

Standing Committee on

Free Trade Agreements

2016



Date: 26th September 2016

REPORT

Standing Committee on

Free Trade Agreements

Chair: Peter Dirk SIEMSEN
Responsible Reporter: Yusuke Inui

1) Report on the activities of your Standing Committee during the reporting period

Please provide a general overview of the activities of your Standing Committee over the last 12 months, but please include at least:

a) meetings of the Standing Committee during the reporting period

Considering the latest developments which took place worldwide, we have the following updated issues:

EGYPT (by Samir M. Hamza)

As for Free Trade Agreements between Egypt and other countries, there have been no agreements signed this year except for a dual trade agreement signed between Egypt and the Republic of Kenya.

GERMANY (by Christian Lederer)

Recent developments concerning Germany/EU as follows:

1. Concerning the United States of America and the EU, thirteen rounds have taken place since July 2013. One additional fully fledged negotiation round is planned before the summer break. The objective is to ensure substantial progress be made in all three pillars of the agreement (market access, regulatory and rules) by the summer break. In between formal rounds there will also be a number of technical, so-called inter-sessional talks. The pivotal and overarching goal is to negotiate an ambitious, high standard TTIP agreement that responds to both EU and US interests.
2. As to the CETA (Comprehensive Economic and Trade Agreement) between Canada and the EU, the Canada-EU summit on 26 September 2014 marked the end of the negotiations. The European Commission and Canada are going now to complete the translation and review of the text in French and the 21 other EU treaty languages. Once the text of the agreement is translated, it will be submitted to the Council and the European Parliament for approval.
3. As to the negotiations between the EU and Japan, in April 2016 the 16th round of negotiations was held in Tokyo. The 17th round will be held at the end of September 2016 in Brussels.
4. As to the EU-China investment agreement, the 10th round of negotiations took place in Brussels in the week of 26 April 2016. The 11th round was scheduled to take place in Qingdao during the week of 27 June 2016.
5. As to the negotiations of a FTA with the ASEAN countries (Brunei, Myanmar, Cambodia, Indonesia, Laos, Malaysia, Philippines, Singapore, Thailand, Vietnam), on 10 July 2015 the European Commission lodged the application initiating proceedings of the already finalised the FTA with Singapore with the Court of Justice for a Court opinion on the EU competence to sign and ratify the FTA. The negotiations with Malaysia are still paused since some issues remained to be

resolved and Malaysia was approaching elections. The negotiations with Vietnam are already concluded. The legal review of the text has begun. The text will then be translated into all EU languages and into Vietnamese before being presented to the Council for ratification and the European Parliament for consent in early 2017. It is expected that the agreement can enter into force beginning of 2018. Negotiation with the Philippines were formally launched on 22 December 2015.

6. As to the EU-Ukraine Association Agreement, the Deep and Comprehensive Free Trade Area (DCFTA) applies provisionally since 1 January 2016. EU and the Ukraine are in the process of implementing the Association Agreement, including the DCFTA.
7. As to Russia, there is no mandate/negotiation for an FTA. Negotiations for a New Agreement to replace and update the existing Partnership and Cooperation Agreement (PCA) have been stalled. The European Council suspended the bilateral talks on the New Agreement.
8. The EU (no mandate for an FTA) and Kazakhstan signed an Enhanced PCA ("EPCA") upgrading the previous PCA in December 2015. The new EPCA started to apply provisionally on 1 May 2016.
9. As to the Agreement between EU and ANDEAN community, following the agreement by Colombia and Peru to the accession of Ecuador to the Agreement, the Trade Committee under the Agreement approved the text of the Protocol in its meeting of 8 February. The Protocol of Accession must now be signed and ratified by the Parties, each in accordance with its internal procedures. On the EU side, the Draft Proposals on signature, provisional application and conclusion of the Protocol of Accession were adopted by written procedure by the Commission on 4 April 2016 and immediately transmitted to the Council.
10. As to Tunisia, negotiations on a DCFTA were launched in October 2015. The first round took place in Tunis between 18 and 21 April 2016. The second round is likely to take place in Brussels during the second semester of 2016.

A very informative document published by the European Commission giving an overview about the FTAs with the EU and their recent developments can be viewed at:
<http://trade.ec.europa.eu/doclib/html/118238.htm>
<http://trade.ec.europa.eu/doclib/html/118238.htm>

SPAIN (by Christian Durán)

An overview of ongoing negotiations in the European Union can be viewed at:
<http://trade.ec.europa.eu/doclib/html/118238.htm>
<http://trade.ec.europa.eu/doclib/html/118238.htm>

PERU (by Maria Del Carmen Arana Courrejolles)

TRANS-PACIFIC PARTNERSHIP AGREEMENT (TPP)

Some TPP aspects of Trademarks and Patents

The TPP was signed on February 4, 2016 in the city of Auckland, New Zealand by the representatives of Peru, Australia, Brunei, Canada, Chile, United States, Japan, Malaysia, Mexico, New Zealand, Singapore and Vietnam.

Structure of Chapter 18 entitled Intellectual Property consists of 83 articles and its divided into eleven Sections (A to K) and Subsections (Section F of Patents and Undisclosed Test or Other Data has 3 Subsections) and 5 Annexes (A to E).

This chapter sets as its goal the protection and enforcement of Intellectual Property rights. It should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of Producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and Obligations.

Article 18.7: International Agreements, in section 2, states that: each Party shall ratify or accede to each of the following agreements, if it is not already a party to that agreement, by the date of entry into force of this Agreement for that Party: a) Madrid Protocol, b) Budapest Treaty, c) Singapore Treaty, d) UPOV 1991, e) WCT y f) WPPT.

It adds that a party may satisfy the obligations in paragraph 2(a) and 2(c) by ratifying or acceding to

either the Madrid Protocol or the Singapore Treaty.

In Section C, Trademarks, we have three interesting articles. Article 18.18: Types of Signs Registrable as Trademarks: no Party shall require, as a condition of registration, that a sign be visually perceptible, nor shall a Party deny registration of a trademark only on the ground that the sign of which it is composed is a sound. Additionally, each Party shall make best efforts to register scent marks. A Party may require a concise and accurate description, or graphical representation, or both, as applicable, of the trademark.

Article 18.19: Collective and Certification Marks, each Party shall provide that trademarks include collective marks and certification marks. A Party is not obligated to treat certification marks as a separate category in its law, provided that those marks are protected. Each Party shall also provide that signs that may serve as geographical indications are capable of protection under its trademark system.

And Article 18.22: Well-Known Trademarks, where well-known trademarks protection is established. Section F: Patents and Undisclosed Test or Other Data it comprises three Subsections, in Subsection A: General Patents, Article 18.37, Patentable Subject Matter, in point 2, it states that "(...)each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit those new processes to those that do not claim the use of the product as such." The term patents are available for inventions that are claimed as at least one of the following: means to be protected one type of use of the three types listed, ie, you can choose to protect: a) new uses of a known product, o b) new methods of using a known product or c) new processes of using a known product.

Point 3 and 4 of Article 18.37 are optional:

"3. A Party may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that such exclusion is not made merely because the exploitation is prohibited by its law. A Party may also exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals
- (b) animals other than microorganisms, and essentially biological processes for the production of plants or animals, other than non- biological and microbiological processes.

4. A Party may also exclude from patentability plants other than microorganisms. However, consistent with paragraph 1 and subject to paragraph 3, each Party confirms that patents are available at least for inventions that are derived from plants."

Article 18.39, Patent Revocation, states that:

1. Each Party shall provide that a patent may be cancelled, revoked or nullified only on grounds that would have justified a refusal to grant the patent. A Party may also provide that fraud, misrepresentation or inequitable conduct may be the basis for cancelling, revoking or nullifying a patent or holding a patent unenforceable.
2. Notwithstanding paragraph 1, a Party may provide that a patent may be revoked, provided it is done in a manner consistent with Article 5A of the Paris Convention and the TRIPS Agreement.

Article 18.46: Patent Term Adjustment for Unreasonable Granting Authority Delays: "Each Party shall make best efforts to process patent applications in an efficient and timely manner, with a view to avoiding unreasonable or unnecessary delays. (...)"

Subsection B: Measures Relating to Agricultural Chemical Products, article 18.47 (points 1, 2 and 3): Protection of Undisclosed Test or Other Data for Agricultural Chemical Products: If a Party requires, as

a condition for granting marketing approval for a new agricultural chemical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product, that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or a similar product on the basis of that information or the marketing approval granted to the person that submitted such test or other data for at least 10 years from the date of marketing approval of the new agricultural chemical product in the territory of the Party.

Subsection C: Measures Relating to Pharmaceutical Products, article 18.48: Patent Term Adjustment for Unreasonable Curtailment (points 1, 2, 3 and 4), establishes the system of adjustment of the patent term to compensate the holder for any unreasonable reductions to the effective patent term resulting from the marketing authorization process:

1. Each Party shall make best efforts to process applications for marketing approval of pharmaceutical products in an efficient and timely manner, with a view to avoiding unreasonable or unnecessary delays.
2. With respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.
3. For greater certainty, in implementing the obligations of this Article, each Party may provide for conditions and limitations, provided that the Party continues to give effect to this Article.
4. With the objective of avoiding unreasonable curtailment of the effective patent term, a Party may adopt or maintain procedures that expedite the processing of marketing approval applications.

Article 18.50: Protection of Undisclosed Test or Other Data

1. (a) If a Party requires, as a condition for granting marketing approval for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product, that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or a similar product on the basis of:
 - (i) that information; or
 - (ii) the marketing approval granted to the person that submitted such information for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party.
- (b) If a Party permits, as a condition of granting marketing approval for a new pharmaceutical product, the submission of evidence of prior marketing approval of the product in another territory, that Party shall not permit third persons, without the consent of a person that previously submitted such information concerning the safety and efficacy of the product, to market a same or a similar product based on evidence relating to prior marketing approval in the other territory for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of that Party.
2. Each Party shall:
 - (a) apply paragraph 1, *mutatis mutandis*, for a period of at least three years with respect to new clinical information submitted as required in support of a marketing approval of a previously approved pharmaceutical product covering a new indication, new formulation or new method of administration; or, alternatively,
 - (b) apply paragraph 1, *mutatis mutandis*, for a period of at least five years to new pharmaceutical products that contain a chemical entity that has not been previously approved in that Party.

3. Notwithstanding paragraphs 1 and 2 and Article 18.51 (Biologics), a Party may take measures to protect public health in accordance with:

- (a) the Declaration on TRIPS and Public Health;
- (b) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration on TRIPS and Public Health and that is in force between the Parties; or
- (c) any amendment of the TRIPS Agreement to implement the Declaration on TRIPS and Public Health that enters into force with respect to the Parties.

Article 18.51: Biologics

1. With regard to protecting new biologics, a Party shall either:

- (a) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection through the implementation of Article

18.50.1 (Protection of Undisclosed Test or Other Data) and Article

18.50.3, mutatis mutandis, for a period of at least eight years from the date of first marketing approval of that product in that Party; or, alternatively,

- (b) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection:

- (i) through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, mutatis mutandis, for a period of at least five years from the date of first marketing approval of that product in that Party,

- (ii) through other measures, and

- (iii) recognising that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market.

2. For the purposes of this Section, each Party shall apply this Article to, at a minimum, a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.

3. Recognising that international and domestic regulation of new pharmaceutical products that are or contain a biologic is in a formative stage and that market circumstances may evolve over time, the Parties shall consult after 10 years from the date of entry into force of this Agreement, or as otherwise decided by the Commission, to review the period of exclusivity provided in paragraph 1 and the scope of application provided in paragraph 2, with a view to providing effective incentives for the development of new pharmaceutical products that are or contain a biologic, as well as with a view to facilitating the timely availability of follow-on biosimilars, and to ensuring that the scope of application remains consistent with international developments regarding approval of additional categories of new pharmaceutical products that are or contain a biologic.

Article 18.52: Definition of New Pharmaceutical Product

For the purposes of Article 18.50.1 (Protection of Undisclosed Test or Other Data), a new pharmaceutical product means a pharmaceutical product that does not contain⁶¹ a chemical entity that has been previously approved in that Party.

Article 18.53: Measures Relating to the Marketing of Certain Pharmaceutical Products

1. If a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety and efficacy information, to rely on

evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory, that Party shall provide:

(a) a system to provide notice to a patent holder⁶² or to allow for a patent holder to be notified prior to the marketing of such a pharmaceutical product, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use;

(b) adequate time and opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies in subparagraph (c); and

(c) procedures, such as judicial or administrative proceedings, and expeditious remedies, such as preliminary injunctions or equivalent effective provisional measures, for the timely resolution of disputes concerning the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use.

2. As an alternative to paragraph 1, a Party shall instead adopt or maintain a system other than judicial proceedings that precludes, based upon patent-related information submitted to the marketing approval authority by a patent holder or the applicant for marketing approval, or based on direct coordination between the marketing approval authority and the patent office, the issuance of marketing approval to any third person seeking to market a pharmaceutical product subject to a patent claiming that product, unless by consent or acquiescence of the patent holder.

FREE TRADE AGREEMENTS SIGNED BY PERU WITH OTHER COUNTRIES:

Table 1 - includes the FTA signed by Peru with different countries, date of signature and date in which such agreements entered into force and whether or not they include Industrial Property Chapters.

Table 2 - includes the FTA in negotiation.

Table 3 - contains FTA which are not still in negotiation but for which feasibility studies have already been performed.

TABLE 1

FREE TRADE AGREEMENTS IN FORCE SIGNED BY PERU (July - 2016)

Agreement/Partner	Date of Signature	Day on Entry into Force	Intellectual Property Rights Chapter
TPP	04 February 2016		Chapter XVIII
Honduras	29 May 2015		Chapter IX
Pacific Alliance	6 June 2012	20 July 2015	There is no Intellectual Property rights chapter
European Union	26 June 2012	Provisional Application 1 March 2013	Title VII
Japan	31 May 2011	1 March 2012	Chapter XI
Costa Rica	26 May 2011	1 June 2013	Chapter IX
Panama	25 May 2011	1 May 2012	Chapter IX
Mexico (ACE 67)	6 April 2011	1 February 2012	Chapter V (Recognition and Protection of Appellations of Origin)

South Korea	14 November 2010	1 August 2011	Chapter XVII
China	28 April 2009	1 March 2010	Chapter XI
European Free Trade Association (EFTA)	14 July 2008	1 July 2011	Chapter VI
Singapore	29 May 2008	1 August 2009	There is no Intellectual Property rights chapter
Canada	29 May 2008	1 August 2009	There is no Intellectual Property rights chapter
Chile	22 August 2006	1 March 2009	There is no Intellectual Property rights chapter
United States of America (TPA)	12 April 2006	1 February 2009	Chapter XVI
MERCOSUR (ACE 68)	30 November 2005	12 December 2005	Title XVII
Thailand	19 November 2005	31 December 2011	There is no Intellectual Property rights chapter
Guatemala	6 December 2011		Chapter IX

TABLE 2
FREE TRADE AGREEMENTS IN NEGOTIATION (July - 2016)

	Beginning Date	Round's Number	Last Date	Intellectual Property
PERU- EL SALVADOR	08 November 2010	4 Negotiating Rounds	02-06 May 2011	Temporarily suspended.

<p>PERU-TURKEY</p>	<p>On 21 and 22 October 2013, during the FTA Exploratory Meetings Peru-Turkey, delegations from both countries announced their intention to start negotiations for a Free Trade Agreement between Peru and Turkey. This decision was formalized by establishing the Terms of Reference of the Agreement, drawn up and signed on 22 October of that same year.</p>	<p>4 Negotiating Rounds: First Round: 20-24 January 2014 (Ankara-Turkey)</p>	<p>Fouth Round: 24-27 November 2015 (Lima-Peru)</p>	<p>Both countries are exchanging counterproposals for outstanding chapter points Intellectual Property, which is expected to close before the fifth round of negotiations to be held in Ankara.</p>
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TABLE 3**TRADE AGREEMENTS NOT YET IN NEGOTIATION (July - 2016)**

	Conversations
PERU - INDIA	The Minister Magaly Silva said that the government of India is interested in starting talks to finalize an FTA: "We have already completed the feasibility study on the possibilities for an FTA with India".
PERU-INDONESIA	During the meeting held in Vladivostok, in the framework of the APEC Summit XX (September 2012), Ollanta Humala and Susilo Bambang agreed to concrete cooperation on biodiversity protection. Negotiations will start to sign a bilateral agreement to prioritize mutual cooperation in education, technology transfer, trade and protection of biodiversity and traditional knowledge (Peru has a proposal). In addition to this, there is a project to create a "Center for the Protection of Biodiversity and Traditional Culture".

PHILIPPINES (by Jose Cochingyan, III)

Recent Developments in the Philippines on Free Trade Agreements

The Philippines currently has seven free trade agreements in effect. Six of these seven free trade agreements are multilateral, having been negotiated through the Association of Southeast Asian Nations or the ASEAN. The Philippines currently has only one comprehensive bilateral free trade agreement in effect – that with Japan.

The seven free trade agreements of the Philippines currently in effect are as follows:

1. ASEAN Free Trade Agreement (AFTA)
2. ASEAN-China Free Trade Agreement (ACFTA)
3. ASEAN-Korea Free Trade Agreement (AKFTA)
4. Philippines-Japan Economic Partnership Agreement (PJEPA)
5. ASEAN-Japan Comprehensive Economic Partnership Agreement (AJCEPA)
6. ASEAN-Australia-New Zealand Free Trade Agreement (AANZFTA)
7. ASEAN-India Free Trade Agreement (AIFTA)

For more details on these seven free trade agreements, please refer to the attached Table.

Ongoing Philippine Free Trade Agreement Negotiations

The Philippines is currently exploring entering into two bilateral free trade agreements: one with Canada and the other with the European Union (EU).

The Philippines and Canada agreed on 8 May 2015 to explore the idea of a free trade agreement between the countries. However, the free trade talks were halted due to a change in administration in both countries. The talks are anticipated to resume sometime this year.

Meanwhile, the Philippines and the EU officially launched negotiations for an EU-Philippines Free Trade Agreement last 22 December 2015. The first round of talks was held last 23-27 May 2016 in Brussels. The parties aim to include in the agreement, among others, trade aspects of intellectual property.

Philippine-EFTA Free Trade Agreement

On 28 April 2016, the Philippines signed a free trade agreement with the European Free Trade Association (EFTA) Member States, Iceland, Liechtenstein, Norway and Switzerland. The Philippines is currently undergoing the domestic process for the ratification and entry into force of this free trade agreement.

The Philippines-EFTA Free Trade Agreement includes provisions on the *Protection of Intellectual Property Rights*. These provisions may be found be in Annex XVII, as referred to in Article 8 of the Philippines-EFTA Free Trade Agreement.

In the said Agreement, the parties affirmed their obligations as set out in international multilateral agreements concerning intellectual property rights, such as the TRIPS Agreement, the Paris Convention, the Berne Convention, and the Patent Cooperation Treaty. In addition, the parties undertook to comply with the substantive provisions of the following agreements: WIPO Copyright Treaty of 20 December 1996, the WIPO Performance and Phonogram Treaty of 20 December 1996, and the Beijing Treaty on Audiovisual Performances of 24 June 2012.

Of particular note in the Philippines-EFTA Free Trade Agreement is Article 20 of Annex XVII regarding *Cooperation in the Field of Intellectual Property*. In recognition of the growing importance of intellectual property in each party's development, the parties agreed to enhance cooperation in the said field. The areas of cooperation may include but are not limited to the following:

1. Exchange of information, experiences, and experts in the field of intellectual property;
2. Promotion of public awareness on intellectual property;
3. Capacity building and technical assistance on intellectual property management and commercialization.
4. Exchange of non-confidential information for the development of publicly accessible databases on intellectual property rights and reference to available literature on intellectual property.
5. Strengthening the intellectual property rights protection and enforcement system; and
6. Other cooperation activities as may be agreed upon by the parties.

Any cooperation activity is subject to the availability of monetary funds and other resources.

AGREEMENT	PARTIES	SIGNING DATE	EFFECTIVE DATE	CHAPTER ON INTELLECTUAL PROPERTY
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ASEAN Free Trade Agreement	Association of Southeast Nations (ASEAN), composed of: Brunei Darussalam Cambodia Indonesia Lao PDR Malaysia Myanmar Philippines Singapore Thailand Vietnam	28 January 1992	1 January 1993	Not Applicable
ASEAN-China Free Trade Agreement	ASEAN China	4 November 2002	1 January 2010	Not Applicable
ASEAN-Korea Free Trade Agreement	ASEAN Korea	24 August 2006	1 June 2007	Not Applicable

Philippines-Japan Economic Partnership Agreement	Philippines Japan	9 September 2006	11 December 2008	The Parties agreed to “ensure adequate and non-discriminatory protection of intellectual property, efficient and transparent administration of intellectual property protection system, and adequate and effective enforcement of intellectual property rights against infringement, counterfeiting and piracy.” Further, the Parties agreed to develop and strengthen cooperation in the field of intellectual property. Accordingly, the Parties established a Sub-Committee on Intellectual Property, which shall meet at such venue and time as agreed upon by the Parties.
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AGREEMENT	PARTIES	SIGNING DATE	EFFECTIVE DATE	CHAPTER ON INTELLECTUAL PROPERTY
ASEAN-Japan Comprehensive Partnership Agreement	ASEAN Japan	14 April 2008	1 December 2008	Not Applicable

<p>ASEAN-Australia-New Zealand Free Trade Agreement</p>	<p>ASEAN Australia New Zealand</p>	<p>27 February 2009</p>	<p>1 January 2010</p>	<p>Chapter 13 The Parties affirmed their rights and obligations under the <i>Agreement on Trade-Related Aspects of Intellectual Property Rights</i> (TRIPS). The Parties agreed to accord the nationals of each other Party treatment no less favorable than it accords its own nationals, subject to the exceptions provided in the TRIPS Agreement and other Multilateral agreements signed under the World Intellectual Property Organization (WIPO). The Parties also created a Committee on Intellectual Property, tasked with monitoring the implementation and administration of the Chapter on Intellectual Property. The Committee shall meet annually or as mutually agreed by the Parties.</p>
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ASEAN-India Free Trade Agreement	ASEAN India	13 August 2009	1 January 2010	Not Applicable
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ISRAEL (by Adv. Tal Band)

Israel is party to 11 free trade agreements (“**FTAs**”) with 44 states (*inter alia*, the EU, the USA, Canada, Mexico, Brazil, Argentina, Uruguay, Switzerland, Norway, Iceland, Liechtenstein, Turkey, Jordan, Egypt, Colombia^[1] and Panama^[2]). Approximately 65% of Israel's exports are directed to states with which it maintains FTAs.

Several of these FTAs regulate the protection of IP rights, as described below:

- The FTA between Israel and Canada provides that the rights and obligations of the parties relating to IP shall be governed by the Agreement on Trade-Related Aspects of Intellectual Property Rights (**TRIPS**), Annex 1C to the WTO Agreement.
- The FTA with the EFTA^[3] adopts a different standard, according to which the level of protection in certain areas extends beyond that stipulated under the WTO agreements, taking into account the principles of most favoured nation treatment and national treatment.
- Similarly, the FTA with the USA also applies national and most favoured nation treatment principles.

[1]^[#_ftnref1] The FTA between Israel and Colombia has been ratified and signed by the State of Israel. Its ratification by the Colombian parliament is still pending.

[2]^[#_ftnref2] Negotiations on a FTA between Panama and Israel were concluded in 2015 and the said agreement is expected to be signed this year. A source in the Israeli Foreign Trade Administration disclosed that IP issues were discussed in the framework of these negotiations.

[3]^[#_ftnref3] Switzerland, Norway, Iceland, Liechtenstein.

- The standard for the protection of IP rights as determined in the FTA with Jordan is the national legislation of the relevant party, coupled with the guidelines set forth in the Paris Convention for the Protection of Industrial Property (Stockholm Act, 1967, and amended in 1979).
- The wording of the article relating to IP in the FTA with Turkey is identical to that used in the FTA with the EU, as shall be further explained below.

Israel is currently engaged in negotiations regarding the prospects of entering into FTAs with each of Ukraine, Vietnam and India. In addition, Israel has declared the onset of negotiations with each of China, South Korea and the Customs Union of Euro-Asia (Russia, Belarus, Kazakhstan, Kirgizstan and Armenia) with the aim of similarly entering into FTAs with these countries.

Naturally, as a result of the strong commercial relations between Israel and the major European and north-American markets, the trade agreements between Israel and the countries to which such markets relate constitute core agreements among the above mentioned list of FTAs. Accordingly, in light of their central role in Israeli commerce, we provide below further details concerning said agreements:

The FTA between Israel and the EU

The FTA between Israel and the EU was signed on November 20, 1995, and includes several caveats and obligations regarding the protection of IP rights. According to article 39 of the said FTA, both parties undertook to provide adequate and effective protection of IP rights in accordance with the **highest international standard**. The article further based a dispute resolution mechanism designated to solve future problems in the area of IP that affects trading conditions. Israel further undertook in this FTA to accede to a number of multilateral IP rights' related conventions.^[4]^[#_ftn1] In addition, both parties expressed the importance they attach to the Paris Convention for the Protection of Industrial Property (Stockholm Act, 1967, and amended in 1979), the Nice Agreement concerning the International Classification of Goods and Services for the purposes of the Registration of Marks (Geneva, 1977, and amended in 1979), and the International Convention for the Protection of New Varieties of Plants (UPOV) (Geneva Act, 1991).

^[4]^[#_ftnref1] Berne Convention for the Protection of Literary and Artistic Works (Paris Act, 1971); Madrid Agreement Concerning the International Registration of Marks (Stockholm Act, 1967 and amended in 1979); Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Madrid, 1989); Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977, modified in 1980); Patent Cooperation Treaty (Washington, 1970, amended in 1979 and modified in 1984). Israel has also undertaken to ratify the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations (Rome, 1961).

The interpretation of the term "highest international standard" became a subject of controversy between the parties. The Israeli position, as disclosed to us by an official in the Israeli Foreign Trade Administration, is that the WTO standard shall apply, thus Israel does not see itself legally bound to provide TRIPS-Plus IP protection.

Recent developments in IP legislation in Israel following the implementation of an agreement between the Government of Israel and the United States Trade Representative (USTR)

Regarding evolvments in the area of Israeli IP legislation, we would like to pinpoint one positive development that occurred in 2014, when Israel was removed from the USTR special 301 report, which identifies countries that do not provide adequate and effective protection of IP rights. This development came about following a revision of the Israeli Patents Law, 1967 ("**the Patents Law**") and the Pharmacists Ordinance [New Version] 1981, that was completed in 2014 ("**the Revision**"). The Revision stemmed from the implementation of a specific agreement signed between the Government of Israel and the USTR on February 18, 2010. The Revision dealt with three main issues concerning mainly the level of IP protection of pharmaceuticals in Israel: data exclusivity ("**DE**"), patent term extension ("**PTE**") and the publication of patent applications.

In a nutshell, the Revision focused on implementing the following changes into the pertinent Israeli legislation, all of which were considered by Israel to be TRIPS-Plus provisions:

PTE

The basis for calculation of the PTE period in Israel has been, since it's enacted, based on a formula linking the Israeli extension term and expiration, with the shortest term of PTE applicable to patents protecting a pharmaceutical product in other reference countries^[5], which similarly provide PTE. The Israeli linkage mechanism also entailed that Israel PTE terms, in and of themselves, would not exceed corresponding PTE terms granted in other countries. Furthermore, the Israeli linkage mechanism included a cap of 14 years, from the date of first marketing authorization for the relevant drug protected by PTE in a reference country. The primary purpose of such linkage mechanism was to ensure that Israeli patents would not expire later than – and could expire earlier than – the expiration of corresponding patents in the US or in other developed countries.

^[5] These were, until the recent amendment, the US, the EU-15, Australia, Iceland, Japan, Norway and Switzerland.

The principle underlying the amendments to the Patents Law made in the framework of the Revision regarding PTE was enhancing business certainty for drug manufacturers, in two senses: (1) reduction in the number of reference countries which was used to calculate the period of PTE in Israel from 21 countries to only 6 (France, Germany, Italy, Spain, the United Kingdom and the USA), thus resulting, in some cases in longer PTEs; and (2) expediting the decision-making process with regard to PTE applications.^[6]

Another core aspect of the Revision pertaining to PTE, was that PTE applications would remain valid until such time as corresponding PTE orders are granted in the US and in at least one other EU reference country, but no later than the expiration of the underlying basic patent in Israel. If by that cut-off date PTE (or SPC) has not been granted in both the US and one of the EU reference countries (where the pharmaceutical product is approved for marketing) no PTE will issue in Israel.

DE

In 2005 Israel enacted a carefully balanced DE protection mechanism, in terms of which confidential data submitted to the Israeli Ministry of Health cannot be relied upon to approve the marketing in Israel of a generic drug, for a period of 5½ years from the date such drug was first approved for use in a "recognized country" (the US, the EU, Switzerland, Australia, Canada, Japan, New Zealand, Iceland, and Norway), or 5 years from the date of approval of such drug for use in Israel, whichever is the earlier.

The objectives underling the Israeli formula for creating a linkage to other countries, were, on the one hand, providing Israeli consumers with early access to innovative pharmaceuticals, by preventing delays in the submission of original drugs to the Ministry of Health, while on the other hand, providing such consumers with access to generic drugs as early as possible.

Within the framework of the Revision, the term of DE protection in Israel was extended to 6½ years from the date the relevant drug was first approved for use in a "recognized country", or 6 years from the date of registration in Israel, whichever is the earlier.

Publication of Patent Applications

Under the Patents Law as it stood prior to the Revision, a patent application would have been published only after the conclusion of its examination and

[6][#_ftnref1] For example, as a consequence of the amendment, the examination of a PTE application will begin within 60 days from its filing date, while completion of the examination process has been limited to 60 days from the filing date (or the correction of any mistakes).

acceptance by the Patent Office. As a consequence of the Revision, patent applications (including any related document) are now published on the internet, as soon as possible after the passage of 18 months from their filing date or the relevant priority date, as applicable. However, in the case of an international application submitted in accordance with the PCT, the application will be published within 45 days after the applicant shall have complied with the requirements for entering the national phase in Israel.

Furthermore, the aforesaid amendment to the Patents Law resulted in a patent owner being able to obtain, retroactively, *i.e.*, once the patent issues, reasonable royalties from any person who exploits the invention, the subject of the patent application, during the period commencing from the date of publication of the patent application[7][#_ftn1] and ending on the date of acceptance thereof.[8][#_ftn2] Thereafter the patent owner will be entitled to full compensation.

The said amendment also entitles any person, other than the applicant, to submit to the examiner publications which directly relate to the invention as well as the right to apply for the immediate and accelerated examination of patent applications.

The Revision came about following lengthy and continuous negotiations between the Government of Israel and the USTR and ultimately had the effect of bridging the gaps on IP rights' protection issues that previously existed between Israel and the USA.

The above constitutes a short and non-exhaustive summary of the amendments that were implemented to the Israeli legislation within the framework of the Revision. We will be glad to elaborate further on the matters discussed herein or any related issue, upon request.

[7][#_ftnref1] As opposed to the date of the publication of the patent grant, as was stated in the Patents Law prior to its amendment.

[8][#_ftnref2] The said right is contingent on the fact that: (1) use of the invention would amount to an infringement of the patent as granted by the Israeli Patent Office after its examination was concluded; and (2) the invention as claimed in the patent is substantially identical to the invention as claimed in the published patent application.

AUSTRALIA (by Grant Fisher / Clare Cunliffe)

Australia - status of free trade agreements

FTAs in Force			
Partner or partners	Date signed	Date in force	Chapters affecting IP rights
<u>ASEAN-Australia-New Zealand FTA</u> (The Governments of Brunei Darussalam, the Kingdom of Cambodia (Cambodia), the Republic of Indonesia (Indonesia), the Lao People's Democratic Republic (Lao PDR), Malaysia, the Union of Myanmar (Myanmar), the Republic of the Philippines (Philippines), the Republic of Singapore (Singapore), the Kingdom of Thailand (Thailand) and the Socialist Republic of Viet Nam (Viet Nam), collectively, the Member States of the Association of Southeast Asian Nations, and Australia and New Zealand)	27 February 2009 (First Protocol to Amend AANZFTA signed 26 August 2014)	The AANZFTA entered into force on 1 January 2010 for eight Parties: Australia, New Zealand, Brunei, Burma, Malaysia, the Philippines, Singapore and Vietnam. Thailand implemented the FTA from 12 March 2010. AANZFTA entered into force for Cambodia and Lao PDR in January 2011. Indonesia implemented the FTA on 10 January 2012.	Chapter 13: Intellectual Property
<u>Australia-Chile FTA</u>	30 July 2008	6 March 2009	Chapter 17: Intellectual Property Side Letter on Wine
<u>Australia-New Zealand Closer Economic Relations</u>	28 March 1983	1 January 1983	
<u>Australia-United States FTA</u>	18 May 2004	1 January 2005	Chapter 17: Intellectual Property Rights Side letters • ISP Liability • Application of IPR • IPR and National Treatment
<u>Japan-Australia Economic Partnership Agreement</u>	8 July 2014	15 January 2015	Chapter 16: Intellectual Property
<u>Korea-Australia FTA</u>	8 April 2014	12 December 2014	Chapter 13: Intellectual Property Rights
<u>Malaysia-Australia FTA</u>	22 May 2012	1 January 2013	Chapter 13: Intellectual Property
<u>Singapore-Australia FTA</u>	17 February 2003 Amended in 2011	28 July 2003 2 September 2011	Chapter 13: Intellectual Property
<u>Thailand-Australia FTA</u>	5 July 2004	1 January 2005	Chapter 13: Intellectual Property
• <u>China-Australia FTA</u>	17 June 2015	20 December 2015	Chapter 11: Intellectual Property

Signed FTAs			
Partner or partners	Date signed	Next steps	Chapters affecting IP rights
<u>Trans-Pacific Partnership Agreement</u> (The Governments of Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States, Vietnam and Australia).	4 February 2016	Australia decided to participate in the Trans-Pacific Partnership (TPP) in 2008. Negotiations between the parties concluded in October 2015. Five of the 12 parties that signed the TPP on 4 February 2016 were among Australia's top 10 trading partners for goods and services in 2013-14 (United States, Japan, Singapore, Malaysia and New Zealand). Australia supports the expansion of TPP membership over time to other economies in the Asia-Pacific region. Ministers from the TPP Agreement countries met on 17 May 2016 to review progress on their respective internal processes to approve the Agreement.	Chapter 18: Intellectual Property

FTAs under negotiation	
Partner or partners	Status
<u>Australia-Gulf Cooperation Council (GCC) FTA</u>	Free Trade Agreement negotiations with the Gulf Cooperation Council (GCC), comprising Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates, commenced in July 2007. Australia is one of a number of countries negotiating FTAs with the GCC, however, the Council has paused its trade negotiations with all partners pending a review of its trade agreement policy. In March 2014, the GCC Ministerial Council approved the resumption of FTA negotiations, but made no announcement on when negotiations would resume and with which countries. The Australian Government is advocating strongly for a resumption of the Australia-GCC FTA negotiations.

FTAs under negotiation	
Partner or partners	Status
Australia-India Comprehensive Economic Cooperation Agreement	Negotiations to conclude a Comprehensive Economic Cooperation Agreement between Australia and India were launched in May 2011. There have been nine rounds of negotiations, the most recent of which was held in September 2015. During official visits to India and Australia in September and November 2014 respectively, Prime Minister Tony Abbott and Prime Minister Shri Narendra Modi renewed both countries' commitment for an early conclusion of an equitable, balanced, comprehensive and high quality agreement.
Environmental Goods Negotiations	The 1994 Marrakesh Agreement refers to the importance of optimally using the world's resources in accordance with the objective of sustainable development and seeking to protect and preserve the environment. As such, the role of the World Trade Organization (WTO) in relation to trade and environment is to ensure that environmental policies do not act as obstacles to trade, and that trade rules do not stand in the way of legitimate domestic environmental protection. Trade and environment issues within the WTO are dealt with by the Committee on Trade and Environment (CTE), which was created by the 1994 Ministerial Decision on Trade and Environment. The Committee's mandate is broad, and provides opportunities for WTO members to raise a wide range of issues relating to <u>trade and environment</u> . Some of the topics currently being examined by the Committee include eco-labelling and environmental technology dissemination.
Indonesia-Australia Comprehensive Economic Partnership Agreement	Indonesia-Australia Comprehensive Economic Partnership Agreement (IA-CEPA) negotiations commenced in Jakarta in September 2012. IA-CEPA aims to strengthen and expand the trade, investment and economic cooperation relationship between Australia and Indonesia. The announcement of the commencement of IA-CEPA negotiations followed the release of the Joint Feasibility Study on an Indonesia-Australia Free Trade Agreement in April 2009 and the entry into force of the ASEAN-Australia-New Zealand Free Trade Agreement (AANZFTA) . It is expected that the IA-CEPA will build on the outcomes of the AANZFTA. In March 2016 IA-CEPA negotiations were reactivated by Australian and Indonesian Trade Ministers and the fourth round of IA-CEPA negotiations were hosted by Australia in Sydney from 23 to 26 August 2016.
Pacific Agreement on Closer Economic Relations (PACER) Plus	The Pacific Agreement on Closer Economic Relations (PACER) Plus negotiations offer an opportunity to help Pacific Islands Forum countries benefit from enhanced regional trade and economic integration. Pacific Islands Forum Leaders launched negotiations on PACER Plus at their fortieth meeting in August 2009. Participants in the PACER Plus negotiations are: <ul style="list-style-type: none"> • Australia • Cook Islands • Federated States of Micronesia • Fiji • Kiribati • Nauru • New Zealand • Niue • Palau • Papua New Guinea • Republic of Marshall Islands • Samoa • Solomon Islands • Tonga • Tuvalu • Vanuatu Australia's approach to the PACER Plus negotiations is different to that taken in traditional free trade agreement negotiations. Australia's primary objective is to promote the economic development of Forum Island Countries through greater regional trade and economic integration.
Regional Comprehensive Economic Partnership	The Regional Comprehensive Economic Partnership (RCEP) negotiations were launched by Leaders from ASEAN and ASEAN's FTA partners in the margins of the East Asia Summit in Phnom Penh, Cambodia on 20 November 2012. The negotiations are based on the Guiding Principles and Objectives for Negotiating the RCEP endorsed by Leaders. RCEP is an ASEAN-centred proposal for a regional free trade area, which would initially include the ten ASEAN member states and those countries which have existing FTAs with ASEAN – Australia, China, India, Japan, Republic of Korea and New Zealand. The RCEP will build on and expand Australia's existing FTA with ASEAN and New Zealand, AANZFTA. It will complement Australia's participation in bilateral trade negotiations and in Trans-Pacific Partnership Agreement (TPP) negotiations. The Twelfth and Thirteenth Rounds of Negotiations took place from 17 to 29 April 2016, in Perth, Australia and from 12 to 18 June 2016, in Auckland, New Zealand.
Trade in Services Agreement	Australia is jointly leading, with the United States and the European Union, negotiations on a services-only free trade agreement known as the Trade in Services Agreement (TISA). The 23 parties participating in the TISA negotiations include: Australia; Canada; Chile; Chinese Taipei; Colombia; Costa Rica; European Union (representing its 28 Member States); Hong Kong; Iceland; Israel; Japan; Liechtenstein; Mauritius; Mexico; New Zealand; Norway; Pakistan; Panama; Peru; Republic of Korea; Switzerland; Turkey and the United States. Formal TISA negotiations began in early 2013, following 12 months of exploratory discussions that Australia led, with the United States and European Union, in Geneva between a subset of World Trade Organization (WTO) Members interested in progressing services trade liberalisation in a way that would support and feed back into multilateral trade negotiations. On 23 January 2016 the TISA party ministers held an informal meeting in Davos, Switzerland, during which they agreed to aim to conclude negotiations by the end of 2016.

[JAPAN \(by Yoshio Kumakura\)](#)

Japanese Up-to-Date Report (MILAN 2016)

EPAs entered by Japan and other countries

Japan, as of August, 2016, entered into the Economic Partnership Agreements with 15 countries and/or regions (See Annex No.1 and No.2).

The concept of EPA will be defined as the economic agreements having wider and practical aspects than FTC.

Except for JECEP (Agreement on Comprehensive Economic Partnership among Japan and Member States of the Association of South Asian Nations), all EPAs agreed between Japan and partner nations

have rather detailed provisions for IP protection.

One more exception is the EPA between Brunei and Japan, which has a single provision which requires the endeavor to establish IP system as well as to enter into IP related international treaties.

In general, IP provisions in Japanese EPA's seem to try to attain the following purposes:

(A) First, provisions to expand the subject matters to be protected by EPA. Many EPAs first confirm the obligations under TRIPs and then expand to broader TRIPs plus subject matters. For example, in some EPAs, computer software related inventions are to be added to patentable subjects. As many FTA, EPAs also has GI related provisions such as Mexico-Japan FTA and EPA

(B) Secondly, EPAs also provide the cooperation mechanism to simplify, expedite and transparent the procedure to obtain IP rights, including the abolishment of requirement of notarization for filing documents, simplifying the translation of priority documents and exchange of examination information. With Singapore, for example, the examination outcome (by Japan) will be sent to the other country to expedite the examination.

(C) Thirdly, many EPAs requires to strengthen the enforcement against infringement of IP rights, including the water front measures, civil remedies and criminal measures. It is interesting to find very specific but domestically common provisions to lessen the responsibility of Internet Service Providers against the deletion of the websites selling IP infringing goods or contents.

The progress of pending EPA negotiations seems to be stopped as TPP may take main role and the aspects left by TPP will be negotiated by bilateral EPAs especially about details of IP issues.

Annex 1 List of EPA effective as of August 2016 between Japan

Annex 2 List of pending or interrupted EPA or FTA negotiation

TABLE 1

Japanese Report (MILAN 2016) (SC on Free Trade Agreements Member)

List No.1 Economic Partnership Agreements (EPA) IN FORCE or SIGNED BY JAPAN as of August , 2016

Agreement/Partner	Day on Entry into Force	Intellectual Property Rights Chapter or Articles
TPP	signed February 2016	Chapter XVIII
Singapore	January 1,2008	Chapter 10
Mexico	April 1 2003	Chapter 14
Malaysia	June 2006	Articles 112-130
Chile	September 2007	Article 159
Thailand	November 2007	Articles 12-144
Indonesia	July 2008	Articles 16-133
ASEAN(AJCEP)	December 2008	None
Philippine	August 2008	Articles117-130
Swiss	December 2009	Articles 107-129
Vietnam	October 2009	Articles 80-98
India	August 2001	Articles 102-109
Peru	March 2012	Articles 167-188
Australia	January 2015	Articles 16.1-16.21
Mongol	June 2016	Chapter 12

Brunei	July 2008	Article 97 Endeavour clause

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Japanese Report List No. 2

Japan is negotiating the following EPA Agreements or FTCAgreement

- 1 Canada (EPA)
- 2 Columbia (EPA)
- 3 China-Republic of Korea-Japan(FTA)
- 4 Republic of Korea FTA
- 5 EU (EPA)
- 6 Turkey(EPA)
- 7 Gulf Cooperation Councils (GCC) FTA
- 8 TPP

b) any external representation on behalf of AIPPI by any member of your Standing Committee

not responded

c) any contribution by your Standing Committee to any external consultations

not responded

d) any studies or analyses undertaken or position papers prepared by your Standing Committee, with a brief summary of the outcome(s)

not responded

e) involvement of your Standing Committee in any other activities of AIPPI, eg Panel Sessions, contribution to Study Guidelines, etc

not responded

f) any other relevant activities

not responded

2) Key issues/developments relevant to the Terms of Reference of your Standing Committee during the reporting period

Please include a short summary of any significant case law, legislative or regulatory developments, or policy initiatives, including their relevance and/or any implications for the work of your Standing Committee or for AIPPI more generally

not responded

3) Any recommendation for AIPPI involvement/action for the next 12 months

This need not be limited to recommendations for your Standing Committee but can be recommendations for AIPPI more broadly. In each case, please explain why such involvement/action is recommended, by whom it should be undertaken and any relevant time frames. For example, please include:

a) any recommendation for involvement/action in relation to any upcoming or foreshadowed case law, legislative or regulatory developments, or policy initiatives

not responded

b) any other recommendation(s) for AIPPI involvement/action

not responded

4) Outline of the work programme of your Standing Committee for the next 12 months

Please set out specific activities and priorities having regard to the matters in 1) - 3) above, including any relevant time frames

not responded

AIPPI

Names and Functions of Committee Members

Chair	Peter Dirk SIEMSEN	Brazil
Co Chair(s)	Yoshio KUMAKURA	Japan
Secretary		
Members	Ahmed ABOU ALI	Egypt
	Tal BAND	Israel
	José COCHINGYAN III	Philippines
	Clare CUNLIFFE	Australia
	Maria DEL CARMEN ARANA	Peru
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	Christian DURÁN	Spain
	Grant FISHER	Australia
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