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The USMCA must be amended to ensure access to affordable drugs in Mexico

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One of the core campaign promises of President Manuel López Obrador (AMLO) was that he would significantly improve health care for the Mexican people and specifically increase access to affordable medicines.[1] Indeed, AMLO promised that his Administration would expand the right of consumers to have access to all medicines independently of whether they are included in the national formulary (Cuadro Básico de Medicamentos). Moreover, he announced that his Administration would start with eight states gradually incorporating all the others within a 2-year term.[2]

However, despite President López Obrador's good intentions if the United States-Mexico-Canada Agreement (USMCA) is approved as it is he is unlikely to achieve his objectives. This is because the intellectual property rights (IPR) chapter grants longer and broader monopolies to originator pharmaceutical companies than those currently in force in Mexico at the expense of consumers and

Abstract

The intellectual property rights (IPRs) chapter of the U.S.-Mexico-Canada-Agreement (USMCA) grants longer and broader monopolies to originator pharmaceutical companies than those currently in force in Mexico, at the expense of patients and taxpayers. Among other things, Mexico would be required to provide patent term extensions both for delays in the granting of patents and for those incurred in the regulatory approval process, broader and longer exclusivity periods, including for expensive biologic drugs, as well as to adopt broader patentability standards, for example by requiring the granting of patents for new uses. Mexico is, without doubt, the country in the USMCA that will be most negatively impacted, but if the Democratic Members of the US House of Representatives are able to renegotiate some of these provisions to restore some balance between the need to foster innovation and competition, the Administration of President López Obrador and the Mexican Congress can still make a difference.

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Le chapitre sur les droits de propriété intellectuelle de l'Accord États-Unis-Mexique-Canada *(AEUMC) étend la durée et la portée des droits de monopole accordés aux sociétés pharmaceutiques innovantes par rapport à ceux actuellement en vigueur au Mexique, au détriment des patients et des contribuables. Dans le cadre de l'accord, le Mexique sera tenu, entre autres choses, d'autoriser des ajustements de la durée de protection des brevets en cas de délais dans le processus de délivrance ou d'approbation réglementaire, d'élargir les droits d'exclusivité commerciale et d'en prolonger la durée, y compris pour les produits biologiques coûteux, et d'adopter des normes de brevetabilité plus élevées, en exigeant par exemple la délivrance de brevets pour les utilisations nouvelles de substance connues. Le Mexique est sans aucun doute parmi les trois pays signataires celui pour lequel l'application de l'Accord aura les conséquences les plus négatives. Si certaines de ses dispositions sont susceptibles d'être renégociées sous l'influence des membres démocrates de la Chambre des représentants des États-Unis afin de rétablir un semblant d'équilibre entre la nécessité d'encourager l'innovation et le besoin de favoriser la libre concurrence, l'administration du Président López Obrador et le Congrès mexicain ont un rôle déterminant à jouer pour changer la donne.*

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El capítulo del Tratado entre México, los Estados Unidos y el Canadá (T-MEC) dedicado a los derechos de propiedad intelectual (DPI) otorga monopolios más prolongados y amplios a las empresas de medicamentos originales que los que están actualmente en vigor en México, a costa de los pacientes y los contribuyentes. Entre otras cosas, México tendría que conceder a las ampliaciones de la vigencia de las patentes períodos de exclusividad más amplios y prolongados, también para los medicamentos biológicos costosos, tanto por las demoras en la concesión de patentes como para aquellas que se encuentren en el proceso reglamentario de aprobación, y ampliar las normas de patentabilidad, por ejemplo, exigiendo la concesión de patentes para nuevos usos. México es, sin lugar a dudas, el país del T-MEC que se verá más perjudicado, pero si los miembros del Partido Demócrata de la Cámara de Representantes de los Estados Unidos pueden renegociar algunas de estas disposiciones para restablecer cierto equilibrio entre la necesidad de fomentar la innovación y la competencia, el Gobierno del presidente López Obrador y el Congreso de México todavía pueden cambiar la situación.

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taxpayers. Mexico is without doubt the country that will be most negatively impacted due to these provisions. The López Obrador Administration has two options: a) to renegotiate some of the provisions related to medicines; or b) to level with the Mexican people by recognizing that it will not be able to ensure more access to affordable drugs as a result of what the Peña Nieto Administration agreed to in the USMCA, and in fact, Mexican patients will have an even harder time to keep up with the current levels of access as a result of this trade negotiation.

Following is a review of some of the key intellectual property provisions related to pharmaceuticals in the USMCA and how they would be affecting access to medicines in Mexico. While intellectual property issues are pretty technical, it is easy to understand that extending monopolies will increase the market dominance of right holders and lead to higher drug prices, which is exactly what the USMCA does. Furthermore, by granting longer monopolies the USMCA will further compromise the sustainability of the generic/biosimilar industry in the three countries, including Mexico.

1. Patent Term Extensions

Consistent with the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) Mexican law does not currently provide patent term extensions. Indeed, the TRIPS Agreement established a 20-year patent term, which is even longer than what the United States law had at the time, but no patent term extensions. This would change under the USMCA and the cost would not be insignificant.

While we are not aware of an economic analysis on the potential impact of these provisions in Mexico, a recent Canadian government report on the likely cost of extending patent terms in Canada as a result of another trade agreement, the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union, may provide an indication of the costs of these extensions. As in the case of Mexico, Canada did not grant extensions so it had to change existing laws as a result of the implementation of CETA which requires Parties to provide up to two years of patent term extensions for delays incurred in the regulatory office. The Canadian Government concluded that the federal government would be paying about ***$270 million dollars extra pre year*** to originator pharmaceutical companies.[3] While this number is concerning enough, the cost for Mexico could be proportionally much higher due to four reasons:

a) The USMCA would not grant patent term extensions solely for delays incurred in the regulatory office but also for delays in the patent office so the impact would be a lot higher (Article 20.44).

b) Patent term extensions granted for delays in the regulatory office are not clearly limited to a maximum of 2 years as it is the case for CETA. Indeed, the USMCA could grant longer patent term extensions and given the power of the originator pharmaceutical industry this is an issue of real concern.

c) The USMCA does not even ensure that the conditions and limitations established under U.S. law would be, at a minimum, reflected in the implementation of this provision in the countries involved, thus leaving patients in a vulnerable position. This provision is not only TRIPS Plus but even U.S. Plus. While Canada may be more likely to maintain the limits set in CETA it is not clear whether Mexico would do the same.

d) While based on 2017 numbers Canada has about 36.6 million people, Mexico has a much larger population of 129 million, so the likely impact of this single provision is truly sobering.[4] If we do a back of the envelope calculation to have a sense of the potential cost of patent term extensions under the CETA conditions (up to 2 years and only for delays in the regulatory office) for 129 million people instead of for 36.6, the cost would be $949.04 million dollars more per year. Given that the USMCA would also be granting patent term extensions for delays in the patent office and that the 2-year limit may not be implemented in Mexico if Members of Congress fail to do so, the cost of this single provision could be much higher. Where would Mexico get the additional resources to pay for the cost of this provision?

2. Patentable Subject Matter

Under Mexican law patents cannot be granted for new uses. This is fully consistent with the standards set in the TRIPS Agreement. Unfortunately, USMCA Article 20.36 is also TRIPS Plus as it would grant patents to new uses so many drugs that today are not protected by a patent could have a new patent or drugs with a patent in force could have longer patent terms beyond 20 years as companies may be able to stack up multiple patents over the same drug granted to new uses over time.

Again this provision will leave Mexican patients at a much more vulnerable position and will be very costly for the government, private healthcare insurance and consumers.

3. Exclusivity for Small Molecule Drugs

Mexico currently grants 5 years of exclusivity to new chemical entities. The USMCA provision on this matter raises various concerns. First, Article 20.48 states that this protection would be granted to undisclosed test or other data "concerning" the safety and efficacy of a product. Instead of "concerning" the agreement should clarify that the protection is granted to the data that is "necessary or essential" to demonstrate the safety and efficacy of a drug. By including the word "concerning", the agreement could lead to the granting of more exclusivities for data that could be related but not "necessary" or "required" to show the safety and efficacy of a drug.

Second, by precluding the granting of marketing approval to "same or similar" products to the one that is under exclusivity it could delay the approval of an entire therapeutic family of drugs that may be deemed to be

"similar". This is clearly not only TRIPS Plus but even U.S. Plus and could be very negative for Mexican patients and drug expenditures.

Third, while the language seems to provide the same period of exclusivity (monopoly) for the three countries, Mexico may face longer monopolies as a result of this provision. This is because Article 20.48:1(a) refers to an exclusivity of "at least 5 years from the date of marketing approval of the new pharmaceutical product in the territory of the Party." Companies normally launch their products in the most profitable markets first such as the United States, but may take years before seeking marketing approvals in other markets. If for whatever reason a company considers that Mexico is not a priority market, it may decide to enter the market at a much later date which would mean that for the Mexican people the monopoly granted under this provision would be 5 years as set in the USMCA plus whatever delay the company incurs in seeking marketing approval in Mexico. For instance, if a company decided to file for marketing approval for a drug 6 years after obtaining marketing approval in the U.S., the actual period of the exclusivity for the Mexican consumers would be 6 years of delay plus 5 years of the actual provision. Clearly this provision puts the Mexican people at a much vulnerable position *vis a vis* consumers in the United States.

Fourth, the USMCA would grant 3 additional years of exclusivity to new clinical "information". Mexico does not grant this type of additional exclusivity. This provision is not only TRIPS Plus but also U.S. Plus as it is setting a much lower bar compared to new clinical "investigation" as set under U.S. law. Consumers both in Mexico and the United States could be deeply affected by this provision.

4. Exclusivity for Biologic Drugs

Mexican law does not currently provide an exclusivity period for biologic drugs. As a result of the USMCA, these drugs, the most expensive in the market, would also be granted 10 years of exclusivity on top of 20-year patent term and patent term extensions.

Biologic drugs are becoming increasingly critical. Many of them could make a difference between life and death as they are used for the treatment of various diseases and conditions such as cancer, diabetes, multiple sclerosis and auto-immune and blood disorders, among many others.

It is important to remember that in the United States a report on follow-on biologics released by the Federal Trade Commission concluded that no exclusivity is necessary for biologics given that the original biologic drugs will keep most of the market price and share even after patent expiration.

While in the United States these products are granted 12 years of exclusivity, President Obama's last 6 budget proposals tried to lower the number of years to seven as a generous compromise, and there are currently two bills in Congress that similarly seek to reduce the period to 7 years. The real objective of including such a long period of exclusivity in the USMCA is to lock the United States market, the largest in the world, as trade agreements are considered international law, which supersedes national law. While Mexico is also an important pharmaceutical market given in part to its population size, it is also collateral damage on this particular matter.

5. Linkage

The so-called patent linkage, which ties the granting of marketing approval by regulatory agencies to the status of a patent, is one of the most regressive provisions in terms of access to medicines given that it tilts the market in favor of originator companies at the expense of generics. Moreover, it has often been misused by the originator industry to delay and/or block competition in the pharmaceutical market, i.e. to extend their monopolies to secure higher revenues.

Linkage is clearly a TRIPS Plus provision. In Mexico, it is restricted to "substance or active ingredients" as set in a Decree issued on September 19, 2003.

The USMCA provides two options: 1) no mandatory linkage, but requiring countries to provide a fair court system to ensure the timely resolution of patent disputes; or 2) mandatory linkage. Option 1 follows the New Trade Policy or May 10th Agreement which was the renegotiation of the Agreements the U.S. negotiated with Colombia, Peru and Panama under which linkage was no longer mandatory. However, this provision includes a notification requirement that goes beyond the notification required under U.S. law where notification is required only in certain circumstances under the Hatch-Waxman Act and only for small molecule drugs (it does not extend to biologics). In general it applies only to *product and methods of use patents listed in FDA's Orange Book*. Furthermore, under U.S. law it only applies for patents that were listed in the Orange Book *before* the Abbreviated New Drug Application (ANDA) was submitted. Therefore it would be important to change the language of the first option provided under the USMCA to ensure at least that it does not go beyond U.S. law.

The second option requiring the Parties to provide broad mandatory patent linkage goes even beyond U.S. law as it would extend linkage to all types of patents for small molecule drugs and even to biologics, where it clearly does not apply today. Indeed, while the United States has mandatory linkage, it is limited to three types of patents (for patents that claim the drug substance (active ingredient), drug product (formulation and composition), or method(s) of use) and only for small molecule drugs, it does not extend to biologics. The second option of the USMCA would provide the broadest possible linkage. While it should be acceptable for Mexico to implement the first option (modifying the section related to the notification requirement), if it were to implement the second option it would be devastating for the domes-

tic industry and for the possibility of having a thriving biosimilar/biocomparable industry.

While the USMCA has a number of mandatory provisions that favor the originator pharmaceutical industry at the expense of generic/biosimilar companies (and consumers), the agreement fails to provide strong pro-access provisions. In fact, the only one that has been included has been watered down thus significantly limiting its potential impact.

1. Bolar

The Bolar or regulatory review exception allows companies to develop, test and file for marketing approval at the regulatory office during the period of the patent. Without this exception to the rights of the patent owner such actions could be considered to be an infringement of patent rights. This provision is critical to ensure access to affordable drugs as it allows the launch of generic/biosimilar drugs immediately after the expiration of patents related to the original drug. Without a Bolar provision, there could be a de facto patent extension of 2-3 years for small molecule drugs and up to 10 years for biologic drugs. Therefore the importance of this provision is very clear.

The USMCA deleted a footnote originally included in the IP chapter of the Trans Pacific Partnership (TPP) that made it clear that this provision should also apply to the import and export of drugs. This deletion could be very detrimental to Mexican consumers who may be tied to the originator product if a generic drug is not being developed in the market, as well as to the Mexican industry and the jobs if generates if generic/biosimilar companies are further delayed from exporting as a result of this provision since they could be prevented from seeking the registration of a follow-on product in a foreign market where the relevant patent has already expired. It could very much be the case that a patent expires first in the U.S. where the company sought to patent it first, and a company in Mexico could be considered to be infringing the patent in Mexico if it seeks registration in the U.S. where competition is no longer restricted by the existence of a patent. The economic consequences of the elimination of this footnote for Mexico (as well as the U.S. and Canada) is highly negative, so the footnote should be reincorporated.

2. Incentives

Another critical element to ensure competition and lower drug prices lies in providing incentives for generic and biosimilar companies to challenge the validity and/or applicability of patents. It has been well documented that the originator pharmaceutical industry resorts to multiple tactics to delay or deter competition[5], such as evergreening and patent thickets. In the U.S., for example, the Hatch-Waxman Act grants a period of 180 days of exclusivity to the first generic applicant who challenges a listed patent by filing a Paragraph IV certification and running the risk of having to defend a patent infringement suit.[6] This has been a critical provision in the United States in order for companies to be able to legally challenge patents to expedite the launch of generic products.

Furthermore, U.S. law also provides an exclusivity period to the first interchangeable biologic drug.

Interestingly enough, the USMCA does not provide any of these pro-competition and pro-consumer incentives, so they should be added to the agreement.

3. Disclosure of the Best Mode

The disclosure of the best mode to reproduce an invention in patent applications is another important provision to ensure competition of generic/biosimilar drugs. It is the trade off for the monopoly granted by the patent. This provision is consistent with the TRIPS Agreement and U.S. law, which requires patent applicants to provide the best mode but, interestingly, it is not included in the USMCA. We believe that the USMCA should incorporate a mandatory requirement and if patent owners mislead the government they should be penalized with the cancellation/revocation of the patent.

4. Penalties for those that Misuse IP Rights

Finally, the USMCA provides strong penalties for those that infringe intellectual property provisions but neglects imposing any type of penalties to originator pharmaceutical companies that game the system to extend their monopoly rights through multiple strategies. In order to put a stop to these abuses or misuses, companies that engage in these types of behavior should be penalized to enforce corporate responsibility.

In conclusion, after analyzing the current laws and regulations in Mexico *vis a vis* the USMCA there is no doubt that Mexico will be the country most negatively impacted in term of access to medicines. Bearing in mind the cost that Canada, with a much smaller population, will have to bear for up to 2 years of patent term extensions solely for delays in the regulatory office (not in the patent office) and that the USMCA includes a number of additional provisions that will further delay competition, it is clear that for Mexico the cost of the USMCA would be devastating.

The Administration of President López Obrador can still make a difference and fulfill his campaign's promises of increasing access to medicines in Mexico. In the U.S., Democratic Members of the House of Representatives are working hard to renegotiate some of these provisions to restore some balance between the need to foster innovation and competition, for example by reintroducing some of the terms set in the May 10th Agreement on IP and access to medicines. The Mexican government should support and join those efforts. Otherwise, the government's goal of ensuring access to medicines for all Mexicans would become unattainable.

Endnotes:

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[3] Canada, Office of the Parliamentary Budget Office, "Patent Term Restoration and the Cost of Pharmaceuticals", April 26, 2018.

[4] UN, World Population Prospects. 2017 Revision, Key Findings and Advance Tables (https://population.un.org/wpp/Publications/).

[5] European Commission, Competition DG, "Pharmaceutical Sector Inquiry. Final Report", July 8, 2009.

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