WORLD TRADE ORGANIZATION

WT/DS50/AB/R
19 December 1997

Appellate Body

INDIA - PATENT PROTECTION FOR PHARMACEUTICAL AND AGRICULTURAL CHEMICAL PRODUCTS

AB-1997-5

Report of the Appellate Body

*Excerpted version prepared by Prof Daniel Gervais
for teaching purposes only.*
Paragraph numbers may not match those of the original report.
Footnotes omitted.

WORLD TRADE ORGANIZATION
APPELLATE BODY

India - Patent Protection for Pharmaceutical and Agricultural Chemical Products	AB-1997-5
	Present:
	Lacarte-Muró, Presiding Member
India, *Appellant*	Bacchus, Member
United States, *Appellee*	Beeby, Member
European Communities, *Third Participant*	

I. Introduction

1. India appeals from certain issues of law and legal interpretations in the Panel Report, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Product* (the "Panel Report"). The Panel Report reached the following conclusions:

> On the basis of the findings set out above, the Panel concludes that India has not complied with its obligations under Article 70.8(a) and, in the alternative, paragraphs 1 and 2 of Article 63 of the TRIPS Agreement, because it has failed to establish a mechanism that adequately preserves novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions during the transitional period to which it is entitled under Article 65 of the Agreement, and to publish and notify adequately information about such a mechanism; and that India has not complied with its obligations under Article 70.9 of the TRIPS Agreement, because it has failed to establish a system for the grant of exclusive marketing rights.

II. Issues Raised In This Appeal

4. The appellant, India, raises the following issues in this appeal:

(a) What is the proper interpretation to be given to the requirement in Article 70.8(a) of the *TRIPS Agreement* that a Member shall provide "a means" by which applications for patents for inventions relating to pharmaceutical or agricultural chemical products can be filed?

(b) Did the Panel err in its treatment of Indian municipal law, or in its application of the burden of proof, in examining whether India had complied with its obligations under Article 70.8(a) of the *TRIPS Agreement*?

III. The *TRIPS Agreement*

5. The *TRIPS Agreement* is one of the new agreements negotiated and concluded in the Uruguay Round of multilateral trade negotiations. The *TRIPS Agreement* brings intellectual property within the world trading system for the first time by imposing certain obligations on Members in the area of trade-related intellectual property rights. As one of the covered agreements under the DSU, the *TRIPS Agreement* is subject to the dispute settlement rules and procedures of that Understanding. The dispute that gives rise to this case represents the first time the *TRIPS Agreement* has been submitted to the scrutiny of the WTO dispute settlement system.

6. Article 65 of the *TRIPS Agreement* provides, in pertinent part:

> 1. Subject to the provisions of paragraphs 2, 3 and 4, 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.
> 2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.
> …
> 4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of

> application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.
>
> 5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

7. With respect to patent protection for pharmaceutical and agricultural chemical products, certain specific obligations are found in Articles 70.8 of the *TRIPS Agreement*. The interpretation of these specific obligations is the subject of this dispute. Our task is to address the legal issues arising from this dispute that are raised in this appeal.

IV. Interpretation of the *TRIPS Agreement*

8. Article 70.8 states:

> Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:
>
> (a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;
>
> (b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and
>
> (c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. With respect to Article 70.8(a), the Panel found that:

> … Article 70.8(a) requires the Members in question to establish a means that not only appropriately allows for the entitlement to file mailbox applications and the allocation of filing and priority dates to them, but also provides a sound legal basis to preserve novelty and priority as of those dates, so as to eliminate any reasonable doubts regarding whether mailbox applications and eventual patents based on them could be rejected or invalidated because, at the filing or priority date, the matter for which protection was sought was unpatentable in the country in question.

10. In India's view, the obligations in Article 70.8(a) are met by a developing country Member where it establishes a mailbox for receiving, dating and storing patent applications for pharmaceutical and agricultural chemical products in a manner that properly allots filing and priority dates to those applications in accordance with paragraphs (b) and (c) of Article 70.8.[33] India asserts that the Panel established an additional obligation "to create legal certainty that the patent applications and the eventual

patents based on them will not be rejected or invalidated in the future".[34] This, India argues, is a legal error by the Panel.

11. The introductory clause to Article 70.8 provides that it applies "[w]here a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27 …" of the *TRIPS Agreement*. Article 27 requires that patents be made available "for any inventions, whether products or processes, in all fields of technology", subject to certain exceptions. However, pursuant to paragraphs 1, 2 and 4 of Article 65, a developing country Member may delay providing product patent protection in areas of technology not protectable in its territory on the general date of application of the *TRIPS Agreement* for that Member until 1 January 2005. Article 70.8 relates specifically and exclusively to situations where a Member does not provide, as of 1 January 1995, patent protection for pharmaceutical and agricultural chemical products.

12. By its terms, Article 70.8(a) applies "notwithstanding the provisions of Part VI" of the *TRIPS Agreement*. Part VI of the *TRIPS Agreement*, consisting of Articles 65, 66 and 67, allows for certain "transitional arrangements" in the application of certain provisions of the *TRIPS Agreement*. These "transitional arrangements", which allow a Member to delay the application of some of the obligations in the *TRIPS Agreement* for certain specified periods, do not apply to Article 70.8. Thus, although there are "transitional arrangements" which allow developing country Members, in particular, more time to implement certain of their obligations under the *TRIPS Agreement*, no such "transitional arrangements" exist for the obligations in Article 70.8.

13. Article 70.8(a) imposes an obligation on Members to provide "a means" by which mailbox applications can be filed "from the date of entry into force of the WTO Agreement". Thus, this obligation has been in force since 1 January 1995. The issue before us in this appeal is not whether this obligation exists or whether this obligation is now in force. Clearly, it exists, and, equally clearly, it is in force now. The issue before us in this appeal is: what precisely is the "means" for filing mailbox applications that is contemplated and required by Article 70.8(a)? To answer this question, we must interpret the terms of Article 70.8(a).

14. We agree with the Panel that "[t]he analysis of the ordinary meaning of these terms alone does not lead to a definitive interpretation as to what sort of 'means' is required by this subparagraph".[36] Therefore, in accordance with the general rules of treaty interpretation set out in Article 31 of the *Vienna Convention*, to discern the meaning of the terms in Article 70.8(a), we must also read this provision in its context, and in light of the object and purpose of the *TRIPS Agreement*.

15. Paragraphs (b) and (c) of Article 70.8 constitute part of the context for interpreting Article 70.8(a). Paragraphs (b) and (c) of Article 70.8 require that the "means" provided by a Member under Article 70.8(a) must allow the filing of applications for patents for pharmaceutical and agricultural chemical products from 1 January 1995 and preserve the dates of filing and priority of those applications, so that the criteria for patentability may be applied as of those dates, and so that the patent protection eventually granted is dated back to the filing date. In this respect, we agree with the Panel that,

> … in order to prevent the loss of the novelty of an invention … filing and priority dates need to have a sound legal basis if the provisions of Article 70.8 are to fulfil their purpose. Moreover, if available, a filing must entitle the applicant to claim priority on the basis of an earlier filing in respect of the claimed invention over applications with subsequent filing or priority dates. Without legally sound filing and priority dates, the mechanism to be established on the basis of Article 70.8 will be rendered inoperational.[37]

16. On this, the Panel is clearly correct. The Panel's interpretation here is consistent also with the object and purpose of the *TRIPS Agreement*. The Agreement takes into account, *inter alia*, "the need to promote effective and adequate protection of intellectual property rights". We believe the Panel was correct in finding that the "means" that the Member concerned is obliged to provide under Article 70.8(a) must allow for "the entitlement to file mailbox applications and the allocation of filing and

priority dates to them". Furthermore, the Panel was correct in finding that the "means" established under Article 70.8(a) must also provide "a sound legal basis to preserve novelty and priority as of those dates". These findings flow inescapably from the necessary operation of paragraphs (b) and (c) of Article 70.8.

17. However, we do *not* agree with the Panel that Article 70.8(a) requires a Member to establish a means "so as to eliminate any reasonable doubts regarding whether mailbox applications and eventual patents based on them could be rejected or invalidated because, at the filing or priority date, the matter for which protection was sought was unpatentable in the country in question". India is *entitled*, by the "transitional arrangements" in paragraphs 1, 2 and 4 of Article 65, to delay application of Article 27 for patents for pharmaceutical and agricultural chemical products until 1 January 2005. In our view, India is obliged, by Article 70.8(a), to provide a legal mechanism for the filing of mailbox applications that provides a sound legal basis to preserve both the novelty of the inventions and the priority of the applications as of the relevant filing and priority dates. No more. But what constitutes such a sound legal basis in Indian law? To answer this question, we must recall first an important general rule in the *TRIPS Agreement*. Article 1.1 of the *TRIPS Agreement* states, in pertinent part:

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

Members, therefore, are free to determine how best to meet their obligations under the *TRIPS Agreement* within the context of their own legal systems. And, as a Member, India is "free to determine the appropriate method of implementing" its obligations under the *TRIPS Agreement* within the context of its own legal system.

18. India insists that it has done that. India contends that it has established, through "administrative instructions", a "means" consistent with Article 70.8(a) of the *TRIPS Agreement*. According to India, these "administrative instructions" establish a mechanism that provides a sound legal basis to preserve the novelty of the inventions and the priority of the applications as of the relevant filing and priority dates consistent with Article 70.8(a) of the *TRIPS Agreement*. According to India, pursuant to these "administrative instructions", the Patent Office has been directed to store applications for patents for pharmaceutical and agricultural chemical products separately for future action pursuant to Article 70.8, and the Controller General of Patents Designs and Trademarks ("the Controller") has been instructed not to refer them to an examiner until 1 January 2005. According to India, these "administrative instructions" are legally valid in Indian law, as they are reflected in the Minister's Statement to Parliament of 2 August 1996. And, according to India:

> There is … *absolute certainty* that India can, when patents are due in accordance with subparagraphs (b) and (c) of Article 70.8, decide to grant such patents on the basis of the applications currently submitted and determine the novelty and priority of the inventions in accordance with the date of these applications.[45] (emphasis added)

19. India has not provided any text of these "administrative instructions" either to the Panel or to us.

20. Whatever their substance or their import, these "administrative instructions" were not the initial "means" chosen by the Government of India to meet India's obligations under Article 70.8(a) of the *TRIPS Agreement*. The Government of India's initial preference for establishing a "means" for filing mailbox applications under Article 70.8(a) was the Patents (Amendment) Ordinance (the "Ordinance"), promulgated by the President of India on 31 December 1994 pursuant to Article 123 of India's Constitution. Article 123 enables the President to promulgate an ordinance when Parliament is not in session, and when the President is satisfied "that circumstances exist which render it necessary for him to take immediate action". India notified the Ordinance to the Council for TRIPS, pursuant to Article 63.2 of the *TRIPS Agreement*, on 6 March 1995. In accordance with the terms of Article 123 of India's Constitution, the Ordinance expired on 26 March 1995, six weeks after the reassembly of Parliament.

This was followed by an unsuccessful effort to enact the Patents (Amendment) Bill 1995 to implement the contents of the Ordinance on a permanent basis. This Bill was introduced in the Lok Sabha (Lower House) in March 1995. After being passed by the Lok Sabha, it was referred to a Select Committee of the Rajya Sabha (Upper House) for examination and report. However, the Bill was subsequently not enacted due to the dissolution of Parliament on 10 May 1996. From these actions, it is apparent that the Government of India initially considered the enactment of amending legislation to be necessary in order to implement its obligations under Article 70.8(a). However, India maintains that the "administrative instructions" issued in April 1995 effectively continued the mailbox system established by the Ordinance, thus obviating the need for a formal amendment to the Patents Act or for a new notification to the Council for TRIPS.

21. With respect to India's "administrative instructions", the Panel found that "the current administrative practice creates a certain degree of legal insecurity in that it requires Indian officials to ignore certain mandatory provisions of the Patents Act"; and that "even if Patent Office officials do not examine and reject mailbox applications, a competitor might seek a judicial order to do so in order to obtain rejection of a patent claim".

22. India asserts that the Panel erred in its treatment of India's municipal law because municipal law is a fact that must be established before an international tribunal by the party relying on it. In India's view, the Panel did not assess the Indian law as a fact to be established by the United States, but rather as a law to be interpreted by the Panel. India argues that the Panel should have given India the benefit of the doubt as to the status of its mailbox system under Indian domestic law. India claims, furthermore, that the Panel should have sought guidance from India on matters relating to the interpretation of Indian law.

23. In public international law, an international tribunal may treat municipal law in several ways. Municipal law may serve as evidence of facts and may provide evidence of state practice. However, municipal law may also constitute evidence of compliance or non-compliance with international obligations. In this case, the Panel was simply performing its task in determining whether India's "administrative instructions" for receiving mailbox applications were in conformity with India's obligations under Article 70.8(a) of the *TRIPS Agreement*. It is clear that an examination of the relevant aspects of Indian municipal law and, in particular, the relevant provisions of the Patents Act as they relate to the "administrative instructions", is essential to determining whether India has complied with its obligations under Article 70.8(a). There was simply no way for the Panel to make this determination without engaging in an examination of Indian law. But, as in the case cited above before the Permanent Court of International Justice, in this case, the Panel was not interpreting Indian law "as such"; rather, the Panel was examining Indian law solely for the purpose of determining whether India had met its obligations under the *TRIPS Agreement*. To say that the Panel should have done otherwise would be to say that only India can assess whether Indian law is consistent with India's obligations under the *WTO Agreement*. This, clearly, cannot be so.

24. And, just as it was necessary for the Panel in this case to seek a detailed understanding of the operation of the Patents Act as it relates to the "administrative instructions" in order to assess whether India had complied with Article 70.8(a), so, too, is it necessary for us in this appeal to review the Panel's examination of the same Indian domestic law.

25. To do so, we must look at the specific provisions of the Patents Act. Section 5(a) of the Patents Act provides that substances "intended for use, or capable of being used, as food or as medicine or drug" are not patentable. "When the complete specification has been led in respect of an application for a patent", section 12(1) *requires* the Controller to refer that application and that specification to an examiner. Moreover, section 15(2) of the Patents Act states that the Controller "shall refuse" an application in respect of a substance that is not patentable. We agree with the Panel that these provisions of the Patents Act are mandatory. And, like the Panel, we are not persuaded that India's "administrative instructions" would prevail over the contradictory mandatory provisions of the Patents Act. We note also that, in issuing these "administrative instructions", the Government of India did not avail itself of the provisions of section 159 of the Patents Act, which allows the Central Government "to make rules for carrying out the provisions of [the] Act" or section 160 of the Patents Act, which requires that such

rules be laid before each House of the Indian Parliament. We are told by India that such rulemaking was not required for the "administrative instructions" at issue here. But this, too, seems to be inconsistent with the mandatory provisions of the Patents Act.

26. We are not persuaded by India's explanation of these seeming contradictions. Accordingly, we are not persuaded that India's "administrative instructions" would survive a legal challenge under the Patents Act. And, consequently, we are not persuaded that India's "administrative instructions" provide a sound legal basis to preserve novelty of inventions and priority of applications as of the relevant filing and priority dates.

27. For these reasons, we agree with the Panel's conclusion that India's "administrative instructions" for receiving mailbox applications are inconsistent with Article 70.8(a) of the *TRIPS Agreement*.

V. Findings and Conclusions

28. For the reasons set out in this Report, the Appellate Body upholds the Panel's conclusion that India has not complied with its obligations under Article 70.8(a) to establish "a means" that adequately preserves novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions during the transitional periods provided for in Article 65 of the *TRIPS Agreement*.