

REGIONAL COMPREHENSIVE ECONOMIC PARTNERSHIP (RCEP) TRADE AGREEMENT

Damaging impact of two proposed TRIPS-plus measures

The Regional Comprehensive Economic Partnership (RCEP) trade agreement's current proposals could severely restrict access to affordable medicines for millions of people around the world. An analysis of the Intellectual Property chapter's¹ leaked text has revealed:

1. The demand for Data Exclusivity: Article 5.16

2. The demand for Patent Term Extensions: Article 5.13

- Similar to the Trans-Pacific Partnership agreement (TPP), which is considered the “worst trade deal ever for access to medicines”, these provisions have been tabled by Japan and South Korea.
- The World Health Organisation and experts describe patent term extension and data exclusivity as “TRIPS-plus” as these go beyond what countries are already obliged to follow under the World Trade Organisation's Agreements on Trade-related Aspects of Intellectual Property Rights (TRIPs).
- Since India is one of the countries included in the RCEP negotiations, these TRIPS-plus measures are all the more concerning. India—often known as the ‘pharmacy of the developing world’ for its wide-scale production of generic medicines—supplies life-saving affordable medicines needed to treat communicable and non-communicable diseases in developing countries. Two thirds of all the drugs MSF purchases to treat HIV, TB and malaria are generic medicines from India.
- If accepted, these proposals would subject India to a more stringent and burdensome intellectual property (IP) regime and thus, undermine the careful balance its Parliament has sought to achieve between protecting private rights and the right to life and health its 2005 Patents Law,
- During trade agreements in the past, Indian negotiators have stood firm against the inclusion of extended patent terms and data exclusivity, which had been proposed but rejected in the India-Japan Comprehensive Economic Partnership Agreement and in the on-going negotiations for a EU-India Free Trade Agreement.
- To ensure an uninhibited supply of generic medicines, which we, along with so many people in developing countries rely upon, MSF urges RCEP negotiators to make sure that the trade agreement does not include the above two provisions.
- The Government of India has a special responsibility to ensure that commercial interests do not trample upon public health interests and that hard-won legal flexibilities under international law and trade rules that are crucial to safeguard public health are not eroded. As these represent a lifeline for people in developing countries, the Indian government must resist pressure during the RCEP negotiations to hastily conclude the trade deal.

Data Exclusivity: A Backdoor Route to Monopoly Status

Exclusive rights over pharmaceutical test data (so called “data exclusivity”) figure prominently in the RCEP negotiations on IP.

¹Knowledge Ecology International, *RCEP IP Chapter*, Washington DC and Geneva: KEI, Available at: <http://keionline.org/node/2472>

Exclusive rights over pharmaceutical test data essentially requires India to amend its Drugs & Cosmetic Act (FDA law) so that the Indian Drug Regulatory Authority (DRA) is prohibited from registering a more affordable version of a medicine as long as the exclusivity lasts over the clinical trial data, which is 5 years according to the leaked text.ⁱ Exclusivity comes into effect when a pharmaceutical company submits its data on a new drug or, as is most often the case, on even a slightly new formulation of an old medicine to the Drug Regulatory Authority (DRA). Since a pharmaceutical manufacturer is not permitted to place an equivalent generic pharmaceutical product on the market without prior DRA registration, it works as an effective barrier to competition.

The barriers posed by data exclusivity are not easy to overcome. Apart from the bio-equivalence data,ⁱⁱ which is currently required, domestic producers of generic medicines will have to additionally repeat clinical trials to generate a new set of safety and efficacy data, a process that takes years and involves costs that these companies usually cannot afford. More importantly, repeating clinical trials—solely for registering the generic version—is unethical.

Perhaps the key concern regarding data exclusivity is that it provides a backdoor way to multinational pharmaceutical companies to ensure they continue to have a monopoly on off-patent products. Exclusive rights over pharmaceutical test data guarantees that as long as a competing drug cannot be registered, pharmaceutical companies can enjoy monopolies on a large number of medicines and can thus, charge high prices even when the drug's patent has expired or it has been found to be not patentable. By allowing for monopoly rights even when patents are not granted or have expired, data exclusivity protects pharmaceutical companies from price-busting generic competition.

The New England Journal of Medicine published a case study of how data exclusivity raises the price of medicines even when no patent exists. In the U.S., the price of colchicine, a treatment used mainly for gout, rose more than 5000% after data exclusivity was enacted. Colchicine has been in use for thousands of years (traditional medicine), costs almost nothing to produce, and cannot be patented. Therefore, generic formulations of the tablet have been widely available since the 19th century. However, a new monopoly on colchicine was created in 2009 when the FDA accepted clinical data from a one-week trial of the drug and granted data exclusivity to URL Pharma. URL Pharma subsequently sued to force other manufacturers off the market and raised prices from USD 0.09 to 4.85 per pill.ⁱⁱⁱ

There is no doubt that data exclusivity will be an additional economic burden for developing countries.

For example, data exclusivity provisions included in the 2001 Jordan-U.S. Free Trade Agreement resulted in the delay of registration of generic versions of 79% of medicines between 2002 and mid-2006. Without generic competition, Jordan spent an additional sum of between USD 6.3 and 22.04 million on drugs during this time period.^{iv}

Trade agreements that place additional barriers—such as ‘data exclusivity’—on the registration of lifesaving medicines should be avoided. It is important to note that there is no obligation, from an international/legal perspective, to grant such exclusivity to pharmaceutical data.^v

Patent Term Extension – Extending Patent Duration

Patent Term Extension known as ‘Patent Term Restoration’^{vi} in the negotiations is a straightforward tactic to extend a pharmaceutical company's monopoly by extending the life of a patent on a medicine beyond 20

years. The extra years added to the patent are additional years in which the patent holder can maintain a monopoly position and continue to charge artificially high prices for the drug, free from generic competition.

A recent study in Thailand projected that if a 10-year patent extension was granted (as proposed under the Thai-US FTA), the following negative consequences would accrue over the next 20 years: a 32% increase in the price index for medicines; spending on medicines would increase from baseline to approximately USD 11,191 million; and the domestic industry would lose USD 3,370 million.^{vii}

It is important to note that there is no obligation, from an international/legal perspective, to grant such extensions.^{viii}

ⁱ Article 5.16: Treatment of Test Data in Marketing Approval Procedure - Each Party shall prevent applicants for marketing approval for pharmaceutical products, which utilize new chemical entities from relying on or from referring to test or other data submitted to its competent authority by the first applicant for a certain period of time counted from the date of approval of that application. As of the date of entry into force of this Agreement, such period of time is stipulated as being no less than five years by the relevant laws of each Party.

ⁱⁱ Bio-equivalence tests are much smaller in scale than full-fledged clinical and pre-clinical trials. Thus, they can be conducted faster and are considerably less expensive.

ⁱⁱⁱ Kesselheim, AS, Solomon, DH, “Incentives for Drug Development —The Curious Case of Colchicine”, *N Engl J Med* 2010, 362:2045-2047.

^{iv} Oxfam, “All Costs, No Benefits: How TRIPS-plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines”, Oxford, Oxfam Briefing Note, March 2007. Available at:

<http://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf>

The Oxfam study examined the Jordanian pharmaceutical market since the US-Jordan FTA came into effect in 2001. It stated that there had been “nearly no foreign direct investment by drug companies into Jordan since 2001 to synthesize or manufacture medicines in partnership with local generics companies.”

^v WHO SEARO Briefing Note, “Data Exclusivity and Other TRIPS Plus”, March 2006,

Available at: http://donttradeourlivesaway.files.wordpress.com/2010/12/global_trade_and_health_gth_no3.pdf

^{vi} Article 5.13: Patent Term Restoration

1. With respect to the patent which is granted for an invention related to pharmaceutical products, each Party shall, subject to the terms and conditions of its applicable laws and regulations, provide for a compensatory term of protection for any period during which the patented invention cannot be worked due to marketing approval process.

[2. For the purposes of paragraph 1:

- (a) “compensatory term of protection” means an extension of a term of patent protection;
- (b) “marketing approval” means approval or any other disposition by the competent authorities that is intended to ensure the safety and, where applicable, efficacy of the pharmaceuticals as provided for in the relevant laws and regulations of each Party; and
- (c) the length of the compensatory term of protection shall be equal to the length of extension which the patentee requests, provided that the compensatory term of protection shall not exceed either the length of time during which the patented invention cannot be worked due to marketing approval processes, or a maximum term as provided for in the laws and regulations. Such maximum term shall be at least five years.]

[KR propose: ASN/IN/AU/NZ/CN/JP oppose: 3. Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent. For purposes of this subparagraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than four years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application, whichever is later. Periods attributable to actions of the patent applicant need not be included in the determination of such delays].]

^{vii} Kessomboon N., Limpananont J., Kulsomboon V., Maleewong U., Eksaengsri A., and Paothong P., “Impact on Access to Medicines from TRIPS-Plus: A Case Study of Thai-US FTA”, *Southeast Asian Journal of Tropical Medicines and Public Health*, 2010, 41(3): 667-677, at 637-638, Available at: <http://www.tm.mahidol.ac.th/seameo/2010-41-3/23-4785.pdf>

^{viii} WHO SEARO Briefing Note, “Data Exclusivity and Other TRIPS Plus”, March 2006. Available at: http://donttradeourlivesaway.files.wordpress.com/2010/12/global_trade_and_health_gth_no3.pdf