WHITE PAPER: LEGAL ANALYSIS ON HOW THE "MANUFACTURING WAIVER" IMPACTS THE EUROPEAN PATENT EXTENSION MECHANISM

1. Introduction

1. Strong IP protection fosters innovation, which serves the dual goals of delivering new treatments to meet patients' needs and competitiveness. Innovative pharmaceutical companies have to spend huge sums to discover and develop new medicines. The regulatory process to gain approval for a new medicine is increasingly complex and time consuming, as regulators rightly focus on patient safety and ensuring a positive balance as between efficacy and risk, while treatments are often more complex. Because the regulatory process reduces the length of patent exclusivity, in order to ensure that innovator companies are rewarded for their innovation, numerous jurisdictions have setup a patent extension mechanism to compensate for the patent duration lost due to the regulatory process. In the EU, this mechanism was set up more than two decades ago through the Supplementary Protection Certificate ("**SPC**") which extends the patent life by up to 5 years.

2. On 12 October 2017, the European Commission ("**EC**") launched a public consultation on the SPC and the patent research exemptions.[1] One of the elements of the consultation was to consider the introduction of an exception to the SPC, the "manufacturing waiver". Such a waiver would allow EU-based manufacturers to export SPC-protected medicinal products and, according to the Commission, would as a result, bridge the competitive gap between EU and non-EU manufacturers (by increasing the revenue of EU-based manufacturers).[2] Moreover, it is argued that the waiver could assist, through stockpiling, the timely entry of generics and biosimilars after patent / SPC expiry.[3]

3. We show below that introducing a manufacturing waiver in the EU is not warranted for the following reasons:

    - It is questionable whether the "manufacturing waiver" will accomplish the EC's objectives (**Section 2**).
    - The waiver is incompatible with the EU Free Trade Agreements ("**FTAs**") and may lead to friction between the EU and its counterparts (**Section 3**).
    - The only EU contracting state introducing such a waiver is Canada, but even the Canadian "manufacturing waiver" has a more limited scope than the envisaged EU waiver (**Section 4**).
    - The waiver could constitute a form of unwarranted protectionism that runs contrary to the EU's trade policy (**Section 5**).

4. These arguments are examined below in turn.

2. The "manufacturing waiver" may not lead to the benefits advocated by the EC

5. Currently, EU-based manufacturers cannot export outside the EU medicinal products that are protected under an SPC. The "manufacturing waiver" would enable an EU-based manufacturer to manufacture products protected under an SPC for export to third countries, or Member States where there is no patent or SPC protection. The objective of this policy shift is to: a) increase net exports for EU-based manufacturers and b) allow manufacturing for "stockpiling", which would ensure a speedier entry of generics and biosimilars produced in the EU following the expiry of patent protection in the EU Member States.[4] In such a way cheaper generic/ biosimilar medicinal products could become available on the market faster,

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1 See link.

2 Inception Impact Assessment, page 5.

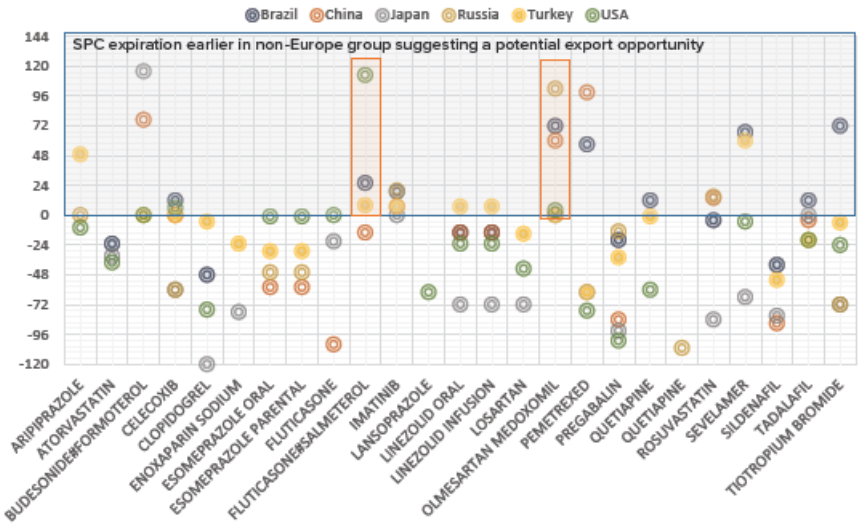
3 Consultation paper assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe, page 2.

4 Inception Impact Assessment, page 5.

facilitating the availability and accessibility of medicines.[5] We argue that these objectives are unlikely to be met through the "manufacturing waiver".

6. First, EU-based manufacturers are unlikely to increase their exports with the waiver. For this to work, patent protection in export countries must expire before the EU SPC expiry date. This is frequently not the case. As the recent study by QuintilesIMS suggests, in only a handful of cases is the SPC expiry date in export jurisdictions earlier than in the EU, representing a potential export opportunity.[6] This is illustrated in **Figure 1** below.

Figure 1: Expiry of patent protection in export jurisdictions vs Europe (months)[7]



7. Importantly, **Figure 1** also illustrates that out of the top 25 originator branded products, the SPC of only two products ("Fluticasone Salmeterol" and "Olmesartan Medoxomil") expired significantly earlier in export countries compared to the EU.[8] By contrast, the European SPC of the top-selling medicine, Pregabalin (Lyrica),[9] expired earlier than the patent protects in six of the major export jurisdictions (Brazil, China, Japan, Russia, Turkey and USA).[10]

8. Second, being able to manufacture medicinal products for stockpiling purposes will not lead to significantly speedier entry for generic or biosimilar manufacturers. Sophisticated pharmaceutical companies are able to swiftly adapt their manufacturing processes to enter the market shortly after patent expiry, even without the manufacturing waiver.

9. There is, thus, very little evidence that introducing a "manufacturing waiver" will provide the benefits envisaged by the EC. On the contrary, exceptions to the SPC will certainly lead to reduction of innovation incentives of originators and could ultimately impact patient health. .

3. The "manufacturing waiver" is incompatible with the FTAs

10. The "manufacturing waiver" is not common in other jurisdictions. No such waiver can be found in most FTAs negotiated between the EU and its counterparts including Korea, Japan, Vietnam, Colombia and Peru and Mercosur (in proposal form) which all provide for an SPC regulatory framework. Interestingly, the

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5 Inception Impact Assessment, page 5.

6 Ramya Logendra, Per Troein (2017), "*Assessing the impact of proposals for a Supplementary Protection Certificate (SPC) Manufacturing Exemption in the EU*", see link, section B.

7 Ramya Logendra, Per Troein (2017), "*Assessing the impact of proposals for a Supplementary Protection Certificate (SPC) Manufacturing Exemption in the EU*", see link, page 7.

8 Ramya Logendra, Per Troein (2017), "*Assessing the impact of proposals for a Supplementary Protection Certificate (SPC) Manufacturing Exemption in the EU*", see link, page 6.

9 See link on *"The Top 15 Best-Selling Drugs of 2016"*.

10 Ramya Logendra, Per Troein (2017), "*Assessing the impact of proposals for a Supplementary Protection Certificate (SPC) Manufacturing Exemption in the EU*", see link, page 6.

latest FTA being negotiated (EU-Mercosur) has no mention of a "manufacturing waiver". By contrast, these FTAs strongly recognise the necessity of an SPC framework which fosters innovation (see relevant language listed in Annex 1). 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.

11. In light of this, it is perfectly feasible that the EU trading partners will voice concerns. If an FTA party viewed the waiver as an infringement of the FTA, it could bring an action against the EU under the respective FTA's "Dispute Settlement" clause. Depending on the FTA, the EU could be obliged to offer compensation to the complaining party,[11] and if the remedy was inadequate, the complaining party could decide to unilaterally suspend its FTA obligations.[12]

12. Some countries are more likely to complain in this respect, either due to their commitment to intellectual property rights (Japan, Korea), or due to the impact the waiver will have on them (Vietnam). Specifically:

- **Japan** is the 6th largest trading partner of the EU.[13] In Japan patent protection lasts for "*20 years from the filing date*",[14] the same as the EU.[15] The Japanese FTA obliges contracting parties to provide an extension to patent protection, up to a limit of five years, to compensate for delays in the marketing approval process, again the same as the EU.[16] In the Impact Assessment of the EU-Japan FTA, EU business organisations called "*for a specific EU-Japan agreement which should cover identical protection for IP right-owners in both markets*",[17] including patent protection. The "manufacturing waiver" could be seen as a step in the opposite direction, and contrary to what Japan agreed in the FTA.

- **South Korea** is the 8th largest trading partner of the EU.[18] In Korea, patent protection lasts for 20 years from the date of filing.[19] The Korean FTA provides for up to 5 years of a patent extension mechanism for patent protection lost due to authorization purposes.[20] The EU-Korea FTA has one of the most comprehensive chapters dedicated to intellectual property rights (IPR). It requires the parties to apply a number of international conventions and introduce provisions for criminal sanctions for IPR violations.[21] This evidences Korea's commitment to strong IPRs. The manufacturing waiver is inconsistent with these provisions.

- **Vietnam** is the 20th largest trading partner of the EU. [22] It affords 20 years patent protection since filing date.[23] The EU-Vietnam FTA obliges contracting parties to introduce an extension of patent protection, up to a limit of two years,[24] to compensate for delays in the marketing approval of pharmaceutical products, if the approval process takes more than 24 months.[25]

13. Vietnam could be negatively impacted by the manufacturing waiver, given that it only offers a two year patent extension compared to the five year EU SPC. If a "manufacturing waiver" is introduced, an EU-based manufacturer will be able to 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. Effectively the EU will be implementing non-tariff barriers with

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11 EU-Korea FTA, article 14.11.1.

12 EU-Korea FTA, article 14.11.2.

13 2016 DG Trade statistics, page 1.

14 EPO Q&A on Japanese patents.

15 EPO Q&A on European patents.

16 EU-Japan FTA, article 35. This has been transposed into national law (Japanese Patent Act, section 67(2)).

17 EU-Japan FTA Impact Assessment, question 11.

18 2016 DG Trade statistics, page 1.

19 EPO Q&A on Korean patents.

20 EU-Korea, article 10.35. This has been transposed into national law (Korean Patent Act, article 89).

21 EEAS presentation, slide 13.

22 2016 DG Trade statistics, page 1.

23 Vietnam Patent Office.

24 EU-Vietnam FTA Guide, slide 31.

25 EU-Vietnam FTA, article 8.3.

Vietnam. Given this scenario, it is not unlikely that Vietnam will argue against the compatibility of the "manufacturing waiver" with the EU-Vietnam FTA.[26]

14. Finally, the EC should be wary of sending mixed signals to its trading partners. The EU has recently voiced concerns to Korean delegates when a Korean Patent Court narrowed down the scope of a patent right whose term was extended. [27] Ironically, the EC now is considering introducing the manufacturing waiver which will lead to the narrowing down of its own patent extension mechanism. Such a policy shift could undermine the EU's future negotiating credibility.

4. Even the Canadian "manufacturing waiver" has more limited scope than the envisaged EU waiver

15. The only FTA which provides for a manufacturing waiver is the EU-Canada Comprehensive Economic and Trade Agreement ("**CETA**"). Before the CETA, 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. In light of the CETA, on 21 September 2017, Canada introduced a regulatory framework for a Certificate of Supplementary Protection ("**CSP**").

16. Stakeholders described the Canadian patent extension system as "*one step forward and two steps back*". The Canadian CSP Framework undermines the protection offered to innovators by narrowing the scope of the patent extension in comparison to other jurisdictions in at least four ways by: a) limiting the SPC protection to two years; b) requiring to coordinate regulatory filings among jurisdictions in order to benefit from SPC protection; c) excluding from the scope of the SPC patents covering minor variations and d) introducing the manufacturing waiver.[28]

17. Specifically, on the Canadian "manufacturing waiver", stakeholders voiced concerns that it was inconsistent with systems in other jurisdictions and that there should have been safeguards regarding its implementation (i.e. notification requirements).[29] The Canadian government passed the "manufacturing waiver" disregarding these concerns. Canada now stands 24th in terms of innovation, evidencing insufficient encouragement of innovation,[30] and this is reflected with the Canadian CSP, with its limitations not found in other jurisdictions.

18. Nonetheless, the Canadian "manufacturing waiver" has a more limited scope than the manufacturing waiver that the EC is considering introducing. Namely the Canadian waiver is limited to the "purpose of export" and is not allowed to be used for stockpiling:

    - The CETA "manufacturing waiver" provision stipulates that "*each Party may also limit the scope of the* [SPC] *protection by providing exceptions for the making, using, offering for sale, selling or importing of products* ***for the purpose of export*** *during the period of protection*".[31]

    - This provision has been implemented in Canadian national law as follows"[…] *it is not an infringement of the certificate of supplementary protection for any person to make, construct, use or sell the*

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26. For Japan and Korea the waiver will have no practical impact in terms of imports from the EU, as patent protection in those export countries is identical to the EU. As such, an EU-based manufacturer will not be able to export to Japan and Korea during the SPC period in which the waiver would have applied, as most likely the medicinal product will still be protected under national patent protection.

27 Minutes for the 5th IP Dialogue between Republic of Korean and the European Union, page 1.

28 IMC Comments on Draft CETA Patented Medicines (Notice of Compliance) and Certificate of Supplementary Protection Regulations, page 3.

29 IMC Comments on Draft CETA Patented Medicines (Notice of Compliance) and Certificate of Supplementary Protection Regulations, page 3.

29 EC 2016 Trade Report, page 2.

29 IMC Comments on Draft CETA Patented Medicines (Notice of Compliance) and Certificate of Supplementary Protection Regulations, page 3.

30 Fraser Institute Report on "Intellectual Property Rights Protection and the Biopharmaceutical Industry: How Canada Measures Up", see link, page 21.

31 CETA, article 20.27.9.

> *medicinal ingredient or combination of medicinal ingredients* ***for the purpose of export*** *from Canada*."[32]

19. Thus, introducing a manufacturing waiver for stockpiling purposes in the EU would go beyond Canadian rules. Indeed the Canadians may be concerned that they were obliged to introduce the CSP to comply with the CETA provisions at the insistence of the EU – only to see the EU then loosen its SPC rules.

5. The "manufacturing waiver" is a form of protectionism that goes against the EC's trade policy

20. One of the aims of DG Growth's "manufacturing waiver" is to increase incentives for EU-based manufacturers to remain in the EU. This objective is incompatible with DG Trade's objective of fighting protectionism, including policies encouraging the localisation of business.

21. In its most recent report on trade barriers, DG Trade noted that anti-protectionist policies create trade ties that "*strongly contribute to lasting peace among nations*".[33] Protectionist policies also include countries using intellectual property rights to promote local businesses. For instance, China considered adopting rules forcing companies that procure information and technology goods for Chinese banks to use Chinese intellectual property. After an intervention by the EC, China decided not to proceed.[34] For pharmaceuticals, Russia[35] adopted regulatory measures aimed at further production localisation, and Turkey[36] went a step further and implemented forced localisation measures. All these localisation measures were condemned by the EU.

22. Introducing a "manufacturing waiver" would mean that the EU is taking a protectionist ("EU-first") stance against other trading partners that do not have a "manufacturing waiver" in place. In particular, partners who have shorter patent protection than the EU will be negatively impacted by the EU's "localisation" strategies leading potentially to some form of trade retaliation (see the Vietnam example above).

23. We do not agree with the argument that the "manufacturing waiver" is not protectionism, but creates a level playing field between EU-based manufacturers and non-EU-based manufacturers. This argument is over simplistic, and in any event, is premised on the idea that patent protection in export jurisdictions is shorter than in the EU, which is often not the case, as evidenced in Section 2 above.

6. Conclusion

24. The EU has been a strong advocate of pursuing innovation as shown by the 2002 Lisbon Strategy, and with the Innovation Union initiative. It would be a mistake for the EU to follow the path led by Canada and introduce a manufacturing waiver. Such a policy shift is unlikely to serve any of the EC's objectives, it is incompatible with EU's trade policy and the existing FTAs and will reduce the EU's chances of becoming the global innovation leader.[37]

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32 Amended Canadian Patent Act, section 115(2)..

33 EC 2016 Trade Report, page 2.

34 EC 2016 Trade Report, page 29.

35 EC 2016 Trade Report, page 14: "Russia has also adopted "Good Manufacturing Practice" certificate requirements for the marketing and the renewal of marketing authorizations for pharmaceuticals, without ensuring sufficient capacities to carry out these procedures in Russia, leading to undue delays for the EU pharmaceutical industry."

36 EC 2016 Trade Report, page 20: "The Turkish Ministry of Health has requested foreign manufacturers of several pharmaceutical products to produce them locally. In the absence of a 'sufficient' localisation commitment by foreign manufacturers, the products will be deleted from the list of items that can be reimbursed under the Turkish health insurance system."

37 The EU's goal was to increase its R&D spending to 3% of GDP (Lisbon Strategy). It is currently at 2.03%, 0.70% less than the US and 1.56% less than Japan (Eurostat).

Annex 1

Patent extension provisions from a selection of FTAs, listed chronologically	
EU-Colombia and Peru (art 230) – applied since 2013; status: party in place.[38]	**ARTICLE 230** 1. The Parties shall comply with Articles 2 through 9 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, done in Budapest on 28 April 1977 and amended on 26 September 1980. 2. The European Union shall make all reasonable efforts to comply with the Patent Law Treaty, adopted at Geneva on 1 June 2000 (hereinafter referred to as the "PLT"). The signatory Andean Countries shall make all reasonable efforts to accede to the PLT. 3. When the marketing of a pharmaceutical or agricultural chemical product**71** in a Party requires to obtain an authorisation by its competent authorities in such matters, such Party shall make its best efforts to process the corresponding application expeditiously with a view to avoiding unreasonable delays. The Parties shall cooperate and provide mutual assistance to achieve this objective. 4. With respect to any pharmaceutical product that is covered by a patent, each Party **may**, in accordance with its domestic legislation, make available a mechanism to compensate the patent owner for **unreasonable curtailment** of the effective patent term resulting from the first marketing approval of that product in that Party. Such mechanism shall confer all of the exclusive rights of a patent, subject to the same limitations and exceptions applicable to the original patent.
EU-Korea (art 10.35) – enforced since 2016; status: in place.[39]	**Article 10.35** **Extension of the duration of the rights conferred by patent protection** 1. The Parties recognise that pharmaceutical products (64) and plant protection products (65) protected by a patent in their respective territories are subject to an administrative authorisation or registration procedure before being put on their markets. 2. The Parties **shall** provide, at the request of the patent owner, for the extension of the duration of the rights conferred by the patent protection to compensate the patent owner for the reduction in the effective patent life as a result of the first **authorisation to place the product on their respective markets**. The extension of the duration of the rights conferred by the patent protection may not exceed five years (66).
EU-Vietnam (art 8.3) – 2016 negotiations concluded; status: pending (it will enter into force in 2018)[40]	**Article 8.3 - Administrative Authorisation** 1. Parties recognise that pharmaceutical products protected by a patent on their respective territory are generally subject to an administrative authorisation procedure before being put on their market, hereinafter referred to as the "marketing authorisation procedure". Parties **shall** provide for an adequate and effective mechanism to compensate the patent owner for the reduction in the effective patent life

[38] DG Trade website.

[39] DG Trade website.

[40] DG Trade website.

Patent extension provisions from a selection of FTAs, listed chronologically	
	resulting from **unreasonable delays** in the granting of first marketing authorisation in the respective territories23. Such compensation may be in the form of an extension of the duration of the rights conferred by patent protection, equal to the time by which the period mentioned in footnote 15 is exceeded. The maximum duration of this **extension shall not exceed 2 years**. 2. Alternatively to paragraph 1 of this Article, a Party **may** make available an extension, not exceeding five years24 of the duration of the rights conferred by the patent protection to compensate the patent owner for the reduction in the effective patent life **as a result of the marketing authorisation procedure**. The duration of the extension shall take effect at the end of the lawful term of the patent for a period equal to the period which elapsed between the date on which the application for a patent was filed and the date of the first marketing authorization to place the product on the market in the party, reduced by a period of five years.
EU-Canada (art 20.27) – applied since 2017; status: partly in place [41]	**Sui generis protection for pharmaceuticals** 1. For the purposes of this Article: basic patent means a patent which protects a product as such, a process to obtain a product or an application of a product, and which has been designated by the holder of a patent that may serve as a basic patent, as the basic patent for the purpose of the granting of sui generis protection; and product means the active ingredient or combination of active ingredients of a pharmaceutical product. 2. Each Party **shall** provide a period of sui generis protection in respect of a product that is protected by a basic patent in force at the request of the holder of the patent or his successor in title, provided the following conditions have been met: (a) an authorisation has been granted to place the product on the market of that Party as a pharmaceutical product (referred to as "marketing authorisation" in this Article); (b) the product has not already been the subject of a period of sui generis protection; and (c) the marketing authorisation referred to in subparagraph (a) is the first authorisation to place the product on the market of that Party as a pharmaceutical product. 3. Each Party **may**: (a) provide a period of sui generis protection only if the first application for the marketing authorisation is submitted within a reasonable time limit prescribed by that Party; and (b) prescribe a time limit of no less than 60 days from the date on which the first marketing authorisation was granted for the submission of the request for the period of sui generis protection. However, where the first marketing authorisation is granted before the patent is granted, each Party will provide a period of at least 60 days from the grant of the patent during which the request for a period of protection under this Article may be submitted. 4. In the case where a product is protected by one basic patent, the period of sui generis protection shall take effect at the end of the lawful

[41] DG Trade website.

Patent extension provisions from a selection of FTAs, listed chronologically	
	term of that patent. In the case where a product is protected by more than one patent that may serve as a basic patent, a Party may provide for only a single period of sui generis protection, which takes effect at the end of the lawful term of the basic patent, (a) in the case where all the patents that may serve as a basic patent are held by the same person, selected by the person requesting the period of sui generis protection; and (b) in the case where the patents that may serve as a basic patent are not held by the same person and this gives rise to conflicting requests for the sui generis protection, selected by agreement between the patent holders. 5. Each Party shall provide that the period of sui generis protection be for a period equal to the period which elapsed between the date on which the application for the basic patent was filed and the date of the first marketing authorisation, reduced by a period of five years. 6. Notwithstanding paragraph 5 and without prejudice to a possible extension of the period of sui generis protection by a Party as an incentive or a reward for research in certain target populations, such as children, the duration of the sui generis protection may not exceed a period of two to five years, to be established by each Party. 7. Each Party may provide that the period of sui generis protection shall lapse: (a) if the sui generis protection is surrendered by the beneficiary; or (b) if any prescribed administrative fees are not paid. Each Party may reduce the period of sui generis protection commensurate with any unjustified delays resulting from the inactions of the applicant after applying for the market authorisation, when the holder of the basic patent is the applicant for market authorisation or an entity related to it. 8. Within the limits of the protection conferred by the basic patent, the sui generis protection shall extend only to the pharmaceutical product covered by the marketing authorisation and for any use of that product as a pharmaceutical product that has been authorised before the expiry of the sui generis protection. Subject to the preceding sentence, the sui generis protection shall confer the same rights as conferred by the patent and shall be subject to the same limitations and obligations. 9. Notwithstanding paragraphs 1 through 8, each Party may also limit the scope of the protection by providing exceptions for the making, using, offering for sale, selling or importing of products for the purpose of export during the period of protection. 10. Each Party may revoke the sui generis protection on grounds relating to invalidity of the basic patent, including if that patent has lapsed before its lawful term expires or is revoked or limited to the extent that the product for which the protection was granted would no longer be protected by the claims of the basic patent, or on grounds relating to the withdrawal of the marketing authorisation or authorisations for the respective market, or if the protection was granted contrary to the provisions of paragraph 2.
EU-Japan (art 35) - 2017 negotiations concluded;	**Article 35**

Patent extension provisions from a selection of FTAs, listed chronologically	
status: pending (awaiting signature)[42]	**Extension of the Period of Protection Conferred by a Patent on Pharmaceutical Products27 and Agricultural Chemical Products** With respect to the patent which is granted for an invention related to pharmaceutical products or agricultural chemical products, each Party **shall**, subject to the terms and conditions of its applicable laws and regulations, provide for a compensatory term of protection for a period during which the patented invention cannot be worked **due to marketing approval process**. As of the date of signing this Agreement, a maximum of such compensatory term is stipulated as being five years by the relevant laws of each Party.
EU-Mercosur (art 8.3) - **PROPOSAL**	**Article 8.3** **Extension of the period of protection conferred by a patent on medicinal products 5** 1. The Parties recognise that medicinal products protected by a patent on their respective territory may be subject to an administrative authorisation procedure before being put on their market. They recognise that the period that elapses between the filing of the application for a patent and the first authorisation to place the product on their respective market, as defined for that purpose by the relevant legislation, may shorten the period of effective protection under the patent. 2. The Parties **shall** provide for a further period of protection for a medicinal product which is protected by a patent and which has been **subject to an administrative authorization procedure**, that period being equal to the period referred to in the second sentence of paragraph 1, reduced by a period of 5 years. 3. Notwithstanding paragraph 2, the duration of the further period of protection may not exceed […] years. 4. In the case of medicinal products for which paediatric studies have been carried out, and the results of those studies are reflected in the product information, the Parties shall provide for a further […] months extension of the period of protection referred to in paragraph 2.

[42] DG Trade website.