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# The US-Mexico-Canada Agreement: Putting Profits Before Patients

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President Trump has repeatedly promised that his Administration would lower U.S. pharmaceutical prices. Yet, in the USMCA (NAFTA 2.0) the U.S. Trade Representative negotiated intellectual property provisions related to pharmaceuticals that would enshrine long and broad monopolies not only in Canada and Mexico but also in the United States, thus tying the hands of U.S. Members of Congress who would be prevented from making drugs more accessible for its citizens. Indeed, the USMCA represents a significant success for the powerful originator pharmaceutical lobbying industry, at the expense of U.S. consumers, taxpayers, and the generic and biosimilar industry.

This policy brief focuses primarily on the negative effect of the USMCA intellectual property provisions on access to medicines in the U.S. The negative impact on access to medicines of this agreement would be even worse for Canada and Mexico.

The importance of this trade agreement goes well beyond the three countries involved as this is the first one negotiated by the Trump Administration and will set a precedent for future trade agreements. Keeping in mind that the Administration is about to start three very important negotiations with Japan, the European Union and the United Kingdom, it is essential that the USMCA:

1) Strike a balance that fosters both innovation and competition thus ensuring patients expedited access to more affordable drugs, and not benefit one side of the U.S. pharmaceutical industry at the expense of the other,

2) Not include barriers to entry for generic/biosimilar companies either abroad or at home, and

3) Support the growth of the generic/biosimilar industry globally by including provisions that will ensure the expedited launch of generic and biosimilar products in other markets.

Unfortunately, a careful review of the USMCA text raises very serious concerns about the impact that this agreement would have on the U.S. generic/biosimilar industry and therefore on access to more affordable drugs throughout the world. Furthermore, we are deeply concerned that the agreement would also have a far-reaching detrimental effect on American patients, health insurance providers and government programs like Medicare and Medicaid as several provisions could potentially change U.S. law and/or undermine the ability of democratically elected Members of Congress to deal effectively with the challenges posed by high drug prices.

## I. The USMCA failed to adopt balanced intellectual property provisions on matters related to pharmaceuticals siding with the originator industry at the expense of consumers, payers and the U.S. generic/biosimilar industry

Much has been said about the importance of protecting intellectual property rights to ensure the research and development into new drugs. As a result, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) set the global standard of intellectual property (IP) protection. Since then, all members of the World Trade Organization with the exception of least developed countries provide 20 year patent terms (monopolies) for new drugs allowing originator companies to charge pric-

**Abstract**

In the US-Mexico-Canada Agreement (USMCA, NAFTA 2.0), the U.S. Trade Representative negotiated intellectual property provisions related to pharmaceuticals that would enshrine long and broad monopolies. This policy brief focuses primarily on the negative effects of the USMCA intellectual property provisions on access to medicines in the U.S. Such effects may be even worse for Canada and Mexico. The impact of this trade agreement goes well beyond the three countries involved as this is the first one negotiated by the Trump Administration and is likely to set a precedent for future trade agreements. A careful review of the USMCA text raises very serious concerns about the impact that this agreement would have on the generic/biosimilar industry and therefore on access to more affordable drugs throughout the world.

es that are as high as the market will bear thus getting a substantial return on their investments.

Unfortunately, it seems that somehow during the last 30 years the need to have trade agreements with balanced provisions related to intellectual property rights and pharmaceuticals has been lost. Instead, the USTR has sought the inclusion of new levels of IP protection that increase the monopoly rights of originator pharmaceutical companies at the expense of generic and biosimilar companies. The broader and longer these monopolies are, the less market access generic/ biosimilar companies have.

It also seems that we have lost sight of the rationale behind the protection of intellectual property rights, which are aimed at *promoting innovation*. Protecting IPRs is not an end in itself but a means to an end: *innovation*. With that in mind, it is worth recalling what the Federal Trade Commission (FTC) said about how to achieve this worthy goal: "Competition and patents stand out among the federal policies that influence innovation. Both competition and patent policy can foster innovation, but each requires a proper balance with the other to do so. Errors or systematic biases in how one policy's rules are interpreted and applied can harm the other policy's effectiveness."[1] Furthermore the FTC report clearly states that "[a] failure to strike the appropriate balance between competition and patent law and policy can harm innovation."

The USMCA fails to strike such balance and therefore also fails to promote innovation by not fostering competition, one of the drivers of innovation.

Following is a list of some of MFJ International's concerns that illustrate how the USMCA has failed to provide the necessary balance between promoting innovation and access to affordable medicines.

**1. Biologics**

Biologic drugs are critical for the future of the pharmaceutical industry. They also offer new hope for the treatment of serious illnesses such as cancer, autoimmune diseases and diabetes. As former FDA Commissioner Gottlieb stated in his remarks on the release of the FDA's Biosimilar Action Plan "[w]hile less than 2 percent of Americans use biologics, they represent 40 percent of total spending on prescription drugs. So, enabling a path to competition for biologics from biosimilars is a key to reducing costs and to facilitating more innovation."[2] Commissioner Gottlieb also added that "[a]t the FDA, we're focused on advancing policies that make the process for developing biosimilars more efficient."

Therefore, to accomplish the Administration's goal of making drugs more affordable, it is critical to ensure the development and growth of a strong biosimilar industry. Given the costs associated with these products, biosimilar companies require access to global markets. Indeed, Commissioner Gottlieb explained the significant economics behind the development of biosimilars which should not be disregarded by other government agencies. During a speech addressing the benefits of competition for patients, he said: "While it can cost about $10 million to develop a generic version of a small molecule drug, the complexity of manufacturing and testing biosimilars currently requires much more significant outlays by biosimilar sponsors: typically $100 million to $250 million per program."[3]

While the FDA's efforts support one of the top priorities identified by President Trump to make drugs more accessible, this is unfortunately being undermined by the provisions included by the Office of the USTR in the USMCA. This lack of consistency on government policies and goals is extremely troubling as it could impair the development of the infant biosimilar industry. Without this industry, patients and payers will be at the whim of those that have secured monopoly rights over the most expensive and critical drugs. Furthermore, it is essential to understand that access to biologics requires a biosimilar industry that can truly thrive. The alternative is simply not sustainable.

The protection granted in the USMCA to original biologics raises several concerns:

- **Exclusivity period**

The USMCA included a period of exclusivity for biologics that is twice as long as the one included in the Trans-Pacific Partnership (TPP).[4] Furthermore, such exclusivity fully disregards the conclusion of the Federal Trade Commission that in fact no exclusivity is necessary for biologics given that originator biologics are expected to retain most of the market price and share even after patent expiration.[5] Given the fact that fostering competition in the biologics market is a top priority at the highest levels of the government to ensure access to affordable drugs, it is surprising that the FTC conclusions are being disregarded by trade negotiators by locking very long exclusivity periods and tying the hands of democratically elected Members of Congress.

While some argue that a period of 12 or 10 years of exclusivity should be included given that U.S. law grants 12 years, this disregards the fact that there are currently two bills in the U.S. Congress to lower the period of exclusivity granted to these very expensive drugs.[6] As mentioned, including such exclusivity in a trade agreement would limit Members of Congress' ability to determine the laws of the land. The 12 years of exclusivity continue to be an issue of debate as many argue that they are not necessary and in fact, not sustainable, as in the future more drugs will be biologics. Indeed, as Commissioner Gottlieb stated, "[b]iologics represent 70 percent of the growth in drug spending from 2010 to 2015. And they're forecasted to be the fastest growing segment of drug spending in the coming years."[7]

During the negotiation of another trade agreement, the USTR argued it could not pursue the inclusion of a requirement to disclose the best mode to reproduce an in-

vention in patent applications, based on the fact that at the time there was a bill in Congress that touched that issue. Following the same rationale that was given to us with regards to mandating the disclosure of the best mode, we strongly believe that at this point trade agreements should not set any exclusivity periods for biologics as it is too premature given that we do not know yet how the biosimilar market will evolve and the law may change before it is settled.

Indeed, while the FDA has approved 18 biosimilars in an effort to allow biosimilar competition, only 6 products[8] have been launched so far while most of the others seem to be tied up in litigation. This also confirms the conclusions of the FTC report on follow-on biologics i.e. that there is no indication that patents would not be able to sufficiently protect originator biologics.[9]

Therefore, it seems that trade negotiators should wait to see and understand the development of the biosimilar market before locking the U.S. into long and very expensive exclusivities that may in fact seriously undermine the development of a much-needed market.

It is clear that the USMCA does not strike the necessary balance to promote innovation and access with regards to the exclusivity period for biologic drugs. Such long exclusivity periods negatively impact the biosimilar industry delaying the launch of its products and therefore negatively impacting its revenues, profits and the bottom line of the companies. This provision clearly benefits the originator industry at the expense of the biosimilar one.

- **Starting date of the exclusivity period**

The starting time of the exclusivity is an issue of extreme importance for the generic and biosimilar industry, so while this section only refers to biologics, this issue affects both.

In the case of biologics, Article 20.49 specifically states that a Party shall provide "a period of at least ten years from the date of first marketing approval of that product in that Party."

The wording is problematic as the period of exclusivity starts running after the marketing approval of the product was granted in a specific market. In most cases, originator companies tend to register their products quickly in the most important markets such as the U.S., but they may take longer to register in other countries. So, if company A registers a product in the U.S. in March 2020 the 10 years would start running then but if for some reason it decides not to register the product in Mexico until April 2030 (for example, the drug is very expensive and may only be accessible to a small population, or the exchange rate is such that it would not be very profitable for the company), consumers in Mexico would face an additional 10 year delay before they could actually have access to the biosimilar version of the product. Therefore, while the exclusivity period is technically the same, in practice it would be 10 years plus whatever period elapses until company A decides to register the product in Mexico. This does not seem to be fair to consumers in those secondary markets, that will need to pay monopoly prices for longer period of time, in this example for 20 years (instead of 10). This also means that the biosimilar industry will have no certainty as to when it would be able to launch its products and may face much longer delays to be able to launch its products with the economic implications that would create.

This is not a new concern and, in fact, it was addressed in the New Trade Policy or May 10th Agreement which provided that if a government relies on the marketing approval granted by the other Party, and grants approval within six months of the filing of a complete application for marketing approval, the periods would be concurrent. By contrast, the USMCA text opens the door to unlimited delays in the registration of the original product and therefore to potential unlimited delays for the biosimilar industry before it can launch products in that market. Another alternative would be to require that in order to benefit from exclusivity protection an applicant has a grace period of six-months to a maximum of 12 month to register in another Party[10]. Once again, the USMCA disregards the template set under the New Trade Policy. By failing to provide concurrent periods of protection, the USMCA makes it harder for biosimilar companies to plan the launch of its products. Indeed, given the investments that are necessary to develop costly biosimilar products companies must rely on a global strategy and market and have some certainty with regards to when they would be able to launch in the different markets.

- **Definition**

The definition included in the USMCA seems to be even broader than the one in U.S. law, which specifically states that chemically synthesized polypeptides are not biologics. This could be interpreted as creating new obligations under the agreement and extending such a long exclusivity period to products that today are not considered to be biologics under U.S. law. This would delay the market entry of competition wasting limited resources.

Indeed, Article 20.49:2 states that: "Each Party shall apply this Article to, at a minimum, a product that is produced using biotechnology processes and that is, or contains, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, for use in human beings for the prevention, treatment, or cure of a disease or condition."

Hence, this definition is broader than the one set under the Public Health Service (PHS) Act (42 U.S.C. § 262(i): "The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein ***(except any chemically synthesized polypeptide)***, or analogous product, or arsphenamine or derivative of arsphenamine (or

any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. "

Moreover, in a recent draft Guidance, the FDA specifically states that "a chemically synthesized polypeptide is not a "biologic product"[11] and will continue to be regulated as a drug under the Federal Food, Drug and Cosmetic Act."[12]

It is significant that the USMCA does not exclude chemically synthesized polypeptides. Therefore, it could be interpreted that the USMCA could extend the 10-year exclusivity to products that are chemically synthesized and not considered biologic today. If this were to happen, it could broaden the definition of biologic products thus granting exclusivity to these additional products and therefore, reducing access to affordable drugs and increasing healthcare expenditures.

The issue, however, goes well beyond the actual terms included in this definition. In fact, we strongly believe that no definition of what constitutes a biologic product should be included in the USMCA. Indeed, such definition should be determined by the FDA and not by trade negotiators, and should not be locked or enshrined in an agreement, preventing it from being adjusted according to the development of science. Therefore this should be left outside the USMCA and any other trade agreement.

Once again, the language included in the USMCA would further benefits originator biologic companies at the expense of consumers, payers and the biosimilar industry. Furthermore, it goes even beyond U.S. law. This provision clearly fails to strike the necessary balance between promoting innovation and ensuring the expedited entry of biosimilar product.

- **Exclusivities for biologic products – Footnote 46**

The USMCA article on biologics includes a footnote that, at a minimum, should be clarified to avoid a potential implementation that could extend the current exclusivity protection granted to certain products in the United States.

Indeed, Footnote 46 states that a biologic product may be approved by the procedures set forth in Article 20.48.1(a) (Protection of Undisclosed Test or Other Data) and Article 20.48.1(b) (Protection of Undisclosed Test or Other Data) on or before March 23, 2020. As explained in a recent FDA guidance, biologic products approved under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) shall be deemed to be a license for a biological product under section 351 of the PHS Act (a "deemed BLA") on March 23, 2020.[13] Article 20.49, however, does not clarify that the exclusivity granted to a biologic product under Article 20.48 should end on March 23, 2020 as set under U.S. law. Therefore, it is essential that the USMCA at least be amended to ensure that all biologic exclusivities granted under Article 20.48 cease on March 23, 2020. Furthermore, it should also be clarified that such products may not seek an exclusivity period of 10 years under Article 20.49 of the USMCA.

In a recent speech Commissioner Gottlieb further clarified that biologic drugs approved under section 505 of the FDCA (mostly insulin and human growth hormone drugs) will lose their exclusivity in March 2020 and they are not going to be able to get a biologic exclusivity on top of the one they already received under section 505. Specifically, he stated that "[w]e wanted to make sure that as these drugs transition to the biologics pathway, they don't receive additional exclusivities that they aren't entitled to. They don't get to start benefiting from the 12 years of exclusivity that the law grants to newly licensed biologics, just because these drugs—some of which were approved decades ago – are being treated as biologics for the first time. Once their patents have lapsed, and certain previously awarded exclusivities like orphan drug protection have run their course, these products can be open to brisk competition from biosimilars."[14]

Therefore, it is critical that the USMCA language leave no doubt that for those products granted marketing approval under section 505 of the FD&C Act (21 U.S.C. 355) any exclusivity will terminate as of March 23, 2020 and that they would not be eligible to obtain a biologic exclusivity after that date.

**2. Linkage**

Patent linkage, which makes the granting of marketing approval dependent on the existence of a patent, has often been misused to delay or block the launch of generic drugs. While some of the issues were addressed in the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) it has been very problematic for generic companies. In a March 2012 stakeholder meeting during the negotiation of the TPP, a generic company presented the findings of a hypothetical analysis applied to all of its actual launched products in the original ex-US eight TPP countries in the previous four years, as if linkage had been in force, concluding that the company would not have launched a single product in any country with the exception of the U.S. The combination of market size, costly litigation and delays in generic market entry would have meant that the launch of products would not have been profitable. Therefore, it is important to understand that patent linkage tilts the system in favor of the originator pharmaceutical industry at the expense of generic companies, which face further delays in the launch of their products. Furthermore, given that in the U.S. the filing of a lawsuit triggers a 30-month stay, this could represent enough of an incentive to file a case, even if it may be weak, as it would in any event delay the entry of competitors for up to 30 months. Linkage should not be included in trade agreements, which should instead have a more balanced approach as reflected in the New Trade Policy where it is permissible but not mandatory. Moreover, under the New Trade Policy if a country decides to implement linkage, it must also provide effective rewards

for a successful challenge of the validity or applicability of the patent. Granting such incentive is critical to ensure that only strong and quality patents are granted.

Article 20.50 of the USMCA provides two alternatives:

1) *No mandatory linkage*. While we support non-mandatory linkage within the lines of the standard set in the New Trade Policy, the USMCA could add a new obligation requiring that generic companies notify the patent owner prior to the marketing of a product. We believe that the text should be modified to ensure that it does not create new obligations for generic companies.

2) *Mandatory linkage*. This alternative is deeply concerning since it establishes a mandatory linkage that could be extended to every single product covered by a patent. Under U.S. law patent linkage only applies to three types of patents related to small molecule drugs: drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents. The USMCA language would extend it to "a pharmaceutical product subject to a patent claiming that product." Therefore if the U.S. were to decide to implement the second option of this article it could change U.S. law by extending this very problematic mechanism to a much broader universe of drugs. Under its regulations (Reglamento de Insumos para la Salud), Mexico has a limited linkage mechanism that applies to patents on active substance or ingredients so this text would further hinder the sale of U.S. generic products in Mexico. It will also set a very negative precedent for future trade agreements. Moreover, it could also extend linkage to biologic drugs, which are not subject to linkage under the BPCIA.[15] This provision should therefore be directly replaced with the one in the New Trade Policy. If this is not possible, at the very least the language should be modified to ensure that it does not create any further obligations for generic and biosimilar companies in any of the three countries and that it does not extend the scope of patent linkage beyond U.S. law. Granting any type of mandatory linkage would mean siding with the originator industry at the expense of generics, leaving consumers in a more vulnerable position.

**3. Exclusivity for small molecule drugs**

Exclusivities are also used to delay and prevent generic competition. The wording of this article is very concerning as it would delay the launch of generic products not only in Canada and Mexico but also potentially in the United States as it could change the way this provision is applied. As stated, the generic/biosimilar industry (like the originator industry) is now global so by restricting and/or potentially blocking the entry of generic and biologic products this article, like many others in the USMCA, could have a very negative impact on consumers, payers and the generic/biosimilar industry as a whole.

Article 20.48 poses several very serious concerns for the generic industry and consumers:

♦ It would preclude the approval of a "same or similar" product to the one under exclusivity. This can have very serious consequences for access to medicines as well as for health care expenditures in all the countries involved, including the United States. In fact, this goes beyond U.S. law which delays only the approval of the "same" product to the one under exclusivity until such exclusivity expires. Including the word "similar" goes beyond U.S. law and could be extremely negative. For instance, a drug in the United States can have a 5-year exclusivity for a new active ingredient and then 3 additional years for a new clinical investigation. Currently, when the 5 years expire competitors can launch their products with the version of the original product whose exclusivity has expired even if there is an additional 3-year exclusivity for a new strength, dosage form, route of administration, etc. Under the USMCA, however, competitors may be blocked from launching a version of the product whose exclusivity has expired as it could be considered to be "similar" to the one protected by a 3-year exclusivity. Furthermore, since there could be many 3 additional years of exclusivity this could become a type of "evergreening" strategy to prevent competition through exclusivities. This could also block the approval of an entire therapeutic family of drugs as well as of biosimilar drugs as they are considered to be "similar". Therefore it is essential that the word "similar" be eliminated from the text. In addition, given that footnote 46 could allow the granting of exclusivity to biologic products covered by this article, the word similar presents further elements of concern.

♦ The USMCA would grant the 3 additional years to new clinical "information", setting a much lower bar compared to new clinical "investigation" and could provide grounds to the granting of this additional exclusivity to many more products that those that may get it today thus potentially changing U.S. law.

♦ As described above in the section on biologics, the exclusivity period should be concurrent with that granted in the first market anywhere in the world so as to expedite the launch of products in secondary markets.

Given that the generic/biosimilar industry needs to sell in other markets, any additional protection granted by the USMCA means new barriers to entry to generic/biosimilar products which will negatively affect the revenues and net profits of these companies while reducing access to medicines in the countries involved. Such revenues are critical for the companies to have the necessary resources to develop biosimilar drugs which, as stated by Commissioner Gottlieb, could require up to $250 million per drug. Furthermore, since this agreement will set a new precedent for future trade agreements, this provision will seriously skew the system in favor of originator pharmaceuticals at the expense of generics. The bipartisan New Trade Policy provides a more balanced approach as it struck a compromise between the two sides of

the industry.

**4. Regulatory Review Exception: Bolar-type provision**

This is a critical provision of U.S. law that allows generic and biosimilar applicants to conduct the development, testing and experimental work required for the registration of their products during the term of a patent so that they may enter the market immediately after patent expiration. Without the Bolar provision, consumers and payers would face unnecessary delays since generic and biosimilar companies would be unable to start the development process until patents have expired. Such delays could be up to 10 years in the case of biosimilar drugs. Despite its importance, most trade agreements signed by the U.S. have only included an optional and weak provision. While the USMCA provides a mandatory Bolar-type provision, it is also weak as it is not specific and therefore fails to redress the shortcomings of existing regulatory review exceptions in force in other countries. For instance, Mexico has a limited Bolar and the USMCA should make sure that it is extended so that U.S. generic and biosimilar companies are able to launch their products in Mexico immediately after patent expiration.

Any trade agreement entered into by the U.S. should include a mandatory and comprehensive Bolar-type provision that ensures expedited competition following the expiration of intellectual property rights. Furthermore, the USMCA deleted footnote 49 of the TPP text, which should be reintroduced in the USMCA as well as any other future trade agreement. This footnote made it clear that the regulatory review exception should apply to imports and exports as well. The deletion of this footnote is very concerning particularly given that the original USTR proposal in the TPP followed the language of U.S. law, but had dropped the word "imports." Limiting the possibility of applying Bolar to imports is very concerning as it is would undermine competition and potentially make the market more susceptible to shortages of much-needed drugs. Furthermore, it is critical for the generic/biosimilar industry that the Bolar provision also apply to foreign markets so that it does not face additional unnecessary delays to sell its products after patent expiration. Patents already grant 20-year monopoly rights, so we do not need additional de-facto monopolies. The Bolar provision must be broad, mandatory and apply to the country involved, as well as to imports and exports.

**5. Patent term restoration**

Article 20.46 grants patent term extensions for delays in the marketing approval process. Once again, the language benefits the originator industry at the expense of the generic/biosimilar one and consumers. Indeed, generic and biosimilar products also face delays in the regulatory office but nothing in the agreement grants them any type of compensation. These extensions to the 20-year patent term further hinder access to affordable drugs. Furthermore, it is very difficult to understand why the USTR has sought mandatory patent term extensions but failed to include any of the conditions and limitations set in U.S. law. This is another example where the USMCA sides with the originator pharmaceutical industry at the expense of consumers, payers and the generic/biosimilar industry.

If originator companies are compensated for delays incurred in the regulatory approval process, generic/biosimilar companies should also be granted some kind of compensation for delays in the granting of marketing approval. However, extending patents is not an efficient way to address delays as consumers should not be the ones who end up carrying the weight as they are the ones burdened with the cost as they have to pay monopoly prices for longer periods of time than otherwise necessary.

The USMCA should follow the language of the New Trade Policy making patent term extensions permissible but not mandatory but, if for some reason the extensions are granted, at the very minimum they should have very clear conditions and limitations. Furthermore there should also be a system to challenge such extensions. Finally, these extensions should only be granted for the specific market where regulatory approval is being sought and should not limit in any way the export of generic/biosimilar drugs to markets were the patent rights have expired. The European Union is already considering and moving ahead with the adoption of an export manufacturing waiver' during the term of the Supplementary Protection Certificate. There is no reason whatsoever to penalize generic/biosimilar companies that may be ready to sell to other markets. Once again, we believe that the best option is to follow the language of the bipartisan New Trade Policy.

**6. Patentable subject matter**

The Pharmaceutical Sector Inquiry of the European Union DG Competition identified evergreening as one of the tactics used by originator companies to delay the entry of competitors in the market. President Trump talks about the need to increase competition of generic and biosimilars so we believe that trade agreements should not broaden the scope of patentability beyond the terms set in the TRIPS Agreement, which already provides strong patentability standards. The broader the scope, the harder it is to bring competition to the market.

## II. The USMCA is putting at risk the sustainability of the generic/biosimilar industry and the savings it generates in the U.S.

The USMCA has sided with the originator pharmaceutical industry by granting broader and longer monopolies, which would delay the entry of generic and biosimilar drugs. Furthermore, in a number of instances the language in the USMCA may in fact change U.S. law thus further restricting access to affordable drugs including in the United States.

These types of provisions put at risk the sustainability

of the generic and biosimilar industry as they raise new barriers to entry to its products, delay the launch of products, potentially increase litigation expenses and negatively impact the bottom line of generic/biosimilar companies.

In order for the generic/biosimilar industry to continue providing the savings it currently does in the United States (generics generated $5bn savings every week in 2016[16] and a total of $265 billion in savings in 2017[17]) these companies must be able to sell in foreign markets. Raising the levels of intellectual property throughout the world simply puts the sustainability of the generic/biosimilar industry at risk.

## III. The USMCA must be changed to strike a balance that promotes innovation and access to medicines while maximizing U.S. exports

The USMCA clearly sides with the originator industry at the expense of consumers, payers and the generic/biosimilar industry. Before the agreement is ratified by the U.S. Congress, it should be modified to ensure balanced provisions that benefit both originator and generic/biosimilar companies and maximize exports. The most efficient way to do so is to adopt the intellectual property template for pharmaceuticals set in the New Trade Policy plus some additional provisions that would ensure the expedited launch of generic and biosimilar products.

Some of those are:

***a. Incentives:*** Trade agreements invariably provide incentives to foster Research and Development through the granting of patents and exclusivity protection but, with the exception of the New Trade Policy, have omitted the granting of incentives to challenge the validity or enforceability of patents to secure early market entry of more affordable generic drugs. As explained by the FDA, in the U.S., the "[t]he statute provides an incentive and a reward to generic drug applicants that expose themselves to the risk of patent litigation. It does so by granting a 180-day period of exclusivity vis-à-vis certain other ANDA applicants to the applicant that is first to file a substantially complete ANDA containing a paragraph IV certification to a listed patent."[18] That means that the exclusivity is granted to the first generic applicant that certifies that a patent listed in the Orange Book is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. In the case of biosimilars, the Biologics Price Competition and Innovation Act (BPCIA) awards a year of exclusivity to the first biosimilar applicant to demonstrate interchangeability.[19] Such incentives are a critical element to ensure that only true innovation is rewarded with such monopolies, thus preventing the waste of resources.

In order to strike a balance between fostering innovation and competition, the USMCA must include incentives that reward generic/biosimilar applicants to challenge the validity and enforceability of patents to ensure competition that lowers prices and therefore fosters patients' access to medicines and the generation of savings for payers and strained health care budgets.

***b. Disclosure of the best mode in patent applications:*** As explained by the U.S. Patent and Trademarks Office, "[t]he best mode requirement is a safeguard against the desire on the part of some people to obtain patent protection without making a full disclosure as required by the statute. The requirement does not permit inventors to disclose only what they know to be their second-best embodiment, while retaining the best for themselves."[20]

The disclosure of the best mode is particularly important for the development of complex biosimilar drugs. Despite its significance and the fact that it is part of U.S. law, the USMCA has failed to require the disclosure of the best mode to reproduce an invention in patent applications. This should be added to this and future trade agreements entered into by the U.S.

***c. Penalties for the misuse of patent rights:*** Trade agreements have included detailed sections aimed at ensuring the effective enforcement of intellectual property rights, but only a broad reference, if any at all, to the ability of Parties to adopt measures necessary to prevent anti-competitive practices that may result from the misuse or abuse of the intellectual property rights. i.e. trade agreements have failed to include mandatory language to address the misuse or abuse of IP by right holders to block or delay competition. In order to have balanced agreements that foster innovation, the USMCA should include a provision imposing similar penalties to those that infringe an intellectual property right as to those that misuse them to prevent or delay competition.

## Conclusion

The USMCA clearly sides with the originator pharmaceutical industry at the expense of generic/biosimilar companies and patients' access to more affordable drugs. The terms set in the intellectual property chapter would delay the entry of competition in the pharmaceutical market thus hindering access to more affordable medicines and putting at risk the sustainability of the generic/biosimilar industry which would face new barriers to entry to the markets of the Parties involved. Furthermore, the USMCA includes several provisions that could potentially change U.S. law further hindering the generic/biosimilar industry, as well as consumers and payers whose access to more affordable drugs may be delayed and/or blocked. This requires that the agreement be amended and the easiest way to do so would be through the adoption of the terms for the protection of intellectual property rights set in the New Trade Policy or May 10th Agreement which, while being "TRIPS Plus", reflected a more balanced compromise that garnered bipartisan support. In addition, the USMCA should also include other provisions to ensure the expedited launch of competition such as incentives to challenge the validity or enforceability of patents, the disclosure of the best mode in patent applications and penal-

ties for those who misuse IP rights to prevent competition.

Given that the USMCA will also set a precedent for future trade agreements it is essential that it be amended to strike a balance that fosters both innovation and competition, thus ensuring patients expedited access to more affordable drugs, as well as benefiting both originator and generic/biosimilar companies and maximizing U.S. pharmaceutical exports.

**Endnotes:**

[1] Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy", October 2003.

[2] Remarks from FDA Commissioner Scott Gottlieb, M.D. as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilar Action Plan, July 18, 2018.

[3] Commissioner Scott Gottlieb, "Capturing the Benefits of Competition for Patients", Speech at America's Health Insurance Plans (AHIP) National Health Policy Conference, March 7, 2018.

[4] In an October 1, 2018 call to brief reporters on the conclusion of the negotiations with Mexico and Canada, a senior U.S. official said: "If you just look on sort of the objective facts ... by and large, the marketing exclusivity period for biologic drugs, in TPP, it was five years, with some protections for three additional years. Here it's going to be a flat 10, which is a great thing for our pharmaceutical innovators." "Quoted: Senior administration officials on the USMCA", Inside U.S. Trade's Daily Report, October 2, 2018. (https://insidetrade.com/trade/quoted-senior-administration-officials-usmca)

[5] Federal Trade Commission, Emerging Health Care Issues: Follow-on Biologic Drug Competition, June 2009.

[6] See, for example: - S.3411 - Affordable Medications Act (https://www.congress.gov/bill/115th-congress/senate-bill/3411/actions?q=%7B%22search%22%3A%5B%22biologic%22%2C%22biologic+and+seven+years%22%5D%7D&r=1) and H.R.1776 - Improving Access To Affordable Prescription Drugs Act (

https://www.congress.gov/bill/115th-congress/house-bill/1776/text)

[7] Remarks from FDA Commissioner Scott Gottlieb, M.D. as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilar Action Plan, July 18, 2018.

[8] Information obtained on April 9, 2019.

[9] Federal Trade Commission, "Emerging Health Care Issues: Follow-on Biologic Drug Competition", June 2009.

[10] Other countries such as Chile and Malaysia have adopted grace periods in their domestic regulations.

[11] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), The "Deemed to be a License" Provision of the BPCI Act, Questions and Answers, Guidance for Industry, Draft Guidance, December 2018, page 4.

[12] Idem. "FDA interprets the term "protein" to mean any alpha amino acid polymer with a specific defined sequence that is greater than 40 amino acids in size. FDA interprets the term "chemically synthesized polypeptide" to mean any alpha amino acid polymer that (1) is made entirely by chemically synthesis and (2) is greater than 40 amino acids, but less than 100 amino acids in size. A "chemically synthesized polypeptide" is not a "biologic product" and will continue to be regulated as a drug under the FD&C Act unless the polypeptide otherwise meets the statutory definition of a "biologic product" (see Q.II.1 in the Biosimilars Q&A Draft Guidance).

[13] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), The "Deemed to be a License" Provision of the BPCI Act, Questions and Answers, Guidance for Industry, Draft Guidance, December 2018, page 3.

[14] Commissioner Scott Gottlieb, Remarks to the FDA CMS Summit, Washington, DC, December 11, 2018.

[15] As explained in a report of the Congressional Research Service, "unlike the Hatch-Waxman Act, the BPCIA does not tightly link FDA approval with patent rights. Brand-name firms must wholly rely upon the judiciary to stay the release of follow-on biologics into the marketplace. See: John R. Thomas, "Follow-On Biologics: The Law and Intellectual Property Issues", Congressional Research Service, January 15, 2014.

[16] Association for Accessible Medicines, "2017 - Generic Drug Access & Savings in the U.S.", 2017 (https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf)

[17] Association for Accessible Medicines, "2018 - Generic Drug Access & Savings in the U.S. Access in Jeopardy", 2018 (https://accessiblemeds.org/sites/default/files/aam_2018_generic_drug_savings_and_access_report.pdf).

[18] FDA, "Guidance for Industry 180-Day Exclusivity: Questions and Answers", Draft Guidance, January 2017.

[19] 42 U.S.C. §262(k)(6).

[20] US Patent and Trademark Office, "Manual of Patent Examination Procedure", Chapter 2100, Section 2165.

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