Intellectual Property

This section is devoted to giving readers an inside view of the crossing point between intellectual property (IP) law and risk regulation. In addition to updating readers on the latest developments in IP law and policies in technological fields (including chemicals, pharmaceuticals, biotechnology, agriculture and foodstuffs), the section aims at verifying whether such laws and policies really stimulate scientific and technical progress and are capable of minimising the risks posed by on-going industrial developments to individuals' health and safety, inter alia.

The Scope of '*Patent Linkage*' in the US-South Korea Free Trade Agreement and the Potential Effects on International Trade Agreements

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I. Introduction

The implementation of the provisions relating to patent linkage in the Free Trade Agreement Between the United States of America and the Republic of Korea[1] (hereinafter, KORUS FTA) has recently triggered a controversy between the two trading partners. At the heart of the exchange between the two administrations is whether the patent linkage requirement included in Chapter 18 of the agreement (on Intellectual Property Rights, hereinafter, IPRs) covers biopharmaceutical products (also referred to as "*biologicals*" or "*biologics*"). Patent linkage requirements, which some jurisdictions maintain as an incentive to stimulate innovation and attract investments in the pharmaceutical sector, have an impact on the marketing and trade of generic medicines and, where applicable, of biosimilars (i.e., non-originator biologic pharmaceutical products). Consequently, patent linkage requirements affect the accessibility and availability of medicines and competition in the pharmaceutical products' sector.

II. Overview of Patent Linkage Requirements

'*Patent linkage*' refers to requirements linking regulatory approval of pharmaceutical products to the patent status of the products. Patents on pharmaceutical inventions and regulatory approval for pharmaceutical products are normally granted by separate agencies (patent offices and health regulators, respectively). However, certain jurisdictions' domestic laws link regulatory approval (which is based on an evaluation of safety and efficacy of the pharmaceutical product) to the patent status of the product. Therefore, under a patent linkage mechanism, the marketing authorisation will not be granted to a generic medicinal product until the patent is found to have expired or to be invalid. This has the consequence of considerably delaying market entry of generic products. In countries where patent linkage is recognised, the regulatory authority effectively acts as a patent enforcement agency, as patent linkage prevents that authority from granting marketing authorisation to a generic medicine where it appears that there is a valid patent still in existence.[2]

Patent linkage requirements are present, in relevant part, in Canada, the United States (hereinafter,

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1 Free Trade Agreement Between the United States of America and the Republic of Korea, originally signed on 30 June 2007, final amendments and review agreed upon on 21 February 2012 and entry into force on 15 March 2012 (available online at https://ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text).

2 C. Garrison, "*Exceptions to patent rights in developing countries*", UNCTAD - ICTSD Project on IPRs and Sustainable Development, August 2006, p. 60.

US) and Japan, as well as in few other jurisdictions as a result of the conclusion of free trade agreements (hereinafter, FTAs,), notwithstanding the fact that patent linkage is not a requirement of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (i.e., the TRIPs Agreement)[3]. The US incorporated patent linkage into the *Drug Price Competition and Patent Term Restoration Act of 1984*[4] (which is usually, and hereinafter, referred to as the "Hatch-Waxman Act").

In relevant part, under the Hatch-Waxman Act, a manufacturer that is seeking marketing approval for a generic pharmaceutical product must notify the holder of the relevant patent. If the holder of the relevant patent objects, such as when it believes that its patent is still valid, the US Food and Drug Administration grants an automatic stay of 30 months to allow for legal challenges. To encourage patents' challenges, the act also provides that the first company that files a generic application containing a patent challenge certification may be rewarded with 180 days of generic market exclusivity. The Hatch-Waxman Act does not apply to biologics. Requirements for manufacturers of biosimilars are found in the *Biologics Price Competition and Innovation Act*[5], which does not foresee patent linkage.

On the other hand, patent linkage requirements are not allowed in the European Union (hereinafter, the EU). As recognised by the European Commission (hereinafter, Commission) in its Pharmaceutical Sector Inquiry of 2008, the EU's regulatory framework for approval of pharmaceutical products does not allow authorities to take the patent status of the originator medicine into account when deciding on marketing authorisations of generic medicines. Therefore, patent linkage is considered by the Commission an anti-competitive instrument to delay generic and biosimilar medicines entry into the market and, as such, subject to EU competition rules. As result, EU trade agreements do not contain patent linkage requirements.

III. Patent Linkage in the Context of the KORUS FTA

As it is common for international trade agreements to which the US is a party, the KORUS FTA contains patent linkage requirements. Under Article 18.9.5, when a non-originator manufacturer of a "*pharmaceutical product*" applies for marketing approval, the relevant patent owner must be notified of the identity of the person making such request, and the government must have measures implemented "*to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner during the term of a patent notified to the approving authority as covering that product or its approved method of use*". Chapter 18 of the KORUS FTA does not define "*pharmaceutical product*". The concept of "*new pharmaceutical product*" is found in Article 18.8.6 as "*a product that at least contains a new chemical entity that has not been previously approved as a pharmaceutical product in the territory of the Party*". A definition of "*pharmaceutical product*" that explicitly covers biologics (i.e., "*pharmaceutical product or medical device means a pharmaceutical, biologic, medical device, or diagnostic product*") is included in Chapter 5 of the KORUS FTA, which pertains to pharmaceuticals and medical devices.[6] However, this definition is valid only for purposes of Chapter 5,[7] and is therefore not applicable to the provisions contained in Chapter 18, including to the patent linkage requirement. The wording employed in the two definitions, and the fact that the latter distinguishes clearly between "*pharmaceutical*" and "*biologic*" arguably suggests that patent linkage for biologics is not a requirement under the KORUS FTA.

This apparent ambiguity of the KORUS FTA has fuelled a debate between South Korea and the US on whether patent linkage under the KORUS FTA covers biologics.

Under the terms of the KORUS FTA, South Korea was required to fully implement patent linkage by 15 March 2015 (i.e., at least three years from entry into force of the agreement). In order to do so, South Ko-

3 Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C.

4 *Drug Price Competition and Patent Term Restoration Act of 1984* (Public Law 98-417), 21 United States Code § 301 et seq., signed on 24 September 1984.

5 *Biologics Price Competition and Innovation Act* of 2009 (Public Law 111-148), 42 United States Code § 262, signed 23 March 2010.

6 Chapter 5 of the KORUS FTA, titled "*Pharmaceutical Products and Medical Devices*", establishes a set of obligations concerning the pharmaceutical sector and medical devices aimed at facilitating trade in these products and reducing regulatory barriers.

7 As clarified by Article 5.8 of the KORUS FTA.

rea had to amend its patent laws and introduce patent linkage requirements. In response to proposals in South Korea's National Assembly aimed at carving out biologics from the government's draft, the US Ambassador to South Korea issued a letter in which he sought to "*assure ... that KORUS patent linkage obligations cover all pharmaceutical products, including biologics, as set forth in the agreement*".[8] The Ambassador also stated that the US "*meets its obligation through the Hatch Waxman Act and the Biologics Price Competition and Innovation Act*".[9] On 3 March 2015, South Korea's National Assembly passed an amendment to the Pharmaceutical Affairs Act, which ultimately implemented a Hatch-Waxman-style patent linkage requirement for both generic and biosimilar medicines.

Therefore, while South Korea applies the same notification requirements to manufacturers of generics and biosimilars, the US framework distinguishes between generics and biosimilars, insofar as patent linkage is concerned. In the US, under the *Biologics Price Competition and Innovation Act* (hereinafter, BPCIA), a non-originator applying for marketing approval of a biologic must simply "*provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing*" of the biosimilar. This obligation is a requirement to notify the marketing of the product, not the kind of notification requirement that exists under the Hatch-Waxman Act for generics, where the applicant for authorisation of a generic medicine must notify of its intent to seek approval for a generic version of the reference product, and which may ultimately trigger the authority to grant an automatic stay in case of objections from the patent holder. In addition, the "*reference product sponsor*", which is the addressee of the notification requirement, is not necessarily the patent holder. The sponsor, who would receive such notice, can be different from the patent holder. In simple terms, marketing authorisation for biosimilars under the BPCIA is not linked to the status of the patent.

IV. Comment

As a result of the apparent ambiguity of the language in the KORUS FTA and the related exchange between the two administrations, South Korea has effectively implemented more burdensome requirements on manufacturers of South Korean biosimilars than those that would arguably be required under the agreement and that apply to manufacturers of biosimilars in the US. The US Ambassador indicated that the US is advocating for similar provisions to be included in the Trans-Pacific Partnership (hereinafter, TPP), which is currently being negotiated by 12 countries (*i.e.*, Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the US and Vietnam). To avoid the type of ambiguity that has affected South Korea's implementation of the KORUS FTA, future trade agreements should at least clarify that patent linkage does not apply to biologics.

In fact, the inclusion of patent linkage requirements in trade agreements should be avoided altogether. Inasmuch as it prevents the authorisation of generic medicines until after a finding of invalidity or expiry of a patent pending marketing approval, patent linkage has the effect of delaying generic market entry and affecting competition in pharmaceutical products. The degree of investment and innovation that patent linkage requirements are supposed to stimulate is outweighed by the burdens caused by the implementation of such requirements, which often result in onerous procedures and instances of patent abuse, especially where appropriate safeguards to prevent this are not put in place.

Patent linkage requirements stand to be particularly problematic in a context such as the TPP negotiating framework, which includes some countries that have little IPR enforcement experience and no patent linkage requirements in place. Inasmuch as the functioning of the patent linkage mechanism relies on the ability of domestic systems to quickly assess the existence or the validity of a patent, pending the grant of regulatory approval, patent linkage requirements imposed on countries whose systems do not currently meet such standard are likely to pose significant challenges and to result in additional burdens and further delays and impediments on trade in pharmaceutical products. In the context of these negotiations, certain countries are reportedly accepting the inclusion of patent linkage requirements in

8 A scanned copy of the letter was leaked on "*Heesob's IP Blog*" in a posting titled "*US Ambassador confirmed patent linkage under FTA includes biologics*", 11 March 2015 (available online at http://hurips.blogspot.be/2015/03/us-ambassador-confirmed-patent-linkage.html).

9 *Ibid.*

exchange for concessions in other sectors or areas of the agreement, without properly considering the impact that patent linkage requirements stand to have on their domestic framework. With respect to biologics, the further consideration to be made is that, given the early stage of competition in the biologic industry and the constantly evolving scientific and regulatory landscape surrounding biologics, the establishment of complex and layered IP protection (including patent linkage requirements) is largely premature. Instead, proposals tabled in the various stages of the TPP negotiations have included suggestions to broaden the scope of patent linkage, even by explicitly extending the scope of patent linkage to biologics,[10] while avoiding the '*check and balances*' that such systems should include (such as requirements to provide for incentives to encourage patent challenge).

V. Conclusion

It is important that all factors be appropriately considered and reflected in the negotiation of IPR Chapters of trade agreements. Negotiators and affected constituencies must ensure that the appropriate balance between encouraging investment and ensuring competition and technology transfer in the pharmaceutical sector is achieved. Where present, patent linkage requirements add to a number of other, WTO "*TRIPs-plus*", protections (e.g., data exclusivity requirements and patent term extensions) that are routinely included in bilateral or plurilateral trade agreements by the US and other countries or blocks, such as the EU, EFTA (i.e., Iceland, Liechtenstein, Norway and Switzerland) and Switzerland, all of which result in delayed generic and biosimilar entry, less competition, higher costs for medicines and loss of significant savings for national healthcare systems and the economy.

With respect to patent linkage requirements, the simplest way of achieving such balance is to avoid including such requirements, just as the EU does. Where included in the negotiations, it must be clear that patent linkage must not apply to biologics, and, with respect to generics, that such requirements be limited as to the scope of the patents that are covered and be balanced by appropriate '*safeguards*' to prevent abuse. On the other hand, stakeholders must also ensure that domestic implementation of such requirements does not in itself result in unnecessary and unwarranted stricter frameworks.

10 See proposals for Article QQ.E.17 of the '*leaked*' "*Intellectual Property [Rights] Chapter: Consolidated Text (Rebooted): Clean version: 11 May 2015*" of the TPP (available online at http://keionline.org/tpp/11may2015-ip-text), which is the most recent consolidated draft text publicly available at the time of writing of this article.