

A black and white photograph of construction workers wearing hard hats and face masks. The image is partially obscured by a white text box on the right and a dark green bar at the bottom.

COMPULSORY LICENSING AND ACCESS TO FUTURE COVID-19 VACCINES

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Abstract

Since the recent World Health Assembly failed to declare future Covid-19 vaccines a global ‘public good’, they are confirmed as private (intellectual) property and will be subject to patent rights protection as a pharmaceutical product. This confirmation could, however, trigger concerns about access to vaccines on the grounds of public health, which is a valid consideration for both developing and developed countries, including EU member states. Would developing countries have access to affordable Covid-19 vaccines, once available? Would an EU member state be eligible to import generic versions of a patented vaccine if it has insufficient or no manufacturing capacity? Moreover, how to enable an expeditious and predictable multiple patent examination process so that Covid-19 vaccines could become market-ready more efficiently?

This paper examines compulsory licensing and Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health as policy alternatives to voluntary licensing for access to affordable future Covid-19 vaccines. With regard to manufacturing capacity, the EU and its member states may not be eligible to import since they opted out of the Paragraph 6 system outright (although they may still export under the same system). Fortunately, this does not appear to be a major problem since statistics show that most EU27 imports of all pharmaceuticals are from Europe itself, with China a distant second supplier.

For China, however, its pharmaceutical-related patent protection measures under the US-China Economic and Trade Agreement on admissibility of supplemental test data and effective patent-term extension are conducive to a predictable multiple patent examination process for streamlined searches and consistent examination results. To this end, a few initiatives launched in the past at regional and international levels, such as the European Patent Convention and the Patent Cooperation Treaty and, among the world’s largest patent office, the Trilateral Cooperation (on patent) and IP5 Cooperation, for example, will be essential to deliver on these objectives. As contracting members, EU member states will benefit from all these mechanisms.

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1. Introduction

Amid the global race to develop breakthrough Covid-19 pharmaceutical products (or medicines), including vaccines, access may become a question for both developing countries and richer countries, which may have insufficient or no capacity to manufacture certain pharmaceutical products. Issues around the manufacturing, export and import of generic versions of patented pharmaceutical products could emerge, especially because the 73rd World Health Assembly failed to declare future Covid-19 vaccines a global public good. As private (intellectual) property, they will be subject to patent protection.¹

The Solidarity Call to Action launched by the WHO and Costa Rica has urged, among others, for the voluntary licensing of Covid-19 medicines once available on a non-exclusive basis.² The European Patent Office (EPO)³ and the National Intellectual Property Administration of China (CNIPA), for example, have responded positively to this request.⁴ But if voluntarism is lacking, then compulsory licensing; that is, authorising licences to another producer to manufacture

¹ The resolution reached by the 73rd World Health Assembly on 18-19 May 2020 (of the WHO) only recognises extensive immunisation against Covid-19 as a global public good, omitting the role of the vaccines, which are essential to immunisation. Initially the EU proposed in the WHA resolution “Recognizes population-wide immunization against COVID-19 as a global public good for health and the crucial role of quality, safe, and efficacious vaccines therein”, and received support from more than 100 countries. But the US opposed the term ‘global public good’. As a compromise the Operational Paragraph 6 of the resolution now reads: “Recognizes the role of extensive immunization against COVID-19 as a global public good for health in preventing, containing and stopping transmission to bring the pandemic to an end, once safe, quality, efficacious, effective, accessible and affordable vaccines are available”. The lack of legal definition of ‘global public good’ was cited to object to the inclusion of the term. In economics, a public good is one that is both non-excludable and non-rivalrous. See also Third World Network (2020), “WHO: Leaders call COVID-19 vaccines a ‘global public good’”, 20 May, (https://www.twn.my/title2/intellectual_property/info.service/2020/ip200507.htm).

² World Health Organization (2020), “Making the response to COVID-19 a public common good”, 1 June, (https://www.who.int/docs/default-source/coronaviruse/solidarity-call-to-action/solidarity-call-to-action-01-june-2020.pdf?sfvrsn=a6c4b03d_4).

³ Established by the European Patent Convention in 1973, the European Patent Office is a European regional initiative. It accepts patent applications for enforceability in multiple jurisdictions in up to 44 countries in the region (<https://www.epo.org/about-us.html>).

⁴ See the European Patent Office (2020), Joint statement of EPO and CNIPA on response to COVID-19, News, 30 June (<https://www.epo.org/news-events/news/2020/20200630.html>).

generic versions of patented products without the patent holder's consent, will be a policy alternative in order for a government to uphold public health.⁵

Further, what if a WTO member needs to import Covid-19 pharmaceutical products on the grounds of public health but has insufficient or no manufacturing capacity, while a potential exporting country faces a legal impediment because Article 31(f) of the TRIPS Agreement⁶ limits supply under a compulsory licence predominantly for the domestic market? Under such a scenario, the 6th paragraph of the Declaration on the TRIPS Agreement and Public Health (hereunder Paragraph 6)⁷ can provide an interim waiver to the restrictions imposed by Article 31(f). Having said that, the EU and its member states, together with a number of other countries, including the US, opted out of the Paragraph 6 system outright, and may not be able to opt back in.

At the same time, although patent rights,⁸ which are monopolistic in nature, and public health may appear as rival rights, they are not necessarily in opposition to each other. The TRIPS Agreement has reconciled them⁹ under the condition that a patent holder's rights, legitimate interests, and those of the third parties must not be unreasonably prejudiced when pursuing the objective of public health. Indeed, a patent holder's exclusive rights of exploitation (for a limited time) must be guaranteed so that innovation will be incentivised and promoted. This is, after all, the premise of patent rights protection.

Aside from affordable access, enabling expeditious access to future patented Covid-19 pharmaceutical products requires an efficient multiple patent examination process, for which closer international cooperation is imperative. This will inevitably involve China's participation,

⁵ By definition, public health means the art and science dealing with the protection and improvement of community health by organised community effort. See Merriam-Webster.

⁶ The TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) was concluded on 15 April 1995, as part of the outcomes of the Uruguay Round of multilateral trade negotiations that established the World Trade Organization. Regarded as the most comprehensive multilateral IPR agreement to date, it ensures that the basic principles, such as the national treatment and the most-favoured-nation treatment enshrined in the preceding international IPR treaties, such as the Paris Convention and the Berne Convention are upheld. TRIPS harmonises the minimum standards for IPR protection, including patent protection, while providing members with the liberty of imposing more extensive and stricter IPR protection measures, as long as the minimum standards are met. See Hu W. (2017), *International Patent Rights Harmonisation, the Case of China*, Routledge, pp.21-2.

⁷ See WT/MIN(01)/DEC/2, 20 November 2001. 'Paragraph 6' has recognised the fact that WTO members with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties making effective use of compulsory licensing under the TRIPS Agreement. The General Council Decision of 30 August 2003 adopted interim waivers to Articles 31(f)(k) of the TRIPS Agreement, which allows producers to export pharmaceutical products manufactured under compulsory licensing to countries with insufficient or no manufacturing capacity.

⁸ Article 28 of the TRIPS Agreement lists the exclusive rights conferred to an owner of a patent product and of a patent process, including making, using, offering for sale, selling, importing, using the process, etc. Patent owners also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

⁹ Article 7 of the TRIPS Agreement calls for a balance of rights and obligations, and for IP rights protection and enforcement to be conducted in a manner conducive to social and economic welfare. As for Article 8, it sanctions members to adopt measures necessary to protect public health and to promote the public interest, but nonetheless such measures must be consistent with the provisions of the Agreement. See also Romero T. (2020), "Articles 7 and 8 as the basis for interpretation of the TRIPS Agreement", *South Centre Policy Brief No.79*, June.

not only because the country is one of the world's largest patent offices,¹⁰ but also for because it is the world's second largest pharmaceutical market, after America,¹¹ and has been the world's biggest producer and consumer of human vaccines for four decades now.¹² For these reasons, it is worth highlighting the two concessions that China has made on pharmaceutical-related patent protection measures under the US-China Economic and Trade Agreement (hereunder the Phase One Agreement), which should also facilitate multinational pharmaceutical companies' in general, including EU's pharmaceutical industry's fair chance of competition in the Chinese market, pandemic or not.

This paper is divided into three parts, looking at: i) affordable and ii) expeditious access to future patented Covid-19 pharmaceutical products; and iii) China's recent commitments on pharmaceutical-related patent protection.

On affordable access, this research report will explain why compulsory licensing and the Paragraph 6 system could complement voluntary licensing so that manufacturing, exporting and importing generic versions of patented COVID-19 pharmaceutical products would be possible. It will illustrate how the two policy instruments have been incorporated in national legislation, and discuss whether the EU and its member states could re-join the Paragraph 6 system after opting out.

To achieve an efficient multiple patent examination process, the research report presents a couple of mechanisms already launched in recent decades for the purposes of eliminating duplicated work, reducing process time and for more consistent examination results. In the same regard, the two concessions¹³ that China has pledged under the Phase One Agreement, on supplemental test data admission and effective patent-term extension will be highlighted. Before concluding, the report raises the issue of data protection for pharmaceuticals, which is envisaged for further negotiations between the US and China, as foreseen by the Phase One Agreement.

¹⁰ See WIPO (2020), "China Becomes Top Filer of International Patents in 2019 Amid Robust Growth for WIPO's IP Services, Treaties and Finances", PR/2020/848, Geneva, April 7 (https://www.wipo.int/pressroom/en/articles/2020/article_0005.html?utm_source=WIPO+Newsletters&utm_campaign=ad819a279a-EMAIL_CAMPAIGN_2020_04_06_08_20&utm_medium=email&utm_term=0_bcb3de19b4-ad819a279a-256692297).

¹¹ China's pharmaceutical market value reached almost \$134 (€119.42) billion in 2018 and is expected to grow to \$154 (€137.25) billion by 2020. However, opportunities aside, multinational pharmaceutical companies in China are facing a series of challenges, including pricing pressure, uncertain medicines approval times and the implementation of medicines regulatory reforms (<https://www.trade.gov/knowledge-product/china-pharmaceuticals>).

¹² See Cision PR Newswire (2019): China Human Vaccine Industry Report, 2019-2025 Featuring 22 Human Vaccine Companies, 7 November (<https://www.prnewswire.com/news-releases/china-human-vaccine-industry-report-2019-2025-featuring-22-human-vaccine-companies-300954129.html>).

¹³ In addition to admitting supplemental data and providing patent term extensions, China has also committed to establish a mechanism for the early resolution of potential pharmaceutical patent disputes, including a course of action to allow a patent holder to seek expeditious remedies before the marketing of an allegedly infringing product, so that innovative pharmaceutical companies can effectively enforce their rights in China (Article 1.11). This last commitment is not addressed in this paper because it is not directly relevant to the Covid-19 pandemic.

2. Compulsory licensing and the Paragraph 6 system: why and how

In accordance with Article 31 of the TRIPS Agreement, under certain circumstances members may authorise compulsory licences. The aforementioned Solidarity Call to Action has urged patent holders to voluntarily place patented products, etc. necessary for Covid-19 (once available) in the Unitaid¹⁴-established and supported Medicines Patent Pool (MPP) to be available on a non-exclusive basis for licensing in every country and be affordable and accessible, especially in low- and middle-income countries. The MPP negotiates with patent holders to obtain voluntary licences and then enable generic companies to manufacture and sell the generic version of patented products on a non-exclusive basis, on payment of royalties.¹⁵ But the MPP will not function if voluntary licensing is not forthcoming. In this case, the policy choice of compulsory licensing and subsequently the Paragraph 6 system could serve to ensure affordable and universal access to patented Covid-19 vaccines and other pharmaceutical products or processes in the pharmaceutical sector, including active ingredients and diagnostic kits.¹⁶

2.1 Why compulsory licensing and the Paragraph 6 system?

In the absence of voluntary licensing, compulsory licensing will grant the manufacture of generic versions of patented pharmaceuticals that cost significantly less to consumers than original branded ones. However, the circumstances under which, and how, a compulsory licence may be granted is restricted by Article 31 of the TRIPS Agreement. The circumstances include situations of “national emergency or other circumstances of extreme urgency”, and “public non-commercial use”; as for the ‘how’, the restrictions include “non-exclusive use” and “predominantly domestic use”, for example.

Article 31(d) of the TRIPS Agreement has prescribed that a compulsory licence must not be exclusively assigned to licensees. This means, in parallel, that a patent-holder is able to retain the exclusive rights to exploit the patent in question in certain markets. As a consequence, supplies of a patented Covid-19 vaccine may be differentiated between richer, developing and least-developed-country (LDC) members, for the former to use the more expensive patented and the latter the generic version of patented vaccine supplies.

However, on the grounds of public health, when a member needs to import particular pharmaceutical products because of insufficient or no manufacturing capacity, but a potential

¹⁴ Unitaid is an international organisation that invests in innovation to prevent, diagnose and treat HIV/AIDS, tuberculosis and malaria more quickly, affordably and effectively. It also works to improve access to diagnostics and treatment for HIV co-infections such as hepatitis C and human papillomavirus (HPV) (<https://unitaid.org/about-us/#en>).

¹⁵ For the history, constraints and limitations of MPP, see S. Chaudhuri (2020), “Making Covid-19 Medical Products Affordable: Voluntary Patent Pool and TRIPS Flexibilities”, 16 June, Southviews, No.200.

¹⁶ Paragraph 6 is applicable to patented pharmaceutical products, arguably also including vaccines, or manufacturing processes. See Vandoren P. and Van Eeckhaute JC (2003), “The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health”, *The Journal of World Intellectual Property*, Vol.6, No.6, November, p.784.

exporting country is prohibited from exporting the full manufactured production because Article 31(f) of the TRIPS Agreement limits supply under a compulsory licence¹⁷ predominantly to the domestic market, the Paragraph 6 system must be brought into play to provide an interim waiver, so that the full production may be exported under a compulsory licence. If not, manufacturing under a compulsory licence must predominantly supply the domestic market unless the authorisation is to remedy an anti-competitive practice, in accordance with Article 31(k) of the TRIPS Agreement.

2.2 How are compulsory licensing and Paragraph 6 implemented in national legislation?

Note that the Paragraph 6 system provides two interim waivers. In addition to Article 31(f), Paragraph 6 waives the requirement prescribed by Article 31(h), under which a patent holder must be compensated adequately for each authorisation of a compulsory licence in the importing country. With Paragraph 6, such compensation will be paid in the exporting, not the importing, country.¹⁸ Other than that, the restrictions on compulsory licensing spelled out in Article 31 of the TRIPS Agreement¹⁹ remain applicable when invoking Paragraph 6.

At the same time, one must bear in mind that TRIPS members have the flexibility to enact more extensive and stricter national patent legislation, including patent examination standards, as long as the enforceable minimum protection standards set by TRIPS are met. For this reason, not all members have incorporated the policy instrument of compulsory licensing into their national patent legislation in order to be qualified to use it. For example, in the US a patent holder is granted the absolute exclusive rights of exploitation during the full protection term, which is 20 years counting from the filing date of a patent application. On an EU level, the legal bases for granting compulsory licences are provided for in the 1998 Biotech Directive regarding plant variety rights. The Regulation (EC) No 816/2006 has implemented the Paragraph 6 system, so member states will be eligible to manufacture the generic versions of patented

¹⁷ In relation to patent and the pharmaceutical product(s) in question, for the exporting country Paragraph 6 may apply when, a) the required pharmaceutical product is subject to one or more patents validly in force in the exporting country; b) the relevant patents are not subject in the exporting country to a compulsory licence to remedy anti-competitive practices that allow the licensee to export. Similarly, if a compulsory licence has been issued under which the licensee is predominantly supplying the domestic market, the licensee may supply an importing country with the non-predominant share of its production, and therefore without resort to the Decision waiver. For the importing country, Paragraph 6 may apply a) whether or not the relevant products and process are patented in the importing country; b) if the required pharmaceutical product, or the process for its manufacturer, is not patented in the importing country or the patent has expired or been revoked, there is no need to grant a compulsory licence in the importing country; c) if the product or process for its manufacturer is patented in the importing country, then the importing country must issue a compulsory licence. See C.M Correa, (2004), "Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", April, pp 9-10.

¹⁸ See World Trade Organization (2003), "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", Annex 1, WT/L/540, 2 September, para.3.

¹⁹ These restrictions include the requirement for licence applicants to first try to obtain authorisation from the right holder on reasonable commercial terms and conditions and within a reasonable period of time. This requirement may be waived by national law in the case of a national emergency or other urgent circumstances or in cases of public non-commercial use, in accordance with Articles 31 (b) of the TRIPS Agreement.

pharmaceutical products and to export them to countries with public health problems. At member state level, all of the EU27 have incorporated compulsory licensing into their respective national legislation, although grounds for authorisation may differ between them, as does the procedural framework leading to the authorisation depending on the national civil or administrative procedures.²⁰

As to the eligibility requirement for invoking Paragraph 6 as an importer, WTO LDC members are automatically qualified to import, whereas non-LDC members must submit two notifications to the TRIPS Council. First, a general notification for its intention to use the system as an importer, and second, a specific notification about the products and quantities needed etc. that it intends to import. As established, these notifications are declaratory in nature, for transparency and information purposes, and do not amount to authorisation requests. Members may automatically use the system once they have made the notifications.²¹

However, there are WTO members that have notified the TRIPS Council that they would only apply Paragraph 6 as an importer in a “national emergency” or “other circumstances of extreme urgency”. Such members include Hong Kong, Israel, and Korea. After incorporating Paragraph 6 in Article 49 of the Patent Law 2008,²² China will be eligible to authorise a compulsory licence on the grounds of public health, and for manufacturing and exporting affordable generic versions of patented pharmaceutical products to countries that have insufficient or no manufacturing capacities.

The EU and its member states and a few other countries, such as Japan and Canada²³ declared that they would not act as an importer. It is valid to ask whether the WTO members that opted out of the system as importers are now able to opt back in, for example in order to ask India – the world’s largest exporter of generic medicines²⁴ – or China – the world’s largest producer of pharmaceutical ingredients²⁵ – to

²⁰ See Compulsory licensing in Europe (2018), A country-by-country review, European Patent Academy.

²¹ Op.cit., Vandoren P. and Van Eeckhaute JC (2003), p.789.

²² Article 49, Patent Law 2008. The 2008 patent legislation has been under a process of amendment since 2015. The latest draft amendments were released for public comment on 3 July 2020. Compared to the previous drafts, the latest amendment text has a focus on pharmaceutical-related patent protection measures which implements the relevant provisions concluded under the US-China Economic and Trade Agreement, on patent-term extension and on patent linkage between the originator drug and its generic versions within the remit of marketing approval. Additionally, the amendment is expected to address the issues of service inventions, exploitation and commercialisation, licensing, administrative enforcement, online infringement, higher amount for statutory damages, and extension of design patent validity from 10 to 15 years.

²³ Available at https://www.wto.org/english/docs_e/legal_e/31bis_trips_annex_e.htm#fnt-3.

²⁴ See Pharma Manufacturing (2018), Generic Pharma, p.4.

²⁵ According to US Department of Commerce data, China accounted for 95% of US imports of ibuprofen, 91% of US imports of hydrocortisone, 70% of US imports of acetaminophen, 40% to 45% of US imports of penicillin and 40% of US imports of heparin, according to Commerce Department data. In all, 80% of the US supply of antibiotics are made in China. See Taylor G. (2020), 'Wake-up call': Chinese control of U.S. pharmaceutical supplies sparks growing concern, The Washington Times, March 17. On the other hand, though India is the world’s largest exporter of generic medicines, it depends on China for sourcing 70-75% of active pharmaceutical ingredients (APIs) in generic medicines formulations. China is the world’s largest producer of pharmaceutical ingredients. See eHealth Network (2017), “Why over dependence on APIs imported from China is harmful for India?”, 15 July (<https://ehealth.letsonline.com/2017/07/why-over-dependence-on-apis-imported-from-china-is-harmful-for-india/>).

produce a generic patented Covid-19 vaccine in bulk if they find their domestic manufacturing capacities to be insufficient for public health purposes during the Covid-19 pandemic.²⁶

2.3 Opting out then back in as an importer under Paragraph 6?

Apart from WTO LDC members, the justification for any other member to invoke Paragraph 6 is its insufficient or no manufacturing capacity for the particular pharmaceutical product(s)²⁷ required. This is a prerequisite because the specific notification that a member must submit to the TRIPS Council should include the following three elements to determine its “insufficient and no manufacturing capacity” of particular pharmaceutical products:

- 1) the name of the needed product(s) and the “expected quantities” that importing countries should assess carefully since the corresponding compulsory licence in the exporting country can be authorised only for a specific amount;
- 2) confirmation that it has established insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question;²⁸
- 3) confirmation that it has already granted or intends to grant a compulsory licence if the pharmaceutical product(s) in question is patented in its territory. The conditions for granting the compulsory licence should be in accordance with Article 31 of the TRIPS Agreement.²⁹

Therefore, determining “insufficient or no manufacturing capacity” is a matter of self-assessment and is not subject to challenge by another member; neither can the TRIPS Council review, reverse or reject this assessment.³⁰ Also, “manufacturing capacity” is not about a member’s pharmaceutical sector in general, but the particular pharmaceutical product(s) required. Countries pooling their procurement needs can make joint notifications.³¹

Among those members that have either wholly opted out of Paragraph 6 or declared that they would use the system only in cases of a national emergency or circumstances of extreme urgency, it is observed that some opt-out declarations are incorporated directly in the Decision

²⁶ See also Grosse Ruse-Khan, H. (2020), Access to Covid-19 Treatment and International Intellectual Property Protection – Part I: Patent protection, voluntary access and compulsory licensing, April 15 (<https://www.ejiltalk.org/access-to-covid19-treatment-and-international-intellectual-property-protection-part-i-patent-protection-voluntary-access-and-compulsory-licensing/>).

²⁷ Within the context of the Doha Ministerial Decision, “pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included. Op.cit., World Trade Organization (2003), para.3 and Op.cit., Vandoren P. and Van Eeckhaute JC (2003), p.784.

²⁸ There are two alternative ways to establish “insufficient or no manufacturing capacities”. The first option applies when the member has established it has no capacity in the pharmaceutical sector; the second option applies when the member has some capacity, but then finds it is insufficient to meet its needs. Op.cit., World Trade Organization (2003), Annex, WT/L/540, 2 September.

²⁹ Ibid., para.2(a).

³⁰ Op.cit., Vandoren P. and Van Eeckhaute JC (2003), p.785.

³¹ See WTO, WIPO, WHO (2013), Extract from the WHO-WIPO-WTO Trilateral Study: The Paragraph 6 System: Special Export Licences for Medicines (https://www.wto.org/english/tratop_e/trips_e/who-wipo-wto2013_par6_extract_e.pdf).

of implementing Paragraph 6,³² and some were made by statement to the General Council before the adoption of the Decision. As members generally have the option under the Decision to modify their status as users of the system at any time, and the establishment of “insufficient or no manufacturing capacity” must be product(s)-specific, which suggests manufacturing capacity circumstances may change, and thereby justifications, the ministerial Decision does not seem to prohibit members that opted out from opting back in, especially if the eligibility requirements as an importing country are fulfilled. This being the case, the intention of these members should help to determine whether they meant to opt out definitely and finally. At the same time, some would argue that members whose opt-outs are incorporated in the text of the Decision are not free to modify their status, in contrast to those that merely state their intention of opting out to the General Council.³³ In the former category are members such as Australia, Canada, the EU (then European Communities) and its member states, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.³⁴ Nonetheless, this does not seem a major problem for the EU and its member states since the majority of EU27 imports of all pharmaceuticals are from Europe itself, amounting to 79.6% in 2019 (62.5% from EU27, 13.3% from Switzerland, 3.9% from the United Kingdom), and; 80.9% of EU27 imports of vaccines came from other EU27 countries (the EU Internal Market).³⁵

3. Multiple patent applications for streamlined searches and consistent examination results

Examining a patent application³⁶ is to conduct a search exercise in patent databases to determine if the invention is novel,³⁷ to assess whether it involves an inventive step for patentability³⁸ and to appraise whether it is capable of industrial application.³⁹ The search process can be a huge undertaking and usually takes at least 18 months to complete since the databases to search are normally ‘astronomical’ in size. For example, EPO’s Espacenet alone

³² See WTO (2003), “Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health”, Decision of the General Council (30 August), WT/L/540.

³³ See Abbott F.M. (2005), “The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health”, the *American Journal of International Law*, Vol.99, p.336.

³⁴ Their decision of opting out from the Paragraph 6 system is noted in the footnote 3 of the Decision (https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm).

³⁵ ECIPE (2020), “Key Trade Data Points on the EU27 Pharmaceutical Supply Chain”, July, pp.5,17.

³⁶ In general, invention, utility model and design are all patentable subjects. The examination steps described in this research paper only apply to invention patent applications.

³⁷ According to Article 54 of the European Patent Convention, invention must not form part of the state of the art – which should comprise everything made available to the public either written or by oral description, by use or in any other way, including the European patent applications filed previously, substance or composition – before the European patent filing date.

³⁸ As stipulated by Article 56 of the European Patent Convention, “inventive step” means if, having regard to the state of the art, it is not obvious to a person skilled in the art.

³⁹ “Industrial application” means the invention can be made or used in any kind of industry, including agriculture. See Article 57 of the European Patent Convention.

contains over 110 million patent documents from around the world.⁴⁰ The process undertaken is painstaking, too, with great importance placed on the justification of exclusive rights of exploitation that an inventor may be rewarded.

As far as multiple patent applications are concerned, the objective for closer international cooperation is to eliminate duplicated search work, reduce processing time and mitigate the possibilities of inconsistent examination results. Applicants for a multiple invention patent encounter these obstacles because of the territorial nature of patent rights – therefore each jurisdiction will conduct its own examination and award the rights enforceable within the jurisdiction thereof. Moreover, since TRIPS members have the flexibility to elect their own patent protection standards in a manner of either TRIPS-plus⁴¹ or TRIPS-minus when the special and differential treatments provided by TRIPS, such as the five-year transitional period, are implemented by a developing country, it is possible that patent protection is granted in one jurisdiction but rejected by another.

3.1 Eliminating duplicate search work among multiple patent offices

The European Patent Convention (EPC), the Patent Cooperation Treaty (PCT),⁴² the Trilateral Cooperation (on patent), and the IP5 Cooperation are examples of initiatives that aim to eliminate duplicate search work launched in previous decades at regional and international levels and among the world's largest patent offices.

Within their respective jurisdictions among the contracting members, the EPO and the PCT work in a similar way when conducting search work to determine the novelty of an invention patent application. Therefore, once an application is submitted, the search work will be conducted by the EPO or, in the case of PCT, by an “international searching authority” (usually served by one of the world's largest patent offices), in order to identify the published patent documents and technical literature (‘prior art’) which have an influence on whether the invention is patentable. A written opinion on the invention's potential patentability may also be established, if requested. In the case of EPO, the national stage of a patent application starts 18 months after the submission date. As for the PCT, at the end of the international search proceeding, usually around 30 months from the earliest filing date of the initial application, it is the national stage of the application. Under both scenarios, after the search work is completed, the applicant will then start to pursue the patent grant before the respective national patent offices where protection is sought.

⁴⁰ Op. cit., European Patent Office (2020).

⁴¹ For example, regarding the “inventive step” test, the threshold of “enhanced efficacy” applied by India is notoriously strict. Novartis AG vs. Union of India is a case in point. For details, Op.cit., Hu W. (2017), pp.157-61.

⁴² Administered by the World Intellectual Property Organization, the PCT makes it possible for applicants to seek patent protection for an invention simultaneously in more than 150 contracting states by filing a single “international” patent application instead of filing separate national or regional patent applications where protection is sought. For details, see Protecting Your Inventions Abroad: Frequently Asked Questions About the Patent Cooperation Treaty (PCT) (<https://www.wipo.int/pct/en/faqs/faqs.html>).

A search report issued by either the EPO or the PCT will be recognised within the jurisdictions concerned among the contracting members, though the exclusive patent rights conferred and their enforceability are demarcated by the individual national offices where the patent will be awarded. Therefore, an EPO patent⁴³ or a PCT patent is a group of independent, nationally enforceable and nationally revocable patents.

Cooperation among the world's largest patent offices, such as the Trilateral Cooperation (on patent) established among the USPTO (the United States Patent and Trademark Office), the JPO (the Japan Patent Office) and the EPO, and the IP5 Cooperation (the USPTO, the JPO, the EPO, and the patent offices of China and Korea),⁴⁴ share the same objectives and working method concerning 'search' as the EPC and the PCT conduct. It is also noted that the Trilateral and the IP5 mechanisms are jointly identified by the EPO and the JPO for enhancing cooperation for an efficient and harmonised international patent system to combat the Covid-19 pandemic.⁴⁵

3.2 Patent Prosecution Highway

Among the patent offices where protection is sought by an applicant, if the first patent office could relay its search results to the second offices the process of multiple patent examination would proceed even faster and, moreover, the possibilities of inconsistent examination results among different offices may also be mitigated.

As highlighted by the Joint Message issued by the US Patent and Trademark Office (USPTO) and the Japan Patent Office (JPO) in June 2020,⁴⁶ the Patent Prosecution Highway (PPH) is such an initiative, where the working method is also known as 'decision-sharing'. Certainly, for such an exercise of decision-sharing to take place, besides the confidence in each other's patent legislation and examination quality shared among the participating offices, the scope of patent claim must be fairly narrow and strictly identical. Indeed, the PPH is highlighted by the above-

⁴³ A European patent is not a unitary right. Once the European unitary patent system comes into being, the EPO will be competent to grant unitary patents whereby the unitary effect within the territories of the 26 EU participating states will be guaranteed at a patent holder's request. Applying the EU unitary patent will become an alternative option for patent protection in the European region, in addition to the national patent system and the classical European patent system. The start of the new system is currently expected for the end of 2021 (<https://www.epo.org/law-practice/unitary.html>).

⁴⁴ The five IP offices (IP5) is the name given to a forum of the five largest IP offices in the world. IP5 cooperation was set up to improve the efficiency of the examination process, addressing the growing backlogs, for patents worldwide. The members of IP5 are: the CNIPA (National Intellectual Property Administration of China), the European Patent Office (EPO), the Japan Patent Office (JPO), the KIPO (Korean Intellectual Property Office), and the US Patent and Trademark Office (USPTO). Established in 2007, the IP5 Offices together handle about 80 per cent of the world's patent applications, and 95 per cent of all work carried out under the PCT (<https://www.fiveipoffices.org/about>).

⁴⁵ See European Patent Office (2020), "Committed to common solutions to global challenges – a joint message from the EPO and the JPO", News, 16 July (<https://www.epo.org/news-events/news/2020/20200716.html>).

⁴⁶ See US Patent and Trademark Office (2020), Joint Message from the USPTO and the JPO: For the Future of Innovation, bulletin, 1 June (<https://content.govdelivery.com/accounts/USPTO/bulletins/28e1cf8>).

mentioned Joint Message issued by the USPTO and the JPO, as a support to inventors to help accelerate patent examination.⁴⁷

Many patent offices share the PPH mechanism. Generally, the PPH consists of a set of initiatives by which the second patent offices can share decisions with the first examination office with regard to patentability of an invention.⁴⁸ Within the context, when a patent applicant receives a decision issued by the first filing office, and if it states that at least one claim in the application is patentable, the applicant will be able to request the second offices to conduct fast-track examination (therefore, the ‘highway’) of the corresponding claims contained in the application filed in the second offices. As a result, the PPH benefits applicants with quicker and more consistent decisions on patentability in multiple jurisdictions within the PPH framework.⁴⁹

4. Commitments on pharmaceutical-related patent protection measures under the US-China Phase One Agreement

The above-mentioned initiatives to streamline search procedures among different patent offices are related to the novelty test of an invention patent application, which is the first step of an examination. For the second step, the question is what would suffice for an invention patent - a pharmaceutical product, for example, to cross the threshold of the inventive step? Different patent offices would have every nuance in their answers,⁵⁰ since after all they have the liberty and flexibility to elect patent protection standards on, for example, patentability.

⁴⁷ Ibid.

⁴⁸ For example, the USPTO has concluded a PPH agreement with many countries, including Australia, Austria, Canada, Denmark, Finland, Germany, Hungary, Japan, South Korea, Singapore, Spain, the UK, and the EPO; the JPO has concluded a PPH agreement with countries including: the US, South Korea, the UK, Germany, Denmark, Finland, Russia, Austria, Singapore, Hungary, Canada, Spain and the EPO.

⁴⁹ Note that, however, within the context of decision-sharing, multiple patent applications will not be examined in the second offices until the examination in the first filing office is entirely completed and, therefore, examination is not conducted in parallel, but sequentially. As a result, the total lead time required for obtaining multiple patents may become longer. Moreover, in order to benefit from the scheme, the scope of a patent claim must be strictly identical in all the applications submitted at the PPH offices, meaning that the scope of a claim submitted in the second filing offices must be limited to the same scope of the claim lodged in the first filing office. This requirement under the PPH may result in narrower patent claims than if an application were to be prosecuted separately in each national office. In any case, decision-sharing could significantly reduce the workload of the second filing offices as far as further examination is concerned if the second offices and the first office share similar examination rules and standards. For details, Op.cit., Hu, W. (2017), pp.71-3.

⁵⁰ The high threshold of “enhanced efficacy” set down by Section 3(d) of India’s Patents (Amendment) Act 2005 is hard to cross, as Novartis AG v. Union of India illustrates. In accordance with Article 22 of China’s Patent Law, if an invention demonstrates “prominent substantive features and indicates remarkable advancements” the inventiveness requirement would be considered to be met.

4.1 Admissibility of supplemental test data submission

To guard against ‘evergreening’ or extending the life of patents for pharmaceutical products which could distort competition,⁵¹ some patent offices do not admit supplemental test data.⁵² At the same time, supplemental test data is important for pharmaceutical companies because, if ever an application is rejected for lacking inventiveness, supplemental test data may be able to prove that, even though the two pharmaceutical products appear similar, the claimed product will work differently and better – the so-called efficacy test – than the *prior art*. Admitting supplemental test data is a practice engaged by America, and pharmaceutical companies tend to file a patent application for a promising composition early and then generate supplemental and comparative data later on. In China, supplemental test data was admissible on a case-by-case basis (with qualifications), until China conceded to full admissibility under the US-China Phase One Agreement.

China’s Patent Examination Guidelines (2017) made clear that experimental data submitted after the patent application filing date would be admissible, provided that the technical effect to be demonstrated by such experimental data can be obtained by a person skilled in the art from the disclosure of the patent application. But there were complaints that Chinese patent examiners were either unduly restrictive or inconsistent in implementing these guidelines, resulting in rejections of supplemental data and denials of patents or invalidations of existing patents on medicines, even when counterpart patents had been granted in other countries.⁵³

Under the Phase One Agreement, China has now pledged to permit pharmaceutical patent applicants to rely on supplemental test data to satisfy relevant requirements for patentability, including sufficiency of disclosure and inventive step, during patent examination proceedings, patent review proceedings, and judicial proceedings.⁵⁴ This commitment will boost the chances for pharmaceutical patent applications to qualify the patentability test.

4.2 Effective patent-term extension

An invention patent may be granted after 18 months following the date of filing under the EPC,⁵⁵ but in China it takes longer. In China’s case, invention patent examination consists of two steps: preliminary and substantive examination. An invention patent will not be granted after preliminary examination, which will take 18 months or less counting from the date of application. Conducting a preliminary examination is but on formality; an invention patent may

⁵¹ In this context, ‘evergreening’ takes place when pharmaceutical companies artificially extend the period of patent protection by patenting trivial secondary elements of their patented drug when the patent is about to expire. See Basheer S. and Prashant R. (2008), “‘Docking’ TRIPS in India: a saga involving Novartis and the legality of Section 3(d)”, 20 National Law School of India Review 131, pp.135-6.

⁵² See also Correa C.M. (2020), “Special Section 301: US Interference with the Design and Implementation of National Patent Laws”, July, Research Paper 115, South Centre, p.14.

⁵³ See USTR (2020), 2019 USTR Report to Congress on China’s WTO Compliance, March, p.41.

⁵⁴ Article 1.10, Section C, Chapter 1: Intellectual Property, US-China Economic and Trade Agreement.

⁵⁵ Article 93, European Patent Convention.

only be awarded after substantive examination, which should take place within three years of the date of application and upon the applicant's request. It is during substantive examination that the qualities of novelty, inventiveness and industrial applicability of a patent application will be examined.

It is of course legitimate to set down national patent examination guidelines, but an unreasonably long examination process will erode the rights and legitimate interests of a patent holder and could discourage innovation activities.

As a general commitment to enhance patent protection, in accordance with Article 1.12.2 (a) of the Phase One Agreement, China has pledged to extend the term of a patent if, when not attributed to the applicant, a patent is only issued more than four years from the date of filing in China, or three years after a request for substantive examination of the application, whichever is later.

The specific commitment on pharmaceutical product patent-term extension is in relation to the delays that may occur during approval. Within this remit, the extension may be applicable to patents that cover i) a new pharmaceutical product, and ii) the methods of making or using a new pharmaceutical product that are approved for the market in China. China has pledged to make adjustment to extend the patent-term up to five years or the term of the patent rights conferred, covering a new pharmaceutical product, its method of use or manufacturing, and up to 14 years for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial use of that product in China.⁵⁶

The up-to-14-year extension is particularly long⁵⁷ for the term of patent rights conferred by a pharmaceutical product or a process, but understandably the term of extension would be commensurate with the number of years of delay that would occur. It is reported by the European pharmaceutical industry in China that current delays could be as long as six to eight years for marketing approval of new innovative vaccines in China.⁵⁸ In light of this, it is no surprise to read about the 'vaccine tourism' undertaken by some Chinese people in recent years,⁵⁹ following the vaccine scandal in China in 2018.⁶⁰ If only the Chinese authorities could accelerate the marketing approval process to stimulate legitimate competition, the public would be able to access potentially life-saving pharmaceutical products and this would help

⁵⁶ Article 1.12.2(b), Section C, Chapter 1: Intellectual Property, US-China Economic and Trade Agreement.

⁵⁷ Under the same scenario of delays incurred in marketing approval, the extension is five years under the EU-Singapore FTA (Article 10.31, the EU-Singapore FTA). Under the EU-Vietnam FTA, the adjustment of extension will be two years for a patent term, and five years to compensate for the effective loss of patent rights conferred (Article 12.40, the EU-Vietnam FTA).

⁵⁸ See EU Chamber of Commerce in China (2019), Pharmaceutical Working Group Position Paper, 24 September, p.253.

⁵⁹ See Einhorn B. & Wei D. (2018), China's Vaccine Tourists Drain Hong Kong's Supply of Cancer Drug (13 June), Bloomberg (<https://www.bloomberg.com/news/articles/2018-06-13/china-s-vaccine-tourists-drain-hong-kong-s-supply-of-cancer-drug>).

⁶⁰ See Shi T., Chik H. (2018), Hong Kong clinics prepare for influx of mainland visitors after China vaccine scandal, (25 July), Reuters (<https://www.reuters.com/article/us-china-vaccines-hongkong-idUSKBN1KF1HC>).

sustain incentives for pharmaceutical innovation, also in the future. Efficient marketing approval of patent rights conferred is an indispensable step towards accessing a Covid-19 pharmaceutical product such as a vaccine, whether they are China- or foreign-patented.

In the same context, it is worth mentioning that in 2018 China's State Drug Administration published the Technical Guidelines for the Acceptance of Overseas Clinical Trial Data for Drugs. The scope of the Guidelines is still fairly limited,⁶¹ but it is an important 'decision-sharing' step when (within the scope) overseas data can be submitted to support clinical evaluation that Chinese authorities will conduct, for faster access to the Chinese market with much lower costs for foreign pharmaceutical and medical device manufacturers. Previously, pharmaceutical products and medical devices could not be approved for the Chinese market without undergoing domestic clinical trials.

4.3 'Patent linkage' and data protection for pharmaceuticals in future US-China trade negotiations

Additionally, under the Phase One Agreement, China committed to establish a nationwide mechanism for the early resolution of potential pharmaceutical patent disputes, including a course of action to allow a patent holder to seek expeditious remedies before the marketing of an allegedly infringing product.⁶² This concession introduces some form of 'patent linkage', although limited to the supply of information to rights-holders and the availability of "preliminary injunctions or equivalent effective provisional measures". 'Patent linkage' means linking drug regulatory authorities' granting of marketing approval with the patent status of a pharmaceutical product, which is a TRIPS-plus protection measure promoted by America. The EU does not apply it.⁶³

It is also envisaged that the US and China will further address data protection for pharmaceuticals in future negotiations. Issues in this regard are related to the alleged unfair commercial use of, and unauthorised disclosure of, undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, data protection for pharmaceutical products first marketed inside and outside China. The differentiation between the two would be decisive in terms of efficient resolution of patent disputes between right holders and the producers of generic pharmaceuticals.⁶⁴ On this account, during its WTO accession China committed to ensure that no subsequent applicant would rely on the aforementioned data for

⁶¹ Examples of overseas trial data that will be accepted include:

- i) clinical trial data of innovative new drugs simultaneously developed in China and overseas; and
- ii) clinical trial data of generic drugs researched and developed overseas possessing fully measurable bioequivalence ('BE') data.

⁶² The mechanism is to cover both small molecule drugs and biologics. See Article 1.11, Section C, Chapter 1: Intellectual Property, US-China Economic and Trade Agreement.

⁶³ For more detailed discussion, Op.cit., C.M Correa, (2020), p.12.

⁶⁴ Op.cit., USTR (2020), p.41.

a period of at least six years from the date of marketing approval in China. But there are discrepancies in compliance.⁶⁵

Under certain bilateral agreements concluded by the US (with developed and developing countries), apart from the requirement of a *sui generis* regime for data protection⁶⁶ for at least five years from the date of first approval of a pharmaceutical product in the country; in some cases, 'linkage' requirements are also prescribed whereby national health authorities are prevented from granting marketing approval for a generic product if a patent covering the product is in force. It may be expected that future negotiations between the US and China would follow this direction, in which case marketing approval for generic pharmaceutical products in China would become more restricted.

5. Conclusion

When future Covid-19 vaccines are under patent rights protection, the policy choice of compulsory licensing and the Paragraph 6 system could be engaged to complement voluntary licensing, to facilitate affordable access to future Covid-19 pharmaceutical products and to deliver on the commitment to public health.

The Paragraph 6 system waives the restriction of "predominantly domestic use" when supplying the generic versions of patented pharmaceutical products, manufactured under a compulsory licence if ever a WTO member finds itself with insufficient or no manufacturing capacity to manufacture particular pharmaceutical products, thus necessitating import. However, the EU and its member states, and a few other TRIPS members such as the US and Japan, may not be able to enjoy the Paragraph 6 system as an importer of the generic version of a patented Covid-19 vaccine, for example, since they opted out of the system and their undertaking is incorporated in the Decision of the WTO General Council to implement the Paragraph 6 system.

With regard to the accessibility of future Covid-19 vaccines, and as far as multiple patent examination is concerned, closer international cooperation is indispensable to deliver an efficient, swift and more predictable examination process. To this end, a number of initiatives launched in recent decades can serve these purposes. These include, among the patent offices, the Patent Prosecution Highway, the EU, Japan and the US Trilateral Cooperation (on patent) and the IP5 Cooperation, and; at regional and international levels; the European Patent Convention, and the Patent Cooperation Treaty that is administered by the World Intellectual Property Organization, with more than 150 contracting states.

⁶⁵ There are reports that generic manufacturers have been granted marketing approval before the six-year protection period had elapsed, or even before the originator's product had been approved. Op.cit., USTR (2020), p.A-85.

⁶⁶ Referring back to the Joint Message issued by the USPTO and the JPO in June 2020, it highlighted that both offices had developed their own databases allowing interested parties to readily access information about patents that are available for licensing of patented technologies and the commercialisation of inventions effective in combating Covid-19.

In the same context of accessibility, the pharmaceutical-related patent protection measures that China has pledged under the Phase One Agreement on the admissibility of supplemental test data and effective patent-term extension will facilitate market access of foreign-patented Covid-19 in China. Pandemic or not, these measures help to address the grievances voiced by the European pharmaceutical industry, too. Nevertheless, on data exclusivity and the protection of pharmaceuticals that the US and China are envisaged to negotiate in future, what might be established as a result is a linkage between marketing approval and any pharmaceutical patent in force. This could impede marketing approval for generic pharmaceutical products in China. In any case, the search for a balance between patent protection and public health is expected to continue.



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