CANADA – PHARMACEUTICAL PATENTS[1]
(DS114)

PARTIES		AGREEMENT	TIMELINE OF THE DISPUTE	
Complainant	*European Communities*	*TRIPS Arts. 27, 28 and 30*	Establishment of Panel	1 February 1999
			Circulation of Panel Report	17 March 2000
Respondent	*Canada*		Circulation of AB Report	NA
			Adoption	7 April 2000

1. MEASURE AND PRODUCT AT ISSUE

- **Measure at issue:** Certain provisions under Canada's Patent Act: (i)"regulatory review provision (Sec. 55.2(1))"[2]; and (ii)"stockpiling provision (Sec. 55.2(2))" that allowed general drug manufacturers to override, in certain situations, the rights conferred on a patent owner.

- **Product at issue:** Patented pharmaceuticals from the European Communities.

2. SUMMARY OF KEY PANEL FINDINGS

Stockpiling provision

- **TRIPS Arts. 28.1 (patent owner rights) and 30 (exceptions):** (Canada practically conceded that the stockpiling provision violated Art. 28.1, which sets out exclusive rights granted to patent owners.) Concerning Canada's defence under Art. 30, the Panel found that the measure was not justified under Art. 30 because there were no limitations on the quantity of production for stockpiling which resulted in a substantial curtailment of extended market exclusivity, and, thus, was not "limited" as required by Art. 30. Accordingly, the Panel concluded that the stockpiling provision was inconsistent with Art. 28.1 as it constituted a "substantial curtailment of the exclusionary rights" granted to patent holders.

Regulatory review provision

- **TRIPS Arts. 28.1 (patent owner rights) and 30 (exceptions):** (Canada also practically conceded on the inconsistency of the provision with Art. 28.1) The Panel found that Canada's regulatory review provision was justified under Art. 30 by meeting all three cumulative criteria: the exceptional measure (i) must be limited; (ii) must not "unreasonably conflict with normal exploitation of the patent"; and (iii) must not "unreasonably prejudice the legitimate interests of the patent owner", taking account of the legitimate interests of third parties. These three cumulative criteria are necessary for a measure to be justified as an exception under Art. 30.

- **TRIPS Art. 27.1 (non-discrimination):** The Panel found that the European Communities failed to prove that the regulatory review provision discriminated based on the field of technology (i.e. against pharmaceutical products in this case), either *de jure* or *de facto*, under Art. 27.1.

3. OTHER ISSUES[3]

- **Burden of proof (TRIPS Art. 30):** Since Art. 30 is an exception to the obligations under the TRIPS Agreement, the burden was on the respondent (i.e. Canada) to demonstrate that the patent provisions at issue were justified under that provision.

1 *Canada – Patent Protection of Pharmaceutical Products*

2 The regulatory review provision permitted the general manufacturers of pharmaceuticals to produce samples of the patented product for use during the regulatory review process. The stockpiling provision allowed producers of generic drugs to make the drugs and begin stockpiling them six months prior to the expiration of the patent.

3 Other issues addressed: application of principles of treaty interpretation (VCLT) to the provisions under the TRIPS Agreement; interpretation of three cumulative criteria under Art. 30 exception.