A new exception for Supplementary Protection Certificates: the manufacturing waiver

Legal justifications and future international challenges

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The University of Strasbourg neither approves or disapproves the opinion expressed in this thesis. These opinions shall be considered as the author’s own judgment.
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Introduction

“Before [the establishment of the patent system], any man might instantly use what another had invented; so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor, for a limited time, the exclusive use of his invention; and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things.” Abraham Lincoln¹.

“A patent is a legal title granting its holder the right – in a particular country and for a certain period of time – to prevent third parties from exploiting an invention for commercial purposes without authorization².”

The duration of this monopolistic right was internationally harmonized in the 1990s with the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) signed by all World Trade Organization (WTO) members, as negotiated in the Uruguay Round. Article 33 of the TRIPS Agreement provides that: “The term of protection available [for patents] shall not end before the expiration of a period of twenty years counted from the filing date.” Prior to the TRIPS Agreement, the patent duration was significantly shorter in many countries. The TRIPS Agreement requires countries to provide patent protection for both processes and products in all fields of technology. Before the TRIPS Agreement negotiations, many countries exclusively provided process (but not product) patents. “Product patents provide for absolute protection of the product, whereas process patents protect the respect of the technology and the process or method of manufacture³.” The lack of protection on the product allowed the competitors to reverse engineer it, to find a new unpatented method or process to reproduce the product. Thus, the countries requiring only process patent protection have enabled the making of generic versions of patented drugs.

A generic medicinal product is a copy of an original non-biologic ‘reference medicine’ of which its intellectual property right and market protection have lapsed, expired or never existed⁴.

¹ A. Lincoln, “Lecture on Discoveries and Inventions”, Young Men’s Association of Bloomington, Illinois, 1858.
⁴ Ibid. “At the time the negotiations began, over 40 countries in the world did not grant patent protection for pharmaceutical products”. 
Most of the time, generic medicine is produced by another company, called ‘manufacturers’ companies. “Generics have the same qualitative and quantitative composition in active substances and the same pharmaceutical form as reference medicinal products.” A generic product needs to be differentiated from a biosimilar product, which is a biologic product - a medication produced in living cells via a multistep process. To be approved, the manufacturers of biosimilars have to demonstrate a sufficient similarity between their products and a biologic product already approved by a national agency, known as a reference product. Besides, they also have to prove that there is “no clinically meaningful differences in terms of safety and effectiveness from the reference product.” Only minor differences in clinically inactive components are allowable in biosimilar products. In other terms, “a biosimilar is a biologic product, and a generic is a small-molecule product. While identical generic versions of small molecules can be chemically synthesized, it is not possible to create identical versions of reference biologic medicines due to their complexity. Consequently, the processes used to develop generic medicines do not apply to the development of biosimilar medicines.

The TRIPS Agreement took the disparity of patent level protection between national legislations into account. Thus, some developing countries had until 2005 to change their national patent law, the term was extended to 2013 for least developed countries, and until 2016 for pharmaceutical patents, with the possibility of further extension. Therefore, in most patent laws nowadays, the term of a patent is twenty years from the filing date of the application for any invention including a pharmaceutical product, or process.

The TRIPS Agreement sets a minimum standard of term protection applicable to any patentable subject matter (as long as they respect the patentability criteria mentioned in TRIPS: an invention must be new, involve an inventive step and be susceptible of industrial application.)

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7 Ibid.
8 Ibid.
11 Throughout this work, we will refer to “pharmaceutical products” as including generic and biosimilar products.
12 Noting that some countries like the United-States apply alternative criteria: new, non-obvious and useful.
However, it is arguable to assume that all inventions deserve the same duration of protection\textsuperscript{13}. The utilitarian logic of intellectual property rights finds its basis in the writing of Jeremy Bentham and implies the existence of a correlation between the duration of the right conferred and the prior investment. Accordingly, some authors sharply criticized the lack of academic studies and economic impact assessments regarding the harmonized duration of twenty years of patent protection granted for all inventions, without consideration of their nature, and investment specificities.\textsuperscript{14}

The TRIPS Agreement does not mention any legal mechanism that could extend the patent life under certain circumstances. Nonetheless, it is essential to precise that the Agreement allows a degree of flexibility, and enough room for countries to accommodate their own patent and intellectual property systems and developmental needs\textsuperscript{15}. In other words, WTO members have a certain amount of freedom in maintaining or pushing their legislation further by the establishment of TRIPS + standards.

Years before the conclusion of the TRIPS Agreement, the need to adapt the term of protection of patents in a specific field, the pharmaceutical industry\textsuperscript{16}, became a major preoccupation for several countries.

Thanks to the TRIPS Agreement pharmaceutical products are now patentable in almost all countries in the world. Pharmaceutical products mean all biological and medicine candidates, compounds, or products being researched, tested, developed, manufactured, or distributed by a company. These inventions are treated differently from others because of their intended impact on health. Therefore, legal obstacles exist before a pharmaceutical invention can enter the market and be exploited by its right holder.

Pharmaceutical companies need to go through a lengthy, costly, and complicated administrative procedure involving clinical trials in order to submit data to the drug regulatory authorities demonstrating the safety, quality, and effectiveness of the product. The level of requirements varies depending on the country. However, the global tendency is to strengthen the marketing authorization process, in order to protect public health and avoid any risk of new

\textsuperscript{15} World Health Organization, “WTO and the TRIPS Agreement”, op.cit., para. 3.
\textsuperscript{16} Throughout this work, we will refer to “pharmaceutical industry” or “pharmaceutical company” as to the companies dealing with brand medications as opposed to generic companies.
disastrous health crises\textsuperscript{17}, so it has become increasingly difficult for pharmaceutical companies to obtain marketing authorization approval. Nowadays, clinical trials involving new medicines are usually split into four phases; each phase of the medicine approval process is evaluated as a separate clinical trial. The rate of failure in medicine development is very high as scientists have to study thousands of compounds before turning substances into a marketable product that generate value for patients\textsuperscript{18}. For the clinical drug development success rate, Bio Industry Analysis calculated that the overall likelihood of approval from the first clinical trial test (first phase) was only 9.6\% between 2006 and 2015, and 11.9\% for all indications outside the field of oncology\textsuperscript{19}. Other studies show that ‘by the time a medicinal product reaches the market, an average of 12-13 years will have elapsed since the first synthesis of the new active substance\textsuperscript{20}. The cost of researching and developing a new chemical or biological entity was estimated at €1,926 million in 2016\textsuperscript{21}. On average, only one to two of every 10,000 substances synthesized in laboratories will successfully pass all stages of development requested to become a marketable medicine\textsuperscript{22}.

The costly and time-consuming phases of research and development and administrative procedure lead to two facts once the marketing approval is finally granted for a pharmaceutical product\textsuperscript{23}: clinical-test data is the major asset of the company, and the patent term erodes during the process. Both issues have been addressed while keeping the balance between the goal of providing incentives for future inventions of new medicines and the goal of affordable access to existing medicines in mind.

First, WTO members are required, under article 39 of the TRIPS Agreement, to protect undisclosed test data. Test data must be submitted to drug regulatory authorities in order to obtain marketing approval, which protects them against unfair commercial use. Since there is no harmonized definition of “unfair commercial use” it is argued that countries can meet their

\textsuperscript{17} In the 1960s in Europe, thalidomide, which originally served as a sedative, was found to work against nausea on pregnant women. Nine months later, many babies were born with malformed limbs, having a death rate of 60\%. At this time, drugs were not tested extensively. The European Commission decided to regulate the possibility to put drugs on the market, by only giving market authorization after the safety of the drug is proven.


\textsuperscript{20} European Federation of Pharmaceutical Industries and Associations (EFPIA), “the Pharmaceutical industry in figures”, 2017, Key data, p.6.

\textsuperscript{21} Ibid. and see J. DiMasi, H. Grabowski, R. Hansen, “\textit{Innovation in the pharmaceutical industry: New estimates of R&D costs}”, Journal of Health Economics”, No 47, 2016, p. 20–33.

\textsuperscript{22} Ibid.

\textsuperscript{23} Give two years market exclusivity during which no generic can be approved.
obligations to protect test data by prohibiting a “dishonest” use of data\textsuperscript{24}. The data exclusivity approach grants the originator exclusive rights over their test data and prevents regulatory authorities from relying on the test data to register generic substitutes\textsuperscript{25}. This approach protects the company which has submitted original test data because competitors are not allowed to rely on this data for a defined period of time\textsuperscript{26}.

Second, the pharmaceutical industry points out that marketing regulation increases the cost and time to get a drug to the market. Consequently, the duration of the clinical tests affects the ‘effective patent life.’ The effective patent life is the period between a product’s introduction to the market and the patent’s expiration date\textsuperscript{27}. During this period, the maker of a product enjoys market exclusivity that may permit him to recover research and development costs. In industries that require regulatory approval to put the product on the market, effective patent life can be insufficient to recover research and development costs. In order to readjust the term of patent protection for these specific inventions, some countries implemented appropriate legal tools.

This inevitable erosion of the pharmaceutical patent has been apprehended in diverse ways around the world and result in a difference of legal nature between the solutions adopted. We will focus our study on the American and the European legal frameworks.

The United-States of America (USA) decided to address the matter by using the mechanism of the patent extension\textsuperscript{28}. In 1984, the patent term restoration (PTR) was created when Congress passed the Drug Price Competition, and Patent Restoration Act commonly referred to as the Hatch-Waxman Act. By this Act, Section 156 was added to the Patent Act allowing patent term extension for patents on products (or processes for making or using the same) that are human drug products, medical devices, food additives, and color additives subject to regulation under the Federal Food, Drug, and Cosmetic Act\textsuperscript{29}. The Act aims to restore a part of the patent term during which the patentee is unable to sell or market a product while awaiting government approval, such as the Food and Drug Administration’s (FDA) review of a prescription drug. In 1988, the Generic Animal Drug and Patent Term Restoration Act added animal drug and

\textsuperscript{24}World Health Organization, “WTO and the TRIPS Agreement”, op.cit., para. 6.

\textsuperscript{25} Ibid.

\textsuperscript{26} For example, five years of data exclusivity in the US and eight years in the EU.


\textsuperscript{28} It exists four different forms of patent extensions in the USA.

veterinary biological products to the list of eligible products for a term extension\(^\text{30}\). Although called “patent term restoration”, the scope of the extension is almost always narrower than the patent itself because it is limited to the product or process subject to the agency review. According to a recent study published in Drug Delivery Today, from 2000 to 2012, 94% of the drugs that received a patent term extension in the USA were new chemical entities, while 74% of drugs that did not receive the extension were new formulations of existing products\(^\text{31}\). Consequently, during an extension period of the patent term, competitors may practice claims on parts of the invention that were not subject to the regulatory review process.

In Europe, the Munich Convention was signed in 1973. The Convention originally authorized the extension of the patent term in only one extraordinary situation\(^\text{32}\). The European Economic Community (ECC) is a party to this Convention and is determined to legislate in order to increase the duration of protection for pharmaceutical products. To achieve its goal, the ECC create a sui generis intellectual property right in 1992: “Council Regulation (ECC) No 1768/92 concerning the creation of a Supplementary Protection Certificate for medical products\(^\text{33}\)”. A Supplementary Protection Certificate (SPC) is a mechanism by which the right holder is compensated at least in part, for the erosion of the period of exclusivity under a patent as a result of the time which elapses between the filing of the patent application and the grant of a marketing authorization to place the product on the market\(^\text{34}\). An SPC protection confers the same rights and obligations as the basic patent. However, like the patent term restoration, it does not extend the protection conferred across the entire scope of the patent claims, but only protect the product covered by the authorization to place the corresponding medicinal product on the market, or any use of that product as a medicinal product that has been authorized before expiry of the SPC. The purpose of the SPC legislation as conceived by the EU legislature was not to reward any research resulting in a patentable invention and a patented medicine, but only research that led to “new active ingredients”, that is, substances that had never been authorized before for a medicinal purpose.

\(^{30}\) Ibid.


\(^{32}\) European Patent Convention, October 5th, 1973, article 63 2. a) : “in order to take account of a state of war or similar emergency conditions affecting that State”.


An SPC can extend a patent right for a maximum of five years, plus six months additional extension to a medicinal product for children. In this last case, the process is longer because the data needs to be submitted according to a Pediatric Investigation Plan (PIP); they ensure that enough data is collected on the effect of medicine of children. The six extra months compensate for the additional clinical trials and testing that PIP requires.

This Regulation aims to address an assumed decline in the development of new molecules for medicinal use and create a sustainable legal framework favorable to the pharmaceutical sector. The fear at the time was to see pharmaceutical industries leaving Europe. “The current situation is creating a risk of research centers situated in the Member States relocating to countries that already offer greater protection”. The Regulation was impacted by economic views but also by the pressure of pharmaceutical lobbies.

Some legislative safeguards soften the scope of the new Regulation and prevent it from being too invasive and detrimental to health interest. Some of these exceptions were implemented globally, others nationally, in order to keep a fair balance between the promotion of pharmaceutical innovation and the access to health with the development of cheaper medicines. For example, on an international level, the TRIPS Agreement was amended in 2005 (entered into force on 2017) in order provide the legal basis for WTO members to grant a special compulsory license for the production and export of generic medicines to other members without sufficient production capacity.

Regarding the production of patented medicines, a few countries created a patent exemption for the preparation of medicines in pharmacies under certain circumstances (legislation in force in France and in the Netherlands since February 2019). Moreover, many countries allow small-scale manufacturing of generic and biosimilar medicines to take place during the patent protection period of the reference medicine in order to conduct the testing required to obtain regulatory approval for these products. This exception from patent law is called the “Bolar exemption” which is originated from the USA and name after a court case. This exemption is

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36 Agreement on Trade-Related Aspects of Intellectual Property Rights TRIPS, article 31 bis, Annex & Appendix.
37 Code de la santé publique, article L. 5125-1-1.
recognized in the European Law by Directive 2001/83 in its article 10(6). Notwithstanding the EU Directive, the exact language, scope, and interpretation of the Bolar exemption vary across Europe. In summary, this legislative overview of the existent protection for pharmaceutical products seems to be balanced and efficient, taking the different interests at stake into account. The reality is quite different. The pharmaceutical market is undergoing profound changes. Global demand for medicines has increased massively, and there is a shift towards an ever-greater market share for generics and biosimilars.

Historically pioneer in the manufacturing of biosimilars, the competitiveness of the EU industry is currently “under threat.” Indeed, the EU is facing a significant issue: during the SPC period of protection of the product in the EU, the manufacturers of generics and biosimilars based in the EU are prohibited by law to manufacture for any purpose, including export outside the EU to countries where SPC protection does not exist or have expired, while manufacturers based outside the Union can do so. Moreover, the manufacture prohibition under the SPC makes it more difficult for EU manufacturers to enter the EU market immediately after its expiry because “they are not in a position to build up production capacity until the protection provided by the certificate has lapsed.” The problem is exacerbated by the dynamics of the generics/biosimilars markets whereby, after the expiry of patent/SPC protection of the reference medicine, only the first few generics/biosimilars to enter the market capture a significant market share and are financially viable.

In order to address this issue, the European Commission presented a proposal establishing a manufacturing waiver to the Parliament and the Council on May 28th, 2018. This new SPC exception is supposed to “remove the competitive disadvantages EU-based manufacturers of generics and biosimilars are currently facing.” First, only drafted by the Commission for export purposes, the waiver allows the making of generics or biosimilars products during the term of an SPC for the sole purpose of exporting their products to non-EU markets where protection does not exist or has expired. It also addresses the EU day-1 entry issue to a certain extent. The day-1 is the day after the certificate expires. In this case, the manufacturer who has

40 “[c]onducting the necessary studies and trials with a view to the application of paragraphs 1 to 4 [i.e. bioequivalents and biosimilars] and the consequent practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.”


42 Ibid., recital 4).

43 Ibid., explanatory memorandum, “main features of the proposal”, para 7.
built up a manufacturing line for export purposes will effortlessly be able, after SPC expiry, to operate on the same line to manufacture generics or biosimilars in order to swiftly supplying the EU market on day-1. Concerned about the day-1 issue, the European Parliament decided to further push the Regulation by amending the Commission’s proposal in order to introduce a stockpiling waiver. The stockpiling waiver will allow the generic and biosimilar manufacturers to start producing their products before the end of the SPC term. By doing so, all the manufacturers located in the EU would be ready to reach the internal-market\textsuperscript{44} on day-1.

By implementing the manufacturer waiver for both export and stockpile purposes, the EU aspires to boost the competitiveness of generic and biosimilar industries in the EU. Thus, we can reasonably assume that these changes are likely to have an impact on the business of the originators. Is it not a risky gamble for the EU to strengthen one industry, by potentially, weaken the other? What are the impacts on public health? Hence, what are the legal justifications for the creation of a manufacturing waiver for export and stockpiling purposes? Furthermore, we will see that the new Regulation goes further than all the previous foreign ones in this area. This pioneer legislation may not be well received on the international stage and could be seen as a protectionist measure and a violation of international obligations. It would be necessary to focus on the future challenges that the manufacturing waiver might face on an international level.

In the first part, we will see how the EU justified the creation of a new exception in the field of SPCs. Taking the fast evolution that leads to some profound changes in the international pharmaceutical market into account, the European Commission had to convince the other institutions about the urgency to act and the benefits of its proposal. We will see that the proposal did not meet the unanimity and was partly amended by both the Council and the Parliament. Sharply criticized by the pharmaceutical industry, the legislation appears to be a compromise between the interests of the originators and the interests of the generic and biosimilar manufacturers, with the principle of “health in all policies” on the bottom line (Part I). Now that the Regulation has entered into force, some questions have been raised regarding its reception on the international scene. Indeed, if the members of TRIPS can go forward in the creation of new laws, they cannot contradict the Agreement itself. Some countries could use international tools in order to challenge the new legislation. Another scenario would be that the new amendment of Regulation 469/2009 will open the door to others, and that new legislations of the same type will follow. (Part II).

\textsuperscript{44} Throughout this work, we will refer to “internal market” as to the market of the European Union.
There is a clear evolution regarding the use of SPC in Europe this last decade. First, there is an overall increase in the total number of applications: the number of SPC applications filed in the Member States has tripled from about 1500 applications. Secondly, there are some more significant fluctuations from one year to another. The reason for this change can be explained by the frequent use of centralized procedures for innovative products, as well as an enlargement of the Union (from fifteen member states before 2003 to twenty eight today) and the development of medicinal products consisting of multiple active ingredients and the “possibility to designate multiple patents with reference to the same medicinal products for the purpose of SPC grant”.

Historically created to boost the pharmaceutical innovation in the EU, the SPC turns out to be a powerful legal tool, which harms the generic and biosimilar companies in the EU by delaying the launch of their products on the international market, but also to some extent, on the internal market. This situation has become a major issue for European competitiveness, and the EU decided to face it by amending the current Regulation concerning SPC for medicinal products with a manufacturing waiver exception.

In the first chapter, we will study several legal justifications for the creation of a manufacturing waiver which aim to curb the unintended consequences of the SPC regulation (Chapter 1). Then, in the second chapter, we will explain why the new exception is, in fact, a compromise between dual interests at stake. Initially drafted in the interest of generic and biosimilar manufacturers, the legislation eventually provides some strong safeguards for the originators, which would undoubtedly weaken the implementation of the legislation (Chapter 2).

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Chapter 1: Rectifying the unintended consequences of the SPC regulations in the European Union

The unintended consequences of the SPC Regulations in the European Union are clearly expressed in recital 4) and 5) of the proposal of the European Commission for a manufacturing waiver 47.

“4) The absence of any exception in Regulation (EC) No 469/2009 to the protection conferred by a supplementary protection certificate has had the unintended consequence of preventing manufacturers of generics and biosimilars established in the Union from manufacturing, even for the exclusive purpose of exporting to third-country markets in which such protection does not exist or has expired. A further unintended consequence is that the protection conferred by the certificate makes it more difficult for those manufacturers to enter the Union market immediately after expiry of the certificate, given that they are not in a position to build up production capacity until the protection provided by the certificate has lapsed, by contrast with manufacturers located in third countries where protection does not exist or has expired.

(5) This puts manufacturers of generics and biosimilars established in the Union at a significant competitive disadvantage compared with manufacturers based in third countries that offer less or no protection.”

The European Commission drafted a proposal to answer these issues. The proposal was a targeted amendment of the Regulation 469/2009 regarding SPC for medicinal products but not a general review of the Regulation. The initiative was backed up by a series of independent studies, an impact assessment published in February 2017, and a twelve-week public consultation taking the interests of different stakeholders into account. The information collected by the European Commission confirmed the “magnitude of the problem and the urgency to act” (Section 1). The European Commission decided to face the situation by proposing the implementation of a manufacturing waiver for export and ensured that this amendment is compatible with the existing policies. (Section 2)

Section 1: The European Commission’s proposal, response to the “magnitude of the problem and urgency to act.”

On October 28th, 2015, the European Commission presented a new strategy that had to be quickly implemented in order to deliver a deeper and fairer Single Market. The Single Market Strategy is the European Commission’s plan to “unlock the full potential of the Single Market.” This latest strategy focused on three key areas; creating new opportunities for consumers and businesses, encouraging modernization and innovation, and ensuring practical benefits for people in their daily lives. The draft of the manufacturing waiver takes place in this context. Although the new exception was first designed to answer economic concerns; this policy, targeting the pharmaceutical field, also takes the public health interest into account based on the principle of “health in all policies” recognized in the Charter of Fundamental Rights of the European Union.

I. An amendment in the context of the European Union Market Strategy

The Commission’s proposal is not the first document that discusses the creation of a manufacturing waiver in the European Union. Nonetheless, it is the first time that the European Commission decided to limit the implementation of a manufacturing waiver within the scope of the SPC, in order to boost the competitiveness of the generic and biosimilar industries.

A. The result of a long process

The idea to implement a manufacturing waiver in the EU is not recent. In 2003, a manufacturing waiver of pharmaceutical products was proposed for the first time by the European Institutions. Three years before that, the Commission lost a case against Canada in front of the Dispute Settlement Body of the WTO which ruled in favor of the compliance of the Bolar exemption with the TRIPS Agreement. At this time, the European Commission, through its proposal of modification of Directive 2001/83 included a Bolar-type provision in the text of the Directive, and the European Parliament suggested the addition of a new exception.

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to patent infringement as an export clause. The argument given by the European Parliament was that it was intended to facilitate the export of generics. The Commission dismissed the proposal and sent it back to the European Parliament without the exception. During the second report of the Directive, the Parliament insisted on the introduction of the exception in its recommendation. Once again, the Commission refused to introduce the export clause. Finally, the Directive was amended with the Bolar exemption but not the export clause. The European Commission, fifteen years after that first proposal of the European Parliament, had come to accept the export clause, but with a limiting application to SPCs.

On a national level, the idea of an export waiver was also gaining ground. In Spain, the New Patent Act was enacted in 2015. Upon this occasion, some political parties proposed an amendment to the New Patent Act, to introduce a new exception to patent infringement: the manufacturing waiver for export. The Spanish government did not support the proposal and rejected the amendment because it considered that the question should be treated and resolved on the European scene.

One year later, the Comprehensive Economic and Trade Agreement (CETA) was conducted between the EU & Canada. The agreement enacted the manufacturer for export, in quite similar terms to these of the Regulation proposed by the Commission on May 28th, 2018 to amend the Regulation 469/2009 concerning SPC for medicines.

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52 The justification given by the European Parliament (see previous footnote) was as follows: “This amendment makes the Commission proposal more precise in that it describes exactly what development work may be carried out in connection with the authorization procedure for a generic medicinal product. This will create legal certainty. Otherwise, generic medicinal products will continue to be developed outside the EU while the original is still under patent, with the consequent loss of jobs, investment and know-how. A provision concerning exportation has been introduced for the following reasons: - to improve access to medicinal products by facilitating exports of generic products so as to meet the health needs in a country which has granted a compulsory licence or which does not have a patents system”.
B. A proposal in the context of the Single Market Strategy

The European Commission finally supported the concept of a manufacturing waiver, as a useful tool to increase the competitiveness of the generic and biosimilar industries, inside and outside the European Union.

As a fast-growing sector, the global pharmaceutical market now represents over €1 000 billion annually, with the most rapid growth in emerging economies. “By 2020, generics and biosimilars will represent 80% of all medicines by volume and about 28% by value56”. Moreover, it has been estimated that with the expiry of industrial property protection, over € 90 billion of the first generation of blockbuster biologics will become open to biosimilar competition in the world by 202057. The originators are very aware of the situation, and some of them already started to anticipate the upcoming patent cliff. For instance, in 2015, the originator firm Pfizer spent $ 17 billion to purchase Hospira; a leading developer of biosimilars with manufacturing capacity in Asia and North America58. This patent cliff will happen in a context of mainstreamed SPC protection across the Union, thus forcing companies which are willing to invest in new opportunities to start – or relocate – their manufacturing outside the EU. There was an urgent need to work on the specific problem faced by the EU-based generic and biosimilar manufacturers, who are in a disadvantage vis-à-vis the countries outside the EU where the SPC protection has lapsed or never existed59.

In this context, the Single Market Strategy highlighted significant problems that impact the European the pharmaceutical industry as a whole60. For instance, the loss of export market in unprotected third countries and a day-1 issue, as well as a fragmentation resulting from the uneven implementation of the current SPC regime in the member states -that could be solved with the upcoming unitary patent-, and a fragmented implementation of the Bolar research exemption. On June 2016, the Council called upon the Commission to engage in a review of

59 European Commission, “Proposal for a Regulation of the European Parliament and the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products”, opt. cit.; Recital 6): “Without any intervention, the viability of the manufacture of generics and biosimilars in the Union could be under threat, with consequences for the Union’s pharmaceutical industrial base as a whole”.
60 Originators and manufacturers of biosimilar and generics products.
intellectual property incentive in the pharmaceutical sector. After this analysis, the Commission considered that particular attention should be given to SPCs regarding two specific problems that decrease the competitiveness of EU based manufactures of generics and biosimilars: the loss of export market shares due to the late entry of the biosimilar or generic manufacturer based in the EU, and the delayed entry in the internal market right after the end of the SPC protection.

Currently, the EU represents 14% of the global pharmaceutical market, with 4 000 companies, 570 000 jobs, €220 billion annual exports, and annual investments of €27 billion in research and development. 3724 small to medium-sized enterprises (SMEs) are active in pharmaceutical manufacturing, of which 1 362 export outside the EU. Generic and biosimilar companies constitute a growing part of the EU pharmaceutical industry, accounting for 160 000 jobs, 350 manufacturing sites and investing between 7% and 17% (in the case of biosimilars and complex generics) of their turnover in research and development 61.

Modifying the SPC legislation by creating a manufacturing waiver for export should “strike a balance between the importance to ensure the attractiveness of Europe for innovative pharmaceutical companies and the urgency to allow EU bases generics and biosimilars to compete on the global market […] It will particularly benefit the many small and medium-sized enterprises in the field” 62. In the continuity of the European policies targeting SMEs, which represent 99% of all businesses in the EU, the proposal is primarily addressed to the 3 724 SMEs active in pharmaceutical manufacturing, of which 1 362 export outside the Union 63. According to the European Commission, “the new exception will help new pharmaceutical companies start-up and scale-up in high growth areas, and is projected to generate, over the next 10 years, additional net annual export sales of well in excess of EUR 1 billion, which could translate into 20 000 to 25 000 new jobs over that period” 64.

62 Ibid.
However, these estimations should be interpreted with caution. Many studies have been conducted in order to estimate the impact of a manufacturing waiver, and none of them had reached the same result.

In 2014, one of the first studies targeting the potential economic gain of an SPC waiver, Vicente and Simões state that an SPC manufacturing waiver will boost the economic activity in the EU and create about 8,890 new direct jobs and 35,560 new indirect jobs and potentially generate the investment associated to the enhancement of manufacturing capacity equivalent to the creation of 37 new SMEs medium-sized pharmaceutical enterprises65.

The authors make a strong point about the national differences in intellectual property protection and potential forum shopping, but “do not give any information about how much production is actually ‘overtaken’ by foreign suppliers and precisely which takeovers occur due to the existing patent and SPC.66”

In 2016, the most comprehensive study on the impact of an SPC export waiver was released by the European Commission67. It uses several methodologies and examines the impact of an SPC export waiver on both EU-based manufacturers of generics and producers of biosimilars. The report finds that the EU pharmaceutical industry could gain an additional net export of up to €8.56 billion due to an SPC export waiver. A number of authors, including Logendra & Troen68, criticized the European Commission study, claiming that it suffers from a severe lack of relevant trade, price, and market share data for both branded drugs and generics medicines and that the numerical outcomes crucially depends on a number of simplifications, assumptions and approximations (for example, not taking the dynamic changes in the market shares into account).

No matter the differences regarding the exact future incidence of a manufacturing waiver, all studies confirmed that a manufacturing waiver would have a marginal impact on overall EU

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economically activity\textsuperscript{69}. Importantly, all these studies fail to address the opportunity costs that an SPC export waiver would create for patients and public health systems of EU Member States as the result of strategic changes in product placement, pricing and investment behavior by innovators\textsuperscript{70}. Despite this lack of information, the Commissioner for Internal Market, Industry, Entrepreneurship and SMEs confirmed that “\textit{In the medium term, more competition [between generics/biosimilars manufacturers and originators] will improve patients’ access to a wider choice of medicines and alleviate public budgets.}” It is clear that the aim of the manufacturing waiver deals with the economic concerns first; however, the amendment also supports, public health interests, to some extent.

\textbf{II. An amendment consistent with public health concerns}

Generic medicines are a crucial tool for governments to sustain their healthcare systems and control pharmaceutical expenditures. This contribution of generic medicines to the sustainability of European healthcare systems has been recognized by the High-Level Pharmaceutical Forums, ‘\textit{Generic medicines provide an opportunity to obtain similar treatments at lower costs for patients and payers while liberating budgets for financing new innovative medicines}\textsuperscript{71}.’ The WHO also emphasizes the cost-saving potential of switching consumption from originator products to generic equivalents\textsuperscript{72}. The prices and market shares of generics fluctuate widely across Europe. For example, prices charged by manufacturers in Switzerland are, on average, 2.5 times more expensive than those in Germany and 6 times more than those in the United Kingdom\textsuperscript{73}. The amount of prescriptions filled with generics varies from 17\% in Switzerland to 83\% in the United Kingdom\textsuperscript{74}. However, the actual tendency of the policymakers is to encourage the use of generics medicines, through public campaigns\textsuperscript{75}, and medical guidance for doctors\textsuperscript{76}, in order to reduce the current or future expenditure on

\textsuperscript{69} The European Union’s GDP was estimated to be $18.8 trillion (nominal) in 2018.


\textsuperscript{73} O. Wouters, P. Kanavos, M. McKnee “Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and spending” September 12\textsuperscript{th} 2017, the Milbank Quarterly, volume 94, issue 3, p.555.

\textsuperscript{74} Ibid.

\textsuperscript{75} French Ministry of Solidarity and Health, Health Insurance and the National Agency for the Safety of Medicines and Health Products (ANSM), “Public campaign encouraging the use of the generic”, 2016.

\textsuperscript{76} Ameli (French Health Insurance) « Règles de prescriptions des médicaments génériques », 13 avril 2018, available at: www.ameli.fr “Since January 2015, the prescription in the international common name has become
medicines. The price of a generic drug costs about 20% to 80% less than a medicine under a patent or an extension to patent.

However, the entry of generic and biosimilar medicines on the European market collides with the SPC legislation. Created to protect the research and development of new drugs in Europe, the European SPC legislations are the strongest in the world, and logically delay the availability of generic and biosimilar medicines in Europe. The EU generic drug industry and some EU health ministers argue that pharmaceutical patents and especially SPC protection ‘have gone too far, causing drug prices to skyrocket while patients struggle to access the latest treatments and cures’. For example, generic treatments of HIV/AIDS have been widely used in other countries for the past ten years; however, it has just begun to become accessible in Europe. The generic equivalents of Abacavir, Atazanavir, and Raltegravir (medicines against HIV/AIDS) were available on the foreign markets since 2006, 2009 and 2015, whereas the SPC protection for the former two medicines only expired this year in Europe, and the latter is remaining under SPC protection until January 2023.

In order to extend market monopolies, some evergreening strategies are being employed by pharmaceutical companies through a variety of means, including the filing of multiple patents on one medicine or pursuing prolonged patent terms. This strategy for patenting minor changes to old medicines and strategy for applying for an SPC on these minor changes allows companies to avoid generics competition and to charge a higher price to patients and governments for an extended period of time, even if affordable and equivalent generic and biosimilar versions of new medicines have been launched outside the EU.

Mandatory. It means using the scientific name of the drug, common to all health professionals, in all countries. It also improves the "generic drug pathway" by facilitating the continuity of treatment between physicians, dispensation by the pharmacist and understanding of the patient who finds the same name on his prescription and on his drug box.”


79 Ibid.

80 Ibid. p2. “For example, due to an additional monopoly granted by SPCs, there was a 10-year delay for European countries to import or produce generic versions of imatinib mesylate, a medicine used to treat leukaemia. Even the lowest current generic price of imatinib mesylate in 10 European countries is up to three times more expensive than the equivalent generic price in India, where generic competition began much earlier.”
In this context, the manufacturers of generics and biosimilars could leave the EU, and start to manufacture in countries where the SPC protection has lapsed or never existed. Such an option would have a detrimental impact on EU patients and national public policy. The concentration of the production in some particular geographical regions outside the EU would lead to less diversity and quality of generics and biosimilars and would reduce the security of supply inside the Union. This increasing dependence on imports of generics has been a trend in the Union. An earlier Commission Staff Working Document from 2014\(^81\) revealed that while in the 1980s, 80% of the active pharmaceutical ingredient destined for the EU market were of European origin, by 2008 that figure decreased to 20%. This situation had led to some episodes of shortages in the EU, documented on the EMA website which provides a catalog of shortages of supply of medicines in the EU\(^82\). Indeed, some shortages in the EU are exclusively due to disruptions to production, which takes place exclusively abroad. Therefore, “increasing risk of imported counterfeit and falsified medicines has also been detected by EU customs authorities, which in 2016 seized almost 400 000 pharmaceutical articles\(^83\).

Moreover, the public consultation launched by the European Commission reveals that patients are in favor of better access to generics, and that they care about the origin of the production of medicines they consume (only 3 respondents out of 43 suggested that they do not care), as well as the quality and supply concerns of the products\(^84\). Even nowadays, some patients in a few Member States are not able to access specific treatments until a biosimilar or a generic medicine is available.

In order to face this problem, Doctors Without Borders, a non-governmental organization (NGO) unfavorable to the SPC system, asked for the abolishment of the SPC mechanism, and to stop encouraging SPCs and similar mechanisms through free trade agreements. Aware that a step backward is unlikely to happen, the NGO also gave advice in the event SPCs remain: the mechanism to oppose the granting of SPCs should be bolstered, and third parties’


observations should be allowed during the examination procedure for SPC applications, and an opposition procedure open to anyone should be made available after an SPC is granted. Moreover, the transparency of the market exclusivity status should be improved. The European Commission should create an easily searchable database, for consumers and governments to identify SPCs that have already been granted and the delays on generics. The Commission’s proposal does not go that far but makes a step forward for quicker entry of biosimilars and generics medicines on the internal market. Indeed, the manufacturing waiver enables the stockpiling of generics or biosimilars to some extent, in order to facilitate the entry on the internal market the day after the expiration of the SPC (day-1). However, this practice would be discriminatory for some manufacturers as only the ones which already have an active production line for export would be ready to reach the day-1 entry in the EU market.

In order to rectify this situation, thereby making medicines more accessible to EU patients, the Parliament amended the Commission’s proposal and added a ‘direct’ stockpiling waiver, which would benefit the generic and biosimilar manufacturers in the Union, as well the EU patients.

Section 2: The trilogue’s result, a manufacturing waiver for export and for stockpiling purposes

Each European Regulation follows the same legislative process. First, the European Commission drafts a proposal and proposes new legislation to the Parliament and the Council. Second, the Parliament and the Council can draft amendments to the proposal. Third, the modified (or not) proposal needs to be approved by both the Parliament and the Council to become a new legislative act. Fourth, the new law needs to be published in the Official Journal of the European Union, and it will enter into force shortly after. Finally, the national governments implement the new law.

Through several studies and public consultation, the European Commission has successfully established the need for a reform of the SPC Regulation for medicinal products. The next step for the European Commission was to address these issues and choose the most favorable option, balancing in one hand, public health, access to medicines and government expenditure, and in the other hand, the conflicting interests of the manufacturers of generics and biosimilars and those of the originators. In the first part, we will study why the European Commission’s proposal only focused on a manufacturing waiver for export, and what motived the European

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Parliament to extend the scope of the proposal to a stockpiling waiver (I). In the second part, we will study how the Union justified the consistency of the new legislation with the existing policies, both within the EU and at an international level (II).

I. Manufacturing waivers as the preferred option

The European Commission examined different options to remedy the SPC’s unintended consequences and chose to draft a narrow exception to the certificate (A). The scope of the exception was later extended, as a result of the negotiations between the institutions (B).

A. Manufacturing waiver for export purposes

On May 28th, 2018, the European Commission published an “impact assessment” accompanying the proposal. In this document, the European Commission presented the different options that could be used in order to fix the SPC’s unintended consequences. Some options had been evoked but were discarded at an early stage. 86

Firstly, the EU could have tried to persuade third countries to adopt the same SPC protection as their own, by putting adequate provisions in Fair Trade Agreements (FTAs). In many cases, this option is impossible to implement, as several trading partners are opposed to the introduction of SPC protection in their legislation. Some countries are willing to accept the introduction of an SPC but at a lower level. For example, the CETA obliges Canada to introduce at least a two-year SPC protection that will favor the exports of European pharmaceuticals to Canada which amount to about € 4 billion annually, but CETA also allows Canada-based generics and biosimilars, during those two-years of SPC protection, to manufacture for export purposes87. Such negotiations are time-consuming and can last for years, whereas there is an urgent need for reform. Therefore, the EU cannot depend on other trade partners to establish its own policy.

Another option raised by some authors would be an extension of the scope of the EU Bolar exemption to include manufacturing for export, as well as a stockpiling for EU day-1. However, the Bolar exemption applies to both SPCs and patents, so expanding the Bolar exemption to allow for export manufacturing and stockpiling during the patent term is likely to conflict with article 28 of TRIPS. This option was not considered in the public consultation.

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87 Ibid.
Inspired by a method that already exists at a national level, the EU could choose to enact some new ad-hoc licensing measures. A particular type of license could be defined, which would be applied for a generic or biosimilar company and granted by a competent authority, or negotiated with an SPC-holder under the supervision of a competent public authority, free of charge or against payment of a license fee\(^\text{88}\). On one hand, this option would benefit the SPC-holders who could identify and control the beneficiaries of such a license. On the other hand, from the perspective of the generic and biosimilar manufacturers, the administrative procedure would certainly be costly and lengthy, making it uncertain for the licensees whether applying for a license would be economically wise. SPC holders could voluntarily delay the grant of a license (by interjecting multiple appeals), making investments for the manufacturers very uncertain or asking for unreasonably high royalties\(^\text{89}\).

A more drastic measure would be to reduce the duration of the SPC (for example, from five years to two years provided in the CETA). By doing so, the EU would scale down the SPC protection asymmetry for third countries. This option would be unreasonable and would negatively impact the EU: it would affect the monopoly enjoyed by the SPC holders; and it would go directly against the aim of the SPC, which is to compensate for the loss of effective patent protection due to R&D and authorization procedures. Moreover, it would not solve the issue of day-1 entry onto the EU market, unless the EU SPC protection was removed entirely in the EU, in order to align the Union with non-SPC third countries with manufacturing capacity, such as India and China. Such an approach would weaken the research and development in the pharmaceutical sector in the EU and would contradict more than twenty-five years of intellectual property policy. This option received no support from the public consultation.

After the analysis of the previous options, the European Commission concluded that the better option was the creation of a narrow and targeted exception from Regulation (EC) No 469/2009. The new exception was established under Article 4 of the Regulation. The title was changed from “subject matter of protection,” to “subject matter of protection and exceptions to rights conferred.” While paragraph 1, regarding the protection granted by the certificate, remains


\(^{89}\) Ibid.
unchanged\textsuperscript{90}, paragraph 2 provides a situation when the certificate shall not confer protection against a particular act, if two conditions are met: the act comprises: (i) “making for the exclusive purpose of export to third countries\textsuperscript{91};” or “(ii) any related act that is strictly necessary for that making or for the actual export itself;”. Thus, the proposal aims to exempt the manufacturing from infringement of an SPC for export purposes of the product (i) as well as all the necessary acts related to manufacturing (ii), which include upstream acts (supply of intermediary products and active ingredients) and downstream acts (transport, storing, packaging, sorting and the actual export)\textsuperscript{92}.

The proposal, drafted to deal with the export issue, will also have an impact, to a certain extent, on the internal market. A manufacturer which set up a manufacturing line for export purposes will easily be able, after SPC expiry, to use the same line to manufacture generics or biosimilars to swiftly supply the EU market, and consequently be ready for day-1 on the internal market. These manufacturers would have to comply with the applicable pharmaceutical legislation and, for example, possess a valid marketing authorization at the time the products are placed on the EU market (they can do so before the end of the SPC by using the Bolar exemption)\textsuperscript{93}.

However, we can argue that this amendment does not address the day-1 issue on equal terms for all the generic and biosimilar companies, the ones which already have production chain will be able to enter the market on day-1, but the others will still have to wait until the last day of SPC production to start producing. The consequence will be that only the most prominent companies with an active production line, able to massively produce for export purposes abroad, will have the necessary resources to start producing on the internal market and benefit from the ‘first mover’ advantage\textsuperscript{94}.

The Commission’s proposal has been submitted to the European Parliament, under the responsibility of the Committee on Legal Affairs (JURI), on May 28\textsuperscript{th} 2018. In order to address

\textsuperscript{90} §1 “Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate”.

\textsuperscript{91} Third countries need to be understood as countries outside the EU.


\textsuperscript{93} Ibid. p.4.

\textsuperscript{94} As we already mentioned, the first generic or biosimilar on the market is most likely to own important market shares.
the day-1 issue, the Committee on Legal Affairs finally concluded that a stockpiling waiver needed to be implemented.

B. Manufacturing waiver for stockpiling purposes

The European Parliament Committee on Legal Affairs launched a first draft report on the Commission’s proposal on October 30th 2018. This report supports the approach of an amendment to the SPC Regulation that would allow third parties to manufacture medicines protected by an SPC for the exclusive purpose of export to countries outside the Union, but it did not mention the creation of a stockpiling waiver.

One month later, on November 22th 2018, the Council of the EU, introduced a proposal based on the discussions in the Council Working Party on intellectual property. This report did not cover stockpiling waiver either, and the Council Presidency clearly expressed its opposition on the matter, “[a stockpiling waiver] would go substantially beyond the scope of the original Commission proposal and would not result in an agreement in Council.” This view was reaffirmed on January 16th 2019, in the text endorsed and proposed by the Council, for negotiations with the Parliament.

The final report of the Committee on Legal Affairs was adopted on January 23th 2019. This final report had undergone significant revisions as compared to the preceding draft report issued by the Committee on Legal Affairs. The most notable legislative amendment finally endorsed by the Committee is the creation of a stockpiling waiver. The manufacturing waiver is to be broadened to allow the making of the SPC-protected active ingredient, the corresponding medicinal product for the exclusive purpose of export to third countries outside the EU, as well as the making and storing of the protected product for “day-1 entry” to the EU market immediately after SPC expiry. Such stockpiling will be allowed “during the final two years of validity” of the respective SPC.

On January 30th 2019, the Committee decided to open-up inter-institutional negotiations with the Council and the Commission, knowing that neither of these institutions supported the

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stockpiling waiver. In this context, it was impossible to assume which position will prevail in the trilogue negotiations between the representatives of the Parliament, the Council, and the Commission.

It turned out that the Parliament negotiators were successful in pressing for the waiver to be extended to stockpiling for day-1 release in the EU. A press statement on February 14th, 2019 stated that the Commission had welcomed Agreement for a proposal but did not give any information on the course of the negotiations between the European Institutions. According to the press statement, the new Regulation introduces a carefully framed exception to the patent protection of an original medicine for export and stockpiling.

The provisional agreement reached in the inter-institutions trilogue negotiations was published a week after the release of the press statement. This new version modified the former proposal in order to include the manufacturing waiver for stockpiling. The act comprises:

“(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 earlier than six months before the expiry of the certificate.”

As a result of the negotiation process, the starting day of the manufacture for the purpose of storing has been reduced from two years before the expiry of the certificate (suggested by the Parliament) to six months before the expiry of the certificate.

Once the negotiations were over and the new Regulation ready to be adopted by both the Parliament and the Council, the European Institutions had to justify the consistency of the new amendment with the existing policies, both within the EU and at an international level.

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II. Implementation of the legislation

In the explanatory memorandum of the proposal, the European Commission justifies the ability of the Union to legislate on the matter (A), as well as the compliance of the proposal with the existing policies in the Union (B).

A. Competence of the Union to legislate

The sole legal basis for the proposal is article 114 of the Treaty on the Functioning of the European Union. This Article confers on the EU the competence to adopt measures on the establishment and functioning of the internal market. The current Regulation (EC) No 469/2009 has already removed the obstacles to trade in the area by harmonizing the rules related to SPCs.

The Union is entitled to push its legislation further and “to adapt that act to any change in circumstances or developments in the relevant sector.” However, we can discuss the legitimacy of the Union to legislate in the case of a manufacturing waiver for export, because this exception is primarily targeting exports to third countries and not the internal market. The Commission justified the competence of the Union to amend the Regulation, by claiming that the actual making under the exception will take place within the Union, albeit exclusively for export to non-EU markets.

The principles of subsidiarity and proportionality of the Union govern the exercise of the EU’s competences. In areas in which the EU does not have exclusive competence, “the principle of subsidiarity defines the circumstances in which it is preferable for action to be taken by the Union, rather than the Member States.” The exclusive competences of the EU in the area of intellectual property are to be found in the article 118 of the Treaty on the Functioning of the European Union and does not provide competence for the creation of an exception to an

102 Treaty on European Union, article 5(3).
103 Ibid, article 5.
105 Treaty on the Functioning of the European Union, article 18 : “In the context of the establishment and functioning of the internal market, the European Parliament and the Council, acting in accordance with the ordinary legislative procedure, shall establish measures for the creation of European intellectual property rights to provide uniform protection of intellectual property rights throughout the Union and for the setting up of centralized Union-wide authorization, coordination and supervision arrangements” [...]

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intellectual property right. Thus, the EU has to prove that a measure needs to be adopted on a European level. Indeed, a Member State could indirectly change the effects of SPC protection in its jurisdiction by changing the effects of its national patents; those changes might be different from one Member State to another, leading to a distortion into the internal market for products protected by an SPC. Taking action on the European level would prevent a heterogeneous development of national rules and practices which directly affect the functioning of the internal market. The Commission added that the voluntary agreements between generic and biosimilar manufacturers and originators concluded at a national level are not considered successful because they did not reach the objective of creating a level playing field for generic and biosimilar manufacturers across the entire Union’s territory, nor did they address the issue of export to third countries.

Consequently, action from the Union is fully justified. Like the principle of subsidiarity, the principle of proportionality governs the exercise of powers by the EU. “Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.”

Regarding the manufacturing waiver, the proposal has been drafted to ensure a balance between the interests of the SPC holders and those of the generic and biosimilar manufacturers, providing some safeguards measures for the SPC holders, and ensuring low administrative burden and compliance costs for generic and biosimilar manufacturers, while ensuring equal treatment throughout the Union.

Additionally, the timing scenarios for the applicability of the proposal have been exposed, including a transitional period, which provides clarity and legal certainty for all concerned. The Commission concluded that the proposal does not go beyond what it is necessary to tackle the identified problem.

B. Consistency with the existing policies

The Union is competent to legislate but needs to verify that the amendment respects the international policies from which it is a party (1), as well as its internal policies (2).

1. Outside the Union

The European Commission affirmed that the proposal was compliant with the international obligations of the EU, such as FTAs and the TRIPS Agreement. However, the Commission did

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not demonstrate its statement. The Regulatory Scrutiny Board\textsuperscript{107} submitted a report regarding the proposal\textsuperscript{108}. The report supported the proposal with reservations. The Board advised the European Commission, among other things, to “better explain the potential impacts of the manufacturing (notably of the stockpiling) waiver with regard to the EU’s trade policy and the compatibility with WTO-TRIPS provisions\textsuperscript{109}.” The Board is here making an indirect reference to a Dispute Settlement Body decision regarding stockpiling. In 1999, the Dispute Settlement Body\textsuperscript{110} of the WTO was established to rule on the European Communities and their Member States’ complaints against Canada, arguing that the stockpiling provision stipulated in the Canadian Patent Act reduced the rights conferred to a patent owner provided in Article 28.1 of TRIPS, and did not belong to the limited exceptions provided by Article 30 TRIPS. The Panel ruled that stockpiling is indeed not justified under Article 30 for patent rights. The decision of the Panel was not appealed. Twenty years later, we can wonder if the outcome of a new WTO decision would be the same as the previous one regarding a stockpiling exception in the context of an SPC. It is reasonable for the Board to ask for some clarification regarding the matter.

Moreover, originators claimed that an export waiver would conflict with the Union’s international obligations, notably FTAs conducted by the EU. The European Commission did not provide clear explanations to refute this idea. The lack of studies published by the European Commission regarding the compliance of its proposal with the FTAs and the TRIPS Agreement lead to legal uncertainty and are currently subject to heated debates on the academic scenes.

2. Inside the Union

At a Union level, the amendment should be consistent with existing policies, such as trade policies and health policies, as well as the fundamental rights set out in the Charter of Fundamental Rights of the European Union.

In this regard, the Commission first highlighted that the proposal was created to complement the EU trade policy but is in no way a protective measure. The proposal aims to reduce the market asymmetry between EU and non-EU manufacturers of generics and biosimilars, by ensuring a better free and fair-trade for the Union-based manufacturers. The measure is in line

\textsuperscript{107} The Regulatory Scrutiny Board is an independent body of the Commission that offers advice to the College. It provides a central quality control and support function for Commission impact assessment and evaluation work. The Board examines and issues opinions and recommendations on all the Commission’s draft impact assessments and major evaluations and fitness checks of existing legislation.


\textsuperscript{109} Ibid.

\textsuperscript{110} Panel Report, Canada-Pharmaceutical Patents (DS114).
with the Commissions 2009 Communication on the pharmaceutical sector inquiry “the sector inquiry confirms that generic entry does not always take place as early as it potentially could under the current relevant legal framework”\(^{111}\).” The report suggested the use of an intellectual property measure to address the issue because “both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof.”\(^{112}\) The amendment targets the pharmaceutical sector, so the Commission had to ensure that it does not conflict with the actual health policies. Thus, the initiative does not provide for any derogation form and is applied without prejudice to relevant Union pharmaceutical legislation on the manufacturers of generics or biosimilars.

The European Commission’s regulatory fitness & performance program (REFIT) specified that the waiver will not affect the other features of the EU SPC regime such as the subject matter of protection and duration, especially since certain CJEU cases related to SPCs are still pending.

On another level, the proposal needs to respect fundamental rights, freedoms, and principles enacted in the Charter of Fundamental Rights of the European Union. The Lisbon Treaty of 2007 refers to article 6 of the Treaty on European Union and gives the Charter a legally binding value (the Charter, therefore, has the same legal value as the treaties)\(^{113}\).

The Charter recognizes the right to health care in its article 35 “Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities”\(^{114}\). In this regard, the stockpiling waiver added by the Parliament fully respects the fundamental right of access to health care because it helps the entry of the biosimilar and generic production on day-1.

The Commission affirms that the manufacturing waiver does not conflict with the fundamental right of property enacted in article 17 of the Charter. Paragraph 2 of article 17 explicitly mentioned intellectual property as a right of property that “[...] shall be protected”. The proposal will not affect the market exclusivity of SPC right holders in the Union. To ensure that

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\(^{112}\) Ibid.

\(^{113}\) “The Union recognises the rights, freedoms and principles set out in the Charter of Fundamental Rights of the European Union of 7 December 2000, as adapted at Strasbourg, on 12 December 2007, which shall have the same legal value as the Treaties”.

the property right of the SPC holders is preserved, the manufacturing waiver is accompanied by transparency and anti-diversion measures, as well as a transitional period before the legislation comes into force. The Commission estimated that the right of property needs to be balanced with another fundamental right enacted in article 16 of the Charter, the freedom to conduct business. Without the waiver, the generic and biosimilar manufacturers could not conduct business in a third country until the SPC protection is over in the Union.

As mentioned before, a remedy to this situation is not supposed to impact the property right of the originators, nor have a substantial impact on their business. This point of view is refuted by the originators and backed up by several studies. We will study how this recently adopted amendment to Regulation (EC) No 469/2009 is a compromise between two dual interests at stake.

**Chapter 2: Reaching an unbalanced compromise between opposite interests at stake**

While the manufacturers of generics and biosimilars strongly supported the manufacturing waiver, the originators saw in this SPC exception a significant threat for their businesses and the pharmaceutical sector as a whole. Nevertheless, the Union justified the importance of the creation of the waiver and decided to legislate it in favor of the generic and biosimilar manufacturers, enacting a manufacturing waiver valid for export but also for stockpiling within the EU. The legislative debate mainly focused on redressing the balance in favor of the originators, by establishing a safe legal framework where the exception could be implemented without harming their intellectual property rights, so they can continue to innovate within the EU.

During the draft of the Commission’s proposal and the trilogue, the safeguards accompanying the new SPC exception were the core of the discussion. Facing heavy pressure from the originators’ companies, the Commission made sure to implement an important number of safeguards. As stated in recital 16) “Safeguards should accompany the exception in order to increase transparency, to help the holder of a supplementary protection certificate to enforce its protection in the Union and to reduce the risk of illicit diversion onto the Union market during the term of the certificate.” Those safeguards are supposed to be effective but also proportionate, in order to protect the originators from intellectual property-infringing products from entering Member State markets, while allowing the manufacturers of generics and biosimilars to use the manufacturing waiver efficiently (Section 1).
The Union was very concerned not to weaken the SPC system and wanted to ensure that the SPC holders will keep their market exclusivity in the Member States during the full SPC protection term. To do so, they implemented safeguards which “impose certain information and labeling obligations on makers wishing to take advantage of those rules.” 115 The Commission made sure that its proposal was compliant with “the principles of proportionality, and does not go beyond what is necessary in order to achieve the objectives pursued." 116 The Parliament and the Council made some significant changes to the first draft regarding the required notifications. The risk is not being able to implement the legislation effectively by providing some strong safeguards accompanying the exception. Indeed, in the case of a manufacturing waiver, the safeguards have led to an unbalanced regulation, which is likely to suffer from implementation issues (Section 2).

Section 1: “Effective and proportionate safeguards” in theory

The reaction of the originators to the creation of a manufacturing waiver was explicit: most of them strongly opposed the new exception and advised against its adoption. In a series of studies, pharmaceutical associations alert against the negative impact of the waiver on pharmaceutical research and innovation in the Union, as well as the diversion risks that might occur on the internal market (I). Aware of these views, the legislators strived to provide some useful and proportionate safeguards 117 in favor of the originators (II).

I. Originators views

The originators’ opinions are expressed in several studies published as a response to the manufacturing waiver proposal, as well as in an online public consultation addressed by the European Commission to 71 originators 118. These studies highlighted three main concerns: first, the originators recalled the need for strong intellectual property framework to secure their investments in the research and development of new drugs (A). Second, the originators believe that it would be difficult to enforce a manufacturing waiver without undermining the monopoly

118 European Commission, “Summary of the replies to the public consultation on Supplementary Protection Certificates and patent research exemption for sectors whose products are subject to regulated market authorizations”, op.cit.
of SPC holders (B). Finally, the studies forewarn the Union about the future strategies that the originators might set up in order to face the new exception.

A. The manufacturing waiver, a threat to pharmaceutical research and innovation in the EU

Over the years, legislators have gradually introduced more restrictions on medicine developers in order to preserve public health. There is often a correlation between the enactment of these regulations and health disasters. For example, the EU passed new pharmacovigilance legislation in 2012 in order to strengthen the regulatory process for marketing authorization, after the Mediator scandal in France. In that case, pharmaceutical company Servier succeeded to mislead the regulatory authorities in order to obtain a marketing authorization on a medicine (first sold as a medicine against diabetes, afterward sold as an appetite suppressant). This medicine turned out to generate pulmonary arterial hypertension, often deadly to the patients. To avoid future health crises, the new Regulation increases mandatory trials and clinical testing, and consequently, the costs associated with the tested products. Several recent studies indicate that the cost of drug development often amounts to up to several billions of dollars per drug. This situation led to a significant decline in pharmaceutical research and development productivity in many therapeutic areas. In this context, the research-based pharmaceutical industry needs strong incentives to produce new drugs. Most innovators consider the SPC, or the possibility of obtaining one, as an essential factor for investment decisions. The number of SPC applications filed in the Member States has tripled from about 500 applications from 1993 to 1518 nowadays. A recent study shows that the share of new medicine introductions having an SPC in at least one Member State increased from 75% in the early 1990s to 86% today. An SPC is, more than ever, a useful tool to serve as a balance to stabilize the market value of a patent as it helps the originators to recoup their investments and continue to innovate.

The European Federation of Pharmaceutical Industries & Associations (EFPIA) stated that the new exception will negatively impact originators companies’ ability to develop new therapies and will “sends a negative signal to the world that Europe is devaluing its intellectual property

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121 Ibid.
122 Ibid. “According to Kyle, there were the change in drug development (e.g. introduction of secondary clinical endpoints) has increased the relevance of SPCs over time”.
framework, making Europe a less attractive location for research and development, impacting on jobs investment.¹²³

It is in this context that the online public consultation was being launched by the European Commission (from 12 October 2017 to 4 January 2018).¹²⁴ The originators expressed their broad – though not overwhelming – opposition to the introduction of an EU SPC manufacturing waiver: 54 out of 71 originators do not consider that EU-based manufacturers face export or EU day-1 entry-related problems vis-à-vis their competitors based in non-EU countries (with shorter or no SPC protection)¹²⁵. According to them, the EU based manufacturers are unlikely to increase their exports with the waiver, because patent protection in export countries must expire before the EU SPC expiry date and this is frequently not the case¹²⁶.

Moreover, being able to manufacture medicinal products for stockpiling purposes will not lead to significantly speedier entry for generic and biosimilar manufacturers as long as sophisticated pharmaceutical companies can swiftly adapt their manufacturing process to enter the market shortly after patent expiry, even without the manufacturing waiver¹²⁷. While the originators argue that the impact of a manufacturing waiver will be minimal for biosimilars and generics manufacturers, they claim that they will suffer from an erosion of their monopoly. Indeed, SPC holders would have to recoup their investments and generate profits in a shorter period. To do so, they will likely reduce investment in research and development, but also increase drug prices during their period of market exclusivity.

Therefore, the originators tried to convince the Union that loosening standards for intellectual property protection is a slippery slope¹²⁸, and would not help the EU based generic and biosimilar manufacturers to achieve a level playing field, as other non-EU countries would seek to emulate these exemptions and compete for their market share. The European Commission does not share this view and decided to implement the manufacturing waiver, limited to export

¹²⁴ European Commission, “Summary of the replies to the public consultation on Supplementary Protection Certificates and patent research exemption for sectors whose products are subject to regulated market authorizations”, Commission Staff Working Document, Public consultation, Brussels, May 28th, 2018, op.cit.; p36.
¹²⁵ Ibid.
¹²⁷ Ibid.
purposes. Indeed, “by limiting the scope of the exception to making for the purpose of export outside the Union and acts strictly necessary for such making or for the actual export itself, the exception introduced by this Regulation will not unreasonably conflict with normal exploitation of the product in the Member State where the certificate is in force, nor unreasonably prejudice the legitimate interests of the certificate-holder, taking account of the legitimate interests of third parties.”

The main challenge of this legislation is to ensure that the Union remains an attractive place for pharmaceutical innovation. This amendment technically leaves the SPC protection fully intact regarding placing products on the EU market: the stockpiling waiver will not authorize the launch of biosimilars or generics on the internal market before day-1.

However, some measures need to be taken to avoid a risk of diversion of pharmaceutical products destined for export, on the internal market.

B. The manufacturing waiver, leading to diversion risks on the internal market

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) members believe it would be difficult to enforce such a measure to make sure that products manufactured under this exception are only exported to, and remain with countries without patent protection, or where the protection has elapsed. The absence of internal customs inside the Union would make it challenging to prevent product diversion, further frustrating the purpose of the proposal. It also may be complicated and burdensome, if not impossible, to control the strict implementation of the manufacturing waiver. Among other potential enforcement issues, some strict obligations to ensure that products only reach permitted countries would be needed, such as a mandatory notification to the originator of quantities produced and the destination of these products, or efficient measures to prevent diversion. Moreover, there would be a risk of facilitating infringement in importing countries because it would be very arduous for the courts in the country of manufacture to assert the presence or lawfulness of patents in the importing countries and operate to prevent potential infringement.


Regarding the stockpiling waiver, the risk of diversion would be higher because the exception would allow manufacturing in the Union during the SPC term.

Aware of these concerns, the European Commission gave consent to implement some strong safeguards. During the legislative process, the safeguards accompanying the exception were carefully examined by the Institutions, and then considerably modified.

II. Strong safeguards in favor of the originators

The European Commission drafted an important number of safeguards in its proposal (A). The Council (B) and the Parliament (C) amended the proposal, bearing in mind the need for a fair balance between the interests of the originators and the generic and biosimilar manufacturers.

A. European Commission’s proposal

According to the proposal, the maker 131 must respect some strict requirements in order to benefit from the waiver.

First, the maker must notify the Patent Office of the Member State where the making is to take place at least 28 days before the intended start date of manufacture. The notification must provide the following information: (a), the name and address of the maker; (b). The address or addresses where the manufacture is to take place; (c) the maker must ensure that a logo is affixed to the outer packaging of the products, indicating that it is a product for EU export 132.; (d). Details of any manufacturing authorization relevant to the proposed manufacture or, if none, a valid certificate of good manufacturing practice covering the premises where the making is to take place; (e). The intended start date of manufacture; and, (f). An indicative list of intended third countries to which the product is to be exported.

The notification received by the Patent Office must be published within fifteen days of receipt.


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Finally, the maker must take action to ensure that the person in a contractual relationship with the maker, is aware that (a) the products are for export only, and (b) placing on the market in the EU, import or re-import may result in infringement of the certificate.

The proposal states that the Regulation will come into force twenty days after publication of the approved Regulation in the Official Journal. However, the amendment will not apply to SPCs which have been granted before the Regulation enters into force, or to SPCs which were then pending and which are granted by the first day of the third month following the date of publishing the Regulation in the Official Journal.

This proposal generated considerable commentaries and public interest. On the one hand, the generics manufacturers were disappointed that the exclusion is not broader, for instance, allowing manufacture for stockpiling for EU launch as soon as SPCs expires. On the other hand, SPC holders were worried about the weakening of intellectual property rights, which could make the EU less attractive for innovative research and development.133

B. European Council position

The Council endorses the Commission’s proposal but also argued for changes in some areas. First of all, the Council thought that amending article 5 (“effects of the certificate”) seemed more appropriate than amending article 4 (“subject matter of protection”), as proposed by the Commission. In other words, only the effects, but not the scope of the SPC right, are modified.134

The main adjustments made by the Council focus on the notification requirements and the transitional arrangements, thus clarifying the cases where the waiver will apply.

Regarding the changes on notification, there are two main consequences. First, it gives the SPC holder additional time. The SPC holder is directly notified at least three months before the making starts rather than indirectly via publication by a national patent office once it has received notification no later than 28 days before the intended start date of the making. Second, the Council’s changes require the maker to provide less information on manufacturing location or timing intended manufacture [changes to (b) and removal of (d) and (e)]. This situation

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134 O. Ridderbusch, A. von Uexküll, “SPC manufacturing waiver enters final legislative stage in the EU, with possible extension to allow stockpiling”, op.cit.; paras. 4-5.
makes it more likely that “makers” with no concrete plans to manufacture will file precautionary notifications for when they want to manufacture in the future\textsuperscript{135}. However, the fact that national patent offices can apply a fee to notifications might balance this position. One thing is sure: it will be more difficult for an SPC holder to identify which makers will enter the market for export outside the EU and when.

Regarding the apposition of the logo, the Council strengthened the norms in order to prevent the risk of diversion on the internal market and argued that the logo should be affixed to the outer packaging of the product or medicinal product and, where feasible, to its immediate packaging.

Another critical issue was the transition arrangements. The Commission proposed that the new legislation would only apply to SPCs which had not been granted on the first day of the third month following the date of publishing the Regulation in the Official Journal\textsuperscript{136}. The Council disagreed with this view stating that it would lead to the distortion between EU member states since the date of a grant can vary significantly from one-member state to another. For example, Luxembourg grants early, shortly after an application for an SPC is filed. However, its neighbor Belgium grants late, not examining an SPC application until shortly before the patent on which it is based is due to expire. The Commission’s proposal would provide for up to 15 years where there would be the potential for those products that are the subject of SPCs to be manufactured in Belgium for export, but not be manufactured in Luxembourg for export\textsuperscript{137}.

The Council argues for the following transitional provisions: no waiver can be applied to an SPC in force at the date of entry into force of the Regulation. On the contrary, the waiver applies to an SPC granted on an SPC application filed after the date of entry into force of the Regulation. In the case where an SPC is granted on SPC application filed before the date of entry into force of the Regulation, but where the SPC is not in force on that date, the waiver applies from the date of entry into force of the Regulation plus three years.

\textsuperscript{136} Ibid.
\textsuperscript{137} Ibid.
C. Parliament’s position

During the negotiations, the Council and the Parliament expressed different views on the formal requirements that the maker should respect to take advantage of the waiver.

Regarding the date of the notification of the making, the Council required the notification to be provided at least three months before manufacture (in contrast to the Commission’s proposal of 28 days) to both patent offices and SPC holders. Parliament’s proposal was less strict to the maker because the notification should occur at least two months before the start date of manufacture. Moreover, the Council and the Parliament disagreed on what information is to be provided to the local patent office, how much of this also needs to be provided to the SPC holder and how much would be published.

Regarding the apposition of the logo, there was a difference between the Council and Parliament’s negotiating position as to whether this needed to be apposed only to the outer packaging (Parliament) or both outer and intermediate packaging (Council).

Regarding the transitional provisions, Parliament agreed with the Council except for the situation where an SPC granted on an SPC application filed before the date of entry into force of the Regulation, but where the SPC is not in force on that date: the Council proposed that the waiver applies from the date of the entry into force of the Regulation plus three years; while the Parliament proposed that the waiver will apply to SPCs where the basic patent expires on or after 1 January 2021.

On February 14th, 2019, a press statement was released by the Parliament stating that the Commission had welcomed the political agreement reached by the European Parliament and the Council. The press release does not reveal how these differences were resolved nor identify which option was agreed.

On April 17th, 2019, the European Parliament in plenary session adopted a proposal to allow manufacturing waivers to SPCs at an overwhelming majority, with 572 votes in favor, 36 votes against and 22 abstentions. On 20th May 2019, the Council, under the qualified majority voting rules, approved the SPC manufacturing waiver regulation with “the votes of 22

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140 Which have only recently been extended to the field of intellectual property by the Lisbon Treaty.
member states in favor representing 80.14% of the EU population, whereby the required qualified majority (at least 55% of the member states, i.e., 16 states, which must account for at least 65% of the population) was comfortably surpassed. Denmark, Malta, Sweden and the United Kingdom notably voted against this legislation, with Austria and Czechia abstaining. After the adoption of the new EU Regulation by both the European Parliament and the Council, the respective presidents of the two institutions officially signed it on May 20th, 2019. Then, the new Regulation (EU) 2019/933 was published in the Official Journal on June 11th, 2019, before entering into force two weeks after, on July 1st, 2019.

Nevertheless, the full implementation of the manufacturing waiver is delayed until June 2nd 2022 for the certificates that have been applied before entering into force of the new Regulation, and that takes effect on or after that date. Speaking to Parliament, European Commission Vice President for Jobs, Growth, Investment, and Competitiveness, Jyrki Katainen said the three-year transition period “respects the dual imperative of being both legally sound and economically useful.” The reliability of this statement is questionable: how could a legislation be useful if partly unenforceable for three years? Despite the efforts of the European Institutions to establish an efficient solution to the unintended consequences of the SPCs, the reality is that the new Regulation will suffer from implementation issues.

Section 2: An unbalanced Regulation that leads to implementation issues in practice

As previously studied, some changes have been made to the European Commission’s proposal during the trilogue process. The European Institutions have been efficient to negotiate the new legislation quickly, in order to adopt it before the European Parliament elections in May 2019. The new Regulation improved in some ways compared to the proposal drafted by the Commission; but still provides abusive safeguards for the originators, as well as a maladjusted transitional period.

While a manufacturer for export is allowed through the entire SPC term, a specific temporary cap to the use of the manufacturer for stockpiling exception has been implemented. The


manufacturing and stockpiling for day-1 in the Union is permitted only during the last six months before the expiry of the certificate, instead of the two years requested by the Parliament. This restriction mostly impacts competition in the biosimilars market. In this last respect, six months is a short period for practical and timely use of the exception by biosimilars producers.\textsuperscript{143}

A generic or biosimilar manufacturer who intends to benefit from the manufacturing waiver has to notify the national patent office that granted the SPC, as well as the SPC holder, using a standardized form, no later than three months “before the start date of the making or the first related act”.\textsuperscript{144} The competent national patent office needs to publish the information provided by the maker, together with the date of notification, as soon as possible.\textsuperscript{145} According to Miguel Vidal-Quadras, the interest in the communication of information is not to inform the patent office but, on the fact, that the notification is published and therefore disclosed to third parties.\textsuperscript{146} Therefore, the SPC holder and the competitors will have knowledge of the intentions of the maker almost three months before it begins to make the medicament protected by the SPC (the communication is made three months prior to the making, and it needs to be published as soon as possible) and could manage to block the use of the exception.

A significant improvement of the new Regulation compared to the Commission’s proposal is that the maker needs to provide less information to the patent office and the SPC holder. Indeed, the first proposal required the maker to deliver specific confidential and commercially sensitive information, such as the address of the making and the intended date of the making.\textsuperscript{147} These requirements could clash with the right to conduct business for the maker,\textsuperscript{148} for example, by revealing its business plans. The Regulation reduced the scope of the requirements, and to some


\textsuperscript{145} Ibid, article 4.

\textsuperscript{146} Vidal-Quadras, “Analysis of the proposal for a Regulation of a manufacturing exception, related to the SPC and timed to make the European Industry competitive”, op.cit.; p20.

\textsuperscript{147} O. Ridderbusch, A. Von Uexküll, “SPC manufacturing waiver enters final legislative stage in the EU, with possible extension to allow stockpiling”, op.cit., para.4.

\textsuperscript{148} The Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, states in its Recital 2 that “Businesses, irrespective of their size, value trade secrets as much as patents and other forms of intellectual property right. They use confidentiality as a business competitiveness and research innovation management tool, and in relation to a diverse range of information that extends beyond technological knowledge to commercial data such as information on customers and suppliers, business plans, and market research and strategies” [Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (Text with EEA relevance), OJ L 157, June 15th 2016, p. 1–18.
extent, increase the monitoring burden that the text proposed by the Commission would have brought; making it more flexible for manufacturers to start their production. The required information that needs to be revealed by the maker includes “(a) the name and address of the manufacturer; (b) an indication whether the intended manufacture is for the purpose of export, storing, or both export and storing; (c) the EU member state where the manufacture is to take place (and, if applicable, the member state where the first related act prior to manufacture is to take place); (d) the number of the certificate in question; and, (e) in the case of export to third countries, the reference number of the marketing authorization in each third country of export.”

Any change to this information must also be notified to the authority. However, some authors still think the information accessible to the originators is not necessary and appropriate. Indeed, at this stage, the SPC holder would already be informed if a manufacturer was infringing its patented medicine. As studied before, a medicine manufactured in the European Union must necessarily obtain previous administrative approval. During this process, the applicant needs to provide information, as well as the identity of the manufacturer of the medicine if it is located in the EU. If a medicine that has been manufactured in the EU was to be introduced or reimported in the territory of one of the member states, the marketing authorization would inform the SPC holder of this fact. The marketing authorization process already provides some safeguards for patent and SPC holders. Therefore, there is no risk of illicit diversion onto the internal market, because the information would inevitably be public and known by the SPC holder beforehand. Under these circumstances, the Regulation 2019/933 has set double protection in favor of the originators, which will negatively impact the manufacturers. Indeed, the information relative to a generic or biosimilar medicine intended to be exported in third countries has to be communicated to the patent office and then published. The publication will have a negative effect on the opportunities of the European manufacturers, as their intentions will be disclosed to the originator and the competitors worldwide. Moreover, the new Regulation gives the possibility to the Member States to ask the maker to pay fees for the publication of the notification of manufacture and updates to notifications. The recital of the Regulation stated that “that fee should be set at a level which does not exceed the

\[150\] Ibid.
\[151\] X. Seuba, “The Export and Stockpiling Waivers: New Exceptions for Supplementary Protection Certificates” op.cit.; p.11.
\[152\] Vidal-Quadras, “Analysis of the proposal for a Regulation of a manufacturing exception, related to the SPC and timed to make the European Industry competitive”, op.cit. at 18; p.18.
Thus, the amount of the fee could vary from country to country and could be detrimental to the SMEs in opposition to the big pharmaceutical companies. This situation could rule against the will of the EU to strengthen SMEs competitiveness.

The most regrettable part of the Regulation is the transitional period. The main goal of the Regulation is to adapt to the pharmaceutical environment to the new changes that are occurring. Since the beginning of the legislative process, the European institutions kept recalling the urgency of the situation and the need to act fast in order to boost the competitiveness of the generic and biosimilar manufacturers; so they can be ready for the outcoming patent cliff. However, the Regulation does not provide immediate solutions. The recital (26) of the Regulation separates the application of the exception in three cases. First, “to safeguard the rights of certificate holders, the exception provided for in this Regulation should not apply to a certificate that has already taken effect at the date of entry into force of this Regulation (July 1st 2019)”, Second “the exception should apply to certificates that are applied for on or after the date of entry into force of this Regulation”. Third, the Regulation decides to implement a transitional period for “the certificate that was applied for before the date of entry into force of this Regulation, but has not yet taken effect before that date, irrespective of whether or not that certificate was granted before that date.” In this case, “the exception should apply from 2 July 2022 to a certificate that takes effect from the date of entry into force of this Regulation”.

The transitional period for a certificate applied for before the date of entry into force of the Regulation, but which has not taken effect before that date, was already considered in the Commission’s proposal and it has been a central point in the trilogue’s negotiations. During the one-year legislative process, the law firms had the time to warn their clients, patent owners of a pharmaceutical product, of the outcoming changes in the SPC legislation. They strongly recommended the patent holders to apply for an SPC before the Regulation passed, so they can enjoy “a reasonable period of transition to adapt to the changed legal context”154. At time of writing, there is no data available regarding the number of SPCs applications in the EU between May 2018 and July 2019, but there is a high probability that they will be higher than usual. In other words, the expectations of the European industry of generics and biosimilars would be frustrated during several years and the threat on the viability of the manufacture of generics and

154 Ibid; recital 26).
biosimilars in the EU, with consequences for the Union’s pharmaceutical industrial sector as a whole, would not be dissipated.\(^{155}\)

The reason for this delay in the application of the Regulation are explained in the recital “[...] Regulation should therefore, be amended so as to allow the making of generics and biosimilars for export and storing, while bearing in mind that intellectual property rights remain one of the cornerstones of innovation, competitiveness, and growth in the internal market.” This statement is contradicting the first part of the recital pointing out the “importance of a timely entry of the generics and biosimilars into the Union.” This late entering into force of the Regulation is due to considerable pressure from the pharmaceutical industries, backed up by some European governments. Germany and France, two countries with a high rate of research and development in the pharmaceutical area, expressed their concerns during the negotiations, regarding the impact of the new legislation on their industrial pharmaceutical competitiveness. Furthermore, Denmark clearly expressed its opposition to the manufacturing waiver\(^ {157}\) and maintained its position until the end, voting against the proposal.

The legislators made a strong point that the manufacturing waiver does not conflict with the SPC holder intellectual property rights. According to this statement, the immediate use of the SPC exception for all certificates, regardless of their applying date, would have been possible. This option had been chosen by the legislators in 2004 for the implementation of another (patent and) SPC exception, the Bolar exemption\(^ {158}\). The exemption applies for all patents and SPCs still in force, without any exception, at the day of the publication of the Directive in the Official Journal of the European Union (however, the Member States still had to implement an exemption in their national legislation, but in a quick period). If a broader and quicker implementation of the SPC manufacturing waiver would have been possible in theory, the legislators were too concerned about providing strong safeguards for the originators to push the Regulation to its maximum capacity. Some authors also argued that the Union could have

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155 Vidal-Quadras, “Analysis of the proposal for a Regulation of a manufacturing exception, related to the SPC and timed to make the European Industry competitive”, op.cit.; para.7, p.23.


157 “By allowing storing of medicinal products and affecting acquired rights of the SPC holders, Denmark believes that the result is disproportionate and goes far beyond what is necessary in order to achieve with the objective of the proposal. The absence of meaningful safeguards for storing will undermine legal certainty for the generic, biosimilar and innovative industry. It will also further deteriorate market conditions for investments in research and innovation, which are, by far, higher than any benefit that the SPC waiver proposal can generate.”

pushed its legislation even further with the manufacturing waiver for export purposes, not only in third countries but also in Europe\textsuperscript{159}. Such a manufacturing waiver inside the Union would add to the difference between the national legislations in the EU and would contradict the unitary patent in preparation.

The exact effects of the new Regulation remain uncertain, as highlighted in the different studies on the subject. The only way to analyze the consequences of the manufacturing waiver is to wait for it to be used by the makers of generics and biosimilars. In order to do so, the manufacturing waiver for export and stockpiling purposes will be analyzed every five years in order to be potentially rectified. The first evaluation of the objectives by the Commission is expected on July 2\textsuperscript{nd} 2024. The aim of the evaluation is to “review the effectiveness of the exception for makers of biosimilars and generics, as well as the impact of the exception on research and production of innovative medicines in the Union by certificate holders, and consider the balance between the different interests at stake, in particular as regards public health, public expenditure, and access to medicine within the Union\textsuperscript{160}”. Particular attention should be given to the effectiveness of the provisions surrounding stockpiling to ensure that they are working as intended. The European Institutions finally found a legislative compromise on the very complex issue, opting for a broad manufacturing waiver, for both export and stockpiling purposes, with strong safeguards for the originators. The impact of the Regulation is nowadays unknown and will depend on the use of the exception by the stakeholders, as well as the whole European legislative framework and the strength of the European market.

On an international level, the development of new sui generis intellectual property rights and their corresponding exceptions raises the question of the applicability of existing international norms\textsuperscript{161}. Moreover, the broad manufacturing waiver for both export and stockpiling could inspire other countries, or international organizations, to implement a similar exception. In the second part of this work, we would, therefore, like to address the outcoming challenges of the manufacturing waiver on the international scene.

\textsuperscript{159} X. Seuba, “The Export and Stockpiling Waivers: New Exceptions for Supplementary Protection Certificates” op. cit., p.18.


\textsuperscript{161} X. Seuba, “The Export and Stockpiling Waivers: New Exceptions for Supplementary Protection Certificates” op.cit.; p.18.
**Part II: The oncoming challenges of the manufacturing waiver on the international scene.**

The manufacturing waiver will take effect in all the EU Member states. However, its economic impact will go far beyond Europe. The makers of generics and biosimilars based in the Union would be able to export their products in third countries where the SPC protection has elapsed or never existed, thus competing with foreign manufacturers. The actual competition would start on July 2nd, 2022; date of the implementation of the exception for the certificates that have been applied for before the entry into force of the new Regulation. Until then, the foreign manufactures will keep a significant advantage as they could reach the market one step ahead. The same situation would technically happen into the internal market, where the generics and manufactures companies based in the EU are currently seeing their entry on the market delayed, thus not being able to provide generics and biosimilars on day-1. This period between the end of the SPC and the active production is favorable to the foreign manufacturers which can enter the EU market before the European businesses. From July 2nd, 2022, the makers would be able to manufacture and stockpile in order to be ready to enter the market the next day the SPC ends. Therefore, manufacturing waivers for export and stockpiling purposes are supposed to remedy to the asymmetry between the EU manufacturers and the ones in third countries with no SPC protection, or a weaker one, thus boosting the competitiveness of generic and biosimilar businesses in the Union in a few years.

From an external EU point of view, there are two situations: first, generic and biosimilar companies based in countries with no SPC (nor any patent extension), will face a competition increase, as the EU manufacturers will reach the market earlier. Second, the generics or biosimilars businesses based in countries with a patent extension (such as the US and Japan), are likely to suffer from this Regulation, as they will stand a step behind Europe in terms of entry of the generics and the biosimilars on the international market.

It is clear that the new Regulation 2019/933, amending Regulation 469/2009 concerning SPC for medicinal products, will have a worldwide repercussion. In this context, specific attention must be paid to the compliance of the Regulation 2019/933 with the WTO Agreement on

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162 Foreign manufacturers need to be understood as manufacturers based outside the EU.
TRIPS, since argument made against the manufacturing waiver relies on the alleged unconformity of this new exception vis-à-vis the TRIPS Agreement (Chapter 1).

At the same time, the creation of a pioneer legislation implementing a broad manufacturing waiver in the EU could provoked heated reactions from the others WTO Members and international organizations, which could either disapprove the Regulation, or get inspired by it and try implement the same type of provisions in the different legal framework from the European one, for example in the area of patent restoration (Chapter 2).

Chapter 1: Questioning the compliance of the new SPC exception with the TRIPS Agreement

The aim of the TRIPS Agreement is “to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.” To do so, the Agreement sets out mandatory minimum standards of protection for WTO Members. Part I of the Agreement provides the “general provisions and basic principles,” and Part II defines the “standards concerning the availability, scope, and use of intellectual property right.” In this last part, each of the main elements of protection is details, namely the subject-matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection.

First of all, the TRIPS Agreement declares in its articles 2.1 and 9.1 that the Member States must be compliant with the existing obligations of the Paris Convention for the Protection of Industrial Property (Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention) in their most recent versions. Secondly, the TRIPS Agreement, to move along with the times, adds several new requirements on matters where the pre-existing conventions are silent or were seen as being insufficient. However, the World Trade Organization recalls that “TRIPS Agreement set out the minimum standards of

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165 Except for moral rights of the author enacts in the Berne Convention.
intellectual property protection.” The Members are free to provide more extensive protection of intellectual property if they so wish (so-called, TRIPS+ standards), as long as they do not contradict the Agreement itself\textsuperscript{166}.

In the first instance, we will examine, through several legal analysis, why SPCs, and thus the manufacturing waiver, do not fall under the scope of the TRIPS Agreement (Section 1). The European Commission, and then the European legislators did not take into account the theoretical inapplicability of the TRIPS Agreement to SPC. To them, the new SPC exception fulfills the legal conditions enounced in the TRIPS Agreement. However, the consistency of the manufacturing waiver with the TRIPS Agreement’s requirements can be challenged (Section 2).

**Section 1: The inapplicability of the TRIPS Agreement to the manufacturing waiver**

In the explanatory memorandum of the proposal, the European Commission stated that “the proposal is consistent with existing international trade agreements, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) between members of the World Trade Organization as well as those free trade agreements that the EU has concluded with non-EU-countries and that include supplementary protection-like provisions\textsuperscript{167}.” However, the Commission did not justify in which ways the proposal is consistent with the TRIPS Agreement.

The lack of precision on the matter has been questioned by both the Max Planck Institute and the Regulatory Scrutiny Board. First of all, the Max Planck Institute, commissioned by the European Commission to provide an extensive analysis of the proposal, stated that ‘it can be argued that because SPC does not conform to the defining elements of patents under TRIPS, they are not subject to the specific obligations’ relative to the latter\textsuperscript{168}.” Moreover, the Regulatory Scrutiny Board Opinion on nine march 2018 also expressed concerns: “the report [the proposal] should better explain the potential impacts of the manufacturing waiver (notably of the stockpiling waiver) with regards to the EU’s trade policy and to the WTO TRIPS-

\textsuperscript{166} Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, op.cit.; article 1.


\textsuperscript{168} Max Planck Institute for Innovation and Competition, “Study on the legal aspects of Supplementary Protection Certificates in the EU. Final Report”, op.cit.; p.27.
provisions.169 Despite these requests, no clarification had been given through the legislative process.

Regulation 2019/933 does not expressly mention the TRIPS Agreement. However, an apparent reference to its article 30, containing the three-step test for new exceptions, has been made in recital (12) of the Regulation. Hence, the EU seems confident that the manufacturing waiver is an exception under the TRIPS Agreement, and could benefit from article 30. This view came from a successful case for the EU before the WTO Dispute Settlement Body against the U.S. in the U.S. Section 211 Appropriations Act case in 2002. In that case, the WTO Appellate Body endorsed the EU Commission’s position and confirmed that the list of intellectual property rights mentioned in the TRIPS Agreement is not numerus clausus. Following the same reasoning, the SPCs should fall within the realm of the TRIPS Agreement because the treaty generally applies to all types of patent rights, including those derived from “patent restoration term” instruments such as SPCs. This theory is shared by some authors.170

However, the major part of the doctrine disagrees with this view. Firstly, a literal reading of the TRIPS Agreement reveals that SPC is not contained in the intellectual property rights category (I). Secondly, the interpretation of TRIPS does not permit to include SPC, and thus SPC exception, into the scope of the Agreement (II).

I. The silence of the TRIPS Agreement on SPCs

In order to answer the question of the applicability of the TRIPS Agreement to the manufacturing waiver, we need to consider a broader issue: whether TRIPS is a treaty that sets minimum standards or, by contrast, a sort of framework Agreement that takes into account all new legal developments in the intellectual property filed.171

First, we need to recall the nature of SPC protection. SPC is a sui generis right that differs from a patent in several essential aspects. An SPC can be granted only at two conditions: the previous existence of a patent and a marketing authorization covering the drug. Thus, the aim of these two intellectual property rights considerably differs, while patent encourages research leading

169 Regulatory Scrutiny Board Opinion, “Title: impact Assessment / SPC manufacturing waiver Brussels”, op.cit.at 32; Adjustments requirements section, p.2.
to patentable inventions, the SPC reward innovations lead to a marketable product\textsuperscript{172}. Patent protection is recognized in TRIPS as an intellectual property right, but SPC protection is not. Indeed, SPC is not listed in Part II of TRIPS, which addresses the standards concerning the availability, scope, and use of intellectual property rights.

Article 2.1 of TRIPS incorporates by reference to the Paris Convention for the protection of intellectual property. The Paris Convention gives a clear and exhaustive definition of Industrial Property in its article 1(2) \textit{“The protection of industrial property has as its object patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition”}\textsuperscript{173}. The definition does not contain patent extensions or SPCs.

Thus, after a literal analysis of the TRIPS Agreement’s provisions, we can rightfully admit that the treaty does not consider SPCs or patent restoration terms as an intellectual property right but as a TRIPS extra-type of measures. “It is only by means of legal fiction and liberal reading of treaties that SPCs can be assimilated to patents.”\textsuperscript{174}

II. The unsuccessful attempt of treaty interpretation in order to include SPCs in TRIPS

The previous literal analysis of TRIPS and the Paris Convention results in an explicit exclusion of the SPC from these two treaties. However, some authors argue that the Paris Convention needs to be read in a broader manner taking into account the “spirit and objectives” of the Convention (A). Moreover, the Vienna Convention, relative to the interpretation of treaties, could be used by the WTO dispute settlement body in order to interpret the TRIPS Agreement (B).

A. “Spirit and objectives” of the Paris Convention

In their study commissioned by the European Commission, the authors of the Max Planck Institute for Innovation and Competition chose to target the interpretation of the Paris Convention in order to justify the consistency of the SPC with the TRIPS Agreement. They

\textsuperscript{172} X. Seuba, \textit{“The Export and Stockpiling Waivers: New Exceptions for Supplementary Protection Certificates”} op.cit.; p15.
\textsuperscript{173} Paris Convention for the Protection of Industrial Property of March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, and as amended on September 28, 1979.
\textsuperscript{174} X. Seuba, \textit{“The Export and Stockpiling Waivers: New Exceptions for Supplementary Protection Certificates”} op.cit.; p15.
attempt to justify that the SPC fall within the definition of intellectual property enshrined in the Paris Convention. From their perspective, the Paris Convention can be broadly interpreted, so patent extensions are contained in the broad interpretation of the term ‘patent.’ Then, the authors insist on the close similarities between patent extensions and SPCs, stating that the purpose and the structure of protection of SPCs “are the same as or clearly related to those of patent extensions in the US & Japan.” According to this view, maintaining SPCs out of the Paris Convention would “overstate the impact of the black letter as compared to the spirit and objectives.”

As explained by Prof. Xavier Seuba, “the result would be that SPCs could not be directly assimilated to the concept of the patent set forth in TRIPS, but could be included in the Paris Convention. Article 27, which contains the patentable subject matter, would be only applicable having due regard to the particularities of SPCs, while TRIPS Part I would be fully applicable.”

Nevertheless, proponents of this view recognize the weakness of this theory, acknowledging that the TRIPS provisions on patents are only partially applicable and must be reinterpreted in light of the nature of SPCs.

This view has been vividly criticized by some authors, who claim that the broad interpretation of the Paris Convention has no legislative basis and therefore is entirely unjustified. According to their views, the interpretation of treaties must follow rules of treaty interpretation known to international law, and which WTO adjudicators are charged to apply in their interpretative quests.

B. The Vienna Convention as a tool for interpretation of TRIPS

The article 3.2 of the Understanding on Rules and Procedures governing the WTO Settlement of Dispute states that the aim of the dispute settlement system is to “preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law”. The rules of interpretation of public international law are codified in article 31 to 33 of

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176 Ibid.
the Vienna Convention on the Law of Treaties\textsuperscript{179}. The latest Convention and WTO law follow
the principle \textit{in claris non fit interpretatio} : if the text is clear, interpretation is not appropriate.
“This principle fully applies in international law and matches particularly well with the
preservation of national sovereignty and the will of states, expressed in the letter of the treaties
they conclude.\textsuperscript{180}"

In the case where an interpretation of a treaty is needed, the WTO DSB will first apply the
article 31.1 of the Vienna Convention (1), and then, will have the possibility to apply the article
31.3 of the Vienna Convention (2).

1. Article 31.1 of the Vienna Convention on the Law of Treaties

Article 31.1 of the Vienna Convention states that “\textit{a treaty shall be interpreted in good faith}
in accordance with the ordinary meaning to be given to the terms of the treaty in their context
and in the light of its object and purpose.”

In an old case regarding the taxes on alcoholic beverage exported in Japan\textsuperscript{181}, the Appellate
body already stated that “\textit{Article 31 of the Vienna Convention provides that the words of the}
treaty form the foundation form the interpretative process: ‘interpretation must be based above
all upon the text of the treaty’}”. Some further decisions of the Appellate Body in the field of
intellectual property confirms this view.

In the in India – Patents case\textsuperscript{182} the Appellate Body explained that the principles of treaty
interpretation “neither require nor condone” the importation into a treaty of “words that are not
there” nor of “concepts that were not intended\textsuperscript{183}.” Two years later, in the Canada – Patent
Term case, the Appellate Body recalled that “we look first, as always, at the text of the treaty
provision.\textsuperscript{184}”

Based on the previous cases, it is clear that SPCs cannot be included into TRIPS as an
intellectual property right; an interpretation based on analogism would go against both the WTO
law and the Vienna Convention.

\textsuperscript{180} X. Seuba, “The Export and Stockpiling Waivers: New Exceptions for Supplementary Protection Certificates”
op.cit.; p.18.
\textsuperscript{182} Appellate Body Report, India – Patents (US), WT/DS50/AB/R, 19/12/1997, para. 45-46.
\textsuperscript{183} WTO Analytical Index, DSU, article 3 (jurisprudence).
2. Article 31.4 of the Vienna Convention on the Law of Treaties

Article 31.4 of the Vienna Convention states that “A special meaning shall be given to a term if it is established that the parties so intended.” Applying this rule to SPC means that the parties to the Paris Convention or to the TRIPS Agreement would have voluntarily given a special meaning to the term “patent,” a meaning which would be broader than the common understanding of “patent” in order to include SPCs. The jurisprudence of WTO made clear that the intention of the parties to give a special meaning to a term needs to be proven.

In the India–Quantitative Restrictions case, the Panel made explained that “India’s interpretation could be considered rather support a special meaning (within the meaning of Article 31.4 of the Vienna Convention…), in respect of which it has not proved that there was an agreement of the negotiators”\(^{185}\). In China – Intellectual Property Rights the Panel made clear that “the general rule of treaty interpretation in Article 31 of the Vienna Convention refers in paragraph 1 to the ordinary meaning of the terms of the treaty, read in context. (…) This is a distinct exercise from that in paragraph 31.4 of the Vienna Convention which requires a ‘special meaning’ to be given to a term if it is established that the parties so intended”\(^{186}\).

In conclusion, the TRIPS Agreement and the Vienna Convention did not mention nor even evoke patent extensions or SPCs. Moreover, these two systems of protection for pharmaceutical products do not exist in most legal orders of WTO Members. The Panel Report in the Canada-Pharmaceutical case made clear that the extension of exclusivity is a normative policy issue that needs to be resolved on the political scene, and that interpretation of TRIPS should not be used to decide on that matter\(^{187}\).

The Member States, keeping in mind their international obligations, are free to create new intellectual property categories, and exceptions to these categories, but they cannot do so within the scope of the TRIPS Agreement. However, Regulation 2019/933 enacting a manufacturing waiver refers to the TRIPS Agreement. The reliance of the Regulation on TRIPS is unnecessary and a matter of legislative choice. The European reference to TRIPS does not constrain other countries when developing their own regimes of exclusivities concerning rights not mentioned nor included in TRIPS by reference. In theory, SPCs Regulations do not belong to the scope of


the TRIPS Agreement. In practice, no case has ever been launched against the EU to challenge SPCs Regulations as such.

However, the new SPC exception is likely to be questioned by WTO Members. Some authors already expressed concerns about the consistency of the manufacturing waiver with TRIPS’ requirements regarding the implementation of a new intellectual property exception.

**Section 2: The doubtful consistency of the manufacturing waiver with the TRIPS Agreement’s requirements**

As previously studied, the EU implicitly considers the manufacturing waiver for export and for stockpiling purposes as an exception to intellectual property right as stated in the TRIPS Agreement. Consequently, the EU needs to prove the consistency of the manufacturing waiver with the requirements enacted in the treaty. There are two significant issues that are now discussed on the academic scene: whether SPCs Regulations as such respect article 27.1 of the TRIPS Agreement relative to the prohibition of discrimination based on the field of technology (I), and whether the manufacturing waiver passes the triple-test enacted in article 30 of the TRIPS Agreement (II). These questions could also be raised by a WTO member state before the WTO DSB, in order to challenge the new 2019/933 Regulation.

**I. Examination of the consistency of the manufacturing waiver with article 27.1 of the TRIPS Agreement**

Article 27.1 of the TRIPS Agreement states, among other things, that “*patents shall be available and patent rights enjoyable without discrimination as to the field of technology.*” Applying this article literally to the manufacturing waiver would lead to the conclusion that because “the (manufacturing waiver) exception applies exclusively to pharmaceutical patents, any domestic measures seeking to implement such an exception is likely to contravened article 21.7 of the TRIPS Agreement”. Following this view, WTO Members could not differentiate between patentable products; therefore, they cannot implement legislation, primarily targeting a ‘special category’ of patents. However, both SPC Regulations respectively target medicinal products and plant products. This view would open the gates for WTO Members to challenge both Regulations on SPCs, based on the violation of the non-discrimination obligation as to the field of technology. However, there is not much chance that this situation ever happens. The SPC Regulation for medicinal products exists since 1992, and its compliance with the TRIPS

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188 E. Solovy, D. Raju, op. cit., p. 69.
Agreement has never been contested. Challenging this SPC Regulation as such, in order to withdraw the new exception, seems to be a risky strategy.

Moreover, other countries have implemented targeted legislations in the field of pharmaceutical. For example, the Bolar exemption is nowadays recognized worldwide (in the USA, the EU, Australia, and several Asian countries).

The Doha Declaration on TRIPS Agreement and Public Health\(^\text{189}\) was adopted in 2001 to clarify ambiguities between the need for governments to apply the principles of public health and the terms of the Agreement on TRIPS\(^\text{190}\). The Doha Declaration allows some flexibility to the interpretation of the TRIPS Agreement, notably the article 27.1: “the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all\(^\text{191}\).” The TRIPS Agreement officially recognized the importance of the pharmaceutical industry in the area of public health.

In the continuity of the Doha Declaration, amendments have been made to the TRIPS Agreement in order to safeguard public health, notably the article 31, which sets forth several conditions for the granting of compulsory licenses. Compulsory licensing allows a competent government authority to license the use of a patented invention to a third party or government agency without the consent of the patent-holder\(^\text{192}\).

At first, the TRIPS Agreement set a clear standard of non-discrimination on the field of technology in its article 27.1. Nevertheless, this rule may be alleviated in the pharmaceutical area, regarding the particularity of the medicinal products and their intended impact on public health. The aim of the manufacturing waiver, especially for stockpiling purposes, is to provide better access to affordable medicines for European patients. Consequently, this exception fulfills the goal to “promote access to medicine for all” enacted in the Doha Declaration and should not be considered contrary to the TRIPS Agreement based on Article 27.1.

The real challenge of the manufacturing waiver regarding its consistency with the TRIPS Agreement is elsewhere. Indeed, the Regulation 2019/933 made an apparent reference to the

\(^{189}\) World Trade Organization, Ministerial Declaration [Doha Declaration], Nov. 14, 2001, WT/MIN(01)/DEC/1; 41 I.L.M. 746(2002).


\(^{191}\) Ibid.

\(^{192}\) Ibid.
three-step test, as stated in article 30 of TRIPS, without mentioning the Treaty itself. However, is the manufacturing waiver a valid exception under article 30 of the TRIPS Agreement?

II. Examination of the consistency of the manufacturing waiver with article 30 of the TRIPS Agreement

The manufacturing waiver is intentionally addressed to comply with the conditions of Article 30 of TRIPS titled ‘exceptions to rights conferred [by a patent],’ although it is not applicable to SPCs. Indeed, the recital 12 of the Regulation 2019/933 echoes the three step-test as it is stated in Article 30: “By limiting the scope of the exception to making for 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 of 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.”

Firstly, we will examine what the rights conferred to a patent holder under the TRIPS Agreement are and why the manufacturing for export and for stockpiling is considered to be infringing activities (A). In the second part, we will analyze if these two activities pass the three-step test conditions enacted in Article 30 and can be recognized as exceptions to a patent right under the TRIPS Agreement (B).

A. Infringement to the right conferred under Article 28 of the TRIPS Agreement

Before analyzing the compliance of the Regulation 2019/933 to Article 30 of the TRIPS Agreement, it is useful to recall why manufacturing for export and stockpiling are considered infringing activities.

Article 28 of the TRIPS Agreement193 do not mention exportation, manufacturing for exportation, nor manufacturing for stockpiling, among the activities that the right holder can

193 Agreement on Trade-Related Aspects of Intellectual Property Rights, article 28.

“1. A patent shall confer on its owner the following exclusive rights:
(a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
(b) where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
impede. However, these activities are de facto linked to some acts that fall within the exclusive right of the patent holder. Indeed, the manufacturing waiver for export and the manufacturing waiver for stockpiling purposes are dependent on other activities that need to be undertaken to implement them: manufacture, offer for sale and sale. Consequently, the two waivers are considered infringing activities. Some authors considered this explanation as a legal shortcut as “it does not take consideration of the final destiny of the products or the principle of connectivity among the act of exploitation of the patent. It does not consider either that the right holder power to exclude could eventually not impact activities that result in profit abroad”\textsuperscript{194}. These justifications have been rejected, and it has become obvious to consider that the manufacturing for export and for stockpiling are prohibited under TRIPS. In these circumstances, an exception should be recognized under Article 30 of TRIPS.

B. The three-step test conditions under Article 30 of TRIPS

The first version of the three-step test appeared at the Stockholm Conference for the Revision of the Berne Convention in 1967\textsuperscript{195}. Five years later, the three-step test was enacted in article 9(2) of the Berne Convention for the Protection of Literary and Artistic Works: “\textit{It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author}”. This article 9(2) serves as a model for three other exceptions clauses in the TRIPS Agreement. Article 13, 17, 26.2 and 30 providing respectively for similar exceptions from obligations on copyright, trademarks, industrial designs and patents\textsuperscript{196}.

Article 30 is slightly different from Article 9(2) of the Berne Convention. Article 30 of the TRIPS states that “\textit{Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal}

exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”

Article 30 is a flexible test since it does not limit exceptions to a particular circumstance or range of situations. Only three conditions must be met in order to qualify for an exception under Article 30: (1) the exception must be ‘limited’, (2) the exception must not ‘unreasonably conflict with a normal exploitation of the patent’; (3) the exception must not ‘unreasonably prejudice the legitimate interests of the patent owner, taking into account of the legitimate interests of third parties’.

In Canada-Pharmaceutical Patents, the Panel found that these conditions apply cumulatively “the three conditions are cumulative, each being a separate and independent requirement that must be satisfied. Failure to comply with any one of the three conditions results in Article 30 exception being disallowed. The three conditions must, of course, be interpreted in relation to each other.” However, this view is opposed in the 2014 Declaration on Patent Protection issued by the Max Planck Institute for Innovation and Competition, where the authors state that the three conditions found in Article 30 are not cumulative.

“The exact scope of Article 30 will depend on the meaning given to its limiting conditions.” The meaning of those conditions had been examined during a dispute in WTO in the Canada-Pharmaceutical Patents case, where two exceptions - the regulatory review exception and the stockpiling exception- were the object of the analysis. The views of the panel report, in this case, clarified the understanding of TRIPS Article 30; however, leaving some shadow zones, subject to interpretation by the doctrine.

The convergence between TRIPS Article 30 and the manufacturing waiver for export and for stockpiling can be analyzed in two different ways. First, the originators and some authors categorically refute the consistency of the two exceptions with Article 30. Second, a large part of the doctrine argues that the exceptions are compatible with the criteria outlined in TRIPS Article 30 as interpreted in the Canada Pharmaceutical Products panel report. Some authors

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201 Notably in the 2014 Declaration on Patent Protection.
go further in the interpretation of the conditions, mostly following the views enacted in the 2014 Declaration on Patent Protection.

1. The ‘limited exception’ requirement

“Each version of the three-step test includes, as the first step, a component that seeks to ensure that an exception or limitation has a restriction on the scope of its operation.” Regarding the patent area, the Canada-Pharmaceutical Patents panel affirms that the term-limited exception must be strictly interpreted. The limited character of an exception is to be assessed with respect to their impact on the rights of the patent owner, involving just a small reduction of its rights.

Finally, the “limited condition” is not related to economic concerns but only to its impact on the patent holder rights.

Regarding the examination of the consistency of the stockpiling exception to the ‘limited’ exception condition, the Panel found that it could not be considered limited because of the absence of any limitation with respect to the quantity that could be produced under the exception. This lack of quantity limitation could entirely suppress the right holder’s rights to impede manufacture and use. Therefore, the inconsistency of the stockpiling provision with TRIPS Agreement Article 28.1 cannot be justified. However, the panel did not, hold that the stockpiling waiver was per se inconsistent with TRIPS. It means that a stockpiling exception accompanied by limitations, for example, authorized quantities, or in relation to a targeted market, would have complied with the conditions set forth in TRIPS Article 30. “The Panel considered it unnecessary to examine the stockpiling provision under the second and third criteria of Article 30, given that it had already found that the provision fails to meet the first criterion.” It is important to recall that this WTO decision has not been appealed.

Based on this precedent case, some authors attempt to provide arguments against and in favor of the consistency of the manufacturing waiver for stockpiling and for export as enacted in the Regulation 2019/933 with Article 30 of the TRIPS Agreement. We will first consider the first requirement of a ‘limited exception.’

Regarding the stockpiling waiver, the number of manufactured products will necessarily be limited because the making of generics and biosimilars can only start six months before the

203 Panel Report, Canada-Pharmaceutical Patents, paras. 7.30.
204 Panel Report, Canada-Pharmaceutical Patents, paras. 7.54-7.55
205 Panel Report, Canada-Pharmaceutical Patents, paras. 7.36, 7.38
expiry of the SPC\textsuperscript{206} (same period under the Canadian law in the Canada-Pharmaceutical Patent case). However, even if the exception for manufacture would be limited by the manufacturing capacity of the generic and biosimilar producers, some authors argue that Article 30 requires the exception to be limited by the measure of creating it, not by market conditions\textsuperscript{207}.

The consistency of the export waiver with Article 30 has never been examined by the WTO Panel, and are currently the subject of vivid debates on the academic scene. Based on the criteria set up in Canada-Pharmaceutical Products, we can admit that the limitation of the right to impede the manufacture for export would be consistent with the principles of Article 30 if it had, at least, limitations as to the volume of productions and markets. The main difference between the stockpiling waiver and the export waiver is that the first one would have to wait for the expiry of the SPC to sell the products, whereas the second could sell the products in third countries during the entire SPC term in the EU.

Nevertheless, there are some justifications to the consistency of the export waiver to Article 30. First of all, the exception for manufacture for export is, by definition, limited in terms of quantity, since it does not allow unlimited production of the patented product but only the productions for market off patents. Second, the exception for manufacture for export does not impact on the right-holder in a general fashion, because he can fully exercise its right during the duration of the SPC on the protected market\textsuperscript{208}.

Moreover, following the 2014 Declaration in Patent Protection statement, an exception is limited if its scope is proportionate to its objective and purpose. To them, Article 30 allows, in fact, limiting the full application of patent rights in light of the specific circumstances and other purposes relating to social and economic welfare\textsuperscript{209}. Applying this view to the export waiver will strengthen the legitimacy of the exception in term of improving the ‘legitimate trade\textsuperscript{210}’ and public health\textsuperscript{211}.

However, some authors strongly opposed this view, considering this contemporary interpretation “a mirror of certain authors views on what the interpretation of the TRIPS

\textsuperscript{206} X. Seuba, “The Export and Stockpiling Waivers: New Exceptions for Supplementary Protection Certificates” op.cit., p.15.
\textsuperscript{207} E. Solavy, D. Raju, “A manufacturing-for-export exception to patent protection: a proposal for exporting violations of the TRIPS Agreement and Beyond.”, op.cit. p.9.
\textsuperscript{209} Declaration on Patent Protection, para. 23., p. 8.
\textsuperscript{210} Agreement on Trade-Related Aspects of Intellectual Property Rights, Preamble.
\textsuperscript{211} Ibid, article 8 “principles”.

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Agreement should be.\textsuperscript{212} The opponents of a broader interpretation to the Article 30 conditions claim that there is nothing in the ordinary meaning of the word ‘limited’ itself that requires questioning whether the scope of the exception an exception is ‘proportionate to its object and purpose.’ To them, such a view will conduct a direct violation of a patent holder’s rights to exclude unauthorized manufacturing.

Moreover, they claim that only an amendment of the TRIPS Agreement could permit a real recognition of the compliance of the manufacturing waiver with the conditions enacted in the treaty\textsuperscript{213}. For example, WTO Members considered that an amendment was necessary to permit the manufacture of drugs for export to lease developed countries pursuant to a compulsory license\textsuperscript{214}. We disagree with this narrow interpretation, because the Panel effectively recognized the Bolar-type provisions as being TRIPS compliant, provided certain conditions are met, opening the door to the interpretation of other exceptions vis-à-vis TRIPS.

2. The exception cannot unreasonably conflict with a normal exploitation of the patent

The panel explained the meaning of the term “normal exploitation” contained in the second condition under Article 30. First, the panel considered that the term exploitation refers to “the commercial activity by which patent owners employ their exclusive patent right to extract economic value from their patent.”\textsuperscript{215} Then, the panel interpreted the term ‘normal’ as a “normative standard of entitlement,” but that does not mean that it simply refers to Article 28 exclusionary rights as such, it also takes into account “the achievement of the goals of patent policy.”\textsuperscript{216} According to the panel, “normal practice” refers to the exclusion of “all forms of competition that could detract significantly from the economic returns anticipated from a patent’s grant of market exclusivity.”\textsuperscript{217} After defining the meaning of ‘normal practice,’ the panel considered whether the market exclusivity following the expiry of the patent term could be considered part of the normal exploitation. The panel admits that some basic rights granted to all patentees may give place to a period of market exclusivity following the expiration of the patent, for example, in the case of prohibition to manufacture a stockpile before the end of the patent term.

\textsuperscript{212} E. Solavy, D. Raju, “A manufacturing-for-export exception to patent protection: a proposal for exporting violations of the TRIPS Agreement and Beyond.”, op.cit., p.6.
\textsuperscript{213} Ibid. p.9.
\textsuperscript{214} Agreement on Trade-Related Aspects of Intellectual Property Rights, article 31b.
\textsuperscript{215} Panel Report, Canada-Pharmaceutical Patents, paras. 7.49.
\textsuperscript{216} Panel Report, Canada-Pharmaceutical Patents, paras. 7.58.
\textsuperscript{217} Panel Report, Canada-Pharmaceutical Patents, paras. 7.55.
In order to justify the consistency of the manufacturing waiver with the normal exploitation of the patent, some authors recall the statement of the Panel “a differentiation should be made between the de facto exclusivity arising from the normal exclusionary acts during the patent term, and the exclusivity arising from regulatory procedures.” An SPC does not confer normal exploitation of the patent, because it is not an extension to patent right but a sui generis legislation related to the marketing authorization procedure. Thus, an exception can be submitted in the same context as the Bolar provision.

Moreover, regarding the manufacturing for export purposes, ‘the exclusive opportunity to manufacturing in patented territories, for the purpose of exportation to off-patent territories, is not part of the normal enjoyment of a patent or of the legitime interests of the patent owner.” Indeed, these types of exports would not deprive the patent holder of the expected economic benefits deriving from market exclusivity in countries where its patent is still in force. According to Solovy and Raju, this view disregards the reality of modern businesses. The patent owner also has the opportunity to be the exclusive exporter of the patented product from the domestic market to all other markets. This exclusivity situation for the right holder impacts the economic value of the patent and serves as a basis for investment decisions. Thus, the proposed exception would conflict with the normal exploitation of the patent. “The patent owner does have a legitimate interest in being the sole manufacturer, and sole exporter from markets covered by the patent.”

In the pharmaceutical area, where public health interests are at stake, this situation preventing the entry of generic and biosimilar products on day-1 on the internal market or for export purposes, goes clearly beyond the reasonable use of a patent and ‘diminishes in an unjustified manner the incentives for innovation provided by the market.”

3. The exception cannot unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties

In the Canada-Pharmaceutical case, the panel first distinguished between ‘legitimate interests’ and ‘legal interests.’ The former has a broader meaning and should be understood as a

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218 E. Solavy, D. Raju, “A manufacturing-for-export exception to patent protection: a proposal for exporting violations of the TRIPS Agreement and Beyond…”, op.cit., p.10.
220 E. Solavy, D. Raju, “A manufacturing-for-export exception to patent protection: a proposal for exporting violations of the TRIPS Agreement and Beyond…”, op.cit., p.10.
normative claim calling for the protection of interests that are “‘justifiable’ in the sense that they are supported by relevant policies or other social norms.”

Because the panel had stopped its analysis on the first condition during the Canada-Pharmaceutical case, the scope and the meaning of “unreasonably prejudice” has not been yet defined by a WTO panel.

However, the panel defines ‘third parties’. They are “parties who have no legal right at all in being able to perform the tasks excluded by Article 28 patent rights.” Third parties include those who have an interest in relation to the availability, consumption, cost, or production of products subject to patent protection. The Declaration on Patent Protection gives a broader interpretation to “third parties,” including, among other things, “competitors, academic researchers, consumers and the public at large.”

However, it remains uncertain how to set the balance between the legitimate interests of the patentee and the legitimate interests of third parties. The Declaration on Patent Protection submitted the idea to implement the principle of proportionally. Some authors evoke the possibility to pay equitable compensation for the right-holder in order to rebalance the situation.

With these precisions on the meaning of the last condition of the three-step test, we can now examine if the fulfillment of this condition with the manufacturing waiver for export and for stockpiling.

First of all, the Recital 12 of the Regulation 2019/933 states that the “exception should not unreasonably prejudice the legitimate interests of the certificate holder, whilst taking account of the legitimate interests of third parties.” Indeed, the manufacturing waiver is “proportional, effective and appropriate, in particular when considering the economic and social interests’ protection in terms of investments, employment, research, and public health.” Moreover, the protection of public health is an obligation for WTO Members under Article 8 of TRIPS.

222 Canada Pharmaceutical Products 7.69, 7.74, 7.75.
223 Canada Pharmaceutical Products 7.69.
224 E. Solavy, D. Raju, “A manufacturing-for-export exception to patent protection: a proposal for exporting violations of the TRIPS Agreement and Beyond...”, op.cit.
225 Declaration on Patent Protection, para 25, p.8

In the same way, Dr. Miguel Vidal-Quadras states that the legitimate interests of the patent owner will not be unreasonably prejudiced. On the contrary, the legitimate interests of third parties, the competitors and the consumers, are appropriately protected through an exception that provides certainty to the pharmaceutical industry producing in the EU.229

Opposing this view, some authors alert against the result of the manufacturing waiver: the redistribution of income from patent holders to infringers, all of which are manufacturing in the country with the patent protection230. To them, the mere fact that third parties may be interested in deriving profits from exporting the patented products does not confer on them a ‘legitimate interest’ that the TRIPS Agreement will protect. However, these authors did not consider the legitimate interest of all third parties, neglecting the interests of patients to have easier access to generic and biosimilar products for patients, and the interests of the governments to reduce medicinal expenditures.

As we previously studied, there are two conflicting views regarding the fulfillment of the new SPC exception to Article 30 in TRIPS. The authors who often refuse to consider the manufacturing waiver as an exception under TRIPS proceed to a strictly literal reading of the treaty and tend to unnoticed the flexibility allowed by the treaty in order to meet public policy objectives. However, some significant changes have been made in this sense. For example, the recognition of the Bolar exemption as TRIPS compliant is a huge step forward to allow the expanding of exceptions in order to respond to new situations. In the case of the manufacturing waiver, public health interests must not be neglected. It is true that the panel in the Canada-Pharmaceutical Patent case, did not allow the manufacture and stockpiling of patented medicines, but only because of a lack of limitations accompanying the exception. Moreover, at the time, the decision had not been appealed by Canada.

Even if it is impossible to predict the decision of a new WTO panel in case of a challenge of the Regulation by a WTO Member, we can state that it is conceivable to interpret TRIPS Article 30 in a more liberal way, different from the analysis of each requirement performed in Canada-Pharmaceutical Patent.231 From this broader perspective, there is no doubt regarding the conformity of the new exception with TRIPS Article 30.

229 M. Vidal-Quadras, “Analysis of the proposal for a Regulation of a manufacturing exception, related to the SPC and timed to make the European Industry competitive”, op.cit., p.18.
230 E. Solavy, D. Raju, “A manufacturing-for-export exception to patent protection: a proposal for exporting violations of the TRIPS Agreement and Beyond...”, op.cit. p.12.
Chapter 2: Towards a future implementation of the manufacturing waiver in other legal systems?

Regulation 2019/933 is pioneer legislation in the area of SPCs and patent extensions. Never before such a broad exception, including a manufacturing waiver for export and for stockpiling purpose, had been implemented in this field. This approach marks a turning point in the balance between originators and generic and biosimilar manufacturers in the EU. The EU has traditionally promoted innovation through the implementation of a strong intellectual property framework, and has been vocal about other countries abiding by international standards, and seeks to export the SPC regime via trade agreements. In this context, even if the manufacturing waiver is considered by the WTO dispute settlement body to be compliant with the TRIPS Agreement (as we previously saw, should there be a challenge), it is not clear how the new Regulation respects the EU’s international free trade agreements (FTAs).

First, we will examine on what grounds some economic partners of the EU could challenge the compatibility of the manufacturing waiver with the FTAs. Another situation would be that the economic partners of the EU see the potential of this exception for their own economy and wish to include it in FTAs. (Section 1). Second, we will analyze how other non-EU-countries could be inspired by this legislation by seeking to emulate the exception in the area of patent restoration (Section 2).

Section 1: Between repression and inspiration of the manufacturing waiver through FTAs

The main goal of the manufacturing waiver is to strengthen the competitiveness of the EU generic and biosimilar industries. In other words, the EU intends to gain market shares in this particular field, so technically, other countries would lose some of theirs. Foreign countries where the patent extension has elapsed or never existed will have to face importation in their territories of generics and biosimilars coming from the EU. To prevent this situation, some countries could challenge the consistency of the legislation with the FTA signed with the EU (I). Others could see the benefit of such a waiver and amend the FTA to include it. This could be the case of Canada regarding the Comprehensive Economic and Trade Agreement -CETA-(II).

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I. Analysis of the consistency of the manufacturing waiver with FTAs

In addition to the TRIPS Agreement, several bilateral, regional treaties on trade and investment contain a provision for the protection of intellectual property. It is the case of the FTAs negotiated between the EU and its economic partners including Colombia - Peru, Korea and Japan which all provide patent extension provisions. However, there is no trace of a manufacturing waiver in these treaties; not even in the very recent EU-Mercosur FTA and the new EU-Vietnam FTA, respectively signed on June 28th, 2019 and June 30th, 2019, almost to the day of the entry into force of the Regulation 2019/933.

By contrast, during the FTAs negotiations, the EU advocates implementing a strong patent extension (SPC or patent restoration) landscape in order to foster pharmaceutical innovation. The creation of a broad SPC manufacturing exception for export and for stockpiling purposes brings some flexibility in the patent extension framework, thus produces a radical change of direction in the EU policy. This situation could send some mixed signals to the EU trading partners, who are very likely to raise a concern about the compatibility of the new exception with the FTA. Indeed, “the introduction of a manufacturing waiver, therefore, seems incompatible with the FTAs, as it is in contradiction with the spirit of the patent extension provisions, which aim to increase the innovative incentives of originators.” A patent owner or a country representing a patent owner could potentially invoke multiple legal instruments to challenge the manufacturing waiver and could bring the action against the EU respective FTA’s Dispute Settlement clause. In this case, the EU would have to demonstrate that such an exception falls within the scope of the relevant treaty exceptions. If the arguments are not persuasive, the EU could be obliged to offer compensation to the complaining party, and if the remedy was inadequate, the complaining party could decide to unilaterally suspend its FTA obligations.

In its study on the manufacturing waiver, the European Federation of Pharmaceutical Industries and Associations (EFPIA) gives a list of countries that are the most likely to oppose the new

234 EU- Peru and Columbia Free Trade Agreement, entered into force in Peru since March 1st 2013 and in Columbia since August 1st 2013.
235 EU-Korea Free Trade Agreement signed on October 15th 2009 and entered into force since December 13th 2015.
236 EU-Japan Free Trade Agreement, signed on July 17th 2018, entered into force on February 1st 2019.
237 EU-Mercosur Free Trade Agreement, signed on June 28th 2019, not yet entered into force.
238 EU-Vietnam Free Trade Agreement, signed on June 30th 2019, will not entered into force before 2020.
exception, either due to their strong intellectual property framework (Japan), or due to the detrimental impact the waiver will have on them (Vietnam).

According to Eurostat, Japan was seventh top trading partners on the of the EU in 2018. Regarding their respective intellectual property standard, both the EU and Japan provides a twenty years patent protection from the filing date. Moreover, article 35 of the EU-Japan FTA binds the parties to provide an extension to patent protection, with a maximum of five years, to compensate for delays in the marketing approval process. In the Impact Assessment of this FTA, EU business organizations called “for a specific EU-Japan agreement which should cover identical protection for intellectual property right-owners in both markets,” including patent protection. The new exception would provoke an asymmetry between the two patent systems and could be seen by Japan as a violation of the conditions agreed in the FTA.

Vietnam is nowadays the 16th largest trading partner of the EU and the second trading partner in the Association of Southeast Asian Nations (ASEAN). Vietnam provided twenty years of patent protection since the filing date. Driven by the EU, the EU-Vietnam FTA obliges Vietnam to introduce an extension of patent protection, up to a limit of two years, to compensate for ‘unreasonable delay” in the granting of the first marketing authorization of pharmaceutical products, if the approval process takes more than two years. Vietnam is known for its important marketing approval delays in the pharmaceutical industry and will have to adjust its patent term to make up for such a delay. While Vietnam has a maximum of two-years patent extension, the EU offers five years. This difference of three years regarding the patent extension protection could be a concern for Vietnam regarding the manufacturing for export. Indeed, “an EU based manufacturer can sell its medicinal products into Vietnam, whereas Vietnam-based manufacturers will be hindered from selling their products into the EU, as the EU SPC will still protect those products for another three years.”

This situation results in the unintended implementation from the EU of non-tariff barriers to trade with Vietnam. Nowadays, Vietnam is mostly dependent on imported medicines (between 60% and 80% of the consumed medicines are imported), and the domestic pharmaceutical production consists of mostly generic drugs

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241 Impact Assessment EU-Japan FTA, question 11
242 Eurostat, loc.cit.
produced for domestic consumption and outsourcing for foreign enterprises. However, Vietnam intends to develop its pharmaceutical market, which is supposed to grow from 3.5 Md USD to 6.6 Md USD in 2020. Consequently, the manufacturing waiver could become a real issue for the future exports of medicinal products to the EU, so Vietnam is very likely to challenge the compatibility of the exception with the EU-Vietnam FTA.

There is no doubt that the introduction of a manufacturing waiver (mainly for export) will have an impact on the economic partners of the EU. The recent FTAs concluded by the EU with its counterparts illustrate the will of the Union to promote patent extension. However, patent extension provision could become a legal mean to challenge the manufacturing waiver. Regarding this threat, we can wonder if the EU will continue to promote patent extension provisions in FTAs in the future.

Another means for the economic partners of the EU to bring claims against the manufacturing waiver would be invoked EU’s obligations under several bilateral or plurilateral agreements on protection on investments. These agreements do not set specific substantial standards on intellectual property, but they protect the rights of investors who use intellectual property as a mode of investment. In this context, a case could be raised against the EU that the implementation of a manufacturing waiver is a way to expropriate the SPC holder from its intellectual property right, which qualifies as investments.

To conclude, the European Institutions did not examine in detail the impact of manufacturing waiver on their trade partners, merely stating that the exception is consistent with FTAs and without taking the investments agreements into account.

As previously studied, there is a strong probability that some economic partners of the Union will challenge the manufacturing waiver. In this case, the EU could answer this issue by engaging diplomatic negotiations in order to find a compromise. Another option would be to...

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246 Ibid.
try to convince its trading partners to amend the FTA to include a broad manufacturing waiver for both parties. This last possibility could happen in relation to the CETA because it already provides a favorable framework for a future amendment.

**II. The particular case of the CETA**

The CETA, signed on October 30th, 2016 and approved by the European Parliament on February 15th, 2017, is an FTA reached between Canada, the EU, and its members. The EU is Canada’s second most important trading partner after the United States, accounting for 9.6% of its trade in goods (exports plus imports) with the world in 2016. This Agreement aims to abolish customs duties on 98% of all the types of products that the EU trades with Canada, including chemicals and pharmaceutical products, which represent 16.7% of EU exports and 7.5% of its imports.

In order to offer companies in both the EU and Canada new opportunities for transatlantic trade and investment; the EU and the Canada had to align their intellectual property rights systems, notably in the pharmaceutical field. The EU implemented a sui generis protection of patents related to medicine in 1992. Canada was the only G7 country that did not offer additional patent life to compensate for time spent in clinical trials and obtaining marketing authorization.

Article 20.27 of CETA rectified the situation by establishing the obligation to grant a specific ‘sui generis protection for pharmaceuticals’ for both contracting parties. Article 20.27 clarified the duration of the sui generis protection, which “may not exceed a period of two to five years, to be established by each Party.” Moreover, the parties agreed on the possibility to provide “exceptions for the making, using, offering for sale, selling or importing of products for the purpose of export during the period of protection.” The CETA is the first FTA implementing a manufacturing waiver for export.

At the time of the negotiations, Canada accepted to introduce SPC protection in the CETA at the condition that it also provides some flexibility. To do so, Canada succeeded to convince the EU to include a manufacturing waiver for export into the Agreement. Back then, some authors

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250 European Commission, Guide to the Comprehensive Economic and Trade Agreement (CETA), 2017, p.5
251 Ibid.
253 CETA, article 20.27. para 6.
254 Ibid, para 9.
had raised concerns about the consistency of the exception with systems in other jurisdictions and the lack of safeguards regarding its implementation (in particular the notification requirements). Despite these arguments, the Canadian government decided to implement the SPC and the manufacturing waiver for export on September 21st, 2017. Canada’s Patent Act introduced an SPC regime of two years under sections 115 to 117. The manufacturing waiver for export can be found under section 115(2).

At the time of writing, the CETA is the only FTA which make reference to the manufacturing waiver for export and recognize the legitimacy of the regulatory exception. Thus, the EU manufacturing for export exception during the sui generis term will not violate the CETA. Nonetheless, the Canadian manufacturing waiver has a narrower scope than the manufacturing waiver in the EU because it does not include a manufacturing waiver for stockpiling purposes. The absence of the latest can be explained by the dispute between the EU (at the time European Community), and Canada. As we previously saw, back in the 1990s, a stockpiling provision sought to be introduced in Canada’s Patent Act was challenged at the WTO by the EU, which has now passed similar provisions. What will be the reaction of Canada to the political shift of the EU? One option would be to oppose the Regulation. Another choice would be to take advantage of the situation and to decide to amend the CETA, in order to include a provision about the manufacturing export for stockpiling as wishing by Canada twenty years ago. However, an amendment could be politically complicated because all the EU Member States will have to sign again, only to implement a “small” exception in a vast treaty.

The European Commission states that “CETA is likely to have a precedent effect in future FTA negotiations. Third countries who agreed to introduce, or increase SPC protection might as well, at the same time, ask for a manufacturing waiver.” As we previously saw, some recent FTAs have been signed between the EU and its economic partners containing SPC or


256 “Despite subsection (1), it is not an infringement of the certificate of supplementary protection for any person to make, construct, use or sell the medicinal ingredient or combination of medicinal ingredients for the purpose of export from Canada.”


258 Canada Pharmaceutical- Patents.

SPC-like provisions; however, these agreements did not introduce a manufacturing waiver for export, nor a manufacturing waiver for stockpiling.

It is also interesting to note that in most of the FTAs conclude with the US, “the regulatory exception includes language expanding its scope to “exportation of such product” when the respective party so permits and for the sole purpose of meeting marketing approval requirements.” In other words, the United-States, first trading partner of the EU, does not recognize manufacturing waiver for export, neither for stockpiling. However, the US is currently facing the same problems as the EU regarding the competitiveness of its generic industry and could see the benefits of a manufacturing waiver.

Section 2: Examination of a potential implementation of the manufacturing waiver in the patent extension system

In 2013, the negotiations were launched between the EU and the US regarding the creation of trade agreement, commonly called the Transatlantic Trade and Investment Partnership (TTIP). The TTIP aims to remove a large number of tariff and regulatory barriers between these two markets by extending the regulation to areas not covered by WTO. Moreover, the agreement reveals a strong ambition to strengthen ties between the EU and the US and to maintain global influence against competing powers, including emerging economies, notably in the pharmaceutical field (I). In 2016, the negotiations stopped without conclusion due to parliamentary and public opposition across the EU. However, according to a US-EU joint statement published on July 2018, the two parties launched “a new phase in the relationship between the United States and the European Union.” The continuity of the trade negotiations (even if the EU claims that ‘the process is new and unrelated to the TTIP’) would be an occasion for the EU to try to persuade the US to implement a broad manufacturing waiver in the agreement, thus, in their patent extension system. (II).

I. The TTIP, as a tool to maintain a global influence in the pharmaceutical area.

The pharmaceutical sector occupied a central place in the previous TTIP negotiations between the EU and the US. It is understandable knowing that nine out of ten of worldwide top pharmaceutical originator companies are located in the US or EU, representing 75% of global

260 Ibid. p172-173. See examples of US trade agreements with Australia (art. 17.9.6); Chile (art. 17.9.4), Colombia and Peru (art. 16.8.5).
research and development in life sciences, and more than 80% of global sales. The TTIP aim, among other things, was to provide a new global standard for strict intellectual property in the EU and the US. Consequently, providing a suitable framework for the development of generics and biosimilars was not the primary concern of the TTIP, far from it.

However, as soon as the TTIP negotiations started in 2013, one position paper has been written by the European Generic medicines Association (EGA), regarding the potential content of the Agreement on generic medicines. The EGA strongly supported the Agreement between the EU and the US and made some recommendations. Among other suggestions, EGA stated that the parties should consider implementing in the TTIP “a regulatory framework allowing advanced manufacturing, i.e., manufacture of generic and biosimilar medicines during the Supplementary Protection Certificate-SPC/patent term extension period.” This manufacturing waiver will apply in two conditions. First “to export to countries where an SPC or the patent term extension right is not in place, has expired, lapsed or ceased to exist in any other way,” second “to allow products manufactured in the EU to be launched in the EU territory immediately upon SPC expiry.”

According to EGA, such a measure would help the generic and biosimilar medicines industries to maintain their manufacturing facilities in the EU and in the US, and would allow them to maintain competitiveness vis-à-vis generic and biosimilar companies manufacturing in third countries markets where SPC or patent term extension does not exist (notably India, and South Korea).

To our knowledge, this option had not been discussed in the different TTIP negotiations rounds. First of all, the parties focused on matters of cooperation (for example regulatory cooperation and exchange of regulatory information between the parties), rather than implementing a new exception, at the time inexistent from both parties.

264 Official representative body of the European generic and biosimilar pharmaceutical industry.
266 Ibid.
267 Ibid.
268 However, a large part of the negotiations remains confidential. This lack of transparency was denounced by the public opinion and several NGOs (included Greenpeace).
Now that the EU has implemented the manufacturing waiver for export and for stockpiling in its legislation, and that the trade negotiations between the EU and the US are on again (regardless of the name of the Treaty under which negotiations take place), it could be in the interest of the EU to include the new exception in the future agreement with the US. It would give the exception some credibility and legitimacy, as the US is the world’s largest pharmaceutical market. However, unless an unintended policy shift from the US, it is very doubtful that the current American administration agrees on this point.

One thing is sure: the US heard about the new SPC exception in the EU and did not seem to be very pleased about it. The generic industry association, Medicines for Europe, even claims that the “US tried to interfere in an EU domestic policy matter by trying to manipulate and influence the debate, in order to defend non-better-specified interests”. Indeed, an informal meeting was organized in Brussels on October 23rd, 2018, by the US patent and trademark office (USPTO), together with the US Trade Office (USTR) and the US Department of Commerce. Even if the meeting has been categorized as a “conduct of routine diplomatic business on issued of shared interests” by the US; others see it as another attempt “to close the US healthcare market to imported biosimilar medicines.”

Indeed, the development of biosimilars in the US is recent, as they were first authorized on the market only three years ago. Meanwhile, the EU, which invented biosimilar medicines, has authorized them on the internal market thirteen years ago. With an effective manufacturing waiver for export, the manufacturers based in Europe will become strong competitors and could be ready to face the upcoming patent cliff in the next few years. This situation is against the interest of the US originators, and the US wants to avoid this rising competition from the EU.

To conclude, if the US maintains its position, the implementation of a manufacturing waiver in a future trade agreement with the EU will not be tolerated.

However, we think that the manufacturing waiver for export and for stockpiling in the US could be beneficial to the manufacturers based in the country as well as the American patients; mostly

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in the area of generic medicines. We will examine why and how such an exception could be implemented in the area of patent restoration.

II. A need for reform in the US generic medicines industry

In the US, the generic medicines market reached a value of $103.8 billion in 2018, and now represents about 30% of total sales worldwide\textsuperscript{272}. In this regard, nine out of ten prescriptions filled are for generic medicines\textsuperscript{273}, representing 23\% of prescription spending in the country\textsuperscript{274}. However, in recent years, the US experienced a significant decrease in competition in the generic field (A), which will require the intervention of policymakers (B). An option to addressed the issue would be the implementation of a manufacturing waiver (C).

A. A recent significant decrease in competition in the generic field

Between 2012 and 2013, the total cost of 280 widely used generic medicines only fell by 4\% in the US, a slower rate of decline than in the previous seven years\textsuperscript{275}. This situation is due to a combination of several factors including “supply-chain disruptions, loopholes in regulations by the US Food and Drug Administration (FDA), tough markets conditions driving firms out of business, many mergers and acquisitions and a lengthy procedure of generic drug application by the FDA\textsuperscript{276}.” This situation led to a significant price increase in generic medicines from several manufacturers. In a study conducted by the US Government Accountability Office, they found “an extraordinary prices increase” of 100\% or more for 315 out of 1441 generic medicines they studied between 2010 and 2015\textsuperscript{277}. Moreover, some studies revealed that a large number of physicians, pharmacists, and patients do not consider generic medicines as bioequivalent to the brand-names ones. Indeed, almost a third of the surveyed physicians preferred prescribing brand-name medicines over the generic option, while 27\% believe that generics cause more adverse effects than the brand-name drugs\textsuperscript{278}.


\textsuperscript{273} US, Food & Drug Office, “Generic Drug”, May 16\textsuperscript{th} 2019, available at: https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs (August 17\textsuperscript{th} 2019).


\textsuperscript{276} Wouters, P. Kanavos, M. McKnee “Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and spending” op.cit.


Unless most of the EU member states, the US leaves medicines pricing to market competition. In other words, the government does not control the price of generics, and substitution law differs from state to state. Generic prescribing is voluntary in all 50 states\textsuperscript{279}. All these elements combined lead to shortcomings in generic medicine market in the US, mostly due to delays in the availability of generics, high price, and low utilization rates\textsuperscript{280}.

B. Call for a legislative intervention

These issues will not be solved without the intervention of national regulators. First, the FDA needs to improve and rationalize the generic granting approval process. A study lead by Kesselheim recommends FDA to reduce the pressure on the price by prioritizing applications from manufacturers trying to bring to a market a generic medicine sold by three or fewer firms. In the case of generic medicines facing limited or no competition, the FDA could temporarily import generics from countries with equally high regulatory standards like Canada or the EU\textsuperscript{281}. Therefore, this context could benefit the EU. The US is the second trading partners of the EU regarding the pharmaceutical products export, representing 31% of the EU export shares in 2017. Furthermore, the EU manufacturing waiver for export could allow the EU based generic manufacturers to reach the American market as soon as the patent term restoration elapses, thus, gaining market shares.

Another way for the US to improve the entry of generics into the market would accelerate the review process of generic medicines. On average, 15 months are needed for generic manufacturers to receive an initial answer from the FDA\textsuperscript{282}. In this regard, the FDA is currently increasing the availability of these generics. In its recent report, the Office welcomes the fact it “approved a record number of generic drug application in 2017, saving $16 billion drug costs for the patients”\textsuperscript{283}.

\textsuperscript{279} Wouters, P. Kanavos, M. McKnee “Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and spending” op.cit. section “Generic Drug Policies in Europe and the United States’ para.5

\textsuperscript{280} Ibid.


The most significant concern is the anticompetitive tactics used by brand-names firms to delay generic medicine launches in the US. A common practice for brand-name manufacturers is to fill a patent infringement lawsuit against generic manufacturers for the launching of their drugs too early preventing the marketing of generic while the companies are tied up in court\textsuperscript{284}. Some brand-name firms only bring lawsuits to enjoy extra revenue obtained after patent expiry, knowing that the revenue will exceed the legal fees. A manufacturing waiver would help to prevent this situation, by providing a legal framework which would allow strict control of the manufacture starting date, and of the launching date of the generic medicines into the market (for example, by filing upstream an annex with required information).

Nowadays, there is a clear need for reform in the generic field in the US. According to a recent study, ¾ of Americans believe the prescription drug is too high, and 76% say pharmaceutical companies are the most to blame\textsuperscript{285}. Federal and states governments are aware of this cost pressure and are looking at ways to increase competition in the generic field in order to decrease prices. Some politicians go even further and consider that “it is time to let the government manufacture generic drugs”\textsuperscript{286}. According to this view, public manufacturing would fix the lack of competition into the generic market and would provide affordable medicines to consumers. This view goes directly against the ‘free market’ spirit, so this option is not shared by the majority of the American politicians.

At the time of writing, health policy regarding generics in the US remains uncertain.

C. Implementation of a manufacturing waiver, a partial hypothetical answer

An option would be to implement the manufacturing waiver in the US patent extension system. To recall, the Hatch-Waxman Act sought to eliminate two distortions to the normal “patent term produced by the requirement that certain products must receive premarket regulatory approval\textsuperscript{287}.” Article 35 USC 156 enables the owners of patents on medicines, among other products, to restore the terms of its patents some of the time lost while awaiting premarket government approval from a regulatory agency. In the US, the patent restoration system

\textsuperscript{284} Wouters, P. Kanavos, M. McKnee “Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and spending” op.cit., section “facilitate generic market” para. 3.


\textsuperscript{287} United States Patent Office.
provides five years when a patent can be restored, and the entire patent life for the product with the patent extension cannot exceed fourteen years from the product's approval date.

The owner of the patent extension has on it the same right as a ‘normal patent.’ The Patent Act states, “[Except as otherwise provided in this title [35 USCS Sects. 1 et seq.], whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent]”. In the light of this article, there is no doubt that a manufacturing waiver for export and for stockpiling would infringe the patent because it would happen in the US and during the term of the patent. However, an exception regarding the making has been authorized in the Act under particular circumstances. Indeed, the US has been the first country to create a safe harbor enacted in the Hact-Waxman Act in order to protect and promote the development of the generic industry. The Bolar exemption provides that it is not an act of patent infringement to engage in otherwise infringe uses ‘reasonably related’ to preparing an abbreviated new drug application for FDA approval.

Nowadays, the American generic industry is currently facing the highest deficit in the international trade of medicines in the world and could use a new balanced exception to boost the competition in favor of the generic industry. Such an exception could improve the industrial development and competitiveness in the generic sector, consequently reducing the cost of generic medicines for millions of American patients.

The manufacturing waiver could be a solution. Paradoxically to the generic ‘crisis,’ the US is still a significant player in the global export of generics scene, and intend to stay competitive in the changing pharmaceutical context. The manufacturing waiver for export would allow the generic industries to manufacture during the patent extension period, thus to continue to export abroad in countries where the protection does not exist or has elapsed. The production line for export could be used as well to provide generics at an internal level as soon as the patent protection expires in the US. It will circumvent the lengthy authorization procedure (because it would have granted before for export purposes). The stockpiling waiver may be considered as well, in order to speed up the entry of generics into the internal market. However, this would imply to start to manufacture during the patent extension term; and might be considered as an excessive erosion of the protection. It is the opinion of the powerful pharmaceutical lobbies

289 Investopedia, definition abbreviate new drug: “An abbreviate new drug application is a written request to the FDA to manufacture and market a generic drug in the United States”.
which play a very active role in order to preserve their interests and are very much opposed to any legislation that could harm the patent protection system.

Consequently, an amendment of the Patent Act would be necessary to implement a manufacturing waiver. Despite its potential economic benefits, such a change is not likely to happen under the current American Administration.

However, other countries which also have patent protection could be inspired by the EU manufacturing waiver. This could be the case of Australia, which previously showed interest in a manufacturing waiver.

III. Australia, favorable to the implementation of a manufacturing waiver in the future

In Australia, the manufacturing waiver was examined for the first time in 2012 by a panel set up to review the Australian pharmaceutical patent law. Australia showed interest in the stockpiling waiver but targeted the discussion on the export waiver. The panel appeared to be in favor of “making manufacture for export a non-infringing act,” notably giving arguments relating to the economic development of generic and biosimilar industries, employment growth and the absence of actual harm to the interests of the patent owner.

However, the committee doubted the consistency of the exception with international obligations, mainly those enshrined in TRIPS and the Australia United States Free Trade Agreement (AUSFTA). In this regard, the panel review found that it was preferable to avoid litigation and not incorporate such an exception immediately. Instead, the draft proposed that the “Government should actively seek the agreement of the owners of Australian pharmaceutical patents to voluntarily agree not to enforce their patents in respect of manufacturing for export.”

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292 AUSFTA is a preferential trade agreement between Australia and the United States signed on 18 May 2004 and came into effect on 1 January 2005.


To conclude, the panel suggested the adoption of an explicit manufacturing waiver in the context of an international normative reform\textsuperscript{295}, calling for the government to negotiate international agreements to ensure Australia’s interests are considered.\textsuperscript{296}

At the moment, no final report has been released on the matter, and it does not seem to be a policy priority\textsuperscript{297}. The implementation of the EU manufacturing waiver could reopen the discussion in Australia.

Conclusion

The EU succeeded to enact a broad manufacturing waiver, both for export and stockpiling purposes. These new exceptions to SPCs are an ambitious response to a global changing pharmaceutical environment. The amendment of Regulation 2009/69 illustrates the shift of position of the EU: from a strict vision of the intellectual property rights to a more flexible view where intellectual property rights can be softened in order to answer new challenging situations. In the past, the EU did not hesitate to use the WTO Dispute Settlement Body to challenge foreign legislations that were considered to weaken the intellectual property international standards\textsuperscript{298}. By amending the SPC legislation in favor of generic and biosimilar manufacturers, the EU intends to compete with foreign countries which provide a more flexible patent regime or patent restoration regime. Therefore, the Union’s first preoccupation is economical. The EU fears to see generic and biosimilar companies based in its territory, moving to third countries where they can manufacture under a more favorable legislation. The manufacturing waiver for export is supposed to provide a broader scope of action for the generic and biosimilar manufacturers, allowing them to boost their competitiveness on the international market.

Consequently, the competition raise will decrease the cost of medicines, thus making them more accessible to governments and patients. Besides, the inclusion of the stockpiling waiver to the Regulation during the legislative process is a benefic step forward to guaranty quicker access to generic and biosimilar medicines within the EU, directly after the expiry of the SPC. This exception reflects the social function of intellectual property rights\textsuperscript{299} and goes in the sense of the Doha Declaration which affirms that “\textit{the TRIPS Agreement does not and should not prevent members from taking measures to protect public health}\textsuperscript{300} “.

The enactment of the legislation happened just in time to face the oncoming patent cliff. However, the power of the lobbies and the skepticism of a large part of the doctrine led to an unbalanced Regulation containing many safeguards for originators, thus potentially difficult to implement for manufacturers. Moreover, the legislation will not be effective before a few years, putting the aim of the Regulation at risk. Nonetheless, a readjustment of the Regulation could

\textsuperscript{298} For example, \textit{Canada- Patent Protection of Pharmaceutical Products}, 2000.
\textsuperscript{300} Doha Declaration, 2001, para. 4.
occur in five years, after a review of the effects of the new exceptions on the originators’ businesses. If the results are conclusive, the scope of the exception could perhaps be extended to “the manufacturing for export to other EU markets where there is no SPC or patent protection\textsuperscript{301}.”

On the international scene, the reactions are likely to be diverse. Some countries could believe the EU is sending a mixed signal. Acting for the strengthening of intellectual property rights through FTAs on one hand, then enacting some exception to these same rights at an internal level on the other hand. This situation is, even more, criticized knowing that several countries are currently strengthening their intellectual property right (it is the case of China). In countries with high intellectual property protection, the reactions could be distinct. Some countries strongly disapprove the waiver, claiming that it will negatively impact the research and development of new medicines and not necessarily serve their national interests. On the contrary, other countries seem favorable to the legislation and could implement the same type of exception in their internal legal system in the future.

The pharmaceutical sector is changing, and the legal standards need to adapt to this reality. Currently, adapting the patent extension system is a matter of national choice\textsuperscript{302}. Providing a collective answer to all WTO members seems now impossible as the patent extension regime is not governed by TRIPS. One option would be to implement the Agreement to include a patent extension regime, as well as exceptions to provide a more flexible framework for generic and biosimilar manufacturers. Such a change remains uncertain, as it would need to be globally approved by the WTO members, which is far from being the case at the time of writing.

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