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April 13, 2015

Ambassador Michael Froman
United States Trade Representative
600 17th Street NW
Washington, D.C. 20508

Dear Ambassador Froman:

Thank you for taking the time to meet with me to discuss our concerns with the intellectual property (IP) provisions in the proposed Trans-Pacific Partnership Agreement (TPP). I am encouraged by your stated commitment to striking a balance in the IP provisions that will ensure access to affordable medicines around the world, in both developing and developed markets; however, I remain deeply concerned that this commitment is not reflected in the text of the actual agreement.

As I described to you, Mylan began in 1961 as a small company dedicated to helping people in rural West Virginia towns and other similar communities gain access to affordable medicine. By the end of the 1970s, Mylan was producing five of the 10 most prescribed generic medicines—all five of which were antibiotics. By 1995, Mylan became the most-dispensed line of brand and generic pharmaceuticals in the U.S. Today, we remain committed to our founding mission of access, but we do it for the world – with a workforce of approximately 30,000, a portfolio of about 1,400 separate products, sales in more than 145 countries and territories, a manufacturing presence of 39 facilities in 10 countries and leading positions in several of the world's largest markets.

This growth occurred under the umbrella of the Hatch-Waxman Act. Hatch-Waxman was not just another patent extension bill – it created an incredibly complex legal and regulatory system which was designed to *both* promote innovation, and spur competition from the generic industry. Prior to Hatch-Waxman, only about 35% of top-selling drugs faced generic competition, whereas today virtually all do, after the brands have had their years of patent protection and years of marketing exclusivity. The Hatch-Waxman Act accomplished this by developing an abbreviated pathway for the approval of generic medicines, establishing a basis for automatic substitution of generic drugs, and incentivizing generic companies to challenge brand patents by rewarding them with 180-days of exclusivity. Big Pharma was in turn provided with the right to patent linkage, automatically blocking generic market entry while patent disputes were resolved, and also given multiple patent extensions.

Today the American generic industry is one of the most competitive in the world – 86% of pharmaceutical products taken in the U.S. are generic, and the generic industry as a whole provides savings of approximately $1 billion *every other day*. However, the path to get here was not always smooth. Unintended loopholes in the Hatch-Waxman Act led to extensive gaming

and "evergreening" by brand companies, which resulted in years and years of additional exclusivity for patented products. In one infamous case, a branded pharmaceutical company managed to use a patent on a new color of a pill to gain over a year of additional exclusivity.

These evergreening loopholes were fixed by Congress in 2003 in the *Medicare Modernization Act* – almost 20 years after the passage of Hatch-Waxman, and the delicate balance between promoting innovation and promoting competition was reset. Safeguards were built into the system to prevent indefinite monopolies for patented pharmaceutical products – and the benefits of those safeguards to patients, payers and others within the health care system are clearly seen today. Generic medicines have saved U.S. taxpayers over $1.5 trillion over the past 10 years. During this same period of time, 268 new drugs have been approved by the FDA and made available to patients who need them, clearly demonstrating that the balance between competition and innovation that Hatch-Waxman established, and the Medicare Modernization Act clarified, is working.

Now, the USTR is proposing a trade policy where one single element of this complex system will be transplanted around the world: block approval of all generic pharmaceutical products if there are any patents on the product. None of the safeguards have been included, nor have any of the incentives to promote generic competition. With all due respect, the USTR has not "captured the principle" or the "spirit" of Hatch-Waxman, it has cherry-picked the single provision designed to block generic entry to the market.

	US System	TPP
☒	Balance between innovation and access	One-sided protection of patent holders
☑	Regulator blocked from issuing market authorization through market approval process	Regulator blocked from issuing market authorization through market approval process
☒	180-day market exclusivity to first generic to challenge patent(s) in Para. IV filing (i.e. demonstrating invalidity or non-infringement)	No incentive or reward for generic companies
☒	Generic can obtain market authorization by demonstrating non-infringement or invalidity of patent(s)	No mechanism to allow non-infringing generic product onto market. Only through patent holder's "consent or acquiescence"
☒	Limitation on types of patents that can be listed in the Orange Book: drug substance (active ingredient), drug product (formulation and composition) and method of use	No limitation on types of patents that can be listed in the Orange Book
☒	Automatic substitution of generic medicines	No requirement for automatic substitution

☒	No patent linkage for biosimilar products under the BPCIA (2010)	Patent linkage would apply to all "pharmaceutical products" including biosimilars

Furthermore, the patent linkage system in the U.S. was never designed for biologic products. U.S. law on approval of generic biologic drugs is in its infancy: the very first generic biologic has yet to be launched. The courts are still determining how exactly the system will operate, and what obligations arise on the parties. While it is crystal clear that including patent linkage for biologics in a trade agreement is contrary to U.S. law, it is also evident that it is premature for the USTR to include *any* provisions on biologics.

Unfortunately, while U.S generic companies were focused on growing from domestic players to global ones, the brand pharmaceutical industry was running ahead, working to instill confusion and establishing, through U.S. trade policy, an international system designed to maximize its monopolies – and the current language in the TPP is a result of those efforts. Even more regrettably, it is doing so in countries that cannot afford it, to patients that cannot afford it. The results will be disastrous – effectively forcing countries who don't have the resources or the infrastructure to manage such a system to immediately close their access to more affordable medicines for patients without offering any other options for challenge. Patent linkage is a complex regulatory system that countries must consider and develop on their own terms (or, as in the case of the EU, find anti-competitive). To require mandatory patent linkage in trade agreements like the TPP is to handpick a single winner - Big Pharma - at the expense of Mylan, the U.S. generic industry and, most importantly, patients around the world.

I would now like to take this opportunity to address the IP provisions in TPP specifically and outline in detail the basis for our concern. While I must rely on leaked texts of the IP Chapter in TPP, as I am not a cleared advisor, I trust that to the extent this language is the same as or similar to the actual text, that our concerns will be considered. I have attached the leaked text here as an Appendix for common reference.

A. Patent Linkage

Our main concern with a mandatory patent linkage requirement in the TPP is that such a measure, even if intended to simply "capture the principle" of patent linkage as described in our meeting, will ultimately result in the creation of a categorical and automatic denial of market authorization to generic applicants.

As referenced above, the patent linkage provision under TPP has several specific differences when compared to U.S. law under the Hatch-Waxman Act.[i] They include:

- No limitations on the *types* of patent;
- No determination on *when* they can be "listed";
- No determination on *who* or *how* it is decided which patents are relevant to blocking a generic applicant's market authorization; and
- No visibility on the length of time market authorization will be denied

As such, we can fully anticipate that this will become a recipe for indefinite evergreening of pharmaceutical monopolies. I note as well the absence of any incentives for generic companies to challenge patents – language that has been previously included in other trade agreements[ii] and earlier drafts of the TPP[iii].

The key aspects creating the "linkage" in the TPP provision are that Parties will be required to provide:

1. Measures to prevent marketing of pharmaceutical products;
2. Through the marketing approval process;
3. If there are any patents on the product

The fact that the preventative measures will be implemented through the *marketing approval process*, (rather than through judicial or administrative means), indicates that the measures must be taken by the regulatory body involved in marketing approval. Further, the requirement that whatever measures are implemented must be to "prevent" marketing affirms that this will be through denial of market authorization as the regulatory body would have no other power to prevent marketing. Further, regulatory bodies will be required to prevent marketing of pharmaceutical products if there are *any* patents with respect to that product. These elements are what establish "patent linkage" and are not to be confused with "early dispute resolution mechanisms", or "notification requirements" or "judicial or administrative processes" – none of which require automatic denial of marketing authorization.

This understanding is supported by the fact that this very language was used to describe patent linkage, *as distinct from judicial or administrative remedies*, under the U.S. free trade agreements with Peru, Colombia and Panama. In those FTAs, preliminary injunctions were provided as an example of a judicial or administrative process, and notification to the patent holder of a pending abbreviated application for generic approval was identified separately from measures to prevent marketing of a product. In other words, historically, a notification-only mechanism was not understood as being encompassed by the patent linkage language.

TPP language further states that such measures would be required if there are "any patents" on the product. Under U.S. law, only product (formulation and composition), substance (active ingredient) and method of use patents can be listed in the Orange Book as relevant to blocking a generic applicant's approval at the FDA (and not, for example, process patents).

Your colleague, and lead IP negotiator for the TPP, Mr. Mehta, stressed in our meeting that patent linkage was mandatory under the U.S. - Peru FTA, and not permissive as we have asserted. With all due respect, this is factually incorrect. Under that FTA, Articles 16.10.3 and 16.10.4[iv] state that it shall be mandatory for the parties to provide for *judicial or administrative remedies* for patent disputes (such as preliminary injunctions), as well as for a transparent system to provide notice to the patent holder that another person is seeking marketing approval of a product covered by a patent. However, it then states that the party *may* choose to do so through patent linkage. In such cases, the Party shall then also provide notification to the patent holder of

the patent dispute and provide expeditious measures for the generic applicant to challenge the validity or applicability of the patent. The language also promises granting of an "effective reward" for the successful challenge of the validity of the patent.

The distinction between the mandatory patent linkage that had previously been included in the U.S. – Peru and U.S. – Panama agreements, and the permissive language that Congress directed for Peru, Panama and Colombia in the May 10 Agreement, was jointly described by the USTR and the Ways and Means Committee (see attached Appendix) as follows:

> "Amend FTA so that there is no "linkage" requirement between drug regulatory agencies and patent issues*:* in particular, no requirement that the drug regulatory agency withhold approval of a generic until it can certify that no patent would be violated if the generic were marketed.
>
> However, a Party would be required to provide procedures and remedies, such as judicial or administrative proceedings and preliminary injunctions (or equivalently effective provisional measures), for adjudicating expeditiously any patent infringement or validity dispute that arises with respect to a product for which marketing approval is sought. There will be a transparent system to give patent holders sufficient time and opportunity to effectively enforce their rights (e.g., immediate notice sufficient to alert the patent holder of submission of applications for marketing approval, such as the approval authority posting any application for marketing approval on its website, so that patent holders have opportunity to discover products that may infringe their patents), and to seek, prior to the grant of marketing approval, available remedies for an infringing product.
>
> A Party could choose to implement the "procedures and remedies" obligation described above through a linkage system, provided that the Party makes available (1) an expeditious administrative or judicial procedure to challenge the validity or applicability of the patent (so as to break the "link" in appropriate cases), and (2) effective rewards for successfully challenging a patent (U.S. law already meets this test.) [Emphasis added].

I appreciate that the USTR is now trying to build some flexibilities into the TPP around patent linkage. In particular, we have learned of the addition of what appears to be a notification requirement. The problem is that the notification requirement is *in addition* to the requirement to "prevent market authorization through market approval processes" – meaning that parties would be required to block market authorization, and then notify the patent holder of the generic application. This is still mandatory patent linkage, and our concerns remain unchanged.

Requiring mandatory patent linkage for TPP countries is a mistake – one that will result in the closing of these markets to the American generic industry. Patent linkage is not a substitute for, or equivalent to, high intellectual property standards. This is evident in Europe, where patent linkage is an unlawful, anticompetitive practice, but where high IP standards are indisputably maintained. The U.S. is not seeking patent linkage in the context of the Transatlantic Trade and Investment Partnership (TTIP) negotiations, but rather has recognized that "both sides agree that it would not be feasible in negotiations to seek to reconcile across the board differences in the IPR obligations that each typically includes in its comprehensive trade agreements."[v] This is also evident in the fact that since 2010, the USTR no longer includes the lack of linkage as one of the elements showing that countries are denying "adequate and effective protection of intellectual

property rights" in the Special 301 Annual Review unless they have specifically agreed to implement linkage.

Patent linkage is a complex system designed to manipulate the market to encourage competition while promoting innovation. The balance is exceedingly difficult to strike, and simply cannot be exported to foreign markets that differ not only in their regulatory frameworks, but in their market size and dynamics. Patent linkage should be permissive, as it was in the Peru, Colombia and Panama trade agreements, and to achieve this end, footnotes or modifications to the initial "market block" are insufficient.

The USTR has a strong precedent with the Peru, Colombia and Panama Agreements, and should follow that precedent in the TPP by making patent linkage permissive, but not mandatory, for Parties.

B. Linkage for Biologics

The leaked text includes biologics as "pharmaceutical products" and therefore includes biologics in the patent linkage obligation, a requirement that goes beyond and is inconsistent with U.S. law. Mr. Mehta stated in our meeting that the U.S. has patent linkage for biologics under the *Biologics Price Competition and Innovation Act*[vi] *(*BPCIA), and in fact, we are aware that the USTR has previously made such assertions to other negotiators of the TPP. Again, this is incorrect. The BPCIA establishes a regulatory regime for two sorts of follow-on biologics, termed "biosimilar" and "interchangeable" biologics respectively[vii]. The Congressional Research Service described it as distinct from the patent linkage regime under Hatch-Waxman:

> "Notably, the BPCIA does not employ the same framework as the patent dispute resolution proceedings that have been available under the Hatch-Waxman Act for more than a quarter century. In particular, unlike the Hatch-Waxman Act, the BPCIA does not require brand-name firms to identify relevant patents in advance of generic competition. [...] Unlike the Hatch-Waxman Act, the BPCIA does not tightly link FDA approval with patent rights. Brand-name firms wholly rely upon the judiciary to stay the release of follow-on biologics into the marketplace."[viii] (Emphasis added)

This was affirmed by the just-issued decision in *Amgen, Inc. v. Sandoz, Inc.* under the BPCIA. There, the U.S. District Court for the Northern District of California denied the patent holder, Amgen's, request for a preliminary injunction and held that the so-called "patent dance requirements" under the BPCIA are not mandatory[ix]. Meanwhile, the generic applicant, Sandoz, received FDA approval for biosimilar Zarxio™ (filgrastim-sndz) on March 6, 2015. What this means is that not only is the FDA not blocked from issuing market authorization on the basis of any patents, but that even the notification requirements are not all mandatory.

In a citizen petition to the FDA, Amgen also asked the FDA to include a certification by the generic applicant (Sandoz) that the "applicant will provide the reference product sponsor with a copy of the biosimilar application and information that describes the process(es) used to manufacture the biosimilar product that is the subject of that application". In rejecting this citizen petition in full, the FDA noted:

> "Neither section 351(k) nor section 351(1) requires FDA to impose a certification requirement as part of the biosimilar review process. Section 351(1) describes procedures for information exchanges and the resolution of certain patent rights between the biosimilar applicant and the reference product sponsor. These procedures are parallel to, but separate from, the FDA review process. The BPCI Act generally does not describe any FDA involvement in monitoring or enforcing the information exchange by creating a certification process or otherwise.
>
> The lack of an explicit certification requirement in the BPCI Act is in contrast to provisions in the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355U)) concerning patent certification for 505(b)(2) applications and abbreviated new drug applications (ANDAs). [Emphasis added].

In describing the U.S. system as having patent linkage for biologics, and in including this requirement in TPP through overly-broad language that would force countries to deny market authorization *through the market approval process* based on the existence of any patents, the USTR is not just confusing patent linkage with notification measures or judicial or administrative recourses, it is also exposing the U.S. to the risk of enforcement measures by TPP countries that could force changes in U.S. domestic law.

This scenario is already taking shape as a result of dangerously ambiguous language for patent linkage in the U.S. - Korea free trade agreement (KORUS). That trade agreement used very similar language to the one proposed in TPP[x]. Addressing the issue of both countries' mutual respect for and implementation of patent linkage obligations under KORUS, the U.S. Ambassador to Korea, His Excellency, Mr. Mark Lippert, stated in a letter to the Korean Minister of Food and Drug Safety dated February 17, 2015 that (attached in Appendix):

> "[…] I would like to assure you that KORUS patent linkage obligations cover all pharmaceutical products, including biologics, as set forth in the agreement. The United States meets this obligation through the Hatch Waxman Act and the Biologics Price Competition and Innovation Act (BPCIA), and the U.S. system is therefore KORUS-consistent. […] As you know, we are seeking such protections in the Trans-Pacific Partnership negotiations.

The Ambassador's assertion that the patent linkage language applies to all pharmaceutical products, including biologics, is extremely concerning, despite his reassurance that such obligations are satisfied already under Hatch-Waxman and BPCIA respectively. The only acceptable explanation is that the USTR, and the Ambassador, have conflated notification requirements with patent linkage.

The only way to avoid such confusion, and protect the U.S. from potential enforcement measures by TPP countries (and potentially foreign companies due to Investor-State Dispute Settlement provisions), is to *explicitly* exempt biologics from any patent linkage provision and to more precisely establish a requirement to provide a transparent system to provide notice for biologics.

C. Other IP Provisions

The USTR has repeatedly maintained that generic industry concerns were reflected in the inclusion and/or modification of other provisions beneficial to generic competition. We would

like to ensure that such improvements are not undermined or nullified by other IP provisions. I am not listing every issue here, but would like to provide you with some examples:

TPP contains language on mandatory patent term extensions: In the U.S., there are *mandatory limitations* on these types of extensions (e.g. the product must be subject to regulatory review period, the product must be the first permitted marketing of the product, only a single patent term extension is permissible per approved product, the patent term extension cannot extend beyond 14 years from the approval date). In contrast, TPP contains no mandatory limitations to the mandatory patent term extensions.

Under the proposed exclusivity period for small molecule products, TPP proposes that this will be granted for "at least" 5 years for new pharmaceutical products, and "at least" 3 years for new clinical information. The U.S. does not set a *minimum* standard, rather, it sets limits of precisely 5 years for new chemical entities (NCE) and 3 years for new products and indications, and with respect to NCEs, allows generic applicants challenging a patent to file for marketing approval after 4 years. Further, in the U.S., only "same" NCEs and products are blocked, not "similar" ones as in TPP – a distinction that can make the difference between a single product being blocked, and an *entire class of products*.

Under U.S. law, patent applicants are required to disclose the "best mode" to practice or to carry out the invention. Further, in the U.S., patent examiners will reject applications during prosecution when the best mode is not disclosed. The TPP, though, is notably silent on this requirement which could allow patent applicants to pursue claims without fair public disclosure.

I raise these issues here (and there are others) because in the U.S., some of this type of "lazy drafting" has resulted in extensive delays for generic companies. These essential provisions have the potential to dramatically alter whether, when, and how Mylan and other U.S. companies will be able to have timely access for our products in TPP countries, in addition to being inconsistent with U.S. law.

The USTR cannot export the entirety of the American pharmaceutical market along with its accompanying regulatory, judicial, administrative, and competitive framework to the world, nor can it cherry pick select aspects of its laws as a proxy for doing so. Instead, fair and democratic trade policy calls on the USTR to ensure that *both* patented and generic medicines are assured competitive entry into foreign markets, and that equitable standards of IP are balanced with competition and access to affordable medicines.

Most importantly, as long as mandatory patent linkage and applying linkage of any form to biologics remains in the TPP, not only can I not support the agreement, but I cannot in good conscience support the U.S. Congress giving a rubber-stamp of approval to TPP through a Trade Promotion Authority. As currently written, TPP will take the pharmaceutical industry back 30 years, which I can't believe is the intent of the USTR or of Congress. I am, therefore, hopeful that the USTR will instead choose a way forward that ensures that both the patented and generic pharmaceutical markets are supported in the TPP and that patients around the world are provided the same benefits of increased competition as American ones.

Sincerely,

Heather Bresch
CEO Mylan

Cc The Honorable Orrin Hatch
Chairman, Senate Finance Committee

The Honorable Paul Ryan
Chairman, House Ways & Means Committee

The Honorable Ron Wyden
Ranking Member, Senate Finance Committee

The Honorable Sander M. Levin
Ranking Member, House Ways and Means Committee

Ralph G. Neas
President and CEO, Generic Pharmaceutical Association

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[i] Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355U) see Sec. 314.52, 314.53

[ii] The Free Trade Agreement between U.S. and Peru, as well as those with Colombia and Panama, included language requiring that any party which opted to implement patent linkage for pharmaceutical products must also provide "effective rewards for a successful challenge of the validity or applicability of the patent."

[iii]Text of Trans-Pacific Partnership, Intellectual Property Rights Chapter, dated September 2011, available through WikiLeaks.

[iv]U .S.-Peru FTA (2007) Art. 16.10.3.

> Each Party shall provide:
> (a) procedures, such as judicial or administrative proceedings, and remedies, such as preliminary injunctions or equivalent effective provisional measures, for the expeditious adjudication of disputes concerning the validity or infringement of a patent with respect to patent claims that cover an approved pharmaceutical product or its approved method of use;
> (b) a transparent system to provide notice to a patent holder that another person is seeking to market an approved pharmaceutical product during the term of a patent covering the product or its approved method of
> use; and

(c) Sufficient time and opportunity for a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies for an infringing product.

Art. 16.10.4.

1. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory, the Party may implement the provisions of paragraph 3 by:

(a) implementing measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved method of use during the term of that patent, unless by consent or acquiescence of the patent owner; FN17

and

(b) providing that the patent owner shall be informed of the identity of any such other person who requests marketing approval to enter the market during the term of a patent identified to the approving authority as covering that product;

provided that the Party also provides:

(c) an expeditious administrative or judicial procedure in which the person requesting marketing approval can challenge the validity or applicability of the identified patent; and

(d) effective rewards for a successful challenge of the validity or applicability of the patent. FN18

FN 17: For greater certainty, the Parties recognize that this provision does not imply that the marketing approval authority should make patent validity or infringement determinations.

FN 18: A Party may comply with clause (d) by providing a period of marketing exclusivity for the first applicant to successfully challenge the validity or applicability of the patent.

Similar language is included in the U.S. – Colombia FTA (Article 16.10, paras. 3 & 4) and U.S. Panama FTA (Article 15.10, paras 3 & 4).

[v] *Interim Report to Leaders from the Co-Chairs,* EU-U.S. High Level Working Group on Jobs and Growth, 19 June 2012, available online at: http://trade.ec.europa.eu/doclib/docs/2012/june/tradoc_149557.pdf

[vi] *Patient Protection and Affordable Care Act*, Pub. L. Nos. 111-148 & 111-152, §§ 7001-7003 (2010) (passing the *Biologics Price Competition and Innovation Act* of 2009 that amended § 351 of the Public Health Services Act, codified at 42 U.S.C. §262)

[vii] John R. Thomas, CRS Report, *Follow-On Biologics: The Law and Intellectual Property Issues*, January 15, 2014, available online at: http://fas.org/sgp/crs/misc/R41483.pdf

[viii] CRS Report, January 15, 2014

[ix] *Amgen Inc. v. Sandoz Inc*., No. 14-CV-04741-RS, 2015 WL 1264756 (N.D. Cal. Mar. 19, 2015)

[x] Article 18.9.5 of KORUS:

Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on that information or on evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory, that Party shall:

(a) provide that the patent owner shall be notified of the identity of any such other person that requests marketing approval to enter the market during the term of a patent notified to the approving authority as covering that product or its approved method of use; and

(b) implement measures in its marketing approval process to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner during the term of a patent notified to the approving authority as covering that product or its approved method of use.