15 March 2017

India-EFTA TEPA:
Chapter on the protection of intellectual property – Note by Switzerland

1. Background

On 2 March 2017, Indian Minister N. Sitharaman, Ministry of Commerce & Industry, and Swiss Minister J. Schneider-Ammann, Federal Department of Economic Affairs, Education and Research, took stock of the ongoing negotiations for a trade and economic partnership agreement (TEPA) between India and the EFTA States in a phone call. Minister Sitharaman asked her Swiss counterpart for a short note setting out two particular points of negotiations in intellectual property rights (IPR) relating to the *protection of patents* and the *protection of undisclosed information of pharmaceutical and agrochemical products in marketing approval procedures (test data protection)*.

2. IP protection under TEPA and negotiations relating to the protection of patents and undisclosed information

Modern, future-oriented global trade today means trading with innovative goods and services. Innovative export-oriented industries rely heavily on solid, predictable and transparent rules to protect their assets in international trade. The protection of IPR is one of the central topics in any modern TEPA, an agreement which India and EFTA intend to conclude. Accordingly, the goal must be to include provisions of added value also in the IPR Chapter, similar to other important chapters of the agreement.

Important topics of the IPR Chapter include, inter alia, the protection of patents and test data, rights enforcement and geographical indications. The aim of the TEPA is to give Parties' companies and all stakeholders the confidence that their intangible assets and investments are protected by the Parties in accordance with internationally accepted protection standards; the confidence that they can expand to other markets due to their intellectual capital being adequately protected, e.g. in the field of pharma, biotechnology and machinery. This applies to both India's and EFTA's exporting enterprises. With a mutual understanding of a few but clear basic rules in place, such partners are prepared to become more actively involved in bilateral trade and invest more, and thereby also facilitate technology transfer. This is the goal of TEPA, to further deepen and intensify the trade relationship among the Parties and provide the appropriate regulatory framework for this purpose. At the same time, other public interest considerations such as public health and access to medicines shall be taken appropriately account of.

The two areas of patents and undisclosed information protection are the foundation of innovative technologies. They are essential to advancing medical science, to ensure new and better treatment for patients as well as to promoting more effective and productive agriculture. The two instruments are a prerequisite for domestic and foreign companies to be ready to invest more in the research and development (R&D) of new and innovative products and services generally. They are key elements in terms of the attractiveness of an economy to domestic and foreign investors, not to mention for R&D-based companies and companies intending to expand into R&D activities.

a) Patent protection

Patent protection is considered to be a key incentive for research and development. Without efficient protection through patents, innovative industries in both India and EFTA countries have no incentive to invest in and develop new products. Solid and reliable patent protection is not only important for any innovative pharmaceutical company, but just as much for other knowledge-based and innovative industries, such as in the electrical machinery, digital communications or computer technology sectors.

Therefore, it is proposed that the IP Chapter of the TEPA reaffirms patentability and patent protection *for all fields of technology, including biotechnology*. Biotechnology is an important innovation-driven field where research and development are particularly time-consuming and costly. At the same time, it is considered one of the most promising sectors for future research and development and carries the response to treatments and the cures for many of today's and future illnesses. Accordingly, various countries have declared research in biotechnological areas such as biopharmacy, bioengineering, bioagriculture or biomanufacturing a national development priority (e.g. China, in its latest, 13th five-year plan, or Singapore and Brazil). Against this backdrop, the EFTA side is proposing that the Parties confirm the principle of patentability of this seminal area of technology. Exclusion grounds as per the TRIPS Agreement shall apply.

In addition, it will be essential for parties to confirm that the *import of a patented product is accepted as working* (i.e. use) of the patent. This in accordance with Article 27.1 of the WTO/TRIPS Agreement, which requires that '...patents shall be available and patent rights enjoyable without discrimination as to ... whether products are imported or locally produced'. The sole fact that a product is imported into a country and not locally produced shall not be a ground for a compulsory licence to be issued against the importing company. This is to confirm a basic principle of WTO law that a local manufacturing requirement of a product is not an economically viable business concept and would be out of touch with established international trade practice. This is particularly so for SMEs, which are the backbone of both India's and EFTA's economies. EFTA considers the inclusion of such a clause in the agreement as being imperative for reassuring innovative companies that importation into the territory of a Party instead of producing their product locally is one option for supplying a market. They need the reassurance that importation is accepted as one option for entering a market, and that it will neither jeopardise their patent right nor their right to enjoy the patent without discrimination.

b) Protection of undisclosed data

The protection of *undisclosed data* of pharmaceutical and agrochemical products *filed with marketing approval authorities* is critical for innovative pharmaceutical and agrochemical companies. In terms of pharmaceutical products, investment in the generation of test data accounts for approximately 50% of the time and costs incurred for the development of a new substance for a drug. Developing new active substances becomes more and more demanding, time and resource intensive. This is also true for the marketing approval procedure for such innovative pharmaceutical and agrochemical products. The marketing approval procedure is however required to safeguard public health and safety. Without adequate protection of those heavy investments, innovative pharmaceutical and agrochemical companies are not in a position to bring new products to the market and address medical needs adequately. If they lack the confidence of obtaining sufficient test data protection, they may also avoid seeking marketing approval and thus avoid a market altogether.

In accordance with Art. 39.3 TRIPS, marketing approval authorities shall protect the undisclosed data they receive from a first applicant against disclosure and *unfair commercial use.* The obligation of non-disclosure does not raise any major questions and IPR experts in the TEPA negotiations agree to reflect that test data in market authorisation procedures shall not be disclosed. The question, however, of how authorities must *ensure protection against unfair commercial use* remains open and requires particular attention in the further discussion between experts. Switzerland is particularly concerned about authorities relying on the test data file of the first applicant for the marketing approval of a copy product by a second or later applicant. If they do this, authorities aid and abet unfair commercial use of and freeriding on the data generated by the first applicant.

Therefore, TEPA should stipulate that for a certain limited period of time after market approval to the first applicant, a second applicant shall not, without the first applicant's consent, be able to refer to - and authorities shall not rely on - the innovator's data to issue a market approval for the second applicant's product. Adequate protection of test data in the context of governmental marketing approval procedures works also as an incentive for an originator to bring his/her innovative pharmaceutical or agrochemical product to a market. Such protection therefore promotes early market entry and sustainable access to innovative medicines and agrochemicals in the public interest.

3. The way forward

To date, IPR experts have accomplished some useful results in the IPR draft text for a TEPA. Yet, to conclude the agreement, they need to further engage and work out solutions for an added value also in the major areas mentioned above, taking into account international as well as their own domestic law.
