such challenges be filed within thirty days of the decision complained of becoming known by the party directly affected by the decision.<sup>18</sup>

39. In the result, it is unambiguously the case that any applicant in a position to request any of the procedural delays at issue either obtained the delay requested, or, chose not to take advantage of its position to request a delay. Consequently, there are no longer any such informal "practice" decisions that would, under the *India - Patent Protection* test, be exposed to reversal under a legal challenge.

40. There are no reported cases in respect of legal challenges brought against the Commissioner on the basis of a formal statutory decision respecting the delays here at issue.

41. In conclusion, Canada submits that, as explained in its answer to the Panel's Question 22, where the first premise of the US complaint fails whether because TRIPS does not prescribe a fixed term or whether because Canadian law complied with the TRIPS standard the second premise of the US complaint becomes irrelevant or redundant.

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<sup>14</sup> *India - Patent Protection For Pharmaceutical And Agricultural Chemical Products (AB-1997-5)*, (WT/DS50/AB/R) (December 19, 1997) at paragraphs 70, 71.

<sup>15</sup> *India - Patent Protection*, at paragraph 59.

<sup>16</sup> *India - Patent Protection*, at paragraph 70.

<sup>17</sup> Affidavit of Peter J. Davies, Chairman of the Patent Appeal Board of the Canadian Patent Office, paragraph 10.

<sup>18</sup> *Federal Court Act*, R.S.C 1985, c. F-7, subsection 18.1(2). Reproduced as Exhibit No. 22.

### The Failure of the Second Premise

42. Ignoring, for the time being, its irrelevance, the second premise on which the US complaint is advanced presupposes that paragraph 2 of Article 70 applies to all patents existing at the date of application of the TRIPS Agreement for the Member in question and which were protected as of that date, and that all such patents are entitled to a term of protection equal to the term described in Article 33.

43. In its initial iteration of this proposition in paragraph 11 of its First Submission, the US maintained that in "its ordinary meaning" Article 70.2 gave "rise to obligations including the obligation to grant a patent term of at least twenty years from the date of filing in respect of all patents ("subject-matter") existing..." on the date of the application of the TRIPS Agreement to, *inter alia*, Canada.

44. It made no reference to any other provision of Article 70.

45. In paragraph 2 of its Oral Statement the US recast this second premise and said that: "Articles 33 and 70.2 are not complicated. They require Canada to provide a twenty year term to all patent holders."

46. It went on to explain in paragraph 10 of that Statement that the "...text of Article 70.2 is key. ... [it] states that except as otherwise provided in the Agreement, TRIPS gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement." (Underlining in the original) Immediately thereafter it contended that: "A patent is a type of subject matter.". It next drew the conclusion that: "Patents that existed at the date of Application of the Agreement thus fall within the scope of Article 70.2."

### The failure of the "subject matter" thesis

47. As the Panel is aware, Canada took issue<sup>19</sup> with the US equation of "patents", being the vehicles of protection, with "subject-matter", being the object work, mark, design, invention etc. of protection. As appears from the US answers to Panel Questions 7 and 13, it has now modified, if not resiled from, its earlier views and agrees with Canada that: "... subject matter as used in the TRIPS Agreement generally refers to the matter that is or can be entitled to intellectual property protection. Indeed, this is exactly how Article 70.2 utilizes the term subject matter."

48. While the US concludes that there is now "no substantive difference between the U.S. and Canadian views of the term subject matter.", Canada does not agree with the US further proposition in which it merges the concepts of "patent", being the vehicle of protection, and "subject-matter", being the object of protection, back together again when it says that: "...both Parties seem to agree that patented inventions are subject matter."

49. Canada does not agree with this formulation for two reasons. First it involves **adding words and concepts** to the TRIPS treaty and as such is to be condemned for the reasons given in the ruling of the Appellate Body in the *India B Patent Protection* case to the effect that:

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<sup>19</sup> See: Paragraphs 66 and 67 of Canada's First (Written) Submission.

The duty of a treaty interpreter is to examine the words of the treaty to determine the intention of the parties. This should be done in accordance with the principles of treaty interpretation set out in Article 31 of the *Vienna Convention*. But these principles of interpretation neither require nor condone the imputation into the treaty of words that are not there or the importation into a treaty of concepts that were not intended.<sup>20</sup>

50. Second, Canada does not agree with the formulation because, within the structure of Article 70.2, "subject-matter" and "protection" or the "vehicle of protection" are segregated to distinguish the two ideas. To merge them together introduces redundancy into the Article 70.2 text by changing the Article 's reference to "...subject matter existing...and which is protected..."; into *patented subject matter...which is protected* which, of course, is the equivalent of saying *protected subject matter...which is protected*.

51. The negotiator-drafters of the TRIPS Agreement could not have intended such an obvious redundancy.

52. The distinction between the concepts of "subject-matter" and "protection" or "vehicle of protection" is not insignificant. It is not insignificant because the "subject-matter" of protection may be defined by certain attributes and, when protected, attract certain rights and obligations; whereas, the "vehicle of protection" may be defined by different attributes and may attract or carry with it a different set of rights and obligations.

53. The distinction is reflected in the TRIPS patent provisions inasmuch as: Article 27 defines what "subject-matter" is "patentable" or "protectable"; Article 28 defines the rights to be conferred and protected by a patent; Article 29 defines an applicant 's obligation to disclose its invention as part of the patent bargain; and, Article 33 defines a variable term of protection during which the rights conferred will endure.

54. The same distinction is reflected in the municipal patent law of Canada where: the definition of "invention" in section 2 combined with sections 27, 28.2 and 28.3 define what may be "patentable" or "protectable"; the rights conferred and to be protected are defined in section 42; sections 10 and 27 require the disclosure of the invention; while, the duration of the protection to be granted to those meeting the requirements of the Act is defined by section 44 or 45, depending on the filing date of the application.<sup>21</sup>

55. Thus, in the municipal law of Canada, as in the international law of TRIPS, the patent conveys or "grants" a bundle of rights, exclusive or otherwise; and the act and words of "grant" establish the term of the duration of the rights granted.<sup>22</sup> In other words, the term of protection flows, under the direction of the statute, from the "grant" and not from the "patent" or the "subject-matter" which it protects with exclusive privilege and property rights.

56. Were this distinction not significant, then the drafters of both the municipal law of Canada and of the international law of TRIPS would have merged or melded the term-defining provision into the rights-granting provisions, such that patents would convey or grant both the bundle of rights and the term of protection. That the drafters did not do so, speaks with persuasive authority.

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<sup>20</sup> *India – Patent Protection*, at pages 17-18.

<sup>21</sup> See: Exhibit No. 23.

<sup>22</sup> See: Section 42 of the Patent Act, reproduced in Exhibit No 23; and, the words of grant used by the Canadian Patent Office which first establish the term and second describe the scope of the rights granted by the patent, reproduced as Exhibit No. 24.

57. In the presence of these structural and substantive distinctions, both the initial US position of equating "subject-matter" with "patents" and its subsequent position of re-merging the two concepts in the compound phrase "patented subject-matter" are revealed as being critical to its case. Thus its failure to sustain either its initial "equation" or its subsequent "re-merging" of the two concepts is fatal to its second premise. And, of course, to its case.

### **The failure of the "acts" thesis**

58. At paragraph 122 of its First (Written) Submission Canada called attention to the fact, noted above at paragraph 45, that the US, in advancing its Article 70.2 premise, had failed to take any account of the non-retroactivity rule in respect of pre-application date "acts" set out in paragraph 1 of Article 70. In this connection it should be noted that the US has conceded that Article 28 of the Vienna Convention is part of customary international law and that Article 70.1 merely restates the treaty rule<sup>23</sup>.

59. The US responded to this observation in paragraph 13 of its Oral Statement, saying that "Article 70.1 of TRIPS did not mandate a different result" from the TRIPS implementation conduct of other Members which it had adduced as evidence it chose to identify as "subsequent practice" evidence.<sup>24</sup>

60. After quoting the substance of the Article 70.1 non-retroactivity rule, the US states that it agrees with Canada that the word "acts" in the Article "refers to, *inter alia*, the acts Canada identifies in paragraph 116 of its first submission, as well as such acts as" those of customs officials administering import control policies.

61. The US then illustrates<sup>25</sup> its view of the operation of Article 70.1 by giving an example of where and how it would apply. From this it concludes that "Article 70.1 simply says that in implementing TRIPS, a country does not have to go back and provide a remedy against [a] person for his 1993 acts." Notwithstanding that the US agrees that "acts" refers to all the "things done" i.e. "acts" described in paragraph 116 of Canada's First (Written) Submission, the example it gives is limited to demonstrating how it would operate in respect of pre-application date acts of infringement or potential infringement.

62. The example therefore does not explain how Article 70.1 would operate in respect of the other types of "acts" at issue. Thus it says nothing about the Article's operation in respect of the

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<sup>23</sup> See: US answers to Questions 6(a) and (b).

<sup>24</sup> See: Paragraphs 69 to 79 of Canada's First Oral Presentation for Canada's views on the value and weight of this alleged "subsequent practice" evidence. In its answers to Panel Questions 4 and 14 the US has responded to Canada's concerns respecting the value of the evidence in question, saying that one of Canada's criticisms: "...had no relevance". Parenthetically, Canada would note that the US suggestion that Canada's points respecting the fact that several, if not most, of the Members amending their laws to implement TRIPS standards had "first to file" systems which granted terms of protection in respect of "first to file" applications which ran from the application filing date and were "arithmetically" less than the twenty year standard prescribed by TRIPS, "have no relevance" is obscure. How such unambiguous deficiencies in "first to file" terms of protection might be "of no relevance" to whether or not those Members' obvious need to amend their laws to be TRIPS compliant had any subsequent value to assessing Canada's need to amend its "first to invent, term from grant" system, is unclear to Canada.

<sup>25</sup> See: Paragraph 14 of its Oral Statement.

"act" of a patent applicant filing an application. Similarly, it says nothing about the Article 's operation in respect of the subsequent "act" of a patent authority issuing a patent.

63. Since the latter two types of "act" are the types that Canada has, in its defense of this complaint, put in issue, it is incumbent on the US to go forward with evidence or, at least, interpretive theory to explain why Article 70.1 would operate any differently from its example when or where a pre-application date administrative act of filing or grant was at issue. A failure to discharge this burden, would threaten its capacity to make out a *prima facie* case. And, of course, threaten its prospect of success in its complaint.

64. In its answer to the Panel' s eleventh question the US was forced to respond to this very issue. In the course of its answer to this question, the US conceded that "By its plain meaning, "acts" would include the administrative act of granting a patent by a patent office."

65. It then explained that: "The acts of Canada 's Patent Office prior to 1996 are not at issue." Without saying anything about whether or not "acts" of applicants for Canadian patents were or were not at issue, the US answer went on, in an obvious reference back to its hypothesis that "subject-matter" means "patented invention", to explain that: "Canada's violation....stems from its failure, ...to extend the term of protection for existing **patented inventions** to at least twenty years from filing. This violation is unrelated to any pre-96 "act", but is related only to the subject matter (**protected inventions**) that existed on 1-1-96.@ (**Bold face** added for emphasis)

66. Canada submits that this theory or explanation of the US complaint is deficient. It is so for two reasons. First for the reasons set forth in paragraphs 49 to 58 of this rebuttal, Canada does not agree that a case can be made for the proposition that "subject-matter" means, or includes in its meaning, "patented or protected inventions".

67. Accordingly, the distinctions elaborated in the referenced paragraphs would operate to detach the term of protection given by the act of the grant of the patent from the exclusive and other rights conferred by the patent itself. "Acts" of grant cannot be viewed as continuing acts that attract the prospective patent-term extensions that the US alleges are due to rights holders possessed of patents that existed on the date of application of the Agreement and, in the view of the US, were "term-deficient".

68. The "act" of grant is decisive and, subject to judicial review, conclusive unlike the consequential rights it gives rise to, which continue, subject to the vagaries of maintenance fee payments, forfeiture, revocation and cancellation, for a defined but variable term. The "act" of grant is a final "act" and is no more a continuing act than life, subject to all its vagaries, is a continuing act of birth.

69. A pre-application date "act" of grant does not therefore exist, nor is it "protected", except by paragraph 1 of Article 70, on the date of application of the Agreement for the Member in whose territory the "act" took place.

70. The second reason why the US theory arguing that "acts" of grant are subject to the obligations of paragraph 2 of Article 70 respecting existing "subject-matter" is deficient is that its "patented or protected invention" theory takes no account of the fact that the "act" of grant is consequential to the "act" of filing an application.

71. In this respect it is significant that since the obligation in Article 33 is triggered by the applicant 's act of filing a patent application, the obligation to provide the term of protection referred

to in that Article is clearly an obligation "in respect of" the "acts" of filing a patent application or granting a patent and, therefore, falls squarely within the meaning and scope of Article 70.1.

72. Article 33 specifies that the term of protection that it requires is "counted from the filing date" of the application. The "act" of filing an application therefore is the trigger which starts the clock of protection. Like the "act" of grant, the "act" of filing an application is, within a term from filing system, a decisive, conclusive, and final act.

73. Thus just like the pre-application "act" of grant, the pre-application "act" of filing does not have a continuing existence, nor is it protected except by paragraph 1 of Article 70 on the date of application of the Agreement for the Member in whose territory the "act" of filing took place.

74. To complete this rebuttal discussion of the US second premise, Canada would first reiterate its view that where the US first premise fails, its second premise becomes irrelevant.

75. Canada would then note that the US has, within the context of the non-retroactivity rule of Article 70.1, made two telling admissions: first, it admits that the word "acts" in the Article includes the "acts" of officials in the Patent Office granting patents; and second, it admits that a pre-1996 "act" of grant would not give rise to obligations under the TRIPS Agreement. The initial version of the US= second premise fails in the face of these admissions.

76. However in admitting that "acts" of grant do not give rise to TRIPS obligations the US refocuses its complaint on the fact that Canada had not, as of January 1996, and has not since extended the terms of protection of allegedly term-deficient section 45 patents that continued to exist on and after that threshold date.

77. In refocusing its premise the US reintroduces its concept that "subject-matter", as used in Article 70.2 includes the US compound notion of "patented or protected subject-matter". In the result the refocused thesis gives rise to the same interpretive flaws that lead to the failure of the "subject-matter" thesis. Accordingly, the refocused thesis fails and it fails for the same reasons.

### III. CONCLUSION

78. This case is not an "exceedingly simple" one as initially contended by the US. However, in light of the undisputed evidentiary record, the subsequent admissions, refinements and changes in the US theory, it lends itself to a simple solution. A solution which in Canada's submission, the Panel is obliged to adopt. That solution is to find: that there is no case to answer.

79. As demonstrated above, the US now accepts that Article 33 of TRIPS, like its own implementing legislation, establishes a variable period of patent protection "beginning on the date the patent issues and ending 20 years from the date on which the application for the patent was filed".<sup>26</sup>

80. Canada has also demonstrated that the normal period of patent protection in Canada under its comparable, TRIPS-compliant section 44 patent term regime is 15 years, while its section 45 patent term regime confers a fixed term of 17 years. This in Canada's submission is, as a matter of fact, equivalent or superior to the variable term obligation agreed to in Articles 33 and 62 of TRIPS.

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<sup>26</sup> United States Code Title 35 s 154 (2). Reproduced as Exhibit No. 25.



81. Similarly, the US has conceded that sixty per cent of all section 45 patent applicants obtained a period of patent protection in excess of twenty years measured from the date of filing of their patent applications. The evidence that any applicant could take advantage of the various formal and informal delays provided under Canadian law and practice is uncontested.

82. There is no evidence that any Canadian law purported to restrict or limit the term of patent protection measured from the filing date. Indeed the evidence is to the contrary. Accordingly, the TRIPS required term as a matter of undisputed fact, was available for the asking, to any and all applicants during the period they were prosecuting their applications for patents. That "availability" is all that TRIPS Article 33 requires.

83. Finally, the US has conceded that "acts" as used in TRIPS Article 70.1 includes the act of granting a patent by a patent office. Issuing a patent for a fixed term is a final act. As demonstrated, section 45 patents are issued by the Commissioner of Patents on a specified date and are issued "for a term which expires seventeen years from the date on which the patent is granted and issues in Canada".<sup>27</sup> The patent itself, once granted, is the vehicle which conveys the exclusive privileges and property rights associated with a patent.

84. The US has failed to establish that a "patent" is "subject-matter" within the meaning of TRIPS and yet now, in January 2000, it still argues that patented subject matter became entitled to an extended term of protection on January 1, 1996, the date of the application of TRIPS for Canada. This, notwithstanding that the "act" of grant, which the US concedes is within the scope of Article 70.1 is, on the evidence, an act of grant for a fixed term. In Canada's submission this is a final act which occurred before the application of the Agreement and, by virtue of Article 70.1, no obligations arise under the Agreement in respect of that act.

#### **IV. DISPOSITION REQUESTED**

85. Canada, therefore respectfully asks that this complaint of the US be dismissed by the Panel as being unfounded in fact, and that, the Panel find that Canada's impugned section 45 measure is, in any event and on all the evidence, compliant with its TRIPS obligations.

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<sup>27</sup> See: Exhibit No. 24.

**ATTACHMENT 2.5**

**ORAL STATEMENT OF CANADA AT THE SECOND MEETING  
WITH THE PANEL**

(25 January 2000)

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## I. INTRODUCTION

1. Canada is pleased to have this opportunity to present its rebuttal argument this morning. Canada, relies on its earlier submissions and answers to questions. It takes issue, however, with the evolving theories the US has been developing in support of its complaint which, in Canada's submission, are founded on false premises and *ad hominem* arguments. That is to say, the US case is based on what the US would prefer the TRIPS Agreement to require, rather than the actual obligations set out in the Agreement that all Members have adopted.

2. Rather than attempt a point by point critique of the US arguments, in rebuttal Canada will present five arguments in answer to the US case. We will address the scope of the obligation under Article 33 and explain why our measure is consistent both in terms of equivalence and availability. Canada will then explain why its section 45 patent term provisions are not subject to the Agreement. It will conclude by explaining that since neither patents nor terms of protection are "subject matter" within the meaning of TRIPS, they do not, where either existed on the application date of the Agreement, attract or otherwise give rise to obligations under paragraph 2 of Article 70 of the Agreement.

## II. THE SCOPE OF THE OBLIGATION IN ARTICLE 33

3. The US persistently and inaccurately seeks to impose an obligation under Article 33 to provide a term of patent protection of twenty years as it did for example: in paragraph 2 of its first Oral Statement; in its answer to Question 10 of the Panel; and, in a modified, but still inaccurate form, where it posits that the Agreement requires a patent term of twenty years measured from the filing date, as it has in the first paragraphs of both its First and Second Submissions.

4. No matter how often these mischaracterizations are repeated, they cannot change or amend the actual requirement created by the words used in Article 33. The object of the Article is not a twenty year term of patent protection. Article 33 does not say that. The US case hinges on reading Article 33 as if the word **available** is not there<sup>1</sup>. But it is.

5. The US case hinges too on the US applying or interpreting the instrument or formula of measurement, namely, "...a period of twenty years counted from the filing date..." as if it were itself the definition of the term of patent protection. But it is not.

6. This is made manifestly clear by paragraph 2 of Article 62 which, as Canada has explained<sup>2</sup> and the US has conceded,<sup>3</sup> recognizes that the period referred to in Article 33 will be "curtailed" by reasonable procedures that are prerequisite to the granting of a patent. This fact is unambiguously confirmed by the US municipal law respecting the term of protection where it specifies that the:

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<sup>1</sup> See, for instance, paragraph 2 of the US' Oral Statement where it omits the word "available" from its quotation of Article 33. See too the subtitle of II A in the US' Rebuttal Submission and the discussion which follows where, in the course of insisting on a plain language interpretation and application of Article 33, the US avoids any reference to the word "available". (It does however quote Article 33 accurately in footnote 5 but in so doing offers no explanation of its meaning.)

<sup>2</sup> See: Paragraphs 67 to 75 of Canada's First (Written) Submission and see, too, Canada's responses to Panel Questions 1 and 3.

<sup>3</sup> See: the US response to Panel Question 1(b) where it states: "...some loss of term due to pendency is **inevitable...**". (Bold face added for emphasis)

...grant shall be for a term beginning on the date the patent issues and ending 20 years from the date on which the application for the patent was filed...<sup>4</sup>

7. As the Panel is aware, Article 33 in fact provides that ‘the term of protection “**available**” shall not end before’ the twenty year period it specifies; and, paragraph 2 of Article 62 in fact recognizes that the period referred to in Article 33 will be **curtailed** such that the substantive term of protection<sup>5</sup> will inevitably be less than that period.

8. In short, Article 33 requires that the “term of protection”—whatever its exact length—be **available** within the twenty year period it specifies. And that—the obligation to make the term **available**—is the only obligation or requirement of the Article.

9. As the Agreement does not, on its plain wording, impose the obligation or requirement upon which the US advances its claim, the US complaint must fail. It is not now open, in the middle of the process, to the US to formulate a fresh or different complaint. Nor should it be the role of this Panel to undertake a general inquiry into Canada’s various measures respecting the term of protection to determine if they are consistent with its TRIPS obligations.

10. This is a dispute settlement proceeding respecting a defined complaint, not a general audit of Canada’s compliance with its TRIPS obligations respecting the term of protection. And within that proceeding the US complaint should stand or fall on its own merit.

### III. CANADA’S “EQUIVALENCY” ARGUMENT AND EVIDENCE

11. Canada observed in its Second Submission<sup>6</sup> that the US has failed to confront Canada’s arguments directly. Instead the US has often resorted to speculative statements<sup>7</sup> and to providing extreme hypothetical examples such as a patent term of 1 day from grant<sup>8</sup>.

12. Such resort to straw dog argumentation is of no assistance in assessing the actual compliance of Canada’s section 45 measure with its TRIPS obligations. In its Rebuttal Submission, the US continues to misstate and mischaracterize Canada’s arguments, and to confuse the concepts of “equivalency” and “availability” and the undisputed facts which support each.<sup>9</sup>

13. Contrary to the suggestion in paragraph 12 of the US’ Rebuttal Submission, Canada has not shifted its position in respect of the “equivalency” argument. In contrast, all Canada has done in its

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<sup>4</sup> See: Canada Exhibit No. 25, being Title 35 Patents, paragraph 154(a)(2). Canada notes that because there will, in such a system, always be a temporal disjunction between the date of filing and the date of grant, the system guarantees that the amount of “effective” protection available will never equal the maximum 20 year period that the US suggests is required of Canadian law.

<sup>5</sup> As the US notes at paragraph 4 of its Rebuttal Submission, Canada frequently refers to the substantive term of protection as the “effective” term of protection or the term of protection for the “exclusive privilege and

<sup>6</sup> See, for instance, paragraph 2

<sup>7</sup> See, for example, the US contention that ‘Canada required applicants to follow an “unnecessarily complicated” procedure’ elaborated, without evidence of any such requirement, in the US response to Panel Question 2. The procedures were “available” not “imposed”. See also Canada’s response to Panel Question 26.

<sup>8</sup> See, for instance, the self styled “extreme” hypothesis set out in the US’ response to the Panel’s Question 10.

<sup>9</sup> See: paragraph 10 of the US’ Rebuttal Submission.



19. Canada therefore turned to look at alternative analytical techniques or tools for judging the equivalency between the fixed-term-from-grant and the variable-term-from-filing systems. Given that a fixed-term-from-grant system always defines a term of “effective” protection, Canada’s inquiry focussed on techniques or tools that could measure the “effective” protection available under variable term systems. Therefore, it looked at the “mean” “effective” term in a variable system. It looked at the “modal” “effective” term in a variable system. It looked at the “average” “effective” term in a variable system. And it looked at the “probable” “effective” term in the variable system.

20. The first three tools all produced similar results and showed a “normal” pendency period of approximately five years resulting, of course, in an “effective” term of protection of approximately fifteen years. The fourth tool showed, as noted in paragraph 14 of this submission, that in nine cases out of ten, a section 44 applicant obtained an “effective” term of seventeen years or less.

21. Thus all of these analytical techniques point to the same conclusion: where the “normal” term of “effective” protection available under a **variable-term** system is, on a statistically sound basis, equal to or less than the “effective” protection guaranteed under a **fixed-term** system, the two systems can fairly be said to be, and are, equivalent in providing the “...effective and adequate protection of<sup>18</sup>—in this case, patent rights—that are at the heart of the TRIPS

Agreement.

22. Notwithstanding the confusing characterizations put forward in paragraphs 6 and 7 of the US’ Oral Statement, Canada has argued consistently that the **fixed and guaranteed term** of protection provided to section 45 patents is equivalent or superior to the **variable term** which results from the operation of Articles 33 and 62 and which is normally shorter and, on average, has been 15 years in Canada.

23. US municipal legislation supports this reasoning. Canada’s Exhibit 25 reproduces the patent term provisions of the current US Title 35 Patent legislation. As also quoted above<sup>19</sup> the provisions stipulate that:

...such grant shall be for a term beginning on the date the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States.

24. To maintain its argument, the US must deny its own law. The period of “patent protection” or, as Canada also refers to it, the period of “effective protection” does not start until the patent issues and it inevitably runs for a variable period that is shorter than the twenty years referred to in the US legislation. Of course, this result might change if the variable-term system in place in the US, were made subject to some legislative amendment that reduced the variability of its current system.

25. Given the substance of the US complaint and its chronology, it was with some surprise that Canada recently learned that the US Title 35 patent legislation had been amended by the enactment of the *Intellectual Property and Communications Omnibus Reform Act of 1999* (S. 1948) in November 1999. The reform proposals appear to have come before the House of Representatives in March 1999 and subsequently, before the Senate in November 1999. In the result the amending proposals were both debated and passed into law during the pendency of this complaint. The Panel

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<sup>18</sup> TRIPS, the opening, or “Desiring”, recital to the Agreement.

<sup>19</sup> At paragraph 6 of this submission, and see: Exhibit No. 25.

will recall from the record of these proceedings that the US Ambassador formally requested consultations on May 6, 1999.

26. As the amendments are not currently before the Panel, Canada would now put them in evidence as Exhibit No. 26. In their material part the amendments appear as Subtitle D of Title IV of the amending Act and may be cited as the: *Patent Term Guarantee Act of 1999* (Term Guarantee Act).<sup>20</sup>

27. The purpose of the Term Guarantee Act is, in the synopsis given by the US Patent and Trademark Office, to ensure that: "Diligent applicants are **guaranteed a minimum 17-year patent term**."<sup>21</sup> (Bold face added for emphasis) A Member of the US House of Representatives, Dana Rohrabacher, expressed the same view in respect of the purpose of the amending legislation, reporting that it was enacted "...to assure a **minimum patent term of 17 years** from the date a patent is **granted**."<sup>22</sup> (Bold face added for emphasis).

28. The parallels between these descriptions of the effect and purpose of the Term Guarantee Act with the US, Mexican and Canadian NAFTA commitments as well as with Canada's section 45 regime are striking.

29. Two provisions of Subtitle D merit particular consideration. The first concerns subparagraph 4402(b)(1)(B). It provides and **guarantees** that, subject to certain prescribed conditions, if, in the face of failures or delays in the Patent and Trademark Office, a patent does not issue within 3 years of the actual filing date, the term shall be extended one day for each day of delay beyond that three year period. In other words, this new US legislation provides that **there is a guaranteed term of "effective" protection for 17 years from the date of grant**.

30. The second provision concerns the exception to the guarantee set out in clause 4402(b)(1)(B)(iii). It is of particular note because it expressly excludes from the calculation of the guarantee period, any processing delays requested by the applicant. Canada believes this provision to be noteworthy because the US has argued that the average pendency period of 5 years under Canada's section 44 regime is too long and unwarranted.<sup>23</sup>

31. However when, in this latter respect, one deducts the delays that occur because of the failure of an applicant to request "examination" on an immediate basis, as the Rules described in Canada's evidence<sup>24</sup> respecting section 44 applications would encourage, the approximate total delay at issue is the same 3 year delay that is sanctioned by the US in its new law as being "a reasonable period of time [which avoids] unwarranted curtailment of the period of protection."<sup>25</sup>

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<sup>20</sup> *Intellectual Property and Communications Omnibus Reform Act of 1999* (S. 1948), Subtitle D—Patent Term Guarantee. Reproduced as Exhibit No. 26.

<sup>21</sup> PTO Pulse –January 2000, *American Inventors Protection Act of 1999 is Law*, at page 2. Reproduced as Exhibit No. 27. (Note that 'guaranteed minimum term' appears to be 'code' for "effective" term.)

<sup>22</sup> Dana Rohrabacher, *Summary of Patent Reform Legislation*, at page 1. Reproduced as Exhibit No. 28.

<sup>23</sup> The 1997 and 1998 Annual Reports of the EPO (European Patent Office) indicate that EPO's average processing time for applications which resulted in a patent during 1996 was 46.9 months, rose to 50.2 months in 1997 and in 1998 decreased to 44.7 months. It would appear that this period begins when an applicant requests examination and consequently EPO response times are of the same order of magnitude as Canada's.

<sup>24</sup> Davies Affidavit, paragraphs 26 to 29.

<sup>25</sup> The quoted words, with necessary grammatical adjustment, are, of course, drawn from paragraph 2 of Article 62.

33. Canada believes that it is pertinent to recall that the US conceded in its response to the Panel's Question 8 that the effect of Article 1.1 is to require **substantive** compliance with the relevant obligations of the TRIPS treaty and that the **form** of compliance is not determinative of a compliance issue.

34. The US' implementing legislation in consequence of TRIPS and its patent term guarantee amending legislation confirm that the US recognises, and accepts in its municipal law and policy, that 17 years of patent protection is substantially equivalent or superior<sup>26</sup> to the variable term of "effective" patent protection which, under the TRIPS term formula, is inevitably shorter than the twenty year period it (and other municipal laws) refer to.

35. Thus while conceding that **substance** is more important than **form**, the US, in direct contradiction to this admission, is asking this Panel to **disregard the substantive compliance** of Canada's measure and to **denounce it as deficient in form**.

36. In the face of this request, and taking into account the TRIPS Agreement's broad and underlying objective of 'promoting the **effective and adequate** protection of intellectual property rights'<sup>27</sup>, the comments of Representative Rohrabacher respecting the rationale underlying the **Patent Term Guarantee Act of 1999** deserve close attention within the context of these proceedings. Those comments were:

As everyone is aware, the current law governing patent term is 20 years from the date of file (*sic*). Patents applied for after June 8, 1995, when the provision eliminating the 17-years-from-grant guarantee took effect, have been losing precious time under the law. Before the enactment of S. 1948, these inventors could no longer rely on a guaranteed term of protection. In some cases, several years of **effective post-grant protection** could have been lost due to Patent and Trademark Office (PTO) administrative delay. **Bold face added for emphasis**

Ultimately, if the PTO does not issue a patent within 3 years from the date of original file, the patent term will be compensated day-for-day until the patent issues, ...

This approach, ... effectively gives back to the non-dilatory patent holder what I have fought for – the right to a guaranteed 17 year patent term.<sup>28</sup>

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<sup>26</sup> It is equal or superior because it establishes a floor, beneath which the variable term may not fall (except when the delays are caused by the applicant).

<sup>27</sup> TRIPS, the opening, or "Desiring", recital to the Agreement.

<sup>28</sup> Exhibit No. 28, Subtitle D – Patent Term Guarantee Act of 1999, paragraph 2 and parts of paragraphs 3 and 4.



37. In providing 17 years of guaranteed patent protection, Canada's measure is not only consistent with and equivalent to the substantive requirement of Article 33 when read in conjunction with Article 62, it is also consistent with the complainant's own law and policy as expressed in US municipal law.

#### IV. CANADA'S "AVAILABILITY" ARGUMENT AND EVIDENCE

38. The US has also misstated and mischaracterized Canada's argument in respect of the "availability" of a term of patent protection that "shall not end before the expiration of a period of twenty years counted from the filing date.". In this respect Canada has stated that "section 45 does not provide, or otherwise require, that the term of protection conferred shall end before the expiration of the twenty year period measured from the filing date of the patent application".<sup>29</sup> The US has never contradicted this statement.

39. As Canada has already observed, the US argument and description of the requirement imposed by Article 33 reads out the word "**available**". The US also relies on inconsistent propositions of law; for example, it has, in developing its Article 70 argument, denied that the Agreement is retroactive.<sup>30</sup> However, in impugning Canada's availability argument, the US argues, at paragraph 13 of its Rebuttal Submission, that Old Act patentees cannot be said to have waived a TRIPS-level term of protection before it existed. This argument not only misrepresents Canada's position, it lacks logical consistency with the US' other arguments.

40. It is obvious that prior to the 1989 changes in Canada's municipal law or the negotiation of TRIPS, patent applicants would not be directing their minds to a "twenty year from filing" time frame. In Canada's view that is beside the point.

41. As Canada observed in paragraphs 31 and 32 of its Second Submission in reference to US Exhibit 11, the normal period of delay between filing a patent application and obtaining regulatory approval for pharmaceuticals typically took 10 years. In these circumstances, and as Canada's explanation clearly demonstrates, the applicant for a patent would have a clear motive to delay the process time so that the start of the period of patent protection would more closely match the time from which it was 'licensed'—received marketing approval—to market the product. Such conduct has nothing to do with a future right or benefit that may flow from TRIPS.

42. The evidence is undisputed that anyone who wanted to delay the issuance of their patent could do so and, within the existing law and practice of Canada, terms of 20 years of patent protection measured from the filing date were available without exception.

43. In Canada's submission, it is not necessary that every applicant made a conscious choice in respect to an unknowable, future 'minimum' term formulation. The substance of the Article 33 requirement is that the term be "**available**". On all the evidence it was, and is. Anyone who saw an advantage in delaying the issuing date of their patent in relation to the filing date could do so, and **did**.

44. Canada will not take up more of the Panel's time by reiterating all of its arguments in relation to availability. They are fully developed in Canada's earlier Submissions and Responses to Panel Questions.<sup>31</sup> Canada will, however, take this opportunity to further respond to the US argument that Canada's Old Act law and practice did not provide a "sound legal basis" for the availability of a twenty year from filing date term.

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<sup>29</sup> Subparagraph 5(b), of Canada's First (Written) Submission.

<sup>30</sup> Paragraph 14 of the Oral Statement of the US.

<sup>31</sup> See: Paragraphs 84 to 110 of Canada's First (Written) Submission; paragraphs 30 to 57 of Canada's first Oral Presentation; and, Canada's response to Panel Question 3.

45. The Panel will recall that, as Exhibit 16, Canada filed evidence of the statutory basis for demonstrating that there is a right, under the combined effect of subsection 30(2) and section 73 of Canada's Old Act regime, to 42 months of delays between the time of filing and issuance. These delays are directly related to essential steps in the processing of an Old Act patent application. They are not dependant on particular circumstances which may give rise to additional delays provided by statute<sup>32</sup> in any given case. Nor are they dependent on the other, informal delays described by Mr. Davies in his affidavit.<sup>33</sup>

46. Nor, as noted in paragraph 44 of Canada's First Oral Presentation, does this showing of the existence of a statutory basis for obtaining a delay in the prosecution of an application, take into account the effect on "availability" that the actual examination time would have on the duration of the term of protection if it were to be assessed against the filing date.

47. The US, in its Rebuttal Submission under section III A, treats the delays under section 30(2) and section 73 as the **only** delays that were available to prolong the fixed seventeen year term, when the latter was measured from the application filing date. As Canada has just explained, this is wrong.

48. The US also seeks to establish that these statutory provisions are unduly complex and somehow abusive. Canada denies this and would refer you to the discussion in paragraphs 10 to 13 in its Second Submission.

49. In this respect Canada recalls that in answer to its third question, the US admits that its own patent legislation "does and did contain provisions similar to Section 30.2 (sic) of Canada's old Act". As Exhibit No. 28 demonstrates, these US statutory opportunities for delay would, as in Canada, be additional to the everyday internal delays which occur within the US Patent and Trademark Office.

50. Canada has demonstrated with uncontradicted evidence that everyone without exception was able to delay the issuance of its patent to a time later than 3 years after the application was filed. No one who chose to take advantage of those delays is subject to a court or any other body interfering with its patent term as a result of the administrative actions taken to effect those delays.<sup>34</sup>

51. Thus Canada has also demonstrated that its laws and practices permitting administrative delays that had the effect of extending the term of protection (when measured from an application filing date) had a 'sound basis in law' as required by the test set out in the case.<sup>35</sup> The US, in contrast, has failed to disprove the "sound legal basis" underlying these Canadian laws and practices.

52. The Panel will also recall that Canada anticipated and addressed the issue that some of the delays under section 30(2) were discretionary in its first Oral Presentation at paragraph 45 to 49. Not only are discretionary limitations expressly authorised under TRIPS Article 62.1, but we are concerned here, in contrast to the prospective issues in the *India – Patent Protection* case, exclusively with historical fact.

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<sup>32</sup> Such other delays would include, for example, requests from a patent examiner for information additional to that already found in the application. Under the statute the applicant has six months to respond to such requests.

<sup>33</sup> Davies Affidavit, paragraph 10.

<sup>34</sup> See: Paragraphs 34 to 41 of Canada's Second Submission.

<sup>35</sup> *India – Patent Protection For Pharmaceutical And Agricultural Chemical Products (AB-1997-5)*, (WT/DS50/AB/R) (December 19, 1997) and see discussion of this issue at paragraph 36 and following of Canada's first Oral Presentation and at paragraphs 35 to 41 of Canada's Second Submission.

53. There is, in addition, no evidence that someone who was granted a delay had its patent term subsequently shortened or otherwise interfered with on judicial or other competent authority review. Nor is there any evidence that someone who sought to delay the issuance of a patent, for whatever their private interest may have been, was ever denied the delay requested.

54. As a matter of uncontested fact the period of twenty years from filing was available to every applicant throughout the period during which their application was pending. There is no evidence which can sustain or support a contrary finding.

55. The evidence is undisputed that anyone who wanted a delay obtained it, because it was available, without exception, to anyone who made such a request. Any applicant could within Canada's existing legal system and practice exercise control over when its patent issued in relation to the application filing date. The twenty year and twenty year plus terms of protection which, when measured from their respective filing dates, were accorded to some 150,000 Old Act patents, and this coupled with the total absence of any evidence that a request to delay or postpone the issuance of a patent was ever refused, is uncontradictable evidence of availability.<sup>36</sup>

56. History is history. In these proceedings the US seeks to unmake it—on the basis of speculative assertion and theory. Not on the basis of evidence.

## V. ARTICLE 70

57. Canada has previously argued that the transitional rules set out in Article 70 are irrelevant because Canada's pre-existing section 45 patent regime is fully compliant with the TRIPS Agreement. Since Canada's section 45 patent term of protection is equivalent to the TRIPS variable standard, and since a term of protection of 20 years measured from the filing date was always available; the TRIPS transitional rules are not engaged.

58. The US as the complaining party must not only establish that Canada's impugned measure does not comply with the requirement in Article 33, it must also establish that section 45 patents are subject to Article 33. In Canada's submission, the US submissions have failed on all counts.

59. Article 70.1 provides that the Agreement, which of course includes Article 33, does not give rise to obligations in respect of "acts" which occurred before the date of application of the Agreement. The US has conceded in response to the Panel's question 11 that "By its plain meaning, 'acts' would include the administrative act of granting a patent by a patent office". The US in paragraph 25 of its Rebuttal Submission appears to further concede that the "act" of filing an application by a right holder is also within the scope of Article 70.1.

60. Canada has produced as Exhibit 24 copies of Canadian Patent certificates for both the section 45 and section 44 regimes. It is clear from the 'language of grant' used that the administrative act of granting a patent includes, as an integral component of that act, a temporal limitation.

61. Thus in respect to a section 45 patent, the patent grants to the owner "for a term which expires seventeen years from the date on which the patent is granted and issued in Canada" certain exclusive rights and privileges in respect of the invention. The certificate is then dated over an official signature. The certificate of grant is therefore conclusive of both the existence of the patent and the duration of its term.

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<sup>36</sup> Davies Affidavit, paragraph 15.

62. The result is that the TRIPS Agreement does not give rise to any obligations in respect of those “acts” which occurred before the implementation date. This does not mean that the Agreement does not have application to the “subject matter” which those patents protect.<sup>37</sup> By force of Article 70.2, it clearly does “Except as otherwise provided in the Agreement”. There is, however, such an express “otherwise” proviso for “acts” under Article 70.1. There is no similar proviso for the rights and privileges that flow from the patent and are attached to the invention or the “subject matter” of patent protection.

63. In paragraph 27 of its Rebuttal Submission, the US again seeks to rely on contradictory and inconsistent reasoning. The US has said unequivocally that the Agreement is not retroactive (see paragraph 14 First Oral Statement). Now, however, it argues that pre-1996 administrative acts are exempt, but only until January 1, 1996 at which time they become subject to what the US characterizes as the prospective<sup>38</sup> application of TRIPS standards. That is, in the US view, pre-application date “acts” are exempt until the application date. Thereafter they become subject to the Agreement. This empty distinction is disingenuous. The “acts” of filing an application and of granting a patent for a fixed term are complete when they are made and, therefore, are not subject to the Agreement.

## VI. SUBJECT MATTER

64. Consistent with their reconstruction of the substance of Article 28 of the *Vienna Convention on the Law of Treaties*<sup>39</sup>, the TRIPS negotiators clearly intended to confirm, not contract out of, the Article 28 Convention rule against the retroactive application of treaties to pre-treaty acts, facts and no longer existing situations, **except as they otherwise provided**.

65. They did this to a limited extent in paragraph 2 of Article 70 where they stipulated that the TRIPS Agreement would, “Except as otherwise provided for in this Agreement”, have a limited retrospective application, and give

...rise to obligations in respect of all subject matter existing at the date of application of this Agreement...and which is protected...on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement...

66. Paragraph 2 of Article 70 is concerned with obligations in respect of “subject matter”. Canada and the US do not agree on the contextual scope of the expression “subject matter”. Canada says that granting a term of patent protection is an integral part of the act of issuing a Canadian patent. Moreover, a term of patent protection is an obligation in respect of the life of the patent. A patent term is not an obligation in respect of subject matter.

67. The US position is more transitory and uncertain. The initial position of the US assumed that patents were “subject matter” and since they were “subject matter”, the Article 70.2 rule applied unambiguously.<sup>40</sup> In its subsequent Oral Statement the US restated this assumption affirmatively, where, after quoting the substance of Article 70.2, it asserted that: “A patent is a type of subject

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<sup>37</sup> Contrary to the US criticism of Canada’s paragraph 113 (first submission), the US now acknowledges that Canada is not making the unequivocal statement that the agreement has no application to pre-1996 patents: paragraphs 31 and 32 US Rebuttal Submission.

<sup>38</sup> See: paragraph 15 of the US Oral Statement.

<sup>39</sup> See: Canada’s response to Panel Question 6(d).

<sup>40</sup> See: Paragraph 11 of the first Submission of the US, where it states that “...TRIPS...gives rise to obligations...in respect of all patents (“subject matter”) existing...”.

matter.”. Given this assertion, here again the Article 70.2 rule was said by the US to apply, unambiguously.<sup>41</sup>

68. Canada denied the validity of the US assertion that patents were “subject matter” within the meaning of TRIPS, noting that it was clear from the textual and contextual use of the phrase “subject **matter**, that is, the ‘work’, ‘mark’, ‘geographical indication’, ‘industrial design’, ‘invention’ or ‘layout-design’, that attracts the exclusive intellectual property rights which serve to protect it.<sup>42</sup>

69. Subsequently<sup>43</sup> the US resiled fully from its two opening positions to agree with Canada that:

...>subject matter’ as used in the TRIPS Agreement generally refers to the matter that is or can be entitled to intellectual property protection. Indeed, this is exactly how Article 70.2 utilizes the term >subject matter’.<sup>44</sup>

70. However, having so resiled from its initial position, the US next attempted to bring the concepts of both “patent” and “term of protection” back within the ambit of “subject matter” and, therefore, of Article 70.2 by the use of a variety of compound terms, such as patented inventions<sup>45</sup>, or expanded phrasings or explanations such as those used in paragraphs 24 to 30 of the Rebuttal Submission of the US.

71. As argued in paragraphs 48 to 58 of Canada’s Second Submission, to read words like “patentable” or “protected” into “subject matter” does violence to Article 70.2 as well as to the term “subject matter” itself. Such words when used in relation to “subject matter” are adjectival only. They do not transform the thing itself.

72. Similarly, the resort to extended phrasings or explanations such as those used in paragraph 26 of the US’ Rebuttal Submission, saying that there is, under paragraph 2 of Article 70, an “...obligation to a grant a TRIPS-level patent term to such inventions that existed on January 1, 1996.”, exceed the plain meaning of the words used in both of paragraph 2 of Article 70 and Article 33.

73. The US now asserts that obligations in respect of subject matter, must be read as obligations in respect of patentable subject matter and this would therefore include the Article 33 obligation for a term of protection. Reading in words is impermissible and reading in “patentable” into Article 70.2 creates redundancies as Canada previously argued.<sup>46</sup>

74. Clearly, a patent, which is the legal device through which the State protects an invention, is not subject matter within the ordinary meaning of Article 70.2. Consequently, the obligations referred to in that Article do not apply to patents themselves, once issued, and would therefore not include Article 33.

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<sup>41</sup> See: Paragraph 10 of the Oral Statement of the US.

<sup>42</sup> See: Paragraphs 66 and 67 of Canada’s first Oral Presentation, paragraphs 48 to 58 of Canada’s Second Submission as well as its answers to Panel Questions 6,7 and 27.

<sup>43</sup> See: the US responses to Panel Questions 7 and 13.

<sup>44</sup> Canada assumes the use of the word “generally” is a reference to the fact, noted in Canada’s answer to Panel Question 27, that in Articles 40.3 and 40.4 “subject matter” is used to refer to the matters under discussion elsewhere in the Article rather than to matters that may be the objects of intellectual property protection.

<sup>45</sup> See, for example the discussion of this issue in the US response to Panel Question 7. See also the discussion of the issue in paragraphs 48 to 58 of Canada’s Second Submission.

<sup>46</sup> See Canada’s Second Submission paragraphs 50 to 52.

## VII. CONCLUSION

75. Canada believes that this, contrary to the US characterization, is a complex case. It is full of subtlety and nuance. It raises important questions of the relationship between form and substance. Of course, it is, more particularly, a case about the meaning and scope of Article 33. And, depending on the answers to those two issues, it is perhaps also a case about the meaning and scope of paragraphs 1 and 2 of Article 70.

### **The context of this dispute**

76. The commercial stakes at issue are undeniably large. The US has made this very clear. It has said that Canada's alleged non-compliance with its TRIPS obligations have "caused tremendous<sup>47</sup>. And that this harm has been particularly severe for the pharmaceutical industry.

77. In its subsequent submissions the US has not pursued this aspect of its case. There is, however, no doubt that windfall monopoly profits would accrue to the pharmaceutical industry from extensions to the terms of protection that were granted by the Commissioner of Patents against applications which were filed in Canada prior to October 1, 1989. And that those windfall monopoly profits would be substantial.

78. Irrespective of quantum, there is an issue of equity that arises against those who, in the past, made an economic choice to exploit their section 45 patent terms in one way and now seek to vary the terms of their bargain with society. They wish now to exploit the new TRIPS term of protection regime for their private advantage and against the broader interest of society. This breaches two Article 7 objectives. It breaches the objective that intellectual property rights should contribute to the mutual advantage of its producers and of its users. And it breaches the objective that the intellectual property rules should contribute "to a balance of rights and obligations".

79. Thus the pith and substance of the US position is that it is attempting to obtain relief from the World Trade Organization that, as the Abbott case<sup>48</sup> demonstrates, would not be available under its own municipal law because of the inequity of the relief sought.

### **Summary of Canada's Case**

80. Against this background, Canada would like to thank the Panel for its close attention. Interpreting the relevant provisions of the TRIPS Agreement is seldom, if ever, an easy task. In this regard it has been Canada's goal throughout these proceedings to assist you in this challenge.

81. In further pursuit of this goal, Canada would sum up and reduce its submissions to their bare essentials by offering the following synopsis of its position.

### **The scope of the obligation in Article 33**

82. First, Article 33 imposes a single requirement which is: to make a term of patent protection **available** beginning on the date the patent issues and ending 20 years from the date on which the application was filed. That is how the US has characterized the requirement in its legislation. The Article does not impose a requirement for a 20 year term of protection as contended by the US in its

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<sup>47</sup> See: paragraphs 5 and 6 of the First (Written) Submission of the US.

<sup>48</sup> See: paragraph 100 of Canada's First (Written) Submission and Footnote 40 to that paragraph.

submissions. As the Agreement does not contain the very requirement upon which the US founds its complaint, it fails.

#### **The “equivalency” of terms of “effective” protection**

83. Second, the term of “effective” patent protection that, under the TRIPS formula, begins sometime during the course of the 20 years measured from the filing date, is **inevitably** less than 20 years. In Canada, it is normally 15 years. In the European Patent Office, it is of the same order.

84. The US, recognising the erosion of the term of protection that occurs as a result of processing delays, has recently guaranteed a minimum period of 17 years from grant, excluding from the calculation of ‘compensable delay’ any delays requested by the applicant. Canada’s section 45 regime guarantees an equivalent term of protection to that which, by virtue of its 17 year statutory guarantee, the US deems reasonable within a 20 year from filing date system.

85. There is no room for debate here. The US cannot seriously seek, on the authority of TRIPS, to have the WTO impose a more onerous substantive requirement on Canada than it, in compliance with its own TRIPS obligations, imposes on itself.

#### **The “availability” of a 20 year-from-filing term under section 45**

86. Third, all of the evidence before you is uncontradicted. It confirms and establishes that a period of protection of twenty years from filing grounded on a sound legal foundation was, under Canada’s Old Act, **available**. And, it was **available** without exception. These are the uncontested facts, there are no points of law involved. The period described in Article 33 was **available**. That is a complete answer to the US complaint.

#### **Article 70.1 and pre-application date “acts”**

87. Fourth, the US now concedes that, consistent with rule against treaty retroactivity set out in Article 28 of the *Vienna Convention on the Law of Treaties*, the acts of filing an application for a patent and the administrative act of granting a patent are within the scope of Article 70.1. These are complete and final acts all of which occurred before the date of application of the Agreement. This allows for only one answer. The Agreement, including Article 33, does not give rise to any obligations in respect of those acts.

#### **Article 70.2 and the meaning of “subject matter”**

88. Finally, the US over reads the meaning of “subject matter” within TRIPS in order to bring either “patents”, or the “term of protection” obligations respecting patents, within the scope of the obligation set out in paragraph 2 of Article 70. This misconstrues both patent law and the Agreement. Neither a “patent” nor the “term of protection” is “subject matter” within the meaning of TRIPS.

89. Nor, since the “term of protection” is not “subject matter”, can the Article 33 obligation respecting the “term of protection” be interpreted, as the US seems to suggest, as being “an obligation in respect of subject matter” within the meaning of paragraph 2 of Article 70. Consequently the obligation in Article 33 does not give rise to obligations under paragraph 2 of Article 70.

### **VIII. DISPOSITION REQUESTED**

90. For all these reasons as well as the reasons set out in Canada’s prior submissions and responses to Panel Questions, the US complaint fails and Canada respectfully asks that it be dismissed.

## ATTACHMENT 2.6

### RESPONSES OF CANADA TO WRITTEN QUESTIONS FROM THE PANEL – SECOND MEETING

(3 February 2000)

#### A. EQUIVALENCE

**Q.29 (Canada)** Even if Canada's Old Act patent term is roughly the same length as the New Act term, how does it satisfy the requirement as to when the patent term should end? Article 62.2 only authorizes curtailment of the patent term at the beginning, not the end, and Article 33 clearly specifies a minimum end date. Does this depend on the success of the availability argument?

As Canada will demonstrate the TRIPS Agreement does not impose a specific end point for a term of patent protection that must be met in all circumstances. In this respect Canada notes that Article 62, when read as a whole, is not limited to the authorization of the “curtailment” of the patent term at the beginning of the term of protection. Article 62 also contemplates and authorizes the termination of the term of protection, **before** the expiry of the period referred to in Article 33.

In contrast to the implicit argument of the United States of America (US), Canada does not believe that the term of protection provisions of Canada's Old Act section 45 and of TRIPS' Article 33 are susceptible, on their face, to direct comparison.

Canada does not believe that the section 45 formula—which provides for a specified, fixed term of protection measured from the date of grant—can be directly compared to the Article 33 formula—which provides for a variable term measured from the application filing date—because the two provisions reference different commencement dates and specify different numbers of years during which the different amounts of protection they refer to shall be “available”.

Since the two types of provision cannot be compared by simple reference to their **forms** of expression, Canada has, within its equivalency argument, sought to compare or assess the consistency of one with the other by an examination and analysis of the **substance** of the amount of protection described by the two different prescriptions of the term of protection.

As the Panel will recall from Canada's previous elaborations of its analysis, it proceeds from the basis that section 45 offers a guaranteed, fixed seventeen year term of protection for the exclusive privilege and property rights which, once granted, flow from a patent. It next observes—and the US concedes<sup>1</sup>—that, in view of the combined operation of Article 33 and paragraphs 1 and 2 of Article 62, the period of “effective” protection of the exclusive privilege and property rights will, under the TRIPS formula, vary.

The amount of variation will depend on the length of the Article 62.2 pendency period which, of course, delays the date of grant and so foreshortens the nominal amount of protection of the exclusive privilege and property rights available under the TRIPS formula. The amount of variation will also depend on the happening, under the authority of Articles 62.1 and 62.4, of any act of

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<sup>1</sup> See: the US response to Question 1(b) in the questions posed by the Panel at the conclusion of its first substantive meeting with the parties (December 20, 1999).



revocation, of cancellation or of default in the payment of maintenance fees. All or any of these will, of course, accelerate the expiry date of the patent in question and so truncate the amount of “effective” protection afforded to the exclusive privilege and property rights granted by a patent.

In the result, under the TRIPS formula neither the commencement date—the date of filing—nor the end date—the expiry of the twenty year period—can be said to represent a **fixed, substantive norm** of the quantum of “effective” protection offered by the scheme of the treaty. Accordingly, neither the commencement nor the end date parameters used by the Article 33 formula for determining the term of protection can be viewed as being fixed, **substantive requirements** or “benchmarks” of the “effective” protection contemplated by the treaty. They are instead elements of **form** within which **substance** is determined. Once the **substance** is determined, **form** loses any further significance in an assessment of the equivalency or consistency between one system for the measurement of the term of patent protection and the other.

As the Panel will also recall<sup>2</sup> in Canada the pendency period under the New Act’s, undeniably TRIPS consistent, formula has, whether as an average, a mean or a modal “norm”, been approximately 5 years.<sup>3</sup> In the result, in Canada the “normal” “effective” term of protection under its undeniably TRIPS compliant section 44 has, correspondingly, been approximately 15 years.<sup>4</sup>

Given this analysis and its results Canada has consistently framed it’s argument as being that a fixed term of 17 years from grant was equivalent or superior to the variable term that results from the formula in Article 33. This argument is not dependant on the availability argument, although the latter is complementary of the first.

In paragraph 8 of it’s Second Submission, the US asserts that Article 62.2 addresses the commencement of the term of protection and not the expiration date while Article 33 is concerned with the end of the period of protection. This assertion is unfounded and is based on an incomplete contextual analysis.

Article 33 addresses the commencement—being, the filing date—and the end—being twenty years from the filing date—of a period during which a patent will provide protection after the patent issues. Moreover, as noted above Articles 62.1 and 62.4 address TRIPS sanctioned actions which operate to deprive the Article 33 end date of any fixed meaning. Accordingly the provisions of Article 62 operate to reduce the dates referred to in Article 33 to matters of the **form of determining, not defining**, the amount of “effective” protection available under the Article.

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<sup>2</sup> See: paragraphs 53 and 54 of Canada’s First (Written) Submission, the Davies Affidavit, paragraph 29 and Exhibit F thereto, paragraphs 21 to 26 of Canada’s First Oral Presentation as well as the discussion in paragraphs 17 to 21 of Canada’s Second Oral Presentation.

<sup>3</sup> The five year pendency period compares favourably with the experience in the European Patent Office (EPO). See paragraph 30 of Canada’s Second Oral Presentation and footnote 23 to that paragraph. This pendency period would also appear to compare favourably with the US experience under its TRIPS compliant legislation since the US has been motivated to enact a *Patent Term Guarantee Act* that compensates successful applicants for delays in the grant of their patents that have exceeded three years. See: paragraphs 25 to 37 of Canada’s Second Oral Presentation and Exhibit No. 26.

<sup>4</sup> Canada has not presented any evidence in respect of the “normal” amount of “effective” protection that may be lost as a result of acts of revocation, cancellation or default of maintenance obligations because neither the TRIPS scheme—in place for about 4 years—nor its municipal counterparts—in place in Canada for about 10 years—have been in place for long enough to generate a reliable indication of the amount of term truncation that may be expected to occur. The doubtful reliability is enhanced by the fact that, *a priori*, acts of default are most likely to occur at the end of the nominal TRIPS term rather than in the early years of protection.

Article 62 by its plain language is concerned with both the acquisition and maintenance of intellectual property rights as stated in its title. Article 62.2 addresses unwarranted curtailment by procedures associated with obtaining the right; while Articles 62.1 and 62.4 address matters relating to the acquisition, maintenance and revocation of “effective” protection.

Canada recalls that in answer to Canada’s Question 4 following the first substantive meeting of the parties with the Panel, the US conceded that a patent owner could forfeit its patent by failing to pay maintenance fees at any time during the 20 year period counted from the filing date. The rationale for this admission is clear. A patent is a private right which the owner can, within certain legal limitations<sup>5</sup>, exploit or abandon as the owner chooses.

US municipal law accurately describes the TRIPS term of patent protection as a term beginning on the date the patent issues and, subject to the fulfilment of maintenance obligations, ending 20 years from the filing date. The term of protection which must be made available occurs within a twenty year time frame but is, as the US concedes<sup>6</sup>, inevitably less, whether by erosion of the commencement date or whether by truncation of the expiry date. There is nothing in the Agreement that requires a patent owner to either choose or accept a patent for an irrevocable period of time. A patent is a privilege, obtained on the application of and largely at a time controlled by the applicant, to be exploited as the grantee chooses. It is not a burden which the grantee must take up and discharge at the behest of and for a period prescribed by the grantor, irrespective of the grantee’s interests—whatever they may be.

Against this background, a Member’s obligation under Article 33 is to make a period of protection “available” which, subject to acts of revocation, cancellation and of default in maintenance obligations, does not end before twenty years from the filing date. That is the **form** or standard of measurement for the protection to be afforded. It is **not** a definition of the **substance** of the protection which is actually to be **realized** under the TRIPS obligation and against which a Member’s compliance is to be considered.

The substantive period of patent protection only arises after a patent issues and may, by either an act of revocation (or cancellation) by the granting authority or an act of default by the grantee, end at any time before the running of the term set out in Article 33. The US has conceded<sup>7</sup> that Article 1.1 allows that, within a Member’s legal system or practice, a Member is free to determine the method of achieving **substantive compliance** with its TRIPS obligations and is not limited by **matters of form**.

Canada has demonstrated that in Canada and Europe<sup>8</sup> the normal pendency period for the processing of an application is approximately five years, resulting in approximately 15 years of substantive or “effective” protection. This is less “effective” protection than the 17 years guaranteed by a section 45 patent.<sup>9</sup>

As the fourth Recital to the TRIPS Agreement acknowledges “intellectual property rights are private rights”, thus a patent owner is free in the exercise of its private property rights to terminate its “effective” term of protection prematurely without any negative impact on the grantor Member’s level

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<sup>5</sup> See, for example, Articles 29, 30, 31 and 40.

<sup>6</sup> See, the US response to the Panel’s December 20, 1999 Question 1.

<sup>7</sup> See: the US response to the Panel’s December 20 1999 Question 8.

<sup>8</sup> See: paragraph 30 of Canada’s Second Oral Submission and footnote 23 to that paragraph respecting the EPO’s average response times in respect of EPO patent applications.

<sup>9</sup> This too is less than the seventeen years of protection from grant recently guaranteed by the US’ new *Patent Term Guarantee Act of 1999*.

of compliance with its TRIPS obligations.<sup>10</sup> Similarly, in the prosecution of its application for patent privileges, an applicant is, within certain limits, free to choose when the privileges will be granted and so give life to the benefits of patent protection. Thus the substantive benefit of 17 years under section 45 is at least equivalent to the substantive, but variable, period of normally 15 years available under the TRIPS formula, no matter when it might occur in respect of the defined, nominal period which falls within the parameters set out in Article 33.

The period of “effective” patent protection is substantively equivalent and not dependant on a specific end date as described in Article 33, particularly as that period may be modified by the operation of the activities referred to in Articles 62.1, 62.2 and 62.4. Article 1.1 suggests that if the substantive obligation is met by a member’s legal system and practice, that is sufficient. As the US put it in answer to the Panel’s Question 8 of December 20, 1999:

So long as the relevant obligation [to provide a **patent** term of protection] is indeed fully implemented and has a sound legal basis in a Member’s legal regime, the precise method of implementation [17 years from grant term versus a variable 15 year from filing term] is left to the Member.

Canada’s section 45 regime does not specify an end date in relation to the application filing date. Canada’s law and practice does not, therefore, require the period to end before the expiry of any particular period measured from the filing date. Accordingly, an applicant acting in it’s own private interest is free to expedite or delay the issuance of it’s patent in the same way it is free, once possessed of a patent, to abandon or forfeit it’s patent and its patent rights whenever it chooses. In other words the commencement and end date benchmarks of the TRIPS formula for determining the term of protection circumscribe the limits of, but do not define, the minimum quantum of the “effective” term of protection that the Agreement requires its Members to provide to successful applicants for the patent privilege.

In Canada’s First Oral Presentation<sup>11</sup>, it observed that the inviolate condition precedent to a term of protection is a patent. It is Canada’s view that Article 33 reflects the TRIPS objective of the **effective** and adequate protection of intellectual property rights”.<sup>12</sup> (**Bold face** added for emphasis) The substantive concern of Article 33 is not the end date, which a patent owner can end early if it chooses, but rather the effective term of protection. Substantively, 17 years from grant provides more “effective” protection than a 20 year from filing regime. The US understanding and acceptance of this fact is reflected in it’s new *Patent Term Guarantee Act of 1999*.<sup>13</sup>

Accordingly, since within Canada’s “equivalency” argument the TRIPS end date only has significance for the purposes of determining the amount of “effective” protection offered by the Article 33 formula, it loses any further significance in the consistency analysis and is ‘spent’ once that analysis is complete.<sup>14</sup> In this sense the “equivalency” argument is sustainable on its own merit and is not dependant on the success of Canada’s “availability” argument.

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<sup>10</sup> This point has been conceded by the US in its response to Canada’s Question 4 posed following the first substantive meeting of the parties with the Panel.

<sup>11</sup> See: paragraphs 12 to 14 of the written version of that Presentation.

<sup>12</sup> TRIPS, the first or “desiring” recital to the Agreement.

<sup>13</sup> See: paragraphs 25 to 37 of Canada’s Second Oral Presentation and the associated exhibit, Exhibit No. 26.

<sup>14</sup> In simplistic arithmetic form the analysis says that: twenty years from filing less the pre-granting pendency period and less any period arising from acts of revocation or default in maintenance obligations equals the term of “effective” protection.

However, as noted above, the “availability” argument is complementary to the “equivalency” argument. Under Canada’s section 45 patent regime, the period of twenty years from filing, although not expressly identified by statutory reference was nevertheless “available” to any section 45 applicant who wished to view, measure, **seek** and **obtain** its term of protection on that basis.

Accordingly, if the end date prescription in Article 33 has, contrary to Canada’s view and analysis, any residual substantive content such that the Article 33 termination standard might be seen to defeat substantive equivalency, then the fact that the twenty year term from filing was unambiguously available under Canadian law and practice would operate to reinforce the “substantively equivalent” argument as a complete and unrefuted answer to the US complaint.

## B. AVAILABILITY (ARTICLE 33)

**Q.30 (Canada) Are the powers under Canada's *Patent Act* to reinstate and restore patent applications discretionary and not automatic? Is the Canadian Patent Office obliged to reinstate or restore applications which have been abandoned or forfeited simply to procure a delay in the term of protection?**

There are two discrete elements to this question. Both invite two answers: one technical; one contextual. The first technical answer is that under the Old Act some of the statutory powers to reinstate and restore patent applications were discretionary, some were automatic.

The section 73 remedy was automatic insofar as the relief was available as of right to an applicant who paid the necessary fee. In this sense the “powers” were not really “powers”. Instead they were, notwithstanding the statutory use of the permissive word “may”, more akin to duties of the Commissioner of Patents. As such the duty to grant relief could, on proof of the payment of the fee, be enforced in the courts by an applicant through the service of a writ of mandamus. There was, therefore, no administrative discretion at play.

The powers of relief under subsection 30(2) were discretionary insofar as, beyond the payment of a fee, they were only exercisable where the applicant-petitioner was able to satisfy the Commissioner that the applicant’s failure to meet the deadlines of the Old Act were “not reasonably

However, the quasi-constitutional rules of natural justice, which the courts will apply to the exercise of discretionary authority by administrative officials, require that the exercise of discretion not be unreasonably denied. Among others standards, the courts will, in applying the rules of natural justice, require that discretion be exercised in good faith, be exercised without discrimination, be exercised taking into account the purpose of the legislation granting the discretion and be exercised without reference to irrelevant or other improper considerations unrelated to the purposes or criteria of the statute granting the authority.

Thus the discretionary authority created by subsection 30(2) does not impose a serious impediment to or burden on any applicant who, knowing the circumstances of its own delay, may offer the explanation implicitly required by the statute and so deprive the Commissioner of the capacity to refuse the relief requested. In sum, although discretion exists it is not a discretion that may be exercised frivolously to deny relief where the delay involved resulted from some reasonable circumstance. In the world of patent applications there are myriad factors that may exist to impede an applicant’s capacity to proceed as expeditiously as the statute, in its arbitrary, general-rule-writing fashion, contemplates.

In respect of the second element of the question asked, the technical answer is that the statutory criteria that frame and limit the exercise of the discretion referred to in subsection 30(2) make no reference to the motive of an applicant seeking to have the discretion exercised in its favour. The test for the exercise of discretion is “not reasonably avoidable”.

In this circumstance, were an applicant to say “I merely wish to delay the issuance of the patent in question in order to obtain a twenty term from my filing date.” the Commissioner could, had the situation ever arisen, have been entitled to refuse the relief requested since the applicant, in revealing its motive, would not have shown that its failure to meet the deadlines of the application process was “not reasonably avoidable”.

However, were the applicant able to say—as the evidence clearly suggests—that, irrespective of its underlying motive, “I was unable to meet the statutory delays because of” some reason related to the timely completion of its application, then the Commissioner would have no authority to look behind that reason to examine the motive of the applicant and refuse relief requested on the basis of “motive”.

The contextual answer begins with the observation that the US complaint is only addressed to those Canadian patents where the application was filed before October 1, 1989—that is before section 44 came into effect—and which were granted before October 1, 1992.

The question posed by the Panel concerning the discretion to re-instate assumes that there may be circumstances where a discretion could be exercised to deny an applicant access to a term of protection equal to the period referred to in Article 33.

There is no evidence that anybody who requested the reinstatement of their patent application was ever refused that reinstatement by the Commissioner. A search of Canadian jurisprudence has revealed that no patent applicant has ever sought judicial review of an administrative decision to deny the reinstatement of a section 45 patent application.

Peter Davies, the Chairman of the Canadian Patent Appeal Board, has sworn that, in 33 years of experience, he is unaware of any situation where an informal request for a delay was refused. The evidence is that informal delays were granted without any necessity for the applicant to resort to the statutory provisions of subsection 30(2) of the Old Act.

As noted above, the statutory delay under section 73 of the Old Act was available automatically on payment of the required fee. The subsection 30(2) discretionary power to refuse reinstatement was never used. The section was ultimately repealed as being redundant. The reinstatement provision now forms part of the procedures under section 73 of the current Act and there is no discretion to refuse reinstatement so long as the applicant seeking reinstatement pays the appropriate administrative fee.<sup>15</sup>

In all these circumstances the existence of a discretionary power in the past has had no impact on any patent applicant. The evidence is uncontested. It shows that no applicant who sought a delay or who utilized the various statutory devices available in order to postpone the issuance of its patent was ever hindered in its achievement of that goal in any way. Neither the existence nor the exercise of the discretionary power in subsection 30(2) ever adversely affected any applicant. Moreover, no

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<sup>15</sup> Subsection 73(3) of the current Act now reads:

(3) An application deemed to be abandoned under this section shall be reinstated if the applicant (a) makes a request for reinstatement to the Commissioner within the prescribed period; (b) takes the action that should have been taken in order to avoid the abandonment; and (c) pays the prescribed fee before the expiration of the prescribed period.

one since October 1, 1992 could have been, or will be, affected by the existence or exercise of such powers because all patents issued after that date provide, or will provide, at least twenty years of term when viewed from the perspective of their application filing dates.

In these circumstances, whether or not the Canadian Patent Office was obliged to re-instate or restore applications which had been or were deemed to have been abandoned or forfeited simply to procure a delay in the issuance of a patent, is moot. The uncontested fact is that it did so in every case. And it did so without exception.

As Canada has argued in its First Oral Presentation at paragraph 46, the discretion in subsection 30(2) to refuse reinstatement where the applicant has failed to satisfy the Commissioner that the reason for its delay was “not reasonably avoidable”, although never exercised, is a reasonable formality for the maintenance of intellectual property rights within the meaning of Article 62 and as Canada also argued in that and the following paragraphs the existence of the discretion at issue posed absolutely no risk to a patent applicant’s right to seek patent protection for its invention.

**Q.31 (Canada) Paragraph 37 of your First Submission states that an Old Act applicant could "slow down the prosecution" of an application "by simply asking the patent examiner" and paragraph 42 of your First Oral Statement states that "the applicant could do so informally, simply by asking, or alternatively the applicant could take advantage of statutorily mandated delays for perfecting applications and other essential procedural steps." In addition to the delays provided under Section 30(1) and (2) and Section 73 of the Old Act:**

**(a) What type of delay can an Old Act applicant ask the patent examiner for?**

Beyond the formal delays available through the abandonment/forfeiture and reinstatement procedures permitted by the statute and the regulatory delay of the final issuance referred to in subparagraph 10 v) of the Davies Affidavit<sup>16</sup>, the “informal” delays referred in the question and in the Canadian materials referenced by the question were, just as described, “informal”. That is to say that they were not a delay of any particular or defined “type” or “class” of delay.

As the Davies affidavit makes clear, where an applicant may have had an interest in postponing the issuance of its patent as, for instance, was often the case with a pharmaceutical applicant seeking a closer confluence between its patent term and its marketing approval, it simply needed to approach the examiner and ask him or her to retard the position of a particular application in the queue of those applications awaiting examination.

Since the patent granting authority and its examiners are typically only interested in getting a targeted amount of work done within a targeted time frame, they have little interest in whether the targets are met by examining any particular application at any particular time. Consequently, they have neither a private nor a rule-based reason not to behave in a fashion that accommodates the private timing interests of an applicant.

However, while there may not be any rule categorizing “types” or “classes” of delay, there were several common types of circumstance in which an applicant might approach an examiner to request the postponement of the examination of its application. One such situation was where the applicant had an interest in a “co-pending” application, and wished to ensure that the two related patents would issue on the same date. Another was where the applicant was in the process of preparing to file a “divisional” application for a previously filed application and wished to delay the

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<sup>16</sup> Affidavit of Peter J. Davies, Chairman of the Patent Appeal Board of the Canadian Patent Office. Reproduced in its entirety as Exhibit No. 8. Hereafter cited as: Davies affidavit.

issuance of the patent against the previous application because one may not divide—“divisionalize”—an issued patent. A third involves the situation where the applicant is preparing a voluntary amendment to its claim and so wishes to forestall the examiner from writing an unnecessary report (to which the applicant would, of course, need to respond).

**(b) What is the duration of the delay that a patent examiner is authorized to allow an Old Act applicant?**

As noted in the answer to paragraph (a) of this question, the delays or postponements described in the Davies affidavit, were informal delays or postponements and as such they were neither authorized nor unauthorized. They were agreed to by examiners as a matter of professional discretion, courtesy and client service.

In these circumstances the delays or postponements involved could have been for a relatively short period or for a longer period of several years. It was not uncommon, for instance, for applicants for pharmaceutical product or process patents to seek postponements of several, sometimes as many as six or seven, years duration so that the term of their exclusive marketing rights under the patent would not be reduced and ‘wasted’ while the pharmaceutical product in question was waiting for marketing approvals from the competent health and safety authorities.

That said, it is important to understand that while examiners enjoy a certain amount of professional discretion in the exercise of their duties, the length of the delay they might be prepared to entertain as a matter of discretion and courtesy would be subject to, or influenced by, the reason advanced by the applicant in support of its request.

Thus, for example, if an applicant requested a delay to amend its original claims or to file a “divisional” application, the time reasonably required to do either of those things would clearly serve to set limits on the length of the delay or postponement that the examiner might tolerate. The tolerance of examiners would also have been disciplined by the productivity standards or expectations of their immediate supervisors as well as of the institutional expectations of the authority in which they work.

**(c) On what grounds can the patent examiner refuse such a request?**

An informal request for postponement, like the informal agreement to postpone, is an “informal” matter. As such an informal request for delay, like the informal agreement to permit a delay, is not bound by any formal rules defining what is “acceptable” and what is “not acceptable”.

However, the informal postponements available under Canadian administrative practice existed in the shadow of the formal procedures available to procure formal postponements or delays in the granting process.

Accordingly, just as the Commissioner may not unreasonably refuse to exercise his or her formal, statutory discretion to reinstate an application in favour of an applicant who offers some reasonable explanation of why its delay was “not reasonably avoidable”, examiners would not, under the discipline of the rules of natural justice and the doctrine of reasonable or legitimate expectations<sup>17</sup>, be able to lightly refuse a reasonable request for a postponement of the issuance of a particular patent.

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<sup>17</sup> The doctrine of reasonable or legitimate expectations holds that the legislative and executive branches of government may not deny an applicant the benefit of some procedure or process where the procedure or process has, as a matter of practice, previously been available to applicants in analogous circumstances. It is usually viewed as being an extension of the rules of natural justice and procedural fairness.

In this latter respect Canada would refer back to the examples justifying postponements that are described in the answer to paragraph (b) of this question, and suggest that they offer some guidance as to when an examiner might refuse to exercise his or her professional discretion to grant a postponement or a postponement for the time requested.

Since the examples of justified postponement are linked to the reason for, and the reasonableness of, the requested postponement, it would, in the absence of any formal rule, be reasonable to conclude that examiners would refuse requests which were “unreasonable”.

**Q.32 (Both parties) Does the TRIPS Agreement permit Members to give patent applicants a choice between either obtaining protection early, or obtaining a term of protection that expires twenty years from the filing date?**

Yes, in theory. Although it is not clear on its face that the TRIPS Agreement actually provides for the bipolar choice described by the question. However, the Agreement certainly does not prevent a Member from making such a choice available.

The obligation in Article 33 is straightforward. It requires Members to provide that “The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.” Once a Member has, consistent with its Article 1.1 rights and obligations, adopted laws or practices that make the term referred to “available” on a sound legal basis, neither Article 33 nor any other TRIPS obligation prevents a Member from also making alternative terms of protection available to such applicants who might, for their own private commercial or other strategic interests, wish to obtain patent protection on a different basis than that referred to by Articles 33 and 62.

In this respect it is useful to recall, as the recitals to the Agreement plainly recognize, that “intellectual property rights are private rights.”<sup>18</sup> It is similarly useful to recall that the US has conceded<sup>19</sup> that, as an incidence of the private nature of patent rights, patent owners have the right to alienate, abandon or forfeit their exclusive patents rights on whatever terms they find acceptable.

It follows from the foregoing that: since TRIPS does not prohibit Members from offering alternative terms of protection to patent applicants so long as the latter have a right to obtain the term referred to in Article 33; and, since, applicants and patentees are free to deal with their private property rights as they choose, a Member could, without breaching its TRIPS obligations, offer an alternative term of protection formula which would provide greater certainty of protection to the applicant by expediting the granting process and specifying a fixed term of protection that would, while offering a substantively equivalent amount of “effective” protection, end on a date that would occur before the date referred to in Article 33.

In such a scheme the applicant’s part of the bargain would, of course, be that it agrees, in the exercise of its private property rights, to forfeit or abandon its right to obtain a term of uncertain duration that would, nevertheless, not end before the expiration of the twenty year period counted from its application filing date.

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See: *Reference re Canada Assistance Plan (British Columbia)*, 1991 2 S.C.R. 525; (1991) 83 D.L.R. (4<sup>th</sup>) 297. (Supreme Court of Canada)

<sup>18</sup> TRIPS, third “recognizing” recital.

<sup>19</sup> See the US response to Canada’s Question 4 as posed during the first substantive meeting of the Parties with the Panel (December 20, 1999).



In sum the alternative scheme would offer patent applicants the hypothetical choice set out in the question. That is to say that the alternative would give applicants a choice between the variable term of protection provided for by the TRIPS formula and a more certain period of protection that would be available on an accelerated basis but would require the applicant to forego the right to a term that did not end before the date referred to in Article 33.

**Q.33 (Both parties) If Article 70.2 rendered Article 33 applicable to inventions under protection in developed country Members on 1 January 1996, would it require those Members to make available on that date a term of protection for existing patents that did not expire before the end of 20 years from their respective filing dates or would it be sufficient that that term was available at the time that the patent application was filed?**

In the circumstance assumed by the question, it would be sufficient if the term was available at the time the application was filed. Indeed, as Canada has argued, the unchallenged facts that the period was indeed available at the time applications were filed for section 45 patents is a complete answer to the US case in any circumstances. Canada of course has argued that Article 70.2 does not render Article 33 applicable to section 45 patents on two grounds.

First, no obligations arise under the Agreement in respect of an act of filing an application or an act of issuing a patent for a fixed term where those acts occurred before January 1, 1996, being the date of application of the Agreement for developed country Members. Second, a patent is not “subject matter” within the meaning of the TRIPS Agreement<sup>20</sup> and consequently an obligation in respect of the **term of a patent** cannot be an obligation in respect of “**subject matter**”.

The burden is on the US to establish that the non-retroactivity rule in Article 70.1 does not apply so as to take those “acts” outside the scope of Article 70.2 upon which, of course, its argument relies. It has not discharged this burden. Moreover, the US has not addressed, let alone refuted, Canada’s submission that the obligation under Article 33 is triggered by the act of filing an application and is confirmed by the act of issuing a patent and that the Article is, therefore, an obligation in respect of those Article 70.1 “acts”. The US admits<sup>21</sup> that both these “acts” are, where they occurred prior to January 1, 1996, within the scope of Article 70.1. Consequently, the US admits that neither “act” gives rise to obligations under the Agreement. However, the US goes on in the face of the plain language of Article 70.1 to argue, without reason or logic, that, nevertheless, the Agreement gives rise to obligations in respect of the patent term that is an integral<sup>22</sup> element and feature of those pre-application date “acts”.

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<sup>20</sup> The US has conceded that a “patent” is not “subject matter” within the meaning of the Agreement, see the US response to the Panel’s December 20, 1999 Question 7. The US has also agreed with Canada that “subject matter” refers to the object of protection, that is the work, mark, indication, industrial design, invention or layout-design that attracts protection.

<sup>21</sup> See the US response to the Panel’s December 20, 1999 Question 11 and paragraph 25 of its Rebuttal Submission.

<sup>22</sup> See paragraph 56 of Canada’s Second (Written) Submission, paragraph 60 of Canada’s Second Oral Presentation and Exhibit No. 24.

**Q.34 (Both parties) How can those applicants whose patents were granted before the date of application of the Agreement be said to have chosen to forego a later term when the TRIPS Agreement had not even been applied?**

Canada has addressed this question in its prior submissions and answers to questions.<sup>23</sup> The issue is not whether a particular TRIPS formula was known years before it was negotiated, obviously it was not.

Section 45 patent applicants knew that when a patent issued it was guaranteed 17 years of “effective” protection. Those applicants also knew that Canada’s law and practice permitted the applicant to take advantage of formal rules and informal administrative practices to control the issuing date of the patent such that it would issue either at an earlier or later time than normal. On the evidence before the Panel applicants clearly exercised this control in pursuit of their own choices as determined by their own private interests.

Canada’s published laws and regulations, which applicants are deemed or presumed by law to know, provided for delays in excess of 42 months. When these formal delays are combined with the other opportunities for formal statutory or informal administrative delays described in Canada’s Exhibit 8, there is no question but that periods of protection of twenty years or more were, when measured from the application filing date, available. The uncontradicted evidence is that more than 150,000 applicants succeeded in obtaining terms of protection that, when measured from the application filing date, were equal to or longer than twenty years. The uncontradicted evidence also shows that no one who desired a similar term was ever denied it.

C. EXISTING SUBJECT-MATTER (ARTICLE 70)

**Q.35 (Canada) Do you argue that Article 70.2 does not apply to inventions under protection of Old Act patents at all because of the words "Except as otherwise provided for in this Agreement...", or do you argue that it applies to them in some respects, or do you argue both as alternatives?**

Canada argues that, by virtue of Article 70.2, some of the obligations under the Agreement apply to and are in respect of “subject matter” recognized by and protected under the Old Act. Canada also argues that Article 70.2 does not apply to all of the obligations of the Agreement respecting patents.

More particularly, Canada argues that the obligation under Article 33 does not fall within the scope of the obligations that are referred to in Article 70.2. Article 70.2 does not apply to the Article 33 obligation both because of its own deference to the “otherwise provided” prescriptions of Article 70.1 and because Article 33 is not an obligation in respect of the “subject matter” referred to in Article 70.2.

In this latter respect, an obligation in respect of the act of applying for or the act of issuing a patent which occurred prior to January 1, 1996 is not within the scope of Article 70.2 because Article 70.1 expressly provides otherwise. A patent term is granted as an integral element of, and attaches to, the patent itself. A patent is not “subject matter” within the meaning of TRIPS. The US concedes this fact.<sup>24</sup> Accordingly Article 33, which sets out the TRIPS obligation respecting the term

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<sup>23</sup> See for example paragraphs 97 to 101 of Canada’s First (Written) Submission, Canada’s response to the Panel’s December 20, 1999 Question 24(a) and paragraphs 39 to 41 of Canada’s Second Oral Presentation.

<sup>24</sup> See the US responses to the Panel’s December 20, 1999 Questions 7 and 13.

of protection to be attached to a patent, cannot be an obligation in respect of “subject matter” as that term is used and understood within the Agreement.

**Q.36 (Canada) If you argue that Article 70.2 applies to inventions under protection of Old Act patents in some respects, do you argue that it only applies to rights conferred in relation to inventions but not to the term of protection? If so, why?**

Yes. As explained in the answer to questions 5 and 7, the obligation respecting the term of protection that is set out in Article 33 is an obligation that is in respect of two acts, namely: the act of filing a patent application; and, the act of granting a patent.

The act of filing is the trigger which, subject to acts of revocation, cancellation and default in maintenance obligations, sets the expiry date for the term of protection. However, there can be no term of protection unless a patent is in fact granted because there is no basis for the protection of the invention unless and until the patent is actually granted. Therefore, the commencement of the term of protection is triggered by the act of grant. Accordingly, both the commencement and the expiry of the term of protection depend upon the occurrence of these two successive and related acts.

The obligation in Article 33 is clearly an obligation in respect of “acts” and Article 70.1, which confirms or reproduces the rule against non-retroactivity set out in Article 28 of the *Vienna Convention on the Law of Treaties* (Vienna Convention), states, in unequivocal terms and without exception, that TRIPS does not give rise to obligations in respect of “acts” which occurred before 1 January 1996.

The wording of the obligation described in Article 33 reinforces this conclusion. The concept of making something “available” which is central to the obligation described in Article 33 clearly indicates an intention that the obligation is to be applied prospectively in respect of future acts and not retrospectively or retroactively in respect of past acts. Were it otherwise the Agreement would be retroactive in respect of this obligation and the US has clearly indicated that, in the case of the Article 70.2 obligation, the Agreement is not retroactive.<sup>25</sup>

Tellingly, the US has regularly used the word “prospectively” in respect of the application of TRIPS obligations throughout the material that it has filed with the Panel.<sup>26</sup> The word prospective means, “in the future”, as distinguished from “retrospectively” or “retroactively”. Canada agrees. Article 33 is to be applied prospectively to acts of grant that occurred on or after 1 January 1996 and not, by virtue of the direction of Article 70.1, retroactively to “acts” of filing or grant that occurred before that date.

Canada assumes that the reference in Question 8 to “rights conferred in relation to inventions” refers to the rights described in Article 28. Article 28 provides that a patent shall confer on its owner certain exclusive rights. Unlike the obligation in Article 33, which is principally temporal in nature because of its linkage of both the commencement and the expiry dates of the term of protection with, as the case may be, the acts of filing and granting, the obligation in Article 28 does not depend upon the occurrence of any act.

The operation of Article 28 depends solely upon a patent being in existence, and would apply to any patent, whether Old Act or New Act, regardless of when issued. As Canada pointed out in paragraph 68 of its Second Submission, these rights are conferred by the patent itself. As is clear from the language of Article 28, they arise by virtue of the fact that the patent exists.

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<sup>25</sup> See paragraphs 14 and 15 of the Oral Statement of the US.

<sup>26</sup> The most recent reference is to be found in its Oral (Rebuttal) Statement at paragraph 22 and see too paragraph 15 of its (first) Oral Statement.

It is significant that the drafters of the TRIPS Agreement dealt with the rights that attach to a patent (Article 28) and the term of protection (Article 33) in two spatially and connotatively separate as well as distinctively worded provisions. Article 28 states unequivocally that a **patent** shall confer the exclusive rights enumerated therein. Such rights do not include a right to a term of protection. (Article 33, of course, sets out the formula for determining the term of protection and establishes the obligation that the term, as thereby circumscribed, shall be made “available” by Members.)

The time at which the rights must be made available is clearly at the time that the act of grant occurs because the rights flow from the patent itself as opposed to the act of grant. However, aside from the fact that both the commencement and the expiry of the term of protection described in Article 33 depend, respectively, upon the occurrence of the acts of grant and filing, Members cannot, simply because the rights arise as of the date of grant, be expected to make available terms of protection in respect of acts of grant that have already occurred.

Had the TRIPS drafters intended this retroactive result, the term of protection would have been included in Article 28 as a right “conferred” by a patent and the rule against retroactivity in Article 70.1 would have been expressly overruled by the association of the term of protection with the other rights conferred by the patent as opposed to its existing association within the Agreement with the acts of filing and granting.

Alternatively and more directly, the drafters could have taken two other approaches to the issue. First they could have adopted a provision, like the Article 70.6 provision, which would have explicitly made the Article 33 obligation retroactive to a time before the coming into effect of the treaty, notwithstanding that, when granted, the term granted was in accordance with the then prevailing municipal law. Second, they could have written Article 70.2 to say that ‘except as otherwise provided by the Agreement, TRIPS would give rise to obligations in respect of “subject matter” and “terms of protection” existing at the application date’

Given their creation of and agreement to the retroactive rule respecting compulsory licences, the fact that the TRIPS negotiators did neither in respect of the term of protection obligation is telling evidence of their intentions. They clearly understood how to make an obligation retroactive, and they clearly did not do so in respect of Article 33.

**Q.37 (Canada) Why is the term of protection an "integral part" of the act of grant but the scope of the rights is not?**

The term of protection is an “integral part” of the act of grant because the term of protection is made (to use the word in Article 33) “available” to a patent owner when the act of grant occurs, and the commencement of the term of protection is triggered by the act of grant.

Since the term of protection is an “integral part” of the act of grant in the sense just described, the obligation in Article 33 is an obligation in respect of the act of granting a patent (as well as the act of filing a patent application) and, thus, subject to the non-retroactivity rule in Article 70.1. The other rights referred to in the question are those described in Article 28. As stated in the response to Question 8, Article 28 is structured completely differently from the term of protection provision in Article 33. It is clear from the wording of Article 28 that the rights referred to there are conferred by the patent and unlike the term of protection, these rights are in respect of the invention (subject matter) and are not dependent on or derived from the happening of the act of grant or any other act.

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<sup>27</sup> See the second last paragraph of that response.

<sup>28</sup> Any Old Act patent granted on or after October 1, 1992 received (or if the application is still pending will receive) a term of protection equal to or in excess of TRIPS obligations.

Canada assumes that the reference to “other obligations in this Question with respect to subject matter already protected” is intended to refer primarily to the rights conferred by a patent and acquired pursuant to Article 28. As noted in the response to Question 8, Article 28 is drafted in a manner such that the rights described therein are conferred by, and therefore attach to, the patent. Canada conferred the rights described in Article 28 under both the Old Act and the New Act, so the application of Article 28 to the affected patents cannot in fact result in any windfall to the affected patent owners.

In any event, the concept of exclusivity lies at the heart of any patent regime. While the application of Article 28 to patents issued before 1 January 1996 in a patent regime of a member that provided less than the full range of rights described in Article 28 might clarify and even expand upon the rights and therefore the profits of an owner of a pre-1996 patent, that owner would already have been enjoying a substantial degree of exclusivity and could hardly be said to have received a windfall of the magnitude that would flow from the wholesale extension of a predetermined patent term that is at issue in these proceedings.

Further and again in any event, the principal TRIPS obligation to which the TRIPS drafters ascribed any real retroactive significance was the obligation respecting the termination of the then lawful compulsory licenses which, by virtue of the demonstrably retroactive provisions of Article 70.6, gave effect to the obligation in Article 31 some four years before the Agreement actually came into effect for developed country Members. The fact that the TRIPS drafters did not include a similar rule respecting time-limited bargains consummated through acts of grant occurring before 1 January 1996 clearly indicates that they did not intend that such bargains be disturbed.

The issue of equity impacts on the entire US case. The US demands that Article 33 and 70.2 be interpreted in a manner that would re-open the bargains with all patent owners whose patents were issued with terms of protection that were less than 20 years measured from the application date. And that those terms be extended resulting in windfall profits of tens and perhaps hundreds of millions of dollars to individual patent owners at the expense of Canadian consumers. And those gratuitous extensions of terms of “effective” protection would do so without any reciprocal benefits for Canadian society.

As previously observed, if the TRIPS negotiators had intended such far reaching and extraordinary results, they were required by Article 28 of the Vienna Convention to use unequivocal language or unequivocal descriptions of circumstance such as that or those to be found in Article 70.6. In marked contrast the TRIPS drafters, through Article 70.1, expressly reaffirmed the non-retroactivity rule which is a general principle of international law and has been specifically recognized as such by the Appellate Body in *European Communities - Regime for Bananas*.<sup>29</sup>

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<sup>29</sup> *European Communities – Regime for Bananas, WT/DS27/AB/R*, at paragraph 235.