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Donald S. Clark
Federal Trade Commission
Office of the Secretary
600 Pennsylvania Ave, NW – Suite CC-5610 (Annex C)
Washington, DC 20580

Re: Hearings on Competition and Consumer Protection in the 21st Century.
Project Number P181201: The role of intellectual property and
competition policy in promoting innovation.

Dear Mr. Clark

I would like to congratulate the Federal Trade Commission for the forthcoming public hearings and for seeking comments in reference to “Competition and Consumer Protection in the 21st Century” including the role of intellectual property and competition policy in promoting innovation.

MFJ International is a small global consulting firm with a significant focus on increasing access to affordable medicines around the world. MFJ regularly works with generic/biosimilar companies, associations and governments to find ways to foster access to affordable medications, with a special emphasis on intellectual property and trade matters. However, this submission is not made on behalf of any client. Having worked on these issues for about 25 years, I would like to draw attention to the fact that trade negotiations are often the conduit for hampering competition to secure higher drug prices both in the United States and abroad, and leaving consumers unprotected.

I. Background

The FTC Report “To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy clearly states:

“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

Indeed, a certain level of protection is important to provide the necessary incentives for companies to develop new drugs but it is also equally important that competition through the launch of generic and biosimilar drugs also drive companies to innovate. In fact, longer monopolies undermine one of the most effective stimuli for innovation: competition.

Trade agreements have significantly evolved in the last 30 years. In the past, they were much simpler, focusing mostly on reducing tariffs. This was (and still is) a critical element as lowering tariffs enables the entry of more products into the market, increasing competition and reducing prices. This clearly benefits consumers. Trade agreements used to be a key tool to increase competition.

Things started to change in the area of pharmaceuticals with the Uruguay Round of GATT (General Agreement on Tariffs and Trade), which for the first time included an intellectual property chapter. This was a direct result of the lobbying of the powerful originator pharmaceutical industry. Ironically, the Uruguay Round started soon after the adoption of the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) in the U.S. At that time, the generic industry, which had a market share of only 19%, was solely focused on growing its business in the United States. By contrast, the originator pharmaceutical industry engaged the Office of the United States Trade Representative and defined U.S. trade policy with regards to pharmaceuticals. The inclusion of a chapter on intellectual property rights was a key milestone for the originator pharmaceutical industry. With it, new barriers to entry were established for generic and biosimilar companies.

President Trump and others have been addressing the problem of access to affordable drugs. The FTC clearly has an important role to ensure competition with regards to access to medicines, which can be challenging when the government grants companies legal monopolies either by issuing patents or exclusivity periods for data.

The problem of high drug prices in the United States is not new. In the early 1990s, under public pressure on high drug prices, the same lobbying group argued that prices were high due to the fact that other countries were not contributing to their fair share of research and development costs. The United States government supported the originator industry and included ambitious intellectual property provisions first in the North American Free Trade Agreement (NAFTA) and then in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS

¹ To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, A Report by the Federal Trade Commission, October 2003

Agreement) of the World Trade Organization. TRIPS requires Member States to grant a 20-year patent term from the date of filing of a patent which was even higher than what the United States had at the time (17 years from the date of the granting of a patent). This single provision forced a change in U.S. law at a high cost for U.S. consumers and the healthcare budget.²

Thus, the TRIPS Agreement delayed competition not only internationally in all Members of the WTO but also in the United States, the largest pharmaceutical market in the world. If the argument of the industry had been correct, i.e. that drug prices in the U.S. were high due to other countries' failure to contribute to R&D costs, the adoption of higher IP protection in the TRIPS Agreement should have resulted in lower drug prices in the U.S. However, this did not happen.

Today, we are living in very similar circumstances, with high drug prices that many Americans cannot afford and, once again, the originator pharmaceutical industry is arguing that the reason lies in the fact that other countries claiming that they are not contributing to their fair share of the costs of R&D. At the same time, the U.S. is also renegotiating NAFTA and once again, the USTR seems to be siding with the originator industry at the expense of consumers, the U.S. healthcare budget and the generic and biosimilar industry.

The FTC's mission is "[t]o prevent business practices that are anticompetitive or unfair to consumers; to enhance informed consumer choice and public understanding of the competitive process; and to accomplish this without unduly burdening legitimate business activity."³ Furthermore, the FTC identifies some of the mission challenges as "[p]romoting competition in health care and pharmaceutical industries, high technology sectors, and energy industries."⁴ It is with this in mind, that we congratulate the Commission for this effort to understand competition and consumer protection in the 21st century. Indeed, one thing the originator pharmaceutical industry learned is that it can maximize its profits if it manages to keep competition out of the market for longer periods of time and therefore it has sought to do so through a number of channels, one of them being trade negotiations. Unlike the laws of the land that are openly debated, trade negotiations are conducted in secrecy so very little is known until an agreement has been reached, and by then there is very little, if anything, that can be done. In fact, within the framework of the renegotiation of NAFTA, the USTR is currently negotiating with Mexico secret intellectual property provisions even though the outcome of such negotiations may have a significant impact on all U.S. consumers.

² Steven Schondelmeyer, "Economic Impact of GATT Patent Extension on Currently Marketed Drugs", PRIME Institute, University of Minnesota, March 1995.

³ Federal Trade Commission's (FTC). Mission, December 2017, which may be accessed at: https://www.ftc.gov/sites/default/files/documents/reports_annual/one-page-ftc-performance-snapshot/2012snapshotpar.pdf

⁴ FTC, *Idem*.

We believe that the FTC has a bigger role to play by being more involved in the determination of U.S. trade policies and negotiations to strike the proper balance between promoting innovation and competition in the pharmaceutical market.

This new type of trade agreement, therefore, creates serious non-tariff barriers to entry for competitors including the U.S. generic and biosimilar companies. While they include many provisions that deter or delay competition, this submission will focus only on two of them: biologic drugs and patent linkage.

II. Biologics

Biologic drugs are complex drugs made from living organisms. They are the most expensive in the market with prices that range from tens of thousands of dollars to over \$500,000 per patient per year.⁵ Needless to say, most patients cannot afford these drugs and their cost increasingly poses significant challenges to Medicare and Medicaid.

A sustainable healthcare system must therefore include not only incentives for the launch of biosimilar drugs but also prevent the gaming of the system to delay or deter the entry of competition. Biologic drugs are the future of the pharmaceutical market so the originator industry may seek to delay or prevent competition to enable it to continue to charge these extremely high prices. Failure to ensure competition after the expiration of patents covering these drugs could have very serious consequences for the healthcare system of this country, its deficit and the health of its citizens.

The issue of biologics is tightly linked to trade agreements, which may also negatively impact U.S. consumers and the healthcare budget.

As mentioned above, the TRIPS Agreement forced a change in U.S. law thus hindering consumers' access to affordable drugs. Trade agreements can also block U.S. Congress from changing some laws. During the negotiation of the Trans-Pacific Partnership (TPP), the USTR submitted a proposal to require TPP Parties to adopt 12 years of exclusivity for biologics on top of the 20-year patent term and patent term extensions. This would have prevented Members of the U.S. Congress from lowering the 12 years of exclusivity set in the Biologics Price Competition and Innovation Act (BPCIA). There have already been several proposals to do so, for example by a bipartisan commission to reduce the deficit⁶ as well as in a bill introduced in Congress⁷ and in six budget proposals introduced by President Obama,

⁵ AHIP, High-Priced Drugs: Estimates of Annual Per-Patient Expenditures for 150 Specialty Medications, April 2016.

⁶ Domenici-Rivlin Debt Reduction Task Force Plan 2.0, 2012 (<http://bipartisanpolicy.org/sites/default/files/D-R%20Plan%202.0%20FINAL.pdf>) and "The National Commission on Fiscal Responsibility and Reform. The Moment of Truth", December 2010.

⁷ The "Price Relief, Innovation, and Competition for Essential Drugs Act or the PRICED Act" may be accessed at: <https://www.congress.gov/bill/114th-congress/senate-bill/3094>

which supported reducing the period to 7 years.⁸ Most recently, a bill was reintroduced in the U.S. Congress to reduce the biologic exclusivity period in the U.S. to 7 years.⁹

In our opinion, the industry is well aware that the prices of these drugs are not sustainable over time particularly considering the growing market share of biologics and given that these new drugs will be increasingly prescribed to patients. Therefore, we believe that they are trying to prevent any reduction in the exclusivity period by including a period of 12 years in a trade agreement, which would lock. If they were to be successful, they would be tying the hands of Members of Congress who would not be able to lower the number of years of exclusivity granted to biologics as international law supersedes national law. If the U.S. wants to ensure access to these extremely expensive drugs, it should not lock this type of protection by including it in a trade agreement. While the U.S. withdrew from the TPP, which required the granting of an exclusivity period of biologics of 5-8 years¹⁰, according to media reports USTR negotiators have already submitted language to grant 12 years of exclusivity in the ongoing negotiations for the modernization of NAFTA. It is therefore important that a period of exclusivity for biologics not be included in NAFTA or any other trade agreement.

The FTC published an excellent report in 2009 titled "Emerging Health Care Issues: Follow-on Biologics Drug Competition." Many of the conclusions of the report have been proven over time. The European Union experience, which has approved the highest number of biosimilar or follow-on biologic drugs, shows that the FTC was correct. For instance, the FTC report estimated that biosimilar prices would be 10 to 30 percent lower.¹¹ This was confirmed in a Congressional Research Service report that states that in Europe biosimilar drugs have reduced prices in some cases

⁸ See President Obama budget proposals FY2012-2016.

⁹ H. R. 6577, "To amend the Public Health Service Act to shorten the exclusivity period for brand name biological products from 12 to 7 years."
(<https://www.congress.gov/115/bills/hr6577/BILLS-115hr6577ih.pdf>)

¹⁰ TPP, Chapter 18:

Article 18.51: Biologics

1. With regard to protecting new biologics, a Party shall either: (a) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic,^{59,60} provide effective market protection through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, mutatis mutandis, for a period of at least eight years from the date of first marketing approval of that product in that Party; or, alternatively, (b) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection: (i) through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, mutatis mutandis, for a period of at least five years from the date of first marketing approval of that product in that Party, (ii) through other measures, and (iii) recognising that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market. 2. For the purposes of this Section, each Party shall apply this Article to, at a minimum, a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.

¹¹ "Emerging Health Care Issues: Follow-on Biologic Drug Competition", Federal Trade Commission, June 2009. Page v.

by 33% compared to the original price.¹² The FTC concluded in the same report that originator biologic companies will maintain most of their market share and prices even after patent expiration due to a combination of factors, including the fact that: a) the high cost of developing biosimilar drugs means that there will be only a few competitors in the market even after patent expiration; b) there is no automatic substitution at the pharmacy level, and doctors may be reluctant to switch to a follow on biologic (FOB) due to the risk that patients may react differently to the FOB; and c) most of these drugs are administered at hospitals, clinics and doctors' offices, which are resistant to switching to other biologic products, restocking inventory and retraining their staff.¹³ As a result the FTC concluded that it is not necessary to grant exclusivity to biologics.

In light of USTR efforts to include biologics' exclusivity provisions in trade negotiations, we believe that it is critical that the FTC be involved in the determination of the U.S. trade policies, reach out to Congress to convey the conclusions detailed in its report, and draw attention to the potential implications of this issue within the inter-agency trade policy staff committee to preclude the inclusion of provisions that would curb, delay or prevent access to more affordable drugs. While the report is not new, it is still relevant.

Another important issue to address is the need to improve the listing of biologic patents at the Patents and Trademark Office. Before developing and launching a biosimilar product companies must assess which patents protect an invention. When researching information on some biologic drugs at the USPTO, however, the process is far from being straightforward. It should be possible to quickly retrieve electronically the total number of patents covering a drug. The USPTO should be able to improve the system as soon as possible.

Furthermore, it is important to reintroduce the Best Mode in U.S. patent law as the basis for an inequitable conduct defense in patent infringement lawsuits. This is critical to ensure competition for more complex drugs such as biologic drugs. While best mode is still part of U.S. law as one of the requirements for the patent applicant to ensure competition after patent expiration, its elimination in an inequitable conduct defense makes it vulnerable to being simply ignored by the patent applicant. In order to be effective, there should be a penalty for those who fail to comply with the requirement to disclose the Best Mode.

III. Linkage

While patent linkage may have sounded reasonable when it was originally conceived, throughout the years it has become a very regressive provision as it relates to access to affordable drugs.

¹² Judith A. Johnson, "Biologics and Biosimilars: Background and Key Issues," Congressional Research Service, October 27, 2017

¹³ Federal Trade Commission, Emerging Health Care Issues: Follow-on Biologic Drug Competition, June 2009, page iv.

In theory, the linkage mechanism seeks to ensure that if a drug is covered by a patent, marketing approval will not be granted to a subsequent applicant until the patent has expired or is found to be invalid. As a result, the system was designed to allow an originator company to file a lawsuit against the generic applicant that files an Abbreviated New Drug Application (ANDA) under a Paragraph IV certification (claiming the patent is not infringed or is invalid), automatically triggering a thirty-month stay. The generic applicant can only launch its product at the end of the lawsuit or after a 30-month stay. However, over the years companies have identified ways to game the system, so patent linkage has opened the door to the misuse of intellectual property rights at the expense of consumers and generic competitors.

In some cases, companies have filed lawsuits even knowing that they have no merit but merely due to the fact that doing so triggers up to 30 months of additional monopoly. The numbers speak for themselves. In the year 2000 we looked at whether there was any correlation between sales and the number of patents covering a drug. We concluded that drugs with higher sales had more patents, but that most of the additional patents were filed near the expiration of the original patent terms to secure maximum monopoly periods. That was the case of Prilosec, which at the time was selling over \$4.1 billion per year. By simply filing lawsuits against generic applicants, a company can block generic competition thus extending its monopoly, receiving additional billions of dollars and delaying additional innovation.

Such anticompetitive corporate behavior to delay the entry of generic pharmaceutical products has also been documented in the United States courts. For example, in a 2010 ruling involving AstraZeneca and Dr. Reddy's, the U.S. District Court of the Southern District of New York, the judge stated: "AstraZeneca insists that its litigation conduct here was appropriate because a lot of money was on the line. (Pl. Opp. Br. At 17). That is a ridiculous claim to make. Astra was not free to throw up roadblocks or to assert a claim construction in bad faith — to abuse the court system — just because it was to its economic advantage to keep a competitor out of the marketplace."¹⁴

Given that litigation is expensive and takes a long time, coupled with the fact that linkage is clearly tilted in favor of originator companies, it is not surprising that some generic manufacturers have ended up settling with originator companies to avoid the uncertainty and costs involved in protracted litigation. We are of the belief that if we want to see less pay-for-delay agreements it would be important to modify the linkage provision so that originator companies are not granted automatic 30-month stays just for filing lawsuits.

Moreover, linkage has been one of the provisions the USTR has pursued with great determination in trade negotiations. In the case of TPP, the USTR proposal would have even extended linkage to biologics thus going beyond U.S. law as BPCIA does

¹⁴ *AstraZeneca AB.v. Dr. Reddy's Laboratories, Ltd.*, No. 07 Civ. 6790(CM) (S.D.N.Y. Mar. 30, 2010).

not automatically block the FDA from approving a biosimilar drug based on the mere existence of a patent. If this had been adopted, it would have changed U.S. law and put at risk the development of the biosimilar industry and therefore any real chance to have more affordable prices for these very expensive medications. We strongly believe that the FTC should provide an input on USTR language proposals in trade agreements before they are put forward to make sure that they would not have unintended consequences by reducing competition and leaving consumers unprotected. The New Trade Policy or May 10th Agreement sets a better balance between promoting innovation and ensuring expedited access to drugs and setting a precedent that future trade agreements should follow. It is important that NAFTA not include patent linkage provisions.

IV. The need to provide incentives

Challenging the validity or applicability of a patent requires generic companies to devote considerable human and economic resources. Governments and consumers also benefit significantly from such investments given that if a patent is found to be invalid or that it does not cover a product, it opens the door to competition thus generating important savings to the healthcare system.

U.S. law recognizes the importance of bringing generic products to the market expeditiously by granting an exclusivity period of 180 days to the first generic applicant that is granted marketing approval. The U.S. should preserve these incentives. It is important to note, however, that U.S. trade agreements, with the exception of those that were the subject of the New Trade Policy (trade agreements with Colombia, Panama and Peru) failed to include any type of incentives. In the absence of such incentives, generic companies are often reluctant to challenge patents, as they are unwilling to spend significant resources to enter the market, when their competitors can launch their competing products at the exact same time without having to bear such litigation costs. Failure to recognize the importance of providing incentives for such challenges could end up being very costly for healthcare budgets, consumers and the generic/biosimilar industry. Weak or questionable patents would be left unchallenged and governments and patients would end up paying artificially higher prices for longer periods of time.

Furthermore, as stated above, it is clear that biologic drugs have an unprecedented number of patents, in some cases, hundreds of them per drug. The development of a healthy biosimilar industry, and therefore competition for these very expensive drugs, requires the adoption of additional incentives to reward companies that launch the first biosimilar product in the market.

To conclude, trade agreements have a serious impact on the role of intellectual property and competition policy and the FTC should have a prominent role in the determination of the language introduced in trade negotiations to prevent unintended consequences that may hinder consumers' access to affordable drugs.

I appreciate the opportunity to submit comments for the forthcoming hearings on competition and consumer protection issues and remain available to respond any questions you may have.

Sincerely,

Maria Fabiana Jorge