India &#8211; Patent Protection for Pharmaceutical and Agricultural Chemical Products

WT/DS79/R

Country: India
Region: Asia
Year: 1998
Court: World Trade Organization World Trade Organization
Health Topics: Diet and nutrition, Medicines

Facts

The European Communities (EC) raised issue with India’s efforts to comply with Articles 70.8 and 70.9 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) due to the alleged absence of adequate patent protection for pharmaceutical and agricultural chemical products. Prior to this case, a panel decision addressed the situation in respect to patents owned by U.S. companies. That panel found that India had violated Articles 70.8 and 70.9.

As part of India’s duties as a party to the TRIPS Agreement, India was expected to enact or enforce domestic laws in a manner that achieved their TRIPS obligations. In response to this duty, the President of India promulgated the Patents Ordinance in 1994 (â€œOrdinanceâ€) amending the Patents Act of 1970. Under the Patents Act of 1970, patents were not available for substances used for food, medicine, or drugs. Instead, patents were only available for the methods of producing the substances. Accordingly, the Ordinance was necessary to amend the situation to protect pharmaceutical and agricultural chemical products. This amendment created a system for handling pharmaceutical and agricultural chemical product patents and granted exclusive marketing rights to such patents as required by Article 70.8 and 70.9 of TRIPS. This Ordinance was in effect from January 1, 1995 to March 26, 1995 when Parliament re-assembled. 125 applications were filed during this period.

Pursuant to its TRIPS duties, the Indian Parliament introduced a Patent Amendment Bill that would give permanent effect to the Ordinance provisions. For a series of reasons, this bill failed to pass before the introducing Parliament was dissolved. In the meantime, the Indian executive authorities claimed to have issued an administrative guideline instructing patent offices to accept pharmaceutical and agricultural chemical product patents and store them to be processed once legislation was passed. The Panel did not have a record of this guideline. Despite the lack of record, India reported that between January 1995 and January 1998, 2,212 patent applications for pharmaceutical and agricultural chemical products Â were received and published in the Gazette of India. Despite providing for a recording mechanism for these patent applications, the Indian executive authorities conceded that they lacked the legal power to provide exclusive marketing rights as required by Article 70.9.

Decision and Reasoning

The World Trade Organization (â€œWTOâ€) panel found that India violated Article 70.8 by providing inadequate means for the filing of pharmaceutical and agricultural chemical product patents. According to the panel, the central purpose of Article 70.8 is to protect novel inventions through the existence of â€œlegally sound filing and priority dates.â€ As the Patents Act of 1970 did not provide for patent filings for these products, there was not an adequate system in place. Further, the panel rejected India’s view that its administrative guidelines remedied the issue. The Indian Constitution only allows for administrative guidelines when the law is otherwise silent on the issue. Here, the law was not silent due to the Patents Act, and thus the administrative guidelines were invalid.

Furthermore, the panel concluded that India had violated Article 70.9 by not providing exclusive marketing rights on the patented products. It was uncontested that no legal system was in place regarding exclusive marketing rights. India contended that because no requests for exclusive marketing rights had been submitted, India had not yet failed under its Article 70.9 obligations. The panel rejected this opinion. According to the panel, the unavailability of the right makes the lack of requests for it to be granted irrelevant.
A right is an entitlement for those eligible to exercise it. Here, the entitlement of exclusive marketing rights was not present because there was no legal system in place creating it.

Additionally, the panel rejected India’s claim that this interpretation of Article 70.9 violated the object and purpose of TRIPS. According to India, a country could delay providing exclusive market rights based on a failure to allow fulfillment of the criteria set out in Article 70.9 for when a country must grant exclusive marketing rights. The panel was not convinced by this argument for two reasons. First, many of the criteria were not under the control of the country. Second, deferring fulfillment of the criteria under the state’s control would give rise to questions regarding good faith application of the TRIPS Agreement. Accordingly, the panel concluded that its interpretation of Article 70.9 was appropriate and that India had violated its obligations under TRIPS.

Decision Excerpts

The Panel report in dispute WT/DS50 points out that the term “right” connotes an entitlement to which a person has a just claim and that, as such, it implies general, non-discretionary availability in the case of those eligible to exercise it. It was held that an exclusive marketing right could not be granted in a specific case unless it was available in the first place. Para. 7.65

Without legally sound filing and priority dates, the mechanism to be established on the basis of Article 70.8 will be rendered inoperational. In our view, preservation of novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions so as to provide for effective future patent protection after examination of the applications. Para. 7.39