WORLD TRADE ORGANIZATION

WT/DS114/13
18 August 2000

(00-3328)

CANADA – PATENT PROTECTION OF PHARMACEUTICAL PRODUCTS

Arbitration
under Article 21.3(c) of the
Understanding on Rules and Procedures
Governing the Settlement of Disputes

Award of the Arbitrator
James Bacchus

I. Introduction

1. On 7 April 2000, the Dispute Settlement Body (the "DSB") adopted the Panel Report in *Canada – Patent Protection of Pharmaceutical Products* ("*Canada – Pharmaceutical Patents*").[1] On 25 April 2000, Canada informed the DSB, pursuant to Article 21.3 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (the "DSU"), that it would implement the recommendations and rulings of the DSB in this dispute; however, Canada said that it would require a "reasonable period of time" to do so, under the terms of Article 21.3 of the DSU.

2. Consultations between Canada and the European Communities on the duration of the reasonable period of time for implementation occurred but these did not result in agreement.

3. By joint letter of 20 June 2000, Canada and the European Communities notified the DSB that they had agreed that the duration of the reasonable period of time for implementation should be determined through binding arbitration, under the terms of Article 21.3(c) of the DSU, and that I should act as Arbitrator. The parties also indicated in that letter that they had agreed to extend the time period for the arbitration, fixed at 90 days by Article 21.3(c) of the DSU, until 31 August 2000. Notwithstanding this extension of the time period, the parties stated that the arbitration award would be deemed to be an award made under Article 21.3(c) of the DSU. My acceptance of this designation as Arbitrator was conveyed to the parties by letter of 21 June 2000.

4. Written submissions were received from Canada and the European Communities on 6 July 2000, and an oral hearing was held on 20 July 2000.

II. Arguments of the Parties

A. *Canada*

5. Canada submits that the implementation of the DSB's recommendations and rulings in this case can be accomplished through regulatory change rather than through legislative amendment, which Canada submits is usually more time consuming.[2] Given the extent of consultations required in this contentious field, Canada believes that the regulatory process can be carried out and finalized in a maximum of 11 months' time from the date of adoption of the Panel Report.

6. In its submission, Canada explains the process by which changes are made to its regulatory regime. According to Canada, the Government of Canada Regulatory Policy ("Regulatory Policy") states that the use of the government's regulatory powers should result in "the greatest net benefit to

[1]WT/DS114/R.

[2]Canada's submission, para. 9.

Canadian society". Accordingly, authorities who propose the exercise of regulatory power are obliged to demonstrate that the benefits of regulating clearly outweigh the costs, and that an effort has been made to structure the regulatory measures so as to maximize the benefits to Canadians and minimize the costs.

7. Canada explains that, in the normal course, the department with responsibility for the area in which the problem has arisen, in this case, the Department of Industry, should include information about the problem in its Report on Plans and Priorities, a document which is tabled in the Canadian Parliament. Where a potential regulatory initiative has not been so planned and reported, the department must nevertheless explain the rationale for its planned regulatory proposal regarding the problem in its Departmental Regulatory Plan. In the Department of Industry, that information is reviewed by the Department's Senior Policy Committee, which evaluates and categorizes the proposal.

8. The responsible department is then required to draft a proposed regulation. The department must also prepare a Regulatory Impact Analysis Statement (the "RIAS"), which describes the purpose of the draft regulation, the alternatives considered, a cost-benefit analysis, the results of consultations with interested parties, the department's response to the concerns raised, and how the regulation will be enforced.

9. Canada further clarifies that, pursuant to the provisions of the Canadian *Statutory Instruments Act*, the proposed regulation and supporting documentation, including the RIAS, must be produced in both English and French, Canada's two official languages. They must then be approved by the responsible department's legal services and senior management, and sent to the Clerk of the Privy Council and to the Deputy Minister of Justice for review. The Privy Council Office ensures that the proposal is consistent with the government's overall program and that the responsible department has adequately considered the communications aspects of the proposed regulatory action. The Regulations Section of the Department of Justice examines the regulation to ensure that it has a proper legal basis and, in particular, that "it does not trespass unduly on existing rights and freedoms and is not, in any case, inconsistent with the purposes and provisions of the *Canadian Charter of Rights and Freedoms* and the *Canadian Bill of Rights*".[3]

10. Canada explains that the Regulatory Policy also requires that the complete documentation in support of a proposal be sent to the Regulatory Affairs and Orders in Council Secretariat of the Privy Council Office, which is the agency responsible for administering the Policy. The Secretariat reviews the proposal to ensure that it is consistent with the Policy and, in particular, that: the responsible

[3]Canada's submission, para. 14.

department has considered other alternatives; the benefits of regulation clearly outweigh the costs; adequate consultation with the public has taken place, to allow Canadians to understand the proposed regulation and to participate in the process; and the responsible department has cooperated with Canada's provincial governments to ensure that the proposed regulation does not duplicate or overlap any provincial measure.

11. Once these reviews have been completed, the Minister of the responsible department approves the regulation and supporting documentation and submits them to the Privy Council Office for consideration by the Cabinet's Special Committee of Council (the "SCC"), which is the Cabinet committee that gives Governor in Council approval for the pre-publication of a draft regulation and its accompanying RIAS. The Regulatory Policy requires pre-publication of a regulation in order to provide the Canadian public at large, as opposed to the more limited constituencies initially consulted by the responsible department, with an opportunity to comment. Upon approval by the SCC Ministers, the regulation and its RIAS are published in the Canada Gazette, Part I, and must be open for public comment for at least 30 days.

12. Comments received from the public must be weighed on their merits and changes to the proposed regulation must be considered. If the proposed regulation is changed, the Department of Justice Regulations Section must again examine and approve the revised version before it is sent for final approval by SCC Ministers. If the proposed regulation is amended, the RIAS must also be changed to reflect the amendment.

13. Ministers consider each proposed regulation on its own merits. If they approve the regulation, it is registered under a statutory orders and regulations number within seven days of the Governor General's signature. The regulation will come into force on a date specified by the Governor in Council or, where not so specified, on the day of registration. The approved regulation and its RIAS are then forwarded for publication in the Canada Gazette, Part II, which is published by the Queen's Printer every second Wednesday. Pursuant to subsection 11(1) of the *Statutory Instruments Act*, publication must take place no later than 23 days after registration. Once published, the regulation becomes enforceable as law, as the public is deemed to have notice of the change in the r5 Tw ( ) Tj 22.m2abinet's/F1 11.25 TTc 0.477t is sent for

time from the date of the adoption of the Panel Report by the DSB. Canada breaks this period down as follows:

(a) 2 weeks for identification and assessment, which involves the preparation of an explanation as to why the measure is needed and a reference by the Department of Industry to its Senior Policy Committee for evaluation of the Regulatory Plan and review of the regulatory proposal;

(b) 3 months for the drafting of the proposed regulation and RIAS; review by relevant Department of Industry committees; review and approval by Department of Industry legal services; development of a communications plan; forwarding of the proposed regulation for examination by Department of Justice Regulations Section; informal review by the Privy Council Office; final Department of Industry review and approval for pre-publication and signature of the Minister of Industry;

(c) 2 weeks for the formal submission of the regulatory package to the Privy Council Office for submission to SCC for pre-publication and approval. The material must be submitted at least one week in advance of a scheduled meeting. Meetings are generally held weekly, but less frequently during Parliamentary recesses. In this respect, Canada notes that its Parliament is currently in recess until the end of September 2000;

(d) 1 month and 1 week for the pre-publication in Canada Gazette, Part I and receipt of questions and comments from the public;

(e) 1-3 months for the response to public comments; amendment of the regulation and RIAS as required; resubmission to Department of Industry legal services and Department of Justice Regulations Section; review and approval for final publication and signature of the Minister of Industry; and

(f) 2 weeks for the formal submission of the regulatory package to the Privy Council Office for submission to SCC for final publication approval; final publication in Canada Gazette, Part II.[4]

15. Canada submits that although the above breakdown totals 8-9 months, it may not be possible to carry out the needed consultations during that time, or to receive the views and advice from all of the relevant constituencies, since critical aspects of the process will occur during the summer vacation

[4]Canada's submission, para. 19.

period of July and August. Accordingly, in order to ensure that these essential steps are properly carried out, Canada argues that the total period should be increased to approximately 10-11 months.

16. Having explained its regulatory process, Canada turns next to a review of previous arbitrations under Article 21.3(c) of the DSU. Canada submits that, in previous arbitrations, arbitrators have consistently begun their assessments by considering the guideline contained in Article 21.3(c) itself. A guideline for the arbitrator should be that the reasonable period of time to implement DSB recommendations should not exceed 15 months from the date of adoption of a panel or Appellate Body report.

17. Canada submits that the reasonable period of time may be shorter or longer, depending on particular circumstances. Canada recalls that, as the arbitrator in *Australia - Measures Affecting Importation of Salmon* ("*Australia – Salmon*") put it, "what constitutes a 'reasonable period of time' depends upon the action which [the implementing Member] takes under its legal system to implement the recommendations and rulings of the DSB."

exception. According to Canada, Subsection 55.2(2) of the *Patent Act* will thereby be rendered of no legal force or effect. Revocation of the Regulations will completely deprive subsection 55.2(2) of the *Patent Act* of any meaning or effect. As a result, no one who has availed themselves of the protection of subsection 55.2(1) -- the "regulatory review" exception -- for the purposes of developing and submitting samples of a competing version of a patented product to regulatory authorities for their review will, on the coming into force of the revoking regulation, be entitled to further manufacture or further stockpile products prior to the expiration of the term of the relevant patent. The protection from infringement liability created by the combination of the theory expressed in subsection 55.2(2) and the practical substance given to that theory by the Regulations will be wholly terminated by the revocation.

21. Canada emphasizes, however, that "the revocation of the *Manufacturing and Storage of Patented Medicines Regulations* will be a very sensitive political matter in Canada", and, thus, that extensive consultations with stakeholders, interest groups and the general public will be required.[7] In Canada's view, a maximum of 11 months' time is, therefore, needed in order to conduct the necessary consultations, as well as to comply with the various procedural requirements of the *Statutory Instruments Act* and the Regulatory Policy.

22. Canada, therefore, requests the arbitrator to rule that 11 months from 7 April 2000, the date of adoption of the Panel Report by the DSB, is the reasonable period of time for the implementation of that ruling in this case. Thus, Canada proposes a "reasonable period of time" for implementation that would end on 7 March 2001.

B. *European Communities*

23. The European Communities submits that to implement fully the recommendations and rulings of the DSB, Canada must repeal Section 55.2(2) of its *Patent Act*, which the Panel in this dispute found to be inconsistent with the requirements of Article 28(1) of the *TRIPS Agreement*.

24. The European Communities is of the view that implementation of the DSB recommendations in this case requires the repeal of Section 55.2(2) of the *Patent Act*, that is, legislative, and not regulatory action. The European Communities considers that "it is only necessary to repeal a single subparagraph, which is separable from the remainder of the provisions of which it forms part".[8] The European Communities argues that "this can be performed in a period of time significantly shorter

[7]Canada's submission, para. 28.

[8]European Communities' submission, para. 4.

than the indicative maximum period" of 15 months provided for in Article 21.3(c) of the DSU.[9] The European Communities argues that, in any event, the "reasonable period of time" in this matter must not be a period longer than 12 months counted from 7 April 2000, the date of the adoption of the Panel Report in this dispute by the DSB.

25.

Patent Act, which can only be achieved through another legislative act (*actus contrarius*

III. Determination

33. Canada has agreed to implement the recommendations and rulings of the Dispute Settlement Body ("DSB") in *Canada – Pharmaceutical Patents*.[15] Canada has also, however, availed itself of Article 21.3 of the Dispute Settlement Understanding ("DSU"), which states in relevant part:

> If it is impracticable to comply immediately with the recommendations and rulings, the Member concerned shall have a *reasonable period of time* in which to do so. (emphasis added)

34. As the duration of the "reasonable period of time" in this case has not been agreed by either the DSB, under Article 21.3(a), or the parties to the dispute, under Article 21.3(b), the parties have requested that I determine this period of time through binding arbitration under Article 21.3(c). This provision of the DSU refers to the possibility of "binding arbitration within 90 days after the date of adoption of the recommendations and rulings".

35. .[15]c)o fulfi shmyhave

another legislative act (actus contrarius)."[19] For this reason, the European Communities states that "it is fundamental for the arbitrator to define the nature of the measure necessary to implement the recommendations and rulings of the DSB."[20] Canada, in turn, maintains that I have no such authority or mandate.

38.

41. As an arbitrator under Article 21.3(c), certainly my responsibility includes examining closely the relevance and duration of each of the necessary steps leading to implementation to determine when a "reasonable period of time" for implementation will end. My responsibility does not, however, include in any respect a determination of the *consistency* of the proposed implementing measure with the recommendations and rulings of the DSB. The proper concern of an arbitrator under Article 21.3(c) is with *when*, not *what*.

42. *What* a Member must do to comply with the recommendations and rulings of the DSB in any particular case is addressed elsewhere in the DSU. Article 21.5 sets out special procedures for determining "the existence or *consistency* with a covered agreement of measures taken to comply with the recommendations and rulings" resulting from a dispute.[23] If there is any question about whether *what* a Member chooses as a means of implementation is sufficient to comply with the recommendations and rulings of the DSB, as opposed to w*hen* that Member proposes to do it, then Article 21.5 applies, not Article 21.3. The reasons are many and obvious. For example, if the consistency of implementing measures could also be examined during arbitrations under Article 21.3(c), then Article 21.5 would lose much of its effect. Parties would have little to lose in requesting also from an arbitrator under Article 21.3(c) an immediate ruling on the consistency of a proposed measure. Also, the more elaborate Article 21.5 procedures, involving a panel of three or five members and a report adopted by the DSB, seem more suitable than the more constrained legal domain of Article 21.3(c) for assessing the consistency of substantive obligations under WTO covered agreements.

43. For these reasons, I cannot agree with the European Communities' request to examine the "nature" of the implementation proposed by Canada, in the sense of determining whether that proposed implementation is consistent with the recommendations and rulings of the DSB. That would exceed my mandate under the DSU. It is clear to me that any examination of the consistency of a proposed measure with the recommendations and rulings of the DSB must be made, not in an Article 21.3 proceeding, but in an Article 21.5 proceeding. Accordingly, I conclude that the "reasonable period of time" for implementation that must be determined in this Article 21.3 proceeding is the "reasonable period of time" for implementing what has been *proposed by Canada*, and nothing else. Thus, I offer no opinion whatsoever on whether Canada's proposed regulatory change is sufficient, or whether legislative change may be required instead for consistency with the recommendations and rulings of the DSB.

[23]Emphasis added.

B. *The meaning of a "reasonable period of time"*

44. My task, then, is a limited one: to determine the "reasonable period of time" it should take Canada to make the regulatory change that Canada proposes to make. To accomplish this task, I begin with the text of Article 21.3, which states that:

> … a guideline for the arbitrator should be that the reasonable period of time to implement panel or Appellate Body recommendations *should not exceed 15 months* from the date of adoption of a panel or Appellate Body report. However, that time may be shorter or longer, depending upon the *particular circumstances*. (emphasis added)

45. I note that the 15-month period is a "guideline", and not an average, or usual, period. It is expressed also as a *maximum* period, subject only to any "particular circumstances" mentioned in the second sentence. Further, and significantly, a "reasonable period of time" is not available unconditionally. Article 21.3 makes it clear that a reasonable period of time is available for implementation only "[i]f it is impracticable to comply *immediately* with the recommendations and rulings" of the DSB.[24] Implicit in the wording of Article 21.3 seems to me to be the assumption that, ordinarily, Members will comply with recommendations and rulings of the DSB "immediately". The "reasonable period of time" to which Article 21.3 refers is, thus, a period of time in what is implicitly

47. Based on the wording of Articles 21.3, and on the context provided in Articles 3.3, 21.1 and 21.4 of the DSU, I agree with the arbitrator in *European Communities – Hormones* that "the reasonable period of time, as determined under Article 21.3(c), should be the shortest period possible within the legal system of the Member to implement the recommendations and rulings of the DSB."[28] Moreover, as immediate compliance is clearly the preferred option under Article 21.3, it is, in my view, for the implementing Member to bear the burden of proof in showing – "[i]f it is impracticable to comply immediately" – that the duration of any proposed period of implementation, including its supposed component steps, constitutes a "reasonable period of time". And the longer the proposed period of implementation, the greater this burden will be.

48. The "particular circumstances" mentioned in Article 21.3 are, therefore, those that can influence what the shortest period possible for implementation may be within the legal system of the implementing Member. Conceivably, several such "particular circumstances", depending on the facts, could be relevant to a case such as the one before me.

49. For example, if implementation is by *administrative* means, such as through a regulation, then the "reasonable period of time" will normally be shorter than for implementation through *legislative* means. It seems reasonable to assume, unless proven otherwise due to unusual circumstances in a given case, that regulations can be changed more quickly than statutes. To be sure, the administrative process can sometimes be long; but the legislative process can oftentimes be longer.

50. Likewise, the *complexity* of the proposed implementation can be a relevant factor. If implementation is accomplished through extensive new regulations affecting many sectors of activity, then adequate time will be required to draft the changes, consult affected parties, and make any consequent modifications as needed. On the other hand, if the proposed implementation is the simple repeal of a single provision of perhaps a sentence or two, then, obviously, less time will be needed for drafting, consulting, and finalizing the procedure. To be sure, complexity is not merely a matter of the number of pages in a proposed regulation; yet it seems reasonable to assume that, in most cases, the shorter a proposed regulation, the less its likely complexity.

51. In addition, the *legally binding*, as opposed to the discretionary, nature of the component steps leading to implementation should be taken into account. If the law of a Member dictates a mandatory period of time for a mandatory part of the process needed to make a regulatory change, then that portion of a proposed period will, unless proven otherwise due to unusual circumstances in a given case, be reasonable. On the other hand, if there is no such mandate, then a Member asserting the need for a certain period of time must bear a much more imposing burden of proof. Something

[28] *Supra*, footnote 11, para. 26.

required by law must be done; something not required by law need not necessarily be done, depending on the facts and the circumstances in a particular case.

52.

Communities, would be "45 to 60 days from pre-publication", which I take to mean 45 to 60 days following the conclusion of the 30-day period required by Canadian law for pre-publication of the proposed regulatory change in the Canada Gazette.[31]

54. In considering the time period for implementation proposed by Canada, I recall my earlier observation that a "reasonable period of time" under Article 21.3 should be the shortest period possible within the legal system of the Member to implement the recommendations and rulings of the

> Response to public comments; amendment of regulation and RIAS as required; resubmission to Department of Industry legal services and Department of Justice Regulations Section; review and approval for final publication and signature of the Minister of Industry. **Time: 1-3 months** (depending on the complexity and contentiousness of the proposal).

57. Canada acknowledges that this period of "1-3 months" is not required by law but is part of the Regulatory Policy, and Canada also acknowledges that the duration of "1-3 months" is an estimate that is not specifically mandated by the Regulatory Policy. Yet Canada maintains that this period of "1-3 months" is necessary nonetheless to allow for the amending of the proposed regulation and RIAS, if needed, as well as for further approvals of the amended text. In explanation, Canada states in part that "comments received from the public must be weighed on their merits and changes to the proposed regulation must be considered."[34] The amount of time it should reasonably take to complete this step that Canada says will take "1-3 months" seems, to me, as Canada has stated, to "depend" in part on the "complexity" of the proposed regulatory change. The more complex the proposed regulatory change, the more "reasonable" a period of "1-3 months" will seem to accomplish this step in the change.

58. With this in mind, I turn to the substantive part of Canada's proposed regulatory change, which reads in its entirety:

> The *Manufacturing and Storage of Patented Medicines Regulations* are repealed.[35]

I see nothing in this proposed regulatory change that can be described as complex. What is more, in this case, comments from the public could not be expected to result in much alteration of the one substantive sentence of Canada's proposed regulatory change, which merely repeals the existing regulation. After all, how many other ways could this one sentence be written? Likewise, in this case, any consideration of any changes that might conceivably be needed in the solitary substantive sentence of the proposed regulatory change could not be expected to take very long. After the several years of this dispute, once these final public comments have been received, how much more can be left to be said? If this proposed regulatory change were more complex, I might reach a different conclusion. Yet it is not complex at all. And, given the sheer simplicity of the wording, function and purpose of this proposed regulation, I consider it implausible that this particular implementation step in this case should take as much time as claimed by Canada.

---

[34]Canada's submission, para. 17.

[35]Text of proposed regulation as notified by Canada in letter of 31 July 2000.

59. This is not to say that the dispute between Canada and the European Communities that has given rise to the need for this change is in any way a simple one. Far from it. This dispute is complicated indeed. And the parties, the Panel, and the DSB have all given the many facets of this dispute the sustained attention that has been warranted by the considerable stakes involved. Nor is this to say that only complex laws or regulations have significant results. Again, far from it. Some of the most significant of legal changes can be stated in the simplest of terms, and with the most telling of effects. And, in contrast, some of the most Byzantine by-products of administrative and legislative endeavour sometimes have little real effect once they are enacted. Instead, this is only to say that, in my view, it should not take Canada as much as three months to finalize this proposed regulatory change once the required 30-day period for pre-publication in the Canada Gazette has ended.

60. As I have noted previously, Canada itself concedes that this proposed "1-3 month" period could vary "depending on the complexity and contentiousness of the proposal."[36] "Complexity", as I have said, is not an issue here. Substantively, at this late point in the resolution of this dispute, we are dealing only with one sentence in one proposed regulation. Nothing more. Nor, I am persuaded, should "contentiousness" ever be an issue. I see nothing in Article 21.3 to indicate that the supposed domestic "contentiousness" of a measure taken to comply with a WTO ruling should in any way be a factor to be considered in determining a "reasonable period of time" for implementation. All WTO disputes are "contentious" domestically at least to some extent; if they were not, there would be no need for recourse by WTO Members to dispute settlement.

61. In looking for additional justification for the time period proposed by Canada, I note that Canada also requests that "the summer vacation period of July and August" should be taken into account in calculating the "reasonable period of time" for implementation, and should, as a consequence, add approximately two months to the period for implementation.[37] I see no reference to "summer vacations" in the DSU. Nor, for that matteU. 37cTximD -d1tl7a Tc ount G DSUe to"sui75

60.

Canada in the edition of the Canada Gazette dated 5 August 2000. I have since confirmed that the proposed regulatory change was indeed published on that date[38], and in the form proposed by Canada

Signed in the original at Geneva this 11th day of August 2000 by:

_____

James Bacchus
Arbitrator