155 Research Paper
27 May 2022

Manufacturing for Export: A TRIPS-Consistent Pro-Competitive Exception

Carlos M. Correa and
Juan I. Correa

SOUTH CENTRE

RESEARCH PAPER

155

MANUFACTURING FOR EXPORT: A TRIPS-CONSISTENT PRO-COMPETITIVE EXCEPTION*

Carlos M. Correa† and Juan I. Correa**

SOUTH CENTRE

27 MAY 2022

* This paper is a revised version of the text to be published in C. Godt & M. Lamping (editors), *A Critical Mind. Hanns Ullrich's Footprint in Internal Market Law, Antitrust and Intellectual Property*, Springer (forthcoming 2022).

† Carlos M Correa is the Executive Director of South Centre, Geneva Switzerland.

**Juan I Correa is an Affiliated Research Fellow of the Max Planck Institute for Innovation and Competition, Munich, Germany.

SOUTH CENTRE

In August 1995, the South Centre was established as a permanent intergovernmental organization. It is composed of and accountable to developing country Member States. It conducts policy-oriented research on key policy development issues and supports developing countries to effectively participate in international negotiating processes that are relevant to the achievement of the Sustainable Development Goals (SDGs). The Centre also provides technical assistance and capacity building in areas covered by its work program. On the understanding that achieving the SDGs, particularly poverty eradication, requires national policies and an international regime that supports and does not undermine development efforts, the Centre promotes the unity of the South while recognizing the diversity of national interests and priorities.

NOTE

The views contained in this paper are attributable to the author/s and do not represent the institutional views of the South Centre or its Member States. Any mistake or omission in this study is the sole responsibility of the author/s.

Any comments on this paper or the content of this paper will be highly appreciated. Please contact:

South Centre
International Environment House 2
Chemin de Balexert 7–9
POB 228, 1211 Geneva 19
Switzerland
Tel. (41) 022 791 80 50
south@southcentre.int
www.southcentre.int

Follow the South Centre's Twitter: South_Centre

ABSTRACT

The paper discusses the flexibilization of the *sui generis* system of supplementary protection certificates (SPCs) under European law recently introduced to allow for the manufacturing, stockpiling and export of covered products. Against this background, it examines the viability under the Agreement on Trade-related Aspects of Intellectual Property Rights (the TRIPS Agreement) of an exception allowing for the manufacture and export of patent-protected products. It concludes that such an exception would promote competition and enhance access to medicines (including biologicals) for the general public while being consistent with Article 30 of the TRIPS Agreement if read in accordance with the principles of interpretation of customary international law.

Ce document traite de la flexibilisation du système sui generis des certificats complémentaires de protection (CCP) en vertu de la législation européenne récemment introduite pour permettre la fabrication, le stockage et l'exportation de produits protégés. Dans ce contexte, il examine la viabilité, dans le cadre de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (l'Accord sur les ADPIC), d'une exception autorisant la fabrication et l'exportation de produits protégés par un brevet. Elle conclut qu'une telle exception favoriserait la concurrence et améliorerait l'accès aux médicaments (y compris les produits biologiques) pour le grand public tout en étant compatible avec l'article 30 de l'accord sur les ADPIC s'il est lu conformément aux principes d'interprétation du droit international coutumier.

El documento analiza la flexibilización del sistema sui generis de certificados complementarios de protección (CCP) en el marco de la legislación europea, introducido recientemente para permitir la fabricación, el almacenamiento y la exportación de productos cubiertos. En este contexto, se examina la viabilidad, en el marco del Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (Acuerdo sobre los ADPIC), de una excepción que permita la fabricación y exportación de productos protegidos por patentes. Llega a la conclusión de que dicha excepción fomentaría la competencia y mejoraría el acceso a los medicamentos (incluidos los biológicos) para el público en general, al tiempo que sería coherente con el artículo 30 del Acuerdo sobre los ADPIC si se lee de acuerdo con los principios de interpretación del derecho internacional consuetudinario.

TABLE OF CONTENTS

I. INTRODUCTION

The adoption of the Agreement on Trade-related Aspects of Intellectual Property Rights[1] (the TRIPS Agreement) marked a paradigm shift in intellectual property law on a global scale. It required the members of the World Trade Organization (currently 164) to establish minimum standards on patent law as well as on other areas of intellectual property, thereby significantly limiting the policy space available to design national policies on the matter and to determine how to balance right-holders' and public interests.[2] It has been argued that changes to patent laws aiming at strengthening and expanding the scope of patentees' rights would have taken place anyway because both the United States and the European Union could use bilateral and regional agreements to increase the levels of protection to the benefit of their industries.[3] The threat of unilateral trade sanctions under the Special 301 Section of the US Trade Act has been another tool to achieve the same objective.[4] The TRIPS Agreement, however, enormously simplified that task because it addresses most areas of intellectual property and it is associated with a mechanism of enforcement that may lead to trade retaliations in case of non-compliance with the minimum standards set forth in the Agreement.[5]

Since the entry into force of the TRIPS Agreement, there has been a fertile and intense debate among academics and policy makers regarding the "flexibilities" (i.e. the policy space to legislate domestically) contained in the Agreement.[6] This was of great relevance, in particular, for developing countries that had to introduce massive changes to their regulatory framework in order to comply with the Agreement's provisions. With regard to patent law, important flexibilities are provided for in Article 27 (on patentable subject matter and patentability requirements), Article 30 (on exceptions) and Article 31 (on compulsory licenses and non-commercial government use).[7] Article 6 regarding exhaustion of rights,

---

[1] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS 299, 33 ILM 1197 (1994) [hereinafter TRIPS Agreement].

[2] See generally, Ruth L Okediji and Margo A Bagley, *Patent Law in Global Perspective* (OUP, 2014). http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780199334278.001.0001/acprof-9780199334278. accessed 20 May 2020.

[3] Frederick Abbott, "Rethinking Patents: From 'Intellectual Property' to 'Private Taxation Scheme'" in Peter Drahos, Gustavo Ghidini and Hanns Ullrich (eds.), *Kritika, Essays on Intellectual Property, Vol 1* (Edward Elgar, 2015) 2-7.

[4] See e.g. Carlos Correa, *Special Section 301: US Interference with the Design and Implementation of National Patent Laws*, Research Paper No. 115 (Geneva, South Centre, March 2020). <https://www.southcentre.int/wp-content/uploads/2020/07/RP-115.pdf> accessed 20 March 2020.

[5] See Part V of the of the TRIPS Agreement.

[6] See e.g., German Velasquez, Carlos Correa and Vitor Ido, *Intellectual Property, Human Rights and Access to Medicines: A Selected and Annotated Bibliography* 3rd edition (Geneva, South Centre, 2020). <https://www.southcentre.int/wp-content/uploads/2020/04/Intellectual-Property-Human-Rights-and-Access-to-Medicines-3rd-Edition-FINAL-ok.pdf> accessed 20 March 2020; see also William Cornish and Kathleen Liddell, "The Origins and Structure of the TRIPS Agreement", in *TRIPS plus 20*, Hanns Ullrich, Reto Hilty, Josef Drexl and Matthias Lamping (eds.), (Springer 2016) <http://link.springer.com/10.1007/978-3-662-48107-3_1> accessed 20 March 2020; Carlos María Correa and Abdulqawi Yusuf, *Intellectual Property and International Trade: The TRIPS Agreement*, 3rd ed. (Wolters Kluwer, 2016); Peter Drahos, Gustavo Ghidini and Hanns Ullrich, *Kritika, Essays on Intellectual Property Vol 1* (Edward Elgar 2015); Christopher Arup and William van Caenegem, *Intellectual Property Policy Reform* (Edward Elgar, 2009) <http://www.elgaronline.com/view/9781848441637.xml> accessed 01 April 2020; Carlos María Correa, *Research Handbook on the Protection of Intellectual Property under WTO Rules* (Edward Elgar, 2010); Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International, 2001); Matthias Lamping, "Declaration on Patent Protection: Regulatory Sovereignty under TRIPS" (2014) 45 IIC 679.

[7] Regarding TRIPS' flexibilities see in general Carlos María Correa and Abdulqawi Yusuf (2016, supra n 6); Carlos María Correa (2010, supra n 6); Carlos María Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (OUP, 2007).

applicable to all the intellectual property rights covered under the TRIPS Agreement, also allows for significant room for maneuver to deal with parallel importation.[8]

As noted by Prof. Ullrich the flaws in the linkage between trade and intellectual property issues introduced by that Agreement and argued for a clear separation "of trade issues from the many other issues of market regulation, such as development, public health, consumer protection as well as precisely intellectual property protection [that would] yet allow them to be seen as parts of a coherent organization of markets".[9] Paradoxically, in the context of a system aimed at liberalizing trade, the disciplines dealt with under the TRIPS Agreement do fragment the international market, as they are based on territorial rights whose exercise can limit rather than promote the international movement of goods. One case in point is the extent to which the exclusive rights conferred under patents can prevent the manufacture of products with the sole purpose of exportation. This is the subject addressed in this chapter. Specifically, it discusses whether a third party can be deemed to be allowed to use a patented invention (whether a product or process) when its acts do not affect the commercial interests of the patent owner in the country where protection is conferred (exporting country), as such a use only leads to commercial activity in a foreign country (importing country). This situation may arise, for instance, where the product is not patent-protected in the country of importation, because a patent was not filed, the application was refused, the patent was revoked or it expired before the granted patent in the country of exportation.

This paper discusses, first, the recent developments regarding the supplementary protection certificates (SPCs) granted under the European law that led to the introduction of a manufacturing for export and stockpiling exception to SPCs; second, it examines the WTO jurisprudence on exceptions to patent rights; and third, the chapter elaborates on the compatibility of a manufacturing for export exception with the TRIPS Agreement.

[8] See e.g., Irene Calboli and Edward Lee, *Research Handbook on Intellectual Property Exhaustion and Parallel Imports* (Edward Elgar, 2016).
[9] Hanns Ullrich, Reto Hilty, Josef Drexl and Matthias Lamping (eds.), *TRIPS plus 20: From Trade Rules to Market Principles* (Springer, 2016) <http://link.springer.com/10.1007/978-3-662-48107-3> accessed 17 March 2020, 121-122.

II. THE SPC AND THE MANUFACTURING FOR EXPORT EXEMPTION

1. Extension of Exclusive Rights under the SPCs

The European Patent Convention (EPC) provides for twenty years of protection of the patent rights (counted from the date of filing of the application). It does not allow for an extension of this term, as is the case under other patent regimes in force in many developed and developing countries.[10] This limitation in the EPC was circumvented by the creation of the SPCs, which do not strictly represent an extension of the patent term but have similar (albeit not identical) effects. An SPC is a *sui generis* right conferred in relation to pharmaceutical and plant protection products only.[11] The purpose of the certificates is to extend the exclusive rights conferred by an expired patent on such products without formally modifying the patent term. The extension cannot last for more than five years.[12] The alleged justification for the EU regulations on SPCs (as well as the patent term extension in the US and other countries) has been that the right-holders of pharmaceutical and plant protection products cannot exploit the patents until they receive marketing authorization pursuant to procedures that may take several years, thereby limiting their ability to recoup the research and development costs.[13]

In this regard, Recital 2 of Council Regulation (EEC) No 1768/92 and Recital 3 of Regulation 469/2009 ("Medicinal SPC Regulation") states: "Medicinal products, especially **those that are the result of long, costly research**, will not continue to be developed in the Community and in Europe unless they are covered by favorable rules that provide for sufficient protection to encourage such research".[14] It adds that "the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into research". As shown in Figure 1, the EU is a major producer and trader of pharmaceutical products; this would explain the preferential treatment given to this sector through the grant of SPCs. As the COVID-19 pandemic has

[10] For instance, in the United States, the Drug Price Competition and Patent Restoration Act (Hatch-Waxman Act) allows the extension of the term of a patent regarding a product that requires regulatory approval prior to being sold, or a method of using or manufacturing the product, for a maximum period of five years. 21 USC 355(b), (j), (l); 35 USC 156, 271, 282. Similarly, in Japan, the Patent Act allows for the patent term to be extended for a maximum period of 5 years (art 67(2)). In Australia, the Australian Patents Act of 1990 (Provision S70), allows for a patent to be extended for five years beyond the standard 20-year term. The extension is only available for patents covering new active pharmaceutical ingredients, new formulations of known active pharmaceutical ingredients and new methods of producing known pharmaceuticals when the methods involve the use of recombinant DNA technology. In Costa Rica, the Patent Law (art 17.4) provides for a term extension in cases of delay for marketing authorization of pharmaceutical products.

[11] See Hanns Ullrich and others (2016, supra n 9); European Commission and Max Planck Institute for Innovation and Competition, *Study on the Legal Aspects of Supplementary Protection Certificates in the EU: Final Report* (EC/MPG 2018) 23 <https://op.europa.eu/en/publication-detail/-/publication/004c1a50-654b-11e8-ab9c-01aa75ed71a1/language-en/format-PDF> accessed 14 June 2020; European Commission, "Supplementary Protection Certificates for Pharmaceutical and Plant Protection Products" (Internal Market, Industry, Entrepreneurship and SMEs 2019) <https://ec.europa.eu/growth/industry/policy/intellectual-property/patents/supplementary-protection-certificates_en> accessed 17 June 2020.

[12] A six-month additional extension is available in accordance with Regulation (EC) No 1901/2006 if the SPC relates to a medicinal product for children for which data has been submitted according to a paediatric investigation plan (PIP).

[13] See Xavier Seuba, "The Export and Stockpiling Waivers: New Exceptions for Supplementary Protection Certificates", *SSRN Electronic Journal* (2019). <https://www.ssrn.com/abstract=3500774> accessed 17 June 2020. European Commission, "Explanatory Memorandum to the Proposal for a European Parliament and Council Regulation (EC), of 09 December 1994, Concerning the Creation of a Supplementary Protection Certificate for Plant Protection Products", COM(1994) 579 final (9.12.1994) <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1994:0579:FIN:EN:PDF>.

[14] Emphasis added.

shown, however, the EU is largely dependent on active pharmaceutical ingredients produced in China and India, which has led to a promotion of initiatives to ensure more self-sufficiency in the pharmaceutical sector.[15]

Since the entry into force (on 2 January 1993) of Council Regulation (EEC) No 1768/92 (later repealed by Regulation (EC) No. 469/2009 which entered into force on 6 July 2009) the total number of SPC applications filed in the EU Member States has tripled from about 500 applications filed in 1993 to 1,518 in 2013; until 2015 the total number of applications was 20,900.[16] The SPC Regulations have been subject to various amendments and jurisprudential interpretation regarding the core elements of protection.[17] A number of studies on the economic impact of the SPC have been conducted as well.[18]

One of the key objectives of the European legislative body has been to provide a uniform solution at the Community/Union level, thereby preventing the heterogeneous development of national law, which might have affected the functioning of the internal market. Although the SPC regulation was adopted at the regional level, the certificate is granted in each national jurisdiction, through the national patent offices, which are in charge of establishing whether the conditions for granting the certificates are met and of determining their scope. Importantly, unlike the basic patent,

> an SPC does not extend the protection conferred across the entire scope of the patent claims, but will only protect the product covered by the authorization to place

[15] See e.g., European Commission, "Pharmaceutical Strategy for Europe – Medicinal Products", (2020) <https://ec.europa.eu/health/human-use/strategy_en> accessed 30 June 2020; Carlos Correa, 'Lessons from COVID-19: Pharmaceutical Production as a Strategic Goal', South Views No 202 South Centre <https://www.southcentre.int/wp-content/uploads/2020/07/SouthViews-Correa.pdf> accessed 17 July 2020.

[16] European Commission and Industrie Generaldirektion Binnenmarkt Unternehmertum und KMU, *Study on the Economic Impact of Supplementary Protection Certificates, Pharmaceutical Incentives and Rewards in Europe: Final Report* (2018) <https://doi.org/10.2873/886648> accessed 05 March 2020.

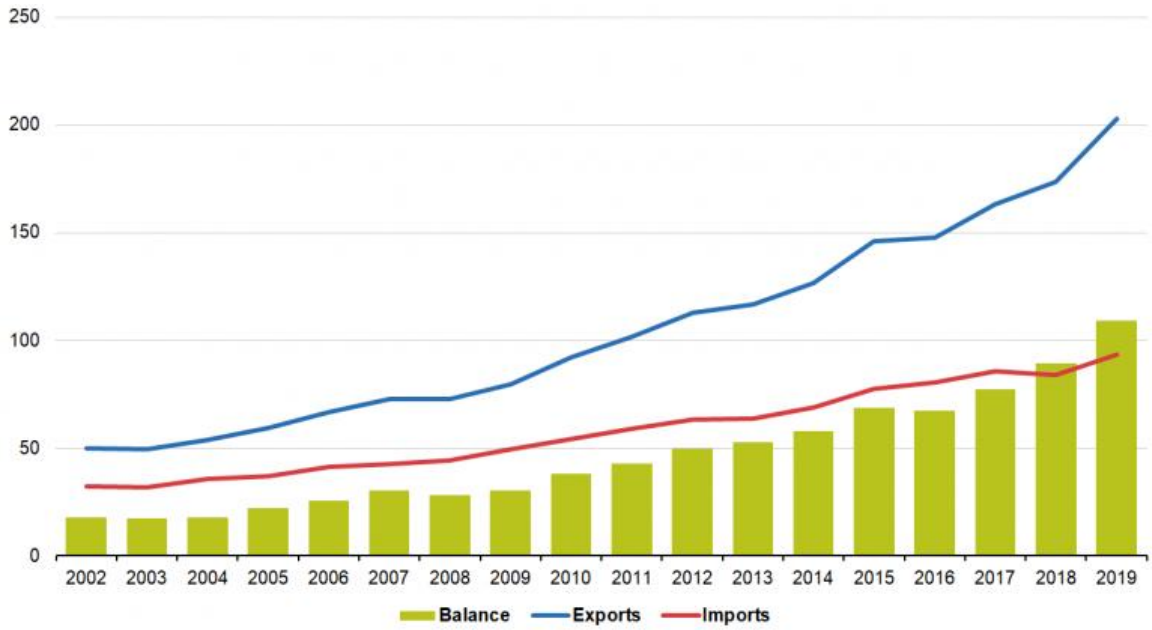
[17] See e.g., CJEU, 14.11.2013, C-210/13 *GlaxoSmithKline Biologicals v Comptroller-General of Patents (GSK)* [2013] ECLI:EU:C:2013:762; CJEU, 04.05.2006, Case C-431/04 *Massachusetts Institute of Technology (MIT)* [2006] ECR 2006 I-04089, ECLI:EU:C:2006:291; CJEU, 27.04.2017, Case C-202/05 *Yissum* [2017] ECR 2007 I-02839, ECLI:EU:C:2007:214; CJEU, 15.01.2015, Case C-631/13 *Forsgren v Österreichisches Patentamt* [2015]; CJEU, 28.07.2011, Case C-195/09 *Synthon v Merz Pharma* [2011] ECR 2011 I-07011, ECLI:EU:C:2011:518 (confirmed in CJEU, 28.07.2011, Case C-427/09 *Generics v Synaptech* [2011] ECR 2011 I-07099, ECLI:EU:C:2011:520); CJEU, 16.09.1999, Case C-392/97 *Farmitalia* [1999] ECR 1999 I-05553, ECLI:EU:C:1999:416; CJEU, 24.11.2011, Case C-322/10 *Medeva* [2011] ECR 2011 I-12051, ECLI:EU:C:2011:773; CJEU, 25.11.2011, C-518/10 *Yeda* [2011] ECR 2011 I-12209, ECLI:EU:C:2011:779; CJEU, 25.11.2011, Case C-6/11 *Daiichi* [2011] ECR 2011 I-12255, ECLI:EU:C:2011:781; CJEU, 25.11.2011, Case C-630/10 *Queensland* [2011] ECR 2011 I-12231, ECLI:EU:C:2011:780.

[18] See for example: European Commission and Max Planck Institute for Innovation and Competition, *Study on the Legal Aspects of Supplementary Protection Certificates in the EU* (EC 2018); Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (European Commission), *Study of the Economic Impact of Supplementary Protection Certificates, Pharmaceutical Incentives and Rewards* (Publication Office of the EU 2018) <https://op.europa.eu/en/publication-detail/-/publication/8ffeb206-b65c-11e8-99ee-01aa75ed71a1/language-en> accessed 17 July 2020; Charles Rivers Associates and Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (European Commission), *Assessing Economic Impact of Changing Exemption Provisions during Patent and SPC Protection in Europe* (Publication Office of the EU 2017) <https://op.europa.eu/en/publication-detail/-/publication/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1/language-en> accessed 17 July 2020; Malwina Meier, "25 Years of SPC Protection for Medicinal Products in Europe: Insights and Challenges" (Publication Office of the EU 2017) <https://ec.europa.eu/growth/industry/policy/intellectual-property/patents/supplementary-protection-certificates_en> accessed 17 July 2020; Margaret Kyle, "Economic Analysis of Supplementary Protection Certificates in Europe", (Publication Office of the EU 2017) <https://ec.europa.eu/growth/industry/policy/intellectual-property/patents/supplementary-protection-certificates_en> accessed 17 July 2020; John Miles, "Supplementary Protection Certificates for Medicinal Products: Where Are We Now and What Challenges Lay Ahead?", (2012) 1 Pharmaceutical Patent Analyst 275; Omkar Umesh Joshi, Archna Roy and Manthan Janodia, "Comparative Quantitative Analysis of Supplementary Protection Certificates (SPCs) in Europe", *JIPR* vol. 22 No. 1, (2017) 16-22; Rens de Boer, "Supplementary Protection Certificate for Medicinal Products: An Assessment of European Regulation", Master Thesis at the Vrije Universiteit Amsterdam, 2015. <http://www.spcwaiver.com/files/Netherlands_SPC_assessment.pdf> accessed 17 July 2020.

> the corresponding medicinal product (or plant protection product) on the market, and any use of that product as a medicinal product (or plant protection product) that has been authorized before expiry of the SPC.[19]

It is worth noting that Regulation (EC) No. 1610/96 created an SPC for plant protection products ("Plant SPC Regulation"), which entered into force on 8 February 1997. Generally speaking, the plant and medicinal SPC regulations contain similar provisions.

Figure 1
EU-27 Trade in medicinal products 2002-2019 (Eur Billion)



Source: Eurostat (online data code: DS-018995)

2. SPC Exceptions for Stockpiling and Manufacture for Export

In 2019, the SPC medicinal regulation was modified by Regulation (EU) 2019/933 to introduce an exemption that allows EU-based companies to manufacture a generic version or biosimilar of an SPC-protected medicine during the term of the certificate, if done either for the purpose of exporting to a non-EU market, or for stockpiling during the final 6 months of an SPC ahead of entry into the EU market.[20] Before the implementation of the new exemption, the European Commission requested a study regarding the economic impact of the new piece of legislation. The findings of this study showed that the introduction of such exception would benefit European industry and promote access to medicines.[21]

The new exemption is known as the "manufacturing waiver", since it would permit manufacturing of an SPC-protected product with the exclusive aim of either exporting to third countries or entering the market right after the expiry date of the SPC.

---

[19] EPO, "Supplementary Protection Certificates", (*European Patent Academia: E-Course Patent Litigation*, June 2020) <https://e-courses.epo.org/wbts_int/litigation/SPCs.pdf> accessed 17 July 2020.

[20] Regulation (EU) 2019/933 of 20 of May amending Regulation (EC) No 469/2009 Concerning the Supplementary Protection Certificate for Medicinal Products [2019] OJ L 153,11.6.2019 pp. 1-10.

[21] European Commission, "Impact Assessment Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 Concerning the Supplementary Protection Certificate for Medicinal Products", SWD(2018) 240 final (28.05.2018) <https://ec.europa.eu/docsroom/documents/29463> accessed 10 July 2020.

The objective of Regulation (EU) 2019/933 is to create a level playing field between European Union-based manufacturers and third-country manufacturers. Its aim is

> to remove a major competitive disadvantage of EU-based manufacturers compared to manufacturers based in non-EU countries (where SPC-type protection is not available or not enforceable) and ensure a better deal for patients. The revision is a well-calibrated adjustment to the current regime striking a balance between ensuring the attractiveness of Europe for innovative pharmaceutical companies and allowing EU-based generics and biosimilars to compete on the global market.[22]

The reform is also linked to public health goals, namely "to reduce prices and to ensure that national healthcare systems are sustainable and that patients in the Union have better access to affordable medicines".[23] Interestingly, the amendment to the SPC medicinal regulation aims at a "day-one entry" of generic and biosimilar medicines to the European healthcare system as it states that it:

> should also allow such makers to make and store products, or medicinal products containing those products, in a Member State for a defined period pending the expiry of the certificate, for the purpose of entering the market of any Member State upon expiry of the corresponding certificate, thereby helping those makers to compete effectively in the Union immediately after protection has expired ('EU day-one entry').[24]

The exemption to the rights conferred under an SPC allows third parties to undertake

> the making of a product, or a medicinal product containing that product, for the purpose of export to third countries or of storing, and any related acts in the Union strictly necessary for that making or for the actual export or the actual storing, where such acts would otherwise require the consent of a certificate holder.[25]

In addition, the new Regulation introduced a right to produce and stockpile a product protected under an SPC to speed up its marketing after the expiry of the SPC. Paradoxically, as examined below, in a case brought by the EU against Canada (Patent Protection of Pharmaceutical Products)[26] under the WTO Dispute Settlement Understanding (DSU), the EU successfully questioned a similar stockpiling provision provided for by Canadian patent law.

The acts exempted from the scope of an SPC are the following:

(i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; or

---

[22] See European Commission, "Supplementary Protection Certificates for Pharmaceutical and Plant Protection Products", (*Internal Market, Industry, Entrepreneurship and SMEs*, 2019) <https://ec.europa.eu/growth/industry/policy/intellectual-property/patents/supplementary-protection-certificates_en> accessed 17 June 2020.

[23] See Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 Concerning the Supplementary Protection Certificate for Medicinal Products, Recital 7; see also, Xavier Seuba (2019, supra n 13).

[24] Regulation (EU) 2019/933, Recital 8.

[25] See Recital 9, Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 Concerning the Supplementary Protection Certificate for Medicinal Products.

[26] Canada – Patent Protection of Pharmaceutical Products – Complaint by the European Communities and their Member States – Report of the Panel WT /DS114/R paragraph 7.92 <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm#> accessed 17 July.

(ii) any related act that is strictly necessary for the making, in the Union, referred to in point (i), or for the actual export; or
(iii) the making, no earlier than six months before the expiry of the certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate; or
(iv) any related act that is strictly necessary for the making, in the Union, referred to in point (iii), or for the actual storing, provided that such related act is carried out no earlier than six months before the expiry of the certificate.[27]

The proposal to amend the SPC Regulation has been warmly welcomed and sharply criticized by different segments of the pharmaceutical industry. While the generics industry supported it, but criticized the conditions spelled out for using the exemption, the so-called "research-based" industry opposed the very idea of the relaxation of the exclusive rights granted under SPCs.[28]

In response to the objections raised by the "research-based" pharmaceutical industry, the new Regulation established certain requirements on the third party that limit the exercise of the exemption.

First, a third party using the exemption must notify it to the national authority of the country where the manufacturing is to take place; second, the third party must share with the SPC holder specific information "through appropriate and documented means", including the "number of the certificate granted in the Member State of making" as well as "the reference number of the marketing authorization, or the equivalent of such authorization, in each third country of export, as soon as it is publicly available"; third, specific labeling and logo requirements apply in the case of products manufactured for export.[29] Hence, unlike other exemptions under patent law, the SPC manufacturing exemption requires specific actions by the third party that may allow the SPC holder to closely monitor the use of the exemption and prevent any potential confusion with its own products. These requirements set out obligations that have been considered anti-competitive, as the third party should disclose information that could put it in a disadvantageous position vis-à-vis competitors and could ultimately be detrimental as it would have to disclose its business plans in advance.[30]

3. An Exemption to a Sui Generis Right outside the TRIPS Agreement, but Compliant with It

While the SPCs cannot be considered a category of intellectual property covered by the TRIPS Agreement, the segment of the pharmaceutical industry that opposed Directive 2019/9333 argued that it was contrary to TRIPS Article 30 (exceptions to patent rights) and Article 27, which includes the principle of non-discrimination based on the field of technology of patentable inventions. Seuba examined the different approaches concerning whether or not SPC certificates are subject to the TRIPS Agreement, and identified three different

[27] Regulation (EU) 2019/933, art 5.2.
[28] See Miguel Vidal-Quadras, "Analysis of EU Regulation 2019/933 on the SPC Manufacturing Waiver Exception" (2019) 50 IIC 971; the European Federation of Pharmaceutical Industries and Associations (EPFIA), rejected the exemption and stated that it "would significantly weaken Europe's research and development". <https://www.efpia.eu/about-medicines/development-of-medicines/intellectual-property/supplementary-protection-certificates/> accessed 17 July 2020; see also Member States' Comments <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_8734_2019_ADD_1_REV_1&from=EN> accessed 17 July 2020.
[29] Ibid., arts 5.5 and 5.2(d), as amended.
[30] Medicines for Europe, "Q&A about SPC Manufacturing Waiver", (*SPC Manufacturing Waiver*, June 2020) <http://www.spcwaiver.com/en/Q&A.html> accessed 17 July 2020.

positions: the Agreement does not apply; only Part I thereof applies; and the Agreement is fully applicable.[31] The first is the only approach consistent with a reading of the TRIPS Agreement in accordance with the Vienna Convention on the Law of Treaties. The intellectual property rights covered by the Agreement are restricted to those dealt with in Part II of the Agreement. Thus, for instance, utility models and the *sui generis* database protection conferred under EU law are outside the Agreement's scope. The same applies to SPCs. Furthermore, the SPC as a *sui generis* right is not recognized by most jurisdictions around the globe, and has only been transplanted to other jurisdictions as a result of free trade agreements signed by the EU.[32]

Although SPCs are not within the orbit of the TRIPS Agreement and, therefore, not subject to the dispute settlement mechanism of the agreement, the manufacturing waiver can nevertheless be analyzed in the light of the three-step-test provided for in Article 30 of the Agreement in order to draw some conclusions regarding a similar exception under patent rights (which would be covered by the TRIPS Agreement).

In examining the SPC manufacturing waiver, Seuba[33] and Vival-Quadras[34] noted that the exception proposed by the Commission was limited, since the exclusive rights conferred under an SPC are restricted to the performance and other related acts for the purpose of exporting to third parties or preparing for the marketing of the exported products under the same conditions applicable to other manufacturers producing in third countries. The exemption does not conflict with the normal exploitation of the SPC as it will have no impact on the market of the country where the protection is conferred during the exclusivity period, nor will the legitimate interests of the right-holder be unjustifiably prejudiced. While developed in the context of the SPC, these conclusions are relevant, as discussed below, for situations in which patents are in force in the country where manufacturing for export would take place.
Notably, the EU legislature took into account the conditions set out in Article 30 of the TRIPS Agreement in introducing the manufacturing waiver. Recital 12 of Regulation (EU) 2019/933 notes:

> By limiting the scope of the exception to making for the purpose of export outside the Union or to making for the purpose of storing, and to acts strictly necessary for such making or for the actual export or the actual storing, the exception provided for in this Regulation should not conflict with the normal exploitation of the product, or the medicinal product containing that product, in the Member State in which the certificate is in force, namely with the core exclusive right of the certificate holder to make that product for the purpose of placing it on the Union market during the term of the certificate. In addition, that exception should not unreasonably prejudice the legitimate interests of the certificate holder, whilst taking account of the legitimate interests of third parties.

The manufacturing waiver can be traced back to the CETA (signed on 30 October 2016), one of the latest free trade agreements entered into by the EU, which introduced a sui generis right at the expiry of a patent that extends the protection for pharmaceutical products. However, it provides for limits to this right. Article 20.27.9 states: "Notwithstanding paragraphs 1 through 8, each Party may also limit the scope of the protection by providing exceptions for the making, using, offering for sale, selling or importing of products for the

[31] Xavier Seuba (2019, supra n 13).
[32] See for example, the Comprehensive Economic and Trade Agreement (CETA) signed between the EU and Canada, <https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/toc-tdm.aspx?lang=eng> accessed 17 July 2020.
[33] Xavier Seuba (2019, supra n 13) 20-23.
[34] Miguel Vidal-Quadras (2019, supra n 28) 982-984.

purpose of export during the period of protection".[35] As it reads, this article allows the parties to exclude from the sui generis right all acts related to the export of the protected products, notably without the cumbersome requirements imposed on the third party by the EU regulation.

[35] See Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:22017A0114(01)> accessed 14 June 2020.

III. WTO JURISPRUDENCE ON PATENT EXCEPTIONS

If, as argued above, the SPCs are not covered by the TRIPS Agreement, would similar exceptions (for stockpiling and exports) be allowable under the TRIPS Agreement in relation to patent rights? Article 30 of the Agreement does allow WTO members to provide for such exceptions, subject to a number of conditions. In accordance with that provision, the exception must, first, be "limited" (without specifying whether in scope, duration, or otherwise). Second, it should not "unreasonably conflict with a normal exploitation of the patent". Thirdly, the exception should not "unreasonably prejudice the legitimate interests of the patent owner". All these three conditions are to be applied, however, "taking account of the legitimate interests of third parties".

The general wording of this provision leaves significant room for interpretation, as well as controversy on the scope of the exception. Such wording can, under the WTO system, be clarified by panels and the Appellate Body in accordance with the DSU, or be subjected to Members' authoritative interpretation pursuant to Article IX.2 of the Agreement Establishing the WTO. As the latter has not taken place, the reading of Article 30 can only be enlightened by the WTO jurisprudence.

Since the establishment of the WTO, several members have requested consultations under the DSU regarding compliance between the TRIPS Agreement; in total 42 WTO cases and consultations cited the Agreement and 11 were related to patents.[36] Several consultations were based on complaints presented by the United States,[37] including some regarding Member states' level of protection for pharmaceutical and agricultural chemical products.[38] Two cases involved claims regarding the patent term of protection.[39] Although the adoption of the TRIPS Agreement essentially aimed at disciplining developing countries, most WTO disputes that led to the establishment of a panel were against developed countries (two against the US,[40] two against the European Communities and their Member States,[41] two against Canada,[42] one against Australia[43]). Only two developing countries were subject to

[36] WTO, "Index of Disputes Issues: Patents", (*DISPUTE SETTLEMENT: THE DISPUTES*, 2020) https://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm?id=I5. Accessed 17 June 2020.

[37] Of eleven cases, six were presented against developing countries: see DS 36 Pakistan – Patent Protection for Pharmaceutical and Agricultural Chemical Products (1996); DS 37 Portugal – Patent Protection under the Industrial Property Act (1996); DS 50 India – Patent Protection for Pharmaceutical and Agricultural Chemical Products; DS 79 India – Patent Protection for Pharmaceutical and Agricultural Chemical Products (1997); DS 171 Argentina – Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals (1999); DS 196 Argentina – Certain Measures on the Protection of Patents and Test Data (2000); DS 199 Brazil – Measures Affecting Patent Protection (2000).

[38] See DS 36 Pakistan – Patent Protection for Pharmaceutical and Agricultural Chemical Products (1996); DS 50 India – Patent Protection for Pharmaceutical and Agricultural Chemical Products; DS 79 India – Patent Protection for Pharmaceutical and Agricultural Chemical Products (1997); DS 171 Argentina – Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals (1999); DS 196 Argentina – Certain Measures on the Protection of Patents and Test Data (2000).

[39] DS 170 Canada – Term of Patent Protection (2000); DS 37 Portugal – Patent Protection under the Industrial Property Act (1996).

[40] See DS 160 Panel Report United States – Section 110(5) of US Copyright Act (2010); Appellate Body Report DS 176 United States – Section 211 Omnibus Appropriations Act of 1998, (2002).

[41] See DS 174 Panel Report European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs (2005); DS 290 European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs (2005).

[42] See WTO, "Report of the WTO Panel Canada – Patent Protection for Pharmaceutical Products", (WT/DS114/R, WTO 2000)*;* WTO, "Report of the Appellate Body Canada – Term of Patent Protection", (WT/DS170/AB/R, WTO 2000).

[43] See Panel Report in DS 435, 441, 458, 467 Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging (2018) (hereinafter "Australia–Tobacco Plain Packaging"). The panel report was appealed by

such procedures:[44] India (two complaints concerning the implementation of Article 70.8, the so called "mailbox" provision)[45] and China (criminal sanctions for copyright infringement and other issues).[46] Only four developing countries (Indonesia, Cuba, Honduras, Dominican Republic) have been complaining parties (against Australia in the tobacco plain packaging case) in WTO disputes under the TRIPS Agreement that reached such stage.[47]

Out of the disputes referred to, in only one case was the interpretation of Article 30 of the TRIPS Agreement specifically raised. In *Canada – Patent Protection for Pharmaceutical Products*, the EU complained against Canada in 1998 regarding two exceptions included in Canada's Patent Act: the regulatory review exception[48] (commonly known as the "Bolar exception")[49] and the stockpiling exception.[50] The panel found that the former was consistent with Articles 27.1 and 28.1 of the TRIPS Agreement and covered by the general exception in Article 30. Since this ruling, many jurisdictions, including the EU,[51] have incorporated the regulatory review exception into their domestic patent laws.[52]

The stockpiling exception, on the contrary, the panel found to be inconsistent with Article 28.1 of the TRIPS Agreement and not justifiable under the exception in Article 30. Interestingly, Canada defended the stockpiling exception arguing that it allowed potential competitors a swift entry to the market after the patent expired, thereby protecting public health "through promoting access to cost-effective generic medicines following patent

---

Honduras and the Dominican Republic (see <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds441_e.htm> accessed 17 June 2020). The Report of the Appellate Body was issued on 9 June 2020 (WT/DS435/AB/R WT/DS441/AB/R). On the situation of the Appellate Body as a result of the US blockade to the appointment of new members, see e.g., Danish and Aileen Kwa, "Crisis at the WTO's Appellate Body (AB): Why the AB Is Important for Developing Members", Policy Brief No 69, South Centre, December 2019. <https://www.southcentre.int/wp-content/uploads/2019/12/PB69_Crisis-at-the-WTO%E2%80%99s-Appellate-Body-AB-Why-the-AB-is-Important-for-Developing-Members_EN-1.pdf> accessed 1 June 2020.

[44] A violation of the TRIPS Agreement was incidentally invoked in the *Indonesia – Autos* case, in relation to the protection of trademarks. The panel, however, found that the United States had not demonstrated that Indonesia was in breach of its TRIPS obligations (WTO, "Report of the WTO Panel Indonesia – Certain Measures Affecting the Automobile Industry", WT/DS 54/R, WT/DS 55/R, WT/DS 59/R, WT/DS 64/R (1998) paras 11.1–11.43).

[45] See WTO, Report of the Appellate Body, "India – Patent Protection for Pharmaceutical and Agricultural Chemical Products", (WT/DS50/AB/R, WTO 1998), and WTO, "Report of the WTO Panel, India – Patent Protection for Pharmaceutical and Agricultural Chemical Products", (WT/DS79/R WTO, 1998).

[46] See WTO, "Panel Report in DS362 China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights", (WT/DS362/15), WTO 2009.

[47] Brazil requested the US consultations with regard to provisions of US legislation that limits the right to use or sell any federally owned invention only to a licensee that agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States: "United States – US Patents Code", (WT/DS224/1, 7 February 2001). In DS 408 India complained about border measures imposed on the transit of medicines [WTO, "European Union and a Member State – Seizure of Generic Drugs in Transit", (WT/DS408/8, 11 May 2010)]. These cases were not finally pursued. See Correa, C.M. (2022). Interpreting the Flexibilities Under the TRIPS Agreement. In: Correa, C.M., Hilty, R.M. (eds) Access to Medicines and Vaccines. Springer, Cham. https://doi.org/10.1007/978-3-030-83114-1_1.

[48] The regulatory review exception allows potential competitors of a patent owner to use the patented invention without the authorization of the patent owner during the term of the patent for the purposes of obtaining government marketing approval, so that they will have regulatory permission to sell in competition with the patent owner by the date on which the patent expires.

[49] See e.g., Carlos M Correa, *The Bolar Exception: Legislative Models and Drafting Options*, Research Paper No 66 (Geneva South Centre, 2016). <https://www.southcentre.int/wp-content/uploads/2016/03/RP66_The-Bolar-Exception_EN1.pdf> accessed 17 July 2020.

[50] The stockpiling exception allowed the manufacture and stockpiling of patented goods during a period of six months before the patent expired, but the goods could not be sold until after the patent expiry.

[51] The Human Medicines Directive and the Veterinary Medicines Directive, as amended in 2004, allow the necessary studies and trials for the purpose of applying for marketing authorizations for new generic, hybrid or biosimilar medicines while patents or SPCs are in force.

[52] See e.g., Carlos M Correa (2016, supra n 49); Lionel Bentley and others, "Experts' Study On Exclusions From Patentable Subject Matter and Exceptions and Limitations to the Rights", (Study SCP/15/3, WIPO 02 September 2010) < https://www.wipo.int/edocs/mdocs/scp/en/scp_16/scp_16_ref_scp_15_3-main1.pdf > accessed 01 June 2020.

expiry".[53] As noted above, similar arguments were now being articulated by the EU in introducing the manufacturing waiver: "The aim of this Regulation is to promote the competitiveness of the Union […] to reduce prices and to ensure that national healthcare systems are sustainable and that patients in the Union have better access to affordable medicines" as it would help third parties "to compete effectively in the Union immediately after protection has expired ('EU day-one entry')".[54]

However, the panel took a very narrow approach in examining the scope for exceptions to patent rights under Article 30 of the TRIPS Agreement. The panel considered that the three conditions spelled out in Article 30 were "cumulative, each being a separate and independent requirement that must be satisfied. Failure to comply with any one of the three conditions results in the Article 30 exception being disallowed".[55] The panel added that:

> The three conditions must, of course, be interpreted in relation to each other. Each of the three must be presumed to mean something different from the other two, or else there would be redundancy. Normally, the order of listing can be read to suggest that an exception that complies with the first condition can nevertheless violate the second or third, and that one which complies with the first and second can still violate the third. The syntax of Article 30 supports the conclusion that an exception may be 'limited' and yet fail to satisfy one or both of the other two conditions. The ordering further suggests that an exception that does not 'unreasonably conflict with normal exploitation' could nonetheless 'unreasonably prejudice the legitimate interests of the patent owner'.[56]

The panel based its reasoning or took as its starting point on a flawed understanding of the relationship among the three conditions under Article 30. As noted in the *Declaration on Patent Protection, Regulatory Sovereignty under TRIPS,* the three-step tests are not cumulative:

> Contrary to what a panel of the WTO's Dispute Settlement Body seemed to assume (cf. WT/DS114/R of 17 March 2000), the three conditions are not cumulative. The three-step test may be understood to require a comprehensive overall assessment rather than a separate and independent assessment of each criterion. Failure to comply with one of the three conditions need not result in the exception being disallowed.[57]

Moreover, the panel read the "steps" in Article 30 narrowly.[58] Thus, in addressing the concept of "limited", the panel focused on the extent of the curtailment of the exclusive rights. As noted in the referred-to Declaration, "limited" does not necessarily mean narrow in effect; it could be understood to be narrow in the scope of the exception, meaning that it is reasonably proportionate to its objective and purpose.[59]

Moreover, an exception can also be limited in respect of the extent of its economic implications, so as not to disallow exceptions with little economic effects in the country of grant of the patent. While, in the panel's view, the economic impact of the exception should

[53] Ibid n 42 para 4.10.
[54] Regulation (EU) 2019/933, Recital 8.
[55] WTO (2000, supra n 42) para 7.20.
[56] Ibid para 7.21.
[57] Matthias Lamping (2014, supra n 8).
[58] See e.g., Peter Yu, "The Objectives and Principles of the TRIPS Agreement", in Carlos María Correa (ed.), *Research Handbook on the Protection of Intellectual Property under WTO Rules* (Edward Elgar 2010) (adapted from Peter Yu, "The Objectives and Principles of the TRIPs Agreement" (2009) 46 HousLRev 797). See also Matthew Kennedy, *WTO Dispute Settlement and The TRIPS Agreement* (CUP 2016) 113-116.
[59] Matthias Lamping (2014, supra n 8).

be evaluated under the other conditions of Article 30,[60] an exception may be deemed limited when it is subject to certain boundaries, for instance, with regard to the **field of technology**, the **acts** involved, the **purpose** of the use, the *outcome* of the invention's use, the **persons** that may invoke the exception, or its **duration**.[61]

Further, the panel in the case against Canada did not address the question of whether the concept of 'normal' in the second "step" ("unreasonably conflict with a normal exploitation of the patent") was to be given an **empirical** meaning as a reference to the usual or regular course of events, or a **normative** connotation in the sense of what is "normal" according to a certain standard.[62] The panel avoided this issue by holding that:

> the term can be understood to refer either to an empirical conclusion about what is common within a relevant community, or to a normative standard of entitlement. The Panel concluded that the word 'normal' was being used in Article 30 in a sense that combined the two meanings.[63]

The option for one or the other approach regarding "normal" is not neutral, as the empirical approach puts an emphasis on actual markets. In contrast, the normative approach also includes potential markets. If the concept of "potential" markets, however, is drawn too widely, this test may be insuperable and the exception rendered meaningless, since it would cover each and every possibility of deriving profit from a patented invention.[64]

In assessing the admissibility of an exception under Article 30, should the encroachment upon the economic value of the patent be considered separately for each individual exclusive right in respect of a whole set of rights? In the *Section 110(5) of the US Copyright Act* case, the panel stated that "whether a limitation or an exception conflicts with a normal exploitation of a work should be judged for each exclusive right individually".[65] It also argued that an exception raises to the level of conflict with a normal exploitation of the work "if uses, that in principle are covered by that right but exempted under the exception or limitation, enter into economic competition with the ways that right holders normally extract economic value from that right to the work (i.e., the copyright) and thereby deprive them of significant or tangible commercial gains".[66]

However, the rationale for this opinion is unclear. Not all exclusive rights generate the same level of income. A 10 per cent limitation to an important income-generating exclusive right (e.g., right to sell) may be more significant than a 100 per cent limitation to another exclusive right (e.g., the right to make when products are imported). Instead of considering different exclusive rights separately, it would be more appropriate to evaluate the extent to which an exception impairs the overall exploitation of the subject matter.[67]

---

[60] See Carlos M. Correa (2007, supra n 7) Chapter 9.
[61] Ibid.
[62] See Martin Senftleben, *Copyright, Limitations, and the Three-Step Test: An Analysis of the Three-Step Test in International and EC Copyright Law* (Kluwer Law International 2004) 168.
[63] WTO (2000, supra n 42) para 7.54.
[64] Carlos M. Correa (2007, supra n 7) 178, 181, 185.
[65] WTO, *United States Section 110(5) of US Copyright Act –Panel Report* (27 July 2000) WT/DS160/R, para 6.173.
[66] Ibid para 6.183.
[67] Martin Senftleben (2004, supra n 62) 193.

IV. MANUFACTURE FOR EXPORT UNDER PATENT LAW

As noted, the amendment to the EU medicinal SPC regulation is not subject to an assessment under Article 30 of the TRIPS Agreement, but a similar exception applied to patent rights may be scrutinized under that provision. Such an assessment should differentiate at least the following issues:

a) the extent to which *exports* of a protected product[68] could be deemed subject to the exclusive rights of the patent owner;
b) whether **manufacturing** solely for exports could be deemed outside such rights;
c) whether a distinction can be made between manufacturing for export that takes place within the original term of a patent, and that made within the **additional term** conferred to compensate for delays in the exploitation of an invention, as provided for in many free trade agreements and national laws (patent term extension);
d) whether an exception for manufacturing and export should apply to all fields of technology or be limited to particular fields.

1. Exports

In accordance with Article 28 of the TRIPS Agreement, a patentee may prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling, or importing for these purposes a patented product or a product obtained directly by a patented process. Hence, the exportation of a patented product or of a product obtained by a patented process is clearly outside the scope of the exclusive rights conferred by a product or process patent.[69]

The rights conferred by the patent are defined in a negative way, as the faculty to prevent certain acts relating to the patented invention (*ius excluendi)*. The exclusive rights represent a derogation from the principle of free access and usability of knowledge as a public good;[70] hence, they should be narrowly interpreted, as a *numerus clausus*.

Since exports *as such* are not covered by the patentee's exclusive rights, it is immaterial what the destination of the exported products is and, notably, whether or not a patent is in force and could be infringed in the country of importation.

The patent is a territorial right that aims to limit third parties' acts that are not of a private nature, such as selling or offering for sale **within the territory** where the invention is protected. Thus, in the *Deepsouth* case, the US Supreme Court reasoned as follows: 'Our patent system makes no claim to extraterritorial effect; "these acts of Congress do not, and were not intended to, operate beyond the limits of the United States... To the degree that the inventor needs protection in markets other than those of this country, the wording of 35 U.S.C. §§ 154 and 271 reveals a congressional intent to have him seek it abroad through patents secured in countries where his goods are being used'.[71] In another decision, the Supreme Court also stressed the territorial nature of patent rights:

---

[68] This concept encompasses both patented products and products directly obtained by a patented process (in accordance with Article 28.1 and 2 of the TRIPS Agreement).
[69] This interpretation is consistent with Article 31 of the Vienna Convention on the Law of Treaties. See e.g., Alison Slade, "The Objectives and Principles of the WTO TRIPS Agreement: A Detailed Anatomy", *Osgoode Hall LJ*, vol. 53, Issue 3 (2016) 948-998 <https://digitalcommons.osgoode.yorku.ca/ohlj/vol53/iss3/6> accessed 13 June 2020.
[70] Carlos M. Correa (2007, supra n 7) 289.
[71] *Deepsouth Packing Co v Laitram Corp* 406 US 518 (1972).

> Any doubt that Microsoft's conduct falls outside §271(f)'s compass would be resolved by the presumption against extraterritoriality. Foreign conduct is generally the domain of foreign law, and in the patent area, that law may embody different policy judgments about the relative rights of inventors, competitors, and the public. Applied here, the presumption tugs strongly against construing §271(f) to encompass as a 'component' not only a physical copy of software, but also software's intangible code, and to render 'supplie[d] … from the United States' not only exported copies of software, but also duplicates made abroad. Foreign law alone, not United States law, currently governs the manufacture and sale of components of patented inventions in foreign countries. If AT&T desires to prevent copying abroad, its remedy lies in obtaining and enforcing foreign patents.[72]

Exportation without manufacturing may take place when imported products are merely in transit in a given territory. In this case, goods that do not enter a market illegally have to be considered legal trade, even though they could be considered infringing in the country of transit if they were imported for commercialization in that country.[73] Another situation in which exports can be deemed outside the exclusive patent rights is when a component of a patented product is made for export. In a recent decision, the US Supreme Court considered a case involving genetic testing kits that contained five components, one of which was an enzyme known as Taq polymerase. The accused infringer made the Taq polymerase in the United States and shipped it to England, where it was combined with the other four components for sale. The patent owner sued, and the case went to court twice (the patent owner and the infringer each won once), leading finally to a Supreme Court decision, which decided in favor of the accused infringer.[74]

In summary, exports as such are outside the scope of the patentee's exclusive rights and, hence, no assessment of compatibility with Article 30 of the TRIPS Agreement is necessary.

2. Manufacturing for Export

Although exports are such are beyond the patentee's exclusive rights, the situation is different if exports are made in respect of products manufactured in the country of protection, which is certainly the most significant hypothesis for consideration. "Making" the protected product is an act covered by Article 28 of the TRIPS Agreement. Can an exception be validated under Article 30 of the Agreement?

The incorporation of Article 31bis to the TRIPS Agreement, which requires a compulsory license – to be granted under restrictive conditions[75] – for the export of pharmaceuticals to countries with no or insufficient manufacturing capacity in that field, would suggest that an exception for manufacturing for export is excluded outright. In negotiating the waiver adopted in 2003 – which later became Article 31bis – the Council for TRIPS did not consider a waiver to Article 30 instead of Article 31 of the TRIPS Agreement.[76] This was possibly the

---

[72] *Microsoft Corp v AT&T Corp* (No 05-1056).
[73] Matthew Kennedy (2016, supra n 58) 255-257.
[74] *Life Technologies Corp v Promega Corp* 773 F 3d 1338.
[75] See e.g., Carlos Correa, "Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?" Policy Brief No 57, South Centre, 2019. <https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf> accessed 17 June 2020; Satish Verma, "TRIPS Agreement and Access to Medicines", <https://www.kansai-u.ac.jp/ILS/publication/asset/nomos/29/nomos29-06.pdf> accessed 10 June 2020; Cynthia Ho, *Access to Medicine in the Global Economy* (OUP, 2011) <http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780195390124.001.0001/acprof-9780195390124>; <https://ssrn.com/abstract=1922825> accessed 17 July 2020.
[76] The solution requested by paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, as originally proposed by developing countries, was an exception to patent law and not a ground for compulsory

result of the reluctance of developed countries (notably the US) to provide for an expeditious solution (as requested in paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health) that would, in their view, weaken the patent rights.[77]

The concept underlying the 2003 waiver (and Article 31bis) does not exclude the possibility of recognizing an exception for manufacturing for export under Article 30. In fact, such a waiver was adopted in response to a specific request by the WTO Ministerial Conference to address situations in which Members cannot make effective use of *compulsory licensing* under the TRIPS Agreement.[78] Hence, addressing Article 30 was outside the multilateral mandate given to the Council for TRIPS and the fact that it was not considered as part of the "expeditious solution" required by the Ministerial Conference does not exclude its possible invocation by Members in relation to manufacturing for export.

Seuba et al.[79] have carried out a detailed analysis of the extent to which such acts can be deemed to comply with the conditions set forth in Article 30 of the TRIPs Agreement.[80] Regarding the first condition ("*Members may provide limited exceptions to the exclusive rights conferred by a patent*"), they argue that the exception would be "limited" as it does not completely limit the exclusive right of the patent holder but is subject to certain boundaries in respect of the acts involved (manufacturing for the purpose of exportation only). It would also be limited in terms of volume of manufacture, since it would be intended for foreign markets and, in practice, only to those in which a parallel patent is not in force or in respect of which the respective government has not issued a compulsory license.[81]

Second, the wording of Article 30 requires a determination of what is "unreasonable" in certain circumstances and whether there is a "conflict" with the "normal" exploitation of a patent.[82] Hence, it is necessary to assess the reasonableness of the interference caused by the exception with the "normal exploitation" of a patent. As noted above, the panel in the *Canada – Pharmaceuticals* case adopted a broad concept, suggesting that the meaning of "normal exploitation" of a patent is dynamic; it would change as new markets unfold and new technologies are used that result in a feasible exploitation of innovations within unexpected contexts. The panel considered that "exploitation" refers to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent, and that the protection of all normal exploitation practices is a key element of the policy reflected in patent laws.[83] The panel's interpretation, however, failed to consider other equally essential objectives of the patent system.[84]

---

licensing. See Cynthia Ho 2011, (supra n 75) 197, 198; Frederick Abbott, "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO", *JIEL* vol. 5 (2002) 469.

[77] Frederick Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health", *AJIL* vol. 99, (2005) p. 339, Public Law Research Paper No. 164, Law and Economics Paper No. 05-19, <https://ssrn.com/abstract=763224> accessed 17 July 2020.

[78] WTO, Ministerial Declaration [Doha Declaration] of 14 November 2001 (WT/MIN(01)/DEC/1 41 ILM 746, WTO 2002) para 6 <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed 17 July 2020.

[79] Xavier Seuba, Luis Mariano Genovesi and Pedro Roffe, "A Manufacturing for Export Exception", in Bryan Mercurio and Daria Kim (eds.), *Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options*, Bryan Mercurio and Daria Kim (eds.) (Routledge 2017) 161-185.

[80] Some authors have been critical regarding the admissibility of a manufacture for export exception; see e.g., Eric M. Solovy and Deepak Raju, "A Manufacturing-for-Export Exception to Patent Protection: A Proposal for Exporting Violations of the Trips Agreement and Beyond?", *JIPLP*, vol. 13, (2018) 68.

[81] Xavier Seuba, Luis Mariano Genovesi and Pedro Roffe (2017, supra n 79) 184; see also Carlos M Correa (2007, supra n 7) 302-304.

[82] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development and UNCTAD-ICTSD Project on IPRs and Sustainable Development (eds.), *Resource Book on TRIPS and Development* (CUP, 2005) 435-436.

[83] WTO (2000, supra n 42) paras 7.54-7.55.

[84] UNCTAD, ICTSD and UNCTAD-ICTSD Project on IPRs and Sustainable Development (2005, supra n 82) 435.

According to Seuba et al., the manufacturing for export exception would not affect the normal exploitation because it does not prevent the owner of the patented invention from obtaining most of the economic profit in the territory where the patent is granted.[85] This is a convincing argument, since the patent owner cannot exercise any right in a foreign country based on the patent granted in the territory where manufacturing takes place.

The third and last step in the test relates to the legitimate interest of patent holders. A possible interpretation of this test is that an exception preserves the economic incentives for innovation through the exercise of the normal means of exploitation of patents when the right holder is able to recover the investments incurred and make a profit.[86] In this sense, there is no prejudice for the patent holders, as there is no impairment to their rights.[87] And there is a legitimate interest of third parties, as they would profit from a competitive entry to a foreign market, as well for consumers, who will get earlier access to affordable medicines. Finally, the authors referred to propose that to solve a possible conflict with the third step, an "equitable remuneration" – as in the case of "remunerated exceptions" under copyright law[88] – could be established[89] in order to remunerate the patent holder for the use of the protected invention. The WTO jurisprudence has, in fact, confirmed that such remunerated exceptions are allowed by the TRIPS Agreement.[90] Remuneration-based limitations to copyright are well established[91] and perform an important function in incentivizing creativity and securing a mechanism for authors to obtain a remuneration. They are generally considered as limitations in the sense that they circumscribe the ability of the creator to decide if he/she wants to authorize a certain use or not, given the exclusive character of copyright.[92] A statutory license or a remuneration-based limitation could, similarly, allow third parties the use of patented material in foreign markets.[93]

---

[85] Xavier Seuba, Luis Mariano Genovesi and Pedro Roffe (2017, supra n 79) 184-185.

[86] See e.g., Edson Beas Rodrigues Jr, *The General Exception Clauses of The TRIPS Agreement* (CUP, 2012) 95-96. See also WTO (2000 supra n 42) para 7.54: 'The Panel considered that "exploitation" refers to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent. The term "normal" defines the kind of commercial activity Article 30 seeks to protect.'

[87] Xavier Seuba, Luis Mariano Genovesi and Pedro Roffe (2017, supra n 79) 185.

[88] See e.g., Jane C Ginsburg, "Fair Use for Free, or Permitted-but-Paid?" Law & Society: International & Comparative Law eJournal (2014); Pamela Samuelson, "Justifications For Copyright Limitations & Exceptions", (*Law.berkeley.edu*, 2018) <https://www.law.berkeley.edu/files/Justications_for_Copyright_Limitations_and_Exceptions_-_Pamuela_Samuelson.pdf>; Ruth Okediji, "The International Copyright System: Limitations, Exceptions and Public Interest Considerations For Developing Countries", UNCTAD – ICTSD Project on IPRs and Sustainable Development Issue Paper No 15 (2006). <http://unctad.org/en/docs/iteipc200610_en.pdf> accessed 28 May 2020.

[89] Xavier Seuba, Luis Mariano Genovesi and Pedro Roffe (2017, supra n 79) 181.

[90] See WTO, "Panel Report United States – Section 110(5) of US Copyright Act", (WT/DS/160/R,WTO, 2010) para 6.173.

[91] See for example, the InfoSoc Directive: "In certain cases of exceptions or limitations, rightholders should receive fair compensation to compensate them adequately for the use made of their protected works or other subject-matter". (Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonization of certain aspects of copyright and related rights in the information society [2001] OJ L167/01).

[92] Christophe Geiger, "Statutory Licenses as Enabler of Creative Uses, in *Remuneration Of Copyright Owners*, Kung-Chung Liu and Reto M Hilty (Springer, 2017); Reto Hilty, "Ways Out of the Trap of Article1(1) TRIPS", in *TRIPS plus 20: From Trade Rules To Market Principles,* Hanns Ullrich, Reto Hilty, Josef Drexl and Matthias Lamping (eds.) (Springer, 2016) 185. See also Marie-Christine Janssens, "The Issue of Exceptions: Reshaping the Keys to the Gates in the Territory of Literary, Musical and Artistic Creation", in *Research Handbook on the Future of EU Copyright*, Estelle Derclaye (ed.) (Edward Elgar Publishing, 2009) 347. <http://www.elgaronline.com/view/9781847203922.xml> accessed 05 February 2021. She emphasizes that the balancing mechanism between exclusive rights and exceptions "is ingrained in the copyright system and is of paramount importance for its legitimacy and credibility".

[93] Christophe Geiger (pp. 311) notes in this regard: 'The term "statutory license", which is often used for limitations coupled with a right to receive fair remuneration, seems more suitable to express the concept of remuneration for the use of a copyrighted work, although the term is itself not entirely satisfying, as it implies that there is an exclusive right and that the permission to use is given only by the law; it could as well be argued that the exclusive right is absent in those cases but that legislator considers that the use should be remunerated as a policy option to secure creators' interests' (Christophe Geiger, op.cit).

3. Patent Term Extension

As noted, some countries provide for an extension of the patent term to compensate for delays in the grant of a patent or the marketing approval of some products, notably medicines. Should an exception for manufacturing and export during the extended term of a patent be subject to scrutiny under Article 30 of the TRIPS Agreement?

The TRIPS Agreement requires protection for patent rights for a (minimum) period of 20 years (counted from the date of filing). Patent term extension obligations are clearly TRIPS-plus[94] and, hence, members that implement the manufacturing for export exception should be deemed to be immunized from complaints from other WTO members. Article 30 applies to the exclusive rights conferred under the TRIPS Agreement. This is the very reason why the EU has considered that SPCs (which provide rights equivalent to patents) are outside the scope of the Agreement. Thus, whether the exception applied during the *extended* patent term would comply or not with the three-step test should not be a matter judiciable under the DSU. A different situation may arise, however, in the context of free trade agreements (FTAs) that provide for patent term extension, as one of the parties could invoke the applicability of such test (or other particular clauses of the FTA) to question – under the specific FTA mechanism of dispute settlement – the legality of the exception even if applied during the term exceeding the 20 regular years of the patent term.

4. Limited Field of Application

Article 31bis of the TRIPS Agreement applies to the export/import of pharmaceuticals under compulsory licenses. Should a manufacturing for export exception be limited to those products? Would it only be justifiable in the context of Article 30 of the TRIPS Agreement when public health interests are at stake?

The possible inclusion at the national level of an exception that would allow a third party to manufacture the subject matter protected by the patent for subsequent export – as provided for in the regulation on medicinal SPCs – could provide a straightforward alternative to the burdensome mechanism established by Article 31bis of the TRIPS Agreement. This will be of particular importance so as to promote access to affordable, quality medicines essential for protecting public health.

The analysis presented above, however, suggests that such an exception would be acceptable across all fields of technology, and not only where essential interests are involved, such as public health or food security. It is true that the issue has been mainly discussed and decided in relation to the protection of public health, but there is no logical reason to exclude the applicability of the exception in other fields, especially if, as suggested above, the exception is subject to an adequate remuneration (which should normally be determined as a royalty on the ex-factory value of the products manufactured and sold by the third party).

The exception, if adopted, would be a pro-competitive measure, since it would allow the immediate entry of competitors into a foreign country where patent protection is not enforced. It will also promote industrial development in the country of manufacture and,

[94] Bryan Mercurio, "TRIPS-Plus Provisions in FTAs: Recent Trends", in *Regional Trade Agreements and the WTO Legal System*, Lorand Bartels and Federico Ortino (eds.) (OUP, 2006) 215. <http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780199206995.001.0001/acprof-9780199206995-chapter-10> accessed 18 July 2020.

eventually, the exploitation of economies of scale that may, in turn, lead to lower prices for consumers.

Of course, if circumscribed to a certain field of technology, such as pharmaceuticals, the argument about compliance with the first step in Article 30 ("limited") would be significantly strengthened. This is an option that Members may opt to follow. In accordance with WTO case law, differentiating the treatment of patent rights in respect of a certain field of technology does not amount to the kind of "discrimination" that is ruled out under Article 27.1 of the TRIPS Agreement ("patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced"). In *Canada – Pharmaceuticals* the panel noted:

> Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than a frustration of purpose.[95]

The limitation of the exception to a health-related issue increases the chances of acceptability under the WTO rules. The Panel in the *Australia – Plain Packaging* case, for instance, noted that Article 8 of the TRIPS Agreement deems the intention of the negotiators to maintain flexibilities when necessary to pursue 'legitimate societal interests' consistent with the Agreement.[96]

[95] WTO (2000, supra n 42) para 7.92 <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm#> accessed 17 July 2020.

[96] Para 7.2404: Specifically, the principles reflected in Article 8.1 express the intention of drafters of the TRIPS Agreement to preserve the ability of WTO members to pursue certain legitimate societal interests, at the same time as it confirms their recognition that certain measures adopted by WTO members for such purposes may have an impact on IP rights, and requires that such measures be "consistent with the provisions of the [TRIPS] Agreement".

V. CONCLUSION

The EU has taken a substantial step towards promoting competition in the European pharmaceutical industry by including stockpiling and export manufacturing exceptions in the legal regime of SPCs. The main objective is to favor the local industry by allowing a pharmaceutical product still covered by an SPC to be manufactured with the purpose of export to third countries where an exclusive right does not protect such product. On the other hand, the new European regulation also favors competition within the Common Market by including the exception on stockpiling up to 6 months before the SPC's expiry, which allows the generic industry to quickly enter the market once the protection granted by the SPC's exclusive rights has expired. Thus, the regulation balances private and public interests; however, it has introduced a number of restrictive conditions that were not necessary to ensure the proper functioning of the exception and which may, on the contrary, limit its use.

While the SPCs do not fall under the TRIPS Agreement, the new exceptions call attention to the possibility of applying similar exceptions in the case of patent rights subject to the disciplines of that Agreement. The analysis made above on the manufacturing for export exception shows that, under a rigorous interpretation of Article 30 of said Agreement, WTO members might legitimately allow (with or without remuneration) for the local production by third parties of patent-protected products for exportation. The rights conferred by a patent, as contained in Article 28 of the Agreement, do not encompass the right to prevent exports; as noted in the jurisprudence of the US Supreme Court, patent rights are territorial. While manufacturing of a patent-protected product for export would amount to a 'making' of the invention, it will not affect the normal exploitation of the patent in the country of grant. While it is arguable that Article 30 applies to patent term extensions, where permitted, and that an exception for manufacturing for export could broadly cover all technology sectors, limiting the exception to certain technological fields, such as pharmaceuticals, would not violate the non-discrimination principle contained in Article 27.1 of the Agreement.

WTO members, notably developing countries wishing to expand their manufacturing capacity in pharmaceuticals, should consider the precedent set by the amendment to the SPCs and examine the possible incorporation of a manufacturing for export exception as well.

REFERENCE LIST

Abbott, Frederick (2002). The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO. *Journal of International Economic Law*, vol. 5, p. 469.

— (2005). The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health. *American Journal of International Law*, vol. 99, p. 339, Public Law Research Paper No 164, Law and Economics Paper No 05-19. Available from https://ssrn.com/abstract=763224.

— (2015). Rethinking Patents: From "Intellectual Property" to "Private Taxation Scheme". In *Kritika: Essays on Intellectual Property Volume 1*, Peter Drahos, Gustavo Ghidini and Hanns Ullrich, eds. Cheltenham: Edward Elgar, p. 1.

Arup, Christopher, and William van Caenegem (2009). *Intellectual Property Policy Reform*. Cheltenham: Edward Elgar. Available from http://www.elgaronline.com/view/9781848441637.xml.

Bentley, Lionel, Brad Sherman, Denis Barbosa, Shamnad Basheer, Coenraad Visser and Richard Gold (2010). "Experts" Study On Exclusions From Patentable Subject Matter And Exceptions And Limitations To The Rights. WIPO SCP/15/3, Available from https://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-main1.pdf.

Calboli, Irene, and Edward Lee (2016). *Research Handbook on Intellectual Property Exhaustion and Parallel Imports*, Edward Elgar: Cheltenham.

Charles Rivers Associates and Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (European Commission) (2017). *Assessing Economic Impact of Changing Exemption Provisions During Patent and SPC Protection in Europe.* Luxembourg: Publications Office of the EU. Available from https://op.europa.eu/en/publication-detail/-/publication/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1/language-en.

Cornish, William, and Kathleen Liddell (2016). The Origins and Structure of the TRIPS Agreement. In *TRIPS plus 20: From Trade Rules to Market Principles,* Hanns Ullrich, Reto Hilty, Josef Drexl and Matthias Lamping (eds.). Berlin/Heidelberg: Springer, p. 3. Available from http://link.springer.com/10.1007/978-3-662-48107-3_1.

Correa, Carlos María (2007). *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*. Oxford: Oxford University Press.

— (2012). *Research Handbook on the Protection of Intellectual Property under WTO Rules*. Cheltenham Edward Elgar.

— (2016). *The Bolar Exception: Legislative Models and Drafting Options*. Research Paper No. 66. Geneva: South Centre. Available from https://www.southcentre.int/wp-content/uploads/2016/03/RP66_The-Bolar-Exception_EN1.pdf.

— (2019). Will the Amendment to the TRIPS Agreement Enhance Access to Medicines? Policy Brief No. 57, South Centre. Available from https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf.

— (2020). *Special Section 301: US Interference with the Design and Implementation of National Patent Laws*. Research Paper No. 115. Geneva: South Centre. Available from https://www.southcentre.int/wp-content/uploads/2020/07/RP-115.pdf.

Correa, C.M. (2022). Interpreting the Flexibilities Under the TRIPS Agreement. In: Correa, C.M., Hilty, R.M. (eds) Access to Medicines and Vaccines. Springer, Cham. https://doi.org/10.1007/978-3-030-83114-1_1

Correa, Carlos María, and Abdulqawi, Yusuf, eds. (2016). *Intellectual Property and International Trade: The TRIPS Agreement,* 3rd ed. Alphen aan den Rijn: Wolters Kluwer.

Danish, and Aileen Kwa (2019). Crisis at the WTO's Appellate Body (AB): Why the AB Is Important for Developing Members. Policy Brief No 69. South Centre, December. Available from https://www.southcentre.int/wp-content/uploads/2019/12/PB69_Crisis-at-the-WTO%E2%80%99s-Appellate-Body-AB-Why-the-AB-is-Important-for-Developing-Members_EN-1.pdf.

de Boer, Rens (2015).Supplementary Protection Certificate for Medicinal Products: An Assessment of European Regulation. Master Thesis at the Vrije Universiteit Amsterdam. Available from http://www.spcwaiver.com/files/Netherlands_SPC_assessment.pdf.

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (European Commission) (2018). *Study on the Economic Impact of Supplementary Protection Certificates, Pharmaceutical Incentives and Rewards in Europe Final Report.* Luxembourg: Publications Office of the EU. Available from https://op.europa.eu/en/publication-detail/-/publication/8ffeb206-b65c-11e8-99ee-01aa75ed71a1/language-en

Drahos, Peter, Gustavo Ghidini and Hanns Ullrich (eds.) (2015). *Kritika, Essays on Intellectual Property Vol 1*. Cheltenham: Edward Elgar.

European Commission. Supplementary Protection Certificates for Pharmaceutical and Plant Protection Products. *Internal Market, Industry, Entrepreneurship and SMEs*. Available from https://ec.europa.eu/growth/industry/policy/intellectual-property/patents/supplementary-protection-certificates_en. Accessed 17 July 2020 .

— (2018). Impact Assessment Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the Supplementary Protection Certificate for Medicinal Products. Commission Staff Working Document. Available from https://ec.europa.eu/docsroom/documents/29463.

— (2020). Pharmaceutical Strategy for Europe. *Medicinal Products*. Available from https://ec.europa.eu/health/human-use/strategy_en.

European Federation of Pharmaceutical Industries and Associations (2009). Supplementary Protection Certificates. Available from https://www.efpia.eu/about-medicines/development-of-medicines/intellectual-property/supplementary-protection-certificates/.

European Patent Office (2020). Supplementary Protection Certificates. *European Patent Academia: E-Course Patent litigation*. Available from https://e-courses.epo.org/wbts_int/litigation/SPCs.pdf.

Geiger, Christophe (2017). Statutory Licenses as Enabler of Creative Uses. In *Remuneration of Copyright Owners*, Kung-Chung Liu and Reto M Hilty eds. Berlin/Heidelberg: Springer, p. 305.

Ginsburg, Jane C. (2014). Fair Use for Free, or Permitted-but-Paid? *Law & Society: International & Comparative Law eJournal*.

Hilty, Reto (2016). Ways Out of the Trap of Article1(1) TRIPS. In *TRIPS plus 20: From Trade Rules to Market Principles*, Hanns Ullrich, Reto Hilty, Josef Drexl and Matthias Lamping (eds.). Berlin/Heidelberg: Springer, p. 185.

Ho, Cynthia (2011). *Access to Medicine in the Global Economy*. Oxford: Oxford University Press. Available from http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780195390124.001.0001/acprof-9780195390124.

Janssens, Marie-Christine (2009). The Issue of Exceptions: Reshaping the Keys to the Gates in the Territory of Literary, Musical and Artistic Creation. In *Research Handbook on the Future of EU Copyright*, Estelle Derclaye (ed.). Cheltenham: Edward Elgar, p. 672**.** Available from: http://www.elgaronline.com/view/9781847203922.xml.

Joshi, Omkar Umesh, Archna Roy and Manthan Janodia (2017) 'Comparative Quantitative Analysis of Supplementary Protection Certificates (SPCs) in Europe' Journal of Intellectual Property Rights Vol 22 No 1, 16-22.

Kennedy, Matthew (2016). *WTO Dispute Settlement and The TRIPS Agreement: Applying Intellectual Property Standards in a Trade Law Framework*. Cambridge: Cambridge University Press.

Kyle, Margaret (2017). *Economic Analysis of Supplementary Protection Certificates in Europe*. Luxembourg: European Commission, Publication Office of the EU. Available from https://ec.europa.eu/growth/industry/policy/intellectual-property/patents/supplementary-protection-certificates_en.

Lamping, Matthias (2014). Declaration on Patent Protection: Regulatory Sovereignty under TRIPS. *International Review of Intellectual Property and Competition Law*, vol. 45, Issue 6, p. 679.

Max Planck Institute (2018). *Study on the Legal Aspects of Supplementary Protection Certificates in the EU Final Report*. Brussels: European Commission. Available from https://op.europa.eu/en/publication-detail/-/publication/6845fac2-6547-11e8-ab9c-01aa75ed71a1/language-en/format-PDF/source-search.

Medicines for Europe (2020). Q&A about SPC Manufacturing Waiver. *SPC Manufacturing Waiver*. Available from http://www.spcwaiver.com/en/Q&A.html.

Meier, Malwina (2017). *25 Years of SPC Protection for Medicinal Products in Europe: Insights and Challenges*. Luxembourg: European Commission. Available from https://ec.europa.eu/growth/industry/policy/intellectual-property/patents/supplementary-protection-certificates_en.

Miles, John (2012). Supplementary Protection Certificates for Medicinal Products: Where Are We Now and What Challenges Lay Ahead? Pharmaceutical Patent Analyst 1.

Mercurio, Bryan (2006). TRIPS-Plus Provisions in FTAs: Recent Trends. In *Regional Trade Agreements and the WTO Legal System*, Lorand Bartels and Federico Ortino, (eds.). Oxford: Oxford University Press, p. 215. Available from http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780199206995.001.0001/acprof-9780199206995-chapter-10.

Okediji, Ruth (2006). The International Copyright System: Limitations, Exceptions And Public Interest Considerations For Developing Countries. UNCTAD – ICTSD Project on IPRs and Sustainable Development Issue Paper No 15. Available from http://unctad.org/en/docs/iteipc200610_en.pdf.

Okediji, Ruth, and Margo A Bagley (eds.) (2014). *Patent Law in Global Perspective*, Oxford: Oxford University Press. Available from

https://oxford.universitypressscholarship.com/view/10.1093/acprof:oso/9780199334278.001.0001/acprof-9780199334278.

Rodrigues Jr, Edson Beas (2012). *The General Exception Clauses of the TRIPS Agreement: Promoting Sustainable Development*. Cambridge: Cambridge University Press.

Senftleben, Martin (2004). *Copyright, Limitations, and the Three-Step Test: An Analysis of the Three-Step Test in International and EC Copyright Law*. Alphen aan den Rijn: Kluwer Law International.

Seuba, Xavier (2019). The Export and Stockpiling Waivers: New Exceptions for Supplementary Protection Certificates. *SSRN Electronic Journal*. Available from https://www.ssrn.com/abstract=3500774.

Seuba, Xavier, Luis Mariano Genovesi and Pedro Roffe (2017). A Manufacturing for Export Exception. In *Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options*, Bryan Mercurio and Daria Kim (eds.). London: Routledge, p. 25.

Slade, Alison (2016). The Objectives and Principles of the WTO TRIPS Agreement: A Detailed Anatomy. *Osgoode Hall Law Journal* 53(3). Available from https://digitalcommons.osgoode.yorku.ca/ohlj/vol53/iss3/6.

Solovy, Eric M, and Deepak Raju (2018). A Manufacturing-for-Export Exception to Patent Protection: A Proposal for Exporting Violations of the TRIPS Agreement and Beyond*? Journal of Intellectual Property Law & Practice*, vol. 13, Issue 1 (January).

Ullrich, Hanns, Reto Hilty, Josef Drexl, and Matthias Lamping, eds. (2016). *TRIPS plus 20: From Trade Rules to Market Principles*. Berlin/Heidelberg: Springer. Available from http://link.springer.com/10.1007/978-3-662-48107-3.

UNCTAD and ICTSD (2005). *Resource Book on TRIPS and Development*, Cambridge: Cambridge University Press.

Velásquez, Germán, Carlos Correa, and Vitor Ido (2020). *Intellectual Property, Human Rights and Access to Medicines: A Selected and Annotated Bibliography*, 3rd ed. Geneva: South Centre. Available from https://www.southcentre.int/wp-content/uploads/2020/04/Intellectual-Property-Human-Rights-and-Access-to-Medicines-3rd-Edition-FINAL-ok.pdf.

Verma, Satish (2011). TRIPS Agreement and Access to Medicines. Available from https://www.kansai-u.ac.jp/ILS/publication/asset/nomos/29/nomos29-06.pdf.

Vidal-Quadras, Miguel (2019). Analysis of EU Regulation 2019/933 on the SPC Manufacturing Waiver Exception. *International Review of Intellectual Property and Competition Law* 50, p. 971.

Watal, Jayashree (2001). *Intellectual Property Rights in the WTO and Developing Countries*. Alphen aan den Rijn: Kluwer Law International.

Yu, Peter (2010). The Objectives and Principles of the TRIPS Agreement. In *Research Handbook on the Protection of Intellectual Property Under WTO Rules,* Carlos M Correa. Cheltenham: Edward Elgar, p. 768.

RECENT SOUTH CENTRE RESEARCH PAPERS

No.	Date	Title	Authors
91	February 2019	Key Issues for BAPA+40: South-South Cooperation and the BAPA+40 Subthemes	Vicente Paolo B. Yu III
92	March 2019	Notification and Transparency Issues in the WTO and ' November 2018 Communication	Aileen Kwa and Peter Lunenborg
93	March 2019	Regulating the Digital Economy: Dilemmas, Trade Offs and Potential Options	Padmashree Gehl Sampath
94	April 2019	Tax Haven Listing in Multiple Hues: Blind, Winking or Conniving?	Jahanzeb Akhtar and Verónica Grondona
95	July 2019	Mainstreaming or Dilution? Intellectual Property and Development in WIPO	Nirmalya Syam
96	Agosto 2019	Antivirales de acción directa para la Hepatitis C: evolución de los criterios de patentabilidad y su impacto en la salud pública en Colombia	Francisco A. Rossi B. y Claudia M. Vargas P.
97	August 2019	Intellectual Property under the Scrutiny of Investor-State Tribunals Legitimacy and New Challenges	Clara Ducimetière
98	September 2019	Developing Country Coalitions in Multilateral Negotiations: Addressing Key Issues and Priorities of the Global South Agenda	Adriano José Timossi
99	September 2019	Ensuring an Operational Equity-based Global Stocktake under the Paris Agreement	Hesham AL-ZAHRANI, CHAI Qimin, FU Sha, Yaw OSAFO, Adriano SANTHIAGO DE OLIVEIRA, Anushree TRIPATHI, Harald WINKLER, Vicente Paolo YU III
100	December 2019	Medicines and Intellectual Property: 10 Years of the WHO Global Strategy	Germán Velásquez
101	December 2019	Second Medical Use Patents – Legal Treatment and Public Health Issues	Clara Ducimetière
102	February 2020	The Fourth Industrial Revolution in the Developing Nations: Challenges and Road Map	Sohail Asghar, Gulmina Rextina, Tanveer Ahmed & Manzoor Illahi Tamimy (COMSATS)
103	February 2020	Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa	Yousuf A Vawda & Bonginkosi Shozi

104	March 2020	Antimicrobial Resistance: Examining the Environment as Part of the One Health Approach	Mirza Alas
105	March 2020	Intersección entre competencia y patentes: hacia un ejercicio pro-competitivo de los derechos de patente en el sector farmacéutico	María Juliana Rodríguez Gómez
106	March 2020	The Comprehensive and Progressive Agreement for the Trans-Pacific Partnership: Data Exclusivity and Access to Biologics	Zeleke Temesgen Boru
107	April 2020	Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents	Carlos M. Correa
108	April 2020	Public Health and Plain Packaging of Tobacco: An Intellectual Property Perspective	Thamara Romero
109	May 2020	Non-Violation and Situation Complaints under the TRIPS Agreement: Implications for Developing Countries	Nirmalya Syam
110	May 2020	Estudio preliminar del capítulo sobre propiedad intelectual del acuerdo MERCOSUR – UE	Alejandra Aoun, Alejo Barrenechea, Roxana Blasetti, Martín Cortese, Gabriel Gette, Nicolás Hermida, Jorge Kors, Vanesa Lowenstein, Guillermo Vidaurreta
111	May 2020	National Measures on Taxing the Digital Economy	Veronica Grondona, Abdul Muheet Chowdhary, Daniel Uribe
112	June 2020	La judicialización del derecho a la salud	Silvina Andrea Bracamonte and José Luis Cassinerio
113	June 2020	La evolución de la jurisprudencia en materia de salud en Argentina	Silvina Andrea Bracamonte and José Luis Cassinerio
114	June 2020	Equitable Access to COVID-19 Related Health Technologies: A Global Priority	Zeleke Temesgen Boru
115	July 2020	Special Section 301:US Interference with the Design and Implementation of National Patent Laws	Dr. Carlos M. Correa
116	August 2020	The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic	Frederick Abbott
117	September 2020	Data in Legal Limbo: Ownership, sovereignty, or a digital public goods regime?	Dr. Carlos M. Correa

118	September 2020	Re-thinking Global and Local Manufacturing of Medical Products After COVID-19	Dr. German Velásquez
119	October 2020	TRIPS Flexibilities on Patent Enforcement: Lessons from Some Developed Countries Relating to Pharmaceutical Patent Protection	Joshua D. Sarnoff
120	October 2020	Patent Analysis for Medicines and Biotherapeutics in Trials to Treat COVID-19	Srividya Ravi
121	November 2020	The World Health Organization Reforms in the Time of COVID-19	German Velásquez
122	November 2020	Analysis of the Overcapacity and Overfishing Pillar of the WTO Fisheries Subsidies Negotiations	Peter Lunenborg
123	November 2020	The United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas: One Step Forward in the Promotion of Human Rights for the Most Vulnerable	Maria Natalia Pacheco Rodriguez and Luis Fernando Rosales Lozada
124	November 2020	Practical Implications of 'Vaccine Nationalism': A Short-Sighted and Risky Approach in Response to COVID-19	Muhammad Zaheer Abbas, PhD
125	December 2020	Designing Pro-Health Competition Policies in Developing Countries	Vitor Henrique Pinto Ido
126	December 2020	How Civil Society Action can Contribute to Combating Antimicrobial Resistance	Mirza Alas Portillo
127	December 2020	Revisiting the Question of Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU – The Need to Rebalance	Daniel Opoku Acquah
128	February 2021	Intellectual Property in the EU–MERCOSUR FTA: A Brief Review of the Negotiating Outcomes of a Long-Awaited Agreement	Roxana Blasetti In collaboration with Juan I. Correa
129	March 2021	The TRIPS waiver proposal: an urgent measure to expand access to the COVID-19 vaccines	Henrique Zeferino de Menezes
130	April 2021	Misappropriation of Genetic Resources and Associated Traditional Knowledge: Challenges Posed by Intellectual Property and Genetic Sequence Information	Nirmalya Syam and Thamara Romero
131	June 2021	TRIPS Flexibilities and TRIPS-plus Provisions in the RCEP Chapter on Intellectual Property: How Much Policy Space is Retained?	Vitor Henrique Pinto Ido
132	June 2021	Interpreting the Flexibilities Under the TRIPS Agreement	Carlos M. Correa

133	August 2021	Malaria and Dengue: Understanding two infectious diseases affecting developing countries and their link to climate change	By Mirza Alas
134	September 2021	Restructuring the Global Vaccine Industry	Felix Lobo
135	September 2021	Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements	Carlos M. Correa, Nirmalya Syam and Daniel Uribe
136	September 2021	Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case	Muhammad Zaheer Abbas
137	October 2021	The Ocean Economy: trends, impacts and opportunities for a post COVID-19 Blue Recovery in developing countries	David Vivas Eugui, Diana Barrowclough and Claudia Contreras
138	October 2021	Beyond Corporate Social Responsibility: Strengthening Human Rights Due Diligence through the Legally Binding Instrument on Business and Human Rights	Daniel Uribe Terán
139	October 2021	Governing Seed for Food Production: The International Treaty on Plant Genetic Resources for Food and Agriculture	Nina Isabelle Moeller
140	November 2021	Del SIDA al COVID-19: La OMS ante las crisis sanitarias globales	Germán Velásquez
141	November 2021	Utilising Public Health Flexibilities in the Era of COVID-19: An Analysis of Intellectual Property Regulation in the OAPI and MENA Regions	Yousuf A Vawda and Bonginkosi Shozi
142	4 January 2022	Competition Law and Access to Medicines: Lessons from Brazilian Regulation and Practice	Matheus Z. Falcão, Mariana Gondo and Ana Carolina Navarrete
143	11 January 2022	Direito Brasileiro da Concorrência e Acesso à Saúde no Brasil: Preços Exploratórios no Setor de Medicamentos	Bruno Braz de Castro
144	27 January 2022	A TRIPS-COVID Waiver and Overlapping Commitments to Protect Intellectual Property Rights Under International IP and Investment Agreements	Henning Grosse Ruse-Khan and Federica Paddeu
145	9 February 2022	The Right to Health in Pharmaceutical Patent Disputes	Emmanuel Kolawole Oke
146	16 February 2022	A Review of WTO Disputes on TRIPS: Implications for Use of Flexibilities for Public Health	Nirmalya Syam
147	28 February 2022	Can Negotiations at the World Health Organization Lead to a Just Framework for the Prevention, Preparedness and Response to Pandemics as Global Public Goods?	Viviana Muñoz Tellez

148	7 March 2022	Marine Genetic Resources Beyond National Jurisdictions: Negotiating Options on Intellectual Property	Siva Thambisetty
149	8 March 2022	The International Discourse on the Right to Development and the Need to Reinvigorate its Implementation	Yuefen Li, Daniel Uribe and Danish
150	21 March 2022	The Liability of Internet Service Providers for Copyright Infringement in Sri Lanka in Relation to Infringing Items Carried on their Networks: A Comparative Analysis with the US and English Law	Ruwan Fernando
151	19 April 2022	Escaping the Fragility/Conflict Poverty Trap: How the interaction between service delivery, capacity development and institutional transformation drives the process of transition out of fragility	Mamadou Dia
152	21 April 2022	An Examination of Selected Public Health Exceptions in Asian Patent Laws	Kiyoshi Adachi
153	26 April 2022	Patent Analysis for Medicines and Biotherapeutics in Trials to Treat COVID-19	Srividya Ravi
154	9 May 2022	COVID-19 Vaccines as Global Public Goods: between life and profit	Katiuska King Mantilla and César Carranza Barona

SOUTH CENTRE

International Environment House 2
Chemin de Balexert 7-9
POB 228, 1211 Geneva 19
Switzerland

Telephone: (41) 022 791 8050
E-mail: south@southcentre.int

Website:
http://www.southcentre.int

ISSN 1819-6926