

United States: An Obsolete Trade Practice Undermines Access to the Most Expensive Drugs at More Affordable Prices

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Abstract

Access to affordable drugs is a top policy priority for the United States with real bipartisan support but it increasingly seems to be an unreachable goal, in part, due to conflicting government policies. While the Administration's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs highlighted the importance of competition to ensure lower drug prices, U.S. trade policy in general, and the Special 301 Annual Review in particular, do exactly the opposite: broaden and lengthen the monopolies granted to pharmaceutical companies thus delaying or deterring the launch of generic and biosimilar drugs and with that, the chances of lowering drug prices. The pharmaceutical industry has changed a great deal in the past 30 years, among other things by developing complex biotechnology drugs that while critical for the treatment of illnesses such as cancer, are out of reach for many patients. While some parts of the government are trying to increase access to medicines through competition provided by generic and biosimilar drugs, their efforts are being undermined by a trade policy that was defined 30 years ago. It is time to adjust U.S. trade policy to the realities of 2020 and stop acting as if it was still 1989.

El acceso a medicamentos asequibles es una de las máximas prioridades de política de los Estados Unidos de América y cuenta con un auténtico apoyo bipartidista, aunque parece ser un objetivo cada vez más inalcanzable, en parte, debido a políticas gubernamentales contrapuestas. Aunque en el plan de la Administración para bajar el precio de los medicamentos y reducir los gastos por cuenta propia se destaca la importancia de la competencia a fin de garantizar una bajada en el precio de los medicamentos, la política comercial estadounidense en general, y el informe Especial 301 anual en particular, hacen exactamente lo contrario: ampliar y alargar los monopolios concedidos a las empresas farmacéuticas, de este modo se retrasa o impide el lanzamiento de medicamentos genéricos y biosimilares y, con ello, la oportunidad de bajar el precio de los medicamentos. La industria farmacéutica ha cambiado mucho en los últimos 30 años, por ejemplo, al desarrollar complejos medicamentos biotecnológicos que, pese a ser fundamentales para el tratamiento de enfermedades como el cáncer, están fuera del alcance de numerosos pacientes. Aunque algunas partes del Gobierno están tratando de aumentar el acceso a los medicamentos a través de la competencia que ofrecen los medicamentos genéricos y biosimilares, sus esfuerzos están siendo socavados por una política comercial que se definió hace 30 años. Es el momento de adaptar la política comercial de los EE.UU. a la realidad de 2020 y dejar de actuar como si aún fuera 1989.

L'accès à des médicaments abordables est une priorité politique majeure pour les États-Unis qui bénéficient du soutien à la fois des démocrates et des républicains, mais il apparaît de plus en plus comme un objectif inatteignable, en partie en raison de politiques gouvernementales contradictoires. Si le plan d'action de l'administration visant à faire baisser le prix des médicaments et réduire les frais à la charge des patients soulignait la nécessité d'introduire davantage de concurrence afin de faire baisser le prix des médicaments, la politique commerciale mise en œuvre par les États-Unis et les recommandations formulées dans le rapport spécial annuel 301 visent, à l'inverse, à étendre et allonger la durée des monopoles accordés aux sociétés pharmaceutiques, contribuant ainsi à retarder ou à décourager le lancement de médicaments génériques et biosimilaires et partant, à réduire à néant les chances de voir le prix des médicaments baisser. L'industrie pharmaceutique a beaucoup changé au cours des 30 dernières années grâce au développement, entre autres, de médicaments biotechnologiques complexes qui, bien qu'ils soient essentiels pour le traitement de maladies telles que le cancer, ont un coût prohibitif pour de nombreux patients. Les efforts déployés par une partie du gouvernement pour lutter contre cet état de fait et instaurer une plus grande concurrence en encourageant la fabrication de médicaments génériques et biosimilaires sont sapés par une politique commerciale définie il y a près de 30 ans. Le moment est venu d'adapter cette politique aux réalités de 2020 et de cesser d'agir comme si nous étions toujours en 1989.

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Access to affordable drugs has become one of the top policy priorities in the United States with real bipartisan support. Indeed, paying for the drugs that patients need has become an increasingly unreachable goal even in the richest country in the world, the United States. The high priority of this challenge was reflected in President Trump's State of the Union Address where he specifically pointed out the efforts of the Federal Food and Drug Administration (FDA) to approve "a record number of affordable generic drugs" in order to increase competition and lower drug prices. The Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs also quotes President Trump as saying: "One of my greatest priorities is to reduce the price of prescription drugs." When referring to accelerating FDA approval of generic drugs, the Blueprint states that "[s]tudies show that greater generic competition is associated with lower prices." Indeed, competition is one of the most fundamental and important principles of free market economies and a critical tool to achieve affordable prices.

Nevertheless, U.S. trade policy has been slow to adjust to emerging government priorities and the Special 301 Report of the Office of the U.S. Trade Representative (USTR) is very much an example of this. Indeed, while President Trump, the Department of Health and Human Services (HHS) and FDA have made deliberate efforts to increase competition in the US pharmaceutical market, some of the agreements negotiated by the USTR and the Special 301 Reports focus on provisions that would do exactly the opposite: broaden and lengthen the monopolies granted to pharmaceutical companies thus delaying or deterring the launch of generic and biosimilar drugs and with that, the chances of lowering drug prices.

The Office of the USTR released its first Special 301 Report in 1989, seeking to raise intellectual property standards throughout the world. This process started only three years into the negotiation of the Uruguay Round of GATT (1986-1994) which led to the adoption of the first global trade agreement that included a chapter of intellectual property rights (Agreement on Trade Related Aspects of Intellectual Property) in December 1994. The TRIPS Agreement, which set a global standard of intellectual property protection for all members of the World Trade Organization (WTO), started being implemented soon after. By now, all WTO members, with the exception of least developed countries that were granted a longer transition period, have fully implemented the terms of the Agreement and in many cases have gone even beyond it. In the case of pharmaceuticals, this means that these countries have been contributing for a number of years to research and development costs by granting a 20-year patent term (from the date of the filing of a patent) which is even longer than what the United States had at the time (17 years from the date of the granting of a patent).

While the Special 301 requires the USTR to identify "those foreign countries that deny adequate and effective protection of intellectual property (IP) rights", after 30 years of focusing solely on increasing IP protection, it seems that the goal has become a moving target based on the inaccurate assumption that more intellectual property is always better. It is now time for the USTR to pause, and shift its focus to adjust to the priorities of the U.S. government, the challenges of an increasingly government deficit, as well as the needs of U.S. consumers and both sides of the pharmaceutical industry, not just one.

Protecting intellectual property while ensuring access to affordable medications

While intellectual property protection is one of the ways to incentivize the research and development of new drugs, this cannot be looked at in a vacuum. Furthermore, such protection should not be an end in itself but a means to an end: to achieve innovation. Moreover, in order to be effective, IP policies that promote the development of new drugs must be balanced with other government policies such as competition policies. Within this context it is relevant to review what the Federal Trade Commission (FTC) states in a report entitled "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy":

"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

The balance between patent and competition policies is critical to ensure innovation. Patents and broader intellectual property rights must be looked at hand in hand with competition. Indeed, both are drivers of innovation.

While for some industries this can be a pretty straightforward exercise, in the case of the pharmaceutical industry, this is a much more complex issue as this industry has two sides: a) the originator pharmaceutical industry, and b) the generic/biosimilar industry. As a result, in this case it is even more critical to strike the right balance between intellectual property laws and regulations and competition policies so that both can thrive to ensure that patients have access to new drugs as well as to more affordable generic/biosimilars following the expiration of IP rights.

Future trade policies need to reflect the changes in the U.S. pharmaceutical industry

Again, it is important to put the Special 301 in the historical context in which it was conceived. As stated above, the first Report was released in 1989, only five years after the adoption of the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) that set new critical rules for the development of the generic pharmaceutical industry. In 1984 generic utilization rates were about 19%² and following the adoption of the Hatch-

Waxman Act the generic industry was fully focused on growing domestically and so it did. At the time, U.S. trade policy in the area of pharmaceuticals was defined by the originator pharmaceutical industry that was already a global player. The generic industry, instead, was solely focused on the domestic market.

Today, generics fill 90% of prescriptions in the U.S. but represent only 22% of drug spending thus contributing to \$292.6 billion in savings in 2018.³ Indeed, the generic industry has played a critical role to ensure access to more affordable drugs in the United States.

30 years have not gone by in vain for this industry that has undoubtedly been part of the solution to address the drug affordability challenges faced both in the United States and abroad. Indeed, this industry has reached a point of saturation in the U.S. and the only way to continue to grow is by expanding globally and into new therapeutic areas. As a result, several U.S. generic companies have become global by acquiring companies around the world. This was a bold move for an industry that needed to adjust to a global market with growing opportunities.

As mentioned above, it is important to understand that the U.S. pharmaceutical industry has two sides: a) originator and b) generic and now biosimilar as well. As the USTR continues to implement U.S. trade policies it is important to reassess whether the actions of 30 years ago are still needed, at least in the area of pharmaceuticals, how these policies such as the Special 301 impact both sides of the industry and whether they are a helpful tool or an obstacle to address current government priorities such as increasing competition to achieve the ultimate goal: to lower high drug prices.

Today we face a new situation: most countries in the world provide intellectual property protection consistent with the TRIPS Agreement so the goal that led to the first Special 301 reports has already been achieved. Moreover, the WTO now provides a system to settle disputes so countries can resort to its dispute settlement procedures if they consider that another member government is not complying with its obligations under the TRIPS Agreement. Most of the elements included in the most recent Reports have a direct correlation with submissions made by the originator pharmaceutical industry that do not respond to objective criteria to identify those that are failing to comply with their IP commitments either set in the TRIPS Agreement or in other free trade agreements, but reflect a "wish-list" of the originator industry aimed at broadening and lengthening monopoly rights.

Furthermore, as mentioned above, the U.S. generic industry has become a global player and further increasing the levels of intellectual property protection in other markets would result in the adoption of new non-tariff barriers to entry for the generic and biosimilar industry. Creating new barriers to entry for the U.S. generic and biosimilar industry will put at risk the sus-

tainability of this critical industry in the United States impacting its ability to provide safe, effective and more affordable drugs and continue grow, thus generating jobs and exports.

Ensuring certainty for the U.S. generic/biosimilar industry

As stated above, in the last decade the U.S. generic industry has become a global player, in part through the acquisition of companies around the world. This required a global business plan, a great deal of investment and certainty about market conditions to ensure that the business plan can be achievable. Unfortunately, this becomes much harder if, whether through the negotiation of trade agreements or the Special 301 U.S. trade policy seeks to change the laws or regulations of other countries thus delaying the launch of its products. This clearly has a negative impact on exports, revenues and the profits of these companies.

Thus, U.S. trade policy should recognize that the situation that originated the first Special 301 Report in 1989 has changed as today intellectual property rights are being protected throughout the world. Moreover, U.S. trade policy must be balanced, supporting both sides of a global pharmaceutical industry by recognizing that both need access to global markets.

U.S. trade policy should be adjusted to the future global market: biologics

It is public knowledge that during the negotiation of the Trans-Pacific Partnership (TPP) and the United States-Mexico-Canada Agreement (USMCA) one of the conflictive issues was a new provision regarding the exclusivity for biologics, which would have granted an additional monopoly to biologic products besides the 20-year patent protection and patent term extensions. Biologics are complex drugs originated from living organisms for the treatment of critical illnesses such as cancer, genetic disorders and anti-immune disorders, among others. These are also some of the most expensive drugs in the market with prices often above \$100,000 per patient, per year and in one case, over \$2 million dollars for a drug that could save the life of a baby.⁴ The cost of one of these drugs is often several times the annual salary of most Americans. There is no health insurance, government program such as Medicare and Medicaid and much less consumers that can absorb such prices. Indeed, numbers provided by former FDA Commissioner Scott Gottlieb, offer a very sobering perspective about these drugs and the desperate need to develop a thriving biosimilar industry that can play a critical role in ensuring accessibility to biologic drugs as the generic industry did in the area of small molecule drugs.

Indeed, according to former Commissioner Gottlieb "[w]hile less than 2 percent of Americans use biologics, they represent 40 percent of total spending on prescription drugs." Moreover, as more biologics are increasingly prescribed, "[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 drugs spending in

the coming years.⁵

That is the reason why there is such a bipartisan agreement on the need to generate more competition for these very expensive drugs. In other words, as more people need to consume these drugs the current system will simply become unsustainable.

Several areas of the government are already engaged in trying to increase competition for these drugs and ensure their uptake. For instance, the FDA approved a record number of 10 biosimilars in 2019 and CMS adopted new unique codes for these drugs. However, these efforts to increase competition in the biologic sector and secure the uptake of biosimilars are undermined by those trade policies pursued until recently that sought the adoption of very long exclusivity periods for biologic drugs that would tie the hands of Members of the U.S. Congress to deal effectively with this very serious situation.

Patents sufficiently protect biologics

It is important to stress that the outcome of the US-MCA with regards to biologics is fully consistent with the conclusions of the FTC's report on Follow-on Biologics as to the fact that no additional data or market exclusivity beyond that provided by patents is necessary for these drugs given that originator drugs are likely to retain 70-90 percent of their market share and prices even after patent expiration.⁶ Furthermore, the FTC also concluded that there is no evidence about the lack of patentability of new biologic products. It is important to keep in mind that many of these drugs have dozens or even hundreds of patents per drug.⁷ Thus, patent protection is sufficient to provide enough incentives for the development of these drugs. This seems to be confirmed by a review of biosimilar drugs approved so far in the United States, where 26 biosimilars have been approved, but only 16 have been launched. While there are different reasons for the failure to launch some of these products it seems that in many cases biosimilars approved by FDA cannot be launched due to litigation initiated by originator companies or because they have reached a settlement agreement as a result of litigation.

Concerns over competition for these complex pharmaceuticals were expressed by Commissioner Gottlieb in the following terms:

"Competition is, for the most part, anemic."...

"It is anemic because litigation has delayed market access for biosimilar products that are, or shortly will be, available in markets outside the U.S. several years before they'll be available to patients here. These delays can come with enormous costs for patients and payors."⁸

Biosimilars need economies of scale and therefore access to global markets

In addition, it is important to understand that the investment required to develop a biosimilar product is much higher than that of a generic drug. Again, for-

mer Commissioner Gottlieb said that "[w]hile 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."⁹

Hence, in order to recover such a large investment biosimilar companies need to be able to sell globally to have economies of scale to be a viable industry. This has also been pointed out by Commissioner Gottlieb: "Finally, the FDA recognizes that creating efficient economies of scale for biosimilars requires a global market."¹⁰

Creating barriers to entry for the biosimilar industry in foreign markets will result in less competition in the U.S. biologics' market and growing healthcare expenditures

This means that in order for the industry to be able to develop biosimilar drugs for U.S. consumers, it will require access to foreign markets. Thus, if U.S. trade policy does not facilitate the sale of biosimilars increasingly needed worldwide and that only a few companies can provide but instead seeks the adoption of higher barriers to entry for U.S. biosimilars, it will end up hurting an industry that must play a critical role in providing more affordable products and impact its development and sustainability. Moreover, it would impact U.S. healthcare expenditures and the growing deficit.

As Former Commissioner Gottlieb stated with regards to biosimilars:

"But I'm worried that the market for these products still isn't established... That doesn't mean that the future doesn't hold a lot of promise for biosimilars. It just means that the future is uncertain. And the policy and regulatory decisions that we make today are going to have a lot to do with whether we realize the promise for this new category of products. Or if we see the opportunities we once envisioned go unrealized."

Conclusions

Thus, U.S. trade policy must adjust to respond to today's policy priorities keeping in mind that:

- More than 30 years after the release of the first Special 301 Report, when most countries of the world protect intellectual property rights through the implementation of the TRIPS Agreement and beyond, the report should not focus on continuing to ratchet-up the standards of IP protection but on ensuring that all countries provide adequate and effective protection in compliance with their international obligations.
- The Special 301 Report cannot be a reflection of the "wish-list" of one side of the pharmaceutical industry at the expense of the other, consumers and payors.
- In the past 30 years, the U.S. pharmaceutical industry has dramatically changed, and today the U.S. generic and biosimilar industry is global and needs access to foreign markets not only to continue to

grow, generate more exports and jobs in the U.S. but also to be able to provide new biosimilar drugs to U.S. citizens. Failure to have such access will put its sustainability at risk.

- U.S. trade policy must be consistent with other government priorities, which in the case of health, is clearly bipartisan: lowering drug prices.
- U.S. trade policy must support the efforts of other government agencies to achieve this important goal, not undermine them. Moreover, U.S. trade policy should not hinder other countries' efforts to foster generic and biosimilar competition by, among other things, availing themselves of the flexibilities provided under the TRIPS Agreement. The U.S. trade policy should respect all the terms of the TRIPS Agreement. The importance of respecting the TRIPS' flexibilities was reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health in which the U.S. is one of the signatories.
- U.S. trade policy, as reflected in the negotiation of trade agreements and/or in the Special 301 will impact the future of access to medicines for generations to come.

Endnotes:


¹ Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy",



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October 2003.

² GAO, "Drug Pricing: Research on Savings from Generic Drug Use", 2012.

³ AAM, "The Case for Competition 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report", 2019

⁴ Zolgensma, a gene therapy for the rare childhood disorder spinal muscular atrophy (SMA) costs \$2.125 million per patient. See: NPR, "At \$2.1 Million, New Gene Therapy Is The Most Expensive Drug Ever", May 24, 2019.

⁵ Scott Gottlieb, M.D., FDA Commissioner, Remarks as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilars Action Plan, July 18, 2018.

⁶ Federal Trade Commission Report, "Emerging Health Care Issues: Follow-on Biologic Drug Competition", page v, June 2009.

⁷ Statement from a bipartisan group of senators who launched effort to stop patent gaming & increase access to lower cost drugs: "Biologic manufacturers often seek to protect their products by using "patent thickets" which range from dozens to even hundreds of patents. Too often, companies design these thickets with the intent of blocking competition, and although some of the patents may be invalid or unenforceable, expensive patent litigation can deter competitors from offering consumers lower-cost alternatives." March 6, 2019. <https://www.kaine.senate.gov/press-releases/bipartisan-group-of-senators-launch-effort-to-stop-patent-gaming-and-increase-access-to-lower-cost-drugs>

⁸ Scott Gottlieb, M.D., FDA Commissioner, Remarks as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilars Action Plan, July 18, 2018.

⁹ Scott Gottlieb, M.D., FDA Commissioner, "Capturing the Benefits of Competition for Patients", Remarks as prepared for delivery at the America's Health Insurance Plans' (AHIP) National Health Policy Conference, March 7, 2018.

¹⁰ Scott Gottlieb, M.D., FDA Commissioner, and "Capturing the Benefits of Competition for Patients", Remarks as prepared for delivery at the America's Health Insurance Plans' (AHIP) National Health Policy Conference, March 7, 2018.

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