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**Written Submission for US International Trade Commission Investigation No. TPA-105-001:  
“Trans-Pacific Partnership Agreement: Likely Impact on the U.S. Economy and on Specific  
Industry Sectors”**

**February 16, 2016**

**Summary of position for inclusion in the appendix to the Commission’s report:**

Doctors Without Borders/ Médecins Sans Frontières (MSF) has provided oral testimony and a written submission regarding the negative impact that the Trans-Pacific Partnership (TPP) will have on access to affordable medicines and biomedical innovation.

MSF is an international independent humanitarian organization that provides medical assistance in over 60 countries, in need of both affordable access to and innovation for medical technologies.

Competition has a proven record as a critical tool to lower drug prices and help deliver effective medical care. Intellectual property trade obligations and other protections for pharmaceutical companies that limit price-lowering generic competition are driving up drug prices.

The TPP puts in place far-reaching new government obligations that lengthen, strengthen and broaden patents and other pharmaceutical monopolies. The effect will be to further delay access to generic medicines beyond current requirements of international trade law. The provisions also undermine public health safeguards that governments and others have to promote access to medicines and limit abuse. The TPP represent a departure from previous U.S. global health commitments towards developing countries, including the 2007 New Trade Policy or May 10th Deal.

Unless is modified, the TPP will exacerbate the global crisis of high drug prices. For example, the TPP will not allow national regulatory authorities to use existing clinical data demonstrating a pharmaceutical product’s safety and efficacy to authorize the sale of competitor products, even in the absence of patents. The additional monopoly protection provided for biologic drugs and vaccines will keep already very expensive products out of the hands of millions. The TPP would also force governments to extend existing patent monopolies beyond current 20-year terms at the request of pharmaceutical companies, and to redefine what type of medicine deserves a patent, including mandating the granting of new patents for modifications of existing medicines.

The TPP also fails to address the urgent need for reform in the biomedical innovation system. The sole reliance on high medicine prices, backed by exclusivities and monopolies, is a flawed paradigm for

funding innovation. This leads to unaffordable prices while failing to stimulate innovation for diseases where patients have limited purchasing power like neglected tropical diseases or where drugs have to be used sparsely like antibiotics.

The negative impact of the TPP on public health will be felt for years to come, and will not be limited to the 800 million people in the current 12 TPP countries. It is a dangerous blueprint for future agreements and aims at being a standard-setting agreement and to create new global trade norms. Instead of doubling down on a broken model, the U.S. Government should collaborate with other governments to introduce new approaches that promote both innovation and access.

It isn't too late to prevent the further restrictions on access to affordable medicines that would be created through the TPP. MSF urges the United States government to protect the right to health of millions of people that will be negatively impacted if the TPP is approved in its current form. The TPP should be modified or rejected.

## **Introduction**

Doctors Without Borders/Médecins Sans Frontières (MSF) would like to provide the following written submission regarding the impact that the Trans-Pacific Partnership (TPP) trade agreement will have on access to affordable medicines and biomedical innovation for consideration in the United States International Trade Commission Investigation No. TPA-105-001: “Trans-Pacific Partnership Agreement: Likely Impact on the U.S. Economy and on Specific Industry Sectors.”

MSF is an international humanitarian organization that provides impartial medical assistance in more than 60 countries. In 2014 we performed more than eight million outpatient consultations, treated more than two million malaria cases, vaccinated more than 1.5 million in measles outbreaks, supported HIV/AIDS and drug-resistant tuberculosis treatment programs, and responded to other medical emergencies ranging from Ebola outbreaks in West Africa, to the refugee crisis in Europe, to armed conflicts in Syria, Yemen and Afghanistan. A more detailed description of our operational activities in 2014 is available in our annual activity report.<sup>1</sup>

As a medical treatment provider that needs both affordable access to and innovation for medical technologies, MSF is able to speak about the relationship between trade, intellectual property and health, and about the role competition has played in enabling access to medical care for millions.

Intellectual property trade obligations and other protections for pharmaceutical companies that limit competition are driving up drug prices worldwide. Unless modified, the TPP will exacerbate the global crisis of high drug prices. Provisions in the TPP will lengthen, strengthen and broaden monopolies for pharmaceutical companies, delaying access to affordable medicines for millions beyond current requirements of international trade law. The TPP will also fail to address the urgent need for reform in the biomedical innovation system.

MSF urges the U.S. International Trade Commission and the United States government to seriously consider the negative impact the TPP will have on the health of millions of people before ratifying, implementing and encouraging additional countries to adopt to the TPP’s restrictive provisions for pharmaceuticals.

## **Importance of competition for access to affordable medicines**

MSF’s medical operations have been challenged by the high price of medicines for many years. In 2001, high prices left MSF unable to save the lives of our patients. Pharmaceutical companies charged MSF and others an astronomical \$10,000 per person, per year for HIV medicines. This meant that MSF and governments, in the face of thousands of people dying daily from AIDS-related illnesses, could only provide treatment to a very limited number of people. In response, affected governments applied legal safeguards to remove patent barriers and foster generic competition and HIV treatment costs fell, virtually overnight, to a dollar a day per person.<sup>2</sup>

With competition, prices for first-line HIV medicines have continued to fall and today almost 16 million people receive treatment,<sup>3</sup> including through U.S. government-funded programs such as the United States President’s Emergency Plan for AIDS Relief (PEPFAR). Ninety-seven percent of the medicines PEPFAR uses are generics.<sup>4</sup> In only three years from 2005 to 2008, the use of generics saved PEPFAR an estimated \$323 million dollars.<sup>5</sup> In 2010, the savings from generics were estimated to be almost \$50 million more than those three years combined.<sup>6</sup> This represents important savings that stretches the U.S. government’s investment in global health, and more importantly saves millions of lives.

Price-lowering generic competition remains critical to the ability to deliver effective care. We need generic competition for new HIV medicines that sustain the lives of patients on treatment and provide better medical outcomes. Currently patented HIV medicines can be 20 times more expensive.<sup>7</sup>

We also need access to affordable treatment for many other diseases. New medicines to treat hepatitis C, which affects up to 150 million people worldwide<sup>8</sup> and an estimated 3.5 million people in the U.S. alone,<sup>9</sup> provide a critical illustration. These medicines, including Gilead's sofosbuvir and combination products, offer the potential for a cure. However, patents and other monopolistic protections have allowed pharmaceutical companies like Gilead to charge exorbitant prices.

In December 2015 the U.S. Senate Finance Committee released a report<sup>10</sup> documenting how Gilead has abused its monopoly in the U.S. by pricing sofosbuvir as high as \$1,000 per pill. Prices for sofosbuvir in combination with other medicines that may be necessary for a full treatment regimen are even higher. This has translated into rationing access and unsustainable public expenditure in the U.S. and around the world. Even with clear evidence of Gilead's monopoly abuse and knowing that it only costs slightly more than one dollar per pill to produce these medicines,<sup>11</sup> the U.S. Government is less powerful to act than other governments, in part because relevant measures to promote competition and negotiate better prices have been sacrificed.

While new hepatitis C medicines are less expensive in other countries, they are still unaffordable, especially in developing countries considered "middle-income" economies where most people with hepatitis C reside. As generic treatments are starting to enter the market, prices are falling<sup>12</sup> in some countries that have safeguards that curb industry abuse and promote competition.<sup>13</sup> However, if the TPP is implemented in its current form, countries will have to change their legal regimes and be in the same position as the U.S., powerless to address industry abuse that undermines treatment and medical care.

### **The TPP will exacerbate the global crisis of rising medicine prices**

Intellectual property global trade obligations for pharmaceuticals, now nearly fully implemented worldwide through the World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) are already driving up drug prices by delaying competition. The TPP will exacerbate these challenges by unnecessarily strengthening pharmaceutical companies' monopolies and market power.

While the text has improved over initial proposals from the Office of the United States Trade Representative, mostly due to the widespread opposition of the rest of the TPP countries, the TPP will still go down in history as the worst-ever trade agreement for access to medicines.

Our analysis of the now publicly released text shows that the TPP puts in place far-reaching new obligations for governments that lengthen, strengthen and broaden patents and other pharmaceutical monopolies beyond international trade rules established by the TRIPS agreement and restrict access to price-lowering generic competition. The provisions also undermine public health safeguards that governments and others have to limit abuse, affirmed by the 2001 WTO Ministerial Declaration on the TRIPS Agreement and Public Health (Doha Declaration) and the 2008 World Health Organization (WHO) Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (WHA 61.21).

Furthermore, the TPP text represent a complete departure from the U.S. government's previous commitments to global health towards developing countries, including safeguards included in the 2007 "New Trade Policy," or May 10th Agreement<sup>14</sup>, as applied to Colombia, Peru and Panama, which was an effort to bring some balance back into US trade agreements. Developing countries currently part of the TPP negotiation, Vietnam, Malaysia, Mexico and Peru, will be forced to change their laws to incorporate abusive new monopoly protections for pharmaceutical companies that will limit access to price-lowering generic competition.

Examples of these new obligations are summarized in an annex to this submission. For a more detailed analysis, please refer to MSF's issue briefs and analysis, available [online](#).<sup>15</sup>

Below we highlight some of the provisions included in the TPP and their potential effects on access to medicines.

### *The TPP lowers standards of patentability*

Under the WTO's TRIPS Agreement governing global intellectual property obligations, governments have to grant 20-year patents on pharmaceutical products but also have important flexibility to define what does and does not deserve a patent in a way that addresses the needs of their own citizens and innovation system and prevents abuse of the patent system, as long as they abide by the patentability criteria and patentable subject matter agreed as international norms.

It is in the public interest for governments to retain these flexibilities, including the ability to strengthen patentability criteria and limit industry patent evergreening and other abusive practices. Allowing for stricter patentability curtails the worst excesses of the patent system, ensuring that innovators focus their energies on truly useful and new drugs and other medical technologies, rather than business strategies that extend existing patent monopolies with low or no inventive and societal contribution. The U.S. is contributing to this effort with a variety of recent Supreme Court decisions that narrow what deserves a patent under U.S. law.<sup>16</sup>

Governments should continue to make adjustments to its patent system to achieve a better balance between rewarding innovation and providing for health and other public needs. The TPP should not prohibit signatory countries from doing the same. However, the current text of the TPP mandates the granting of secondary patents on modifications of existing drugs. The relevant section is Article 18.37 Patentable Subject Matter of Chapter 18 (Intellectual Property) that reads as following:

*2. Subject to paragraphs 3 and 4 and consistent with paragraph 1, each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit those new processes to those that do not claim the use of the product as such.*

The obligation to grant new patents on modifications of known products is not required under international trade law, and it threatens to restrict or delay access to price-lowering generic competition by extending patent monopolies beyond the 20-year original patent term. It is difficult to completely estimate how long monopolies will be extended, and most likely the effects will differ drug by drug and country by country, but a recent study found that granting secondary pharmaceutical patents extends the life of monopoly protections by an average of more than six years in the U.S.<sup>17</sup>

### *The TPP mandates additional data regulatory protection*

The TPP mandates that clinical test data be protected with a period of exclusivity, including a specially-extended period for biologic products for the first time in a US-led trade agreement. Biologics are a class of product that include many drugs and vaccines that are already very expensive and in too many instances unavailable as a prevention and treatment option in many of the developing countries where MSF works.

Data protection with exclusivity prevents drug safety regulators from using existing clinical data to give market approval to generic or biosimilar medicines, delaying price-lowering competition and keeping medicines prices high for longer.

Protection of data with exclusivity for any class of drugs is not required by the TRIPS Agreement or any other international law and the United Nations recommends against implementation of data exclusivity, especially in developing countries. An evaluation of the impact of ten years of implementation of data exclusivity rules in Colombia from 2003-2011 found that they resulted in an increase of more than US \$396 million in additional expenses for the public health system.<sup>18</sup> Another study found once Guatemala enacted data exclusivity due to DR-CAFTA obligations, some medicine prices rose as much as 846 percent.<sup>19</sup> In Jordan data exclusivity enacted due to the US-Jordan trade agreement, delayed the introduction of cheaper generic versions of 79% of medicines between 2002 and 2006. Prices of medicines under data exclusivity in Jordan were up to 800% higher than in neighboring Egypt.<sup>20</sup>

Data protection with exclusivity raises the price of medicines even when no patent exists. For example, in the U.S., the price of colchicine, a treatment used mainly for gout, rose more than 5000% after data exclusivity was enacted.<sup>21</sup>

Even within the U.S., where the period of exclusivity for biologics is currently 12 years, the existence of this parallel regulatory monopoly has been challenged. As the Federal Trade Commission's analysis on the subject found, additional exclusivity for biologics is not warranted to promote innovation, and it imperils the public health and budgetary benefits to accelerate the entry of follow-on biologics.<sup>22</sup> Furthermore, for six consecutive years, the Obama administration has proposed through budget proposals to reduce the term for biologic exclusivity from twelve to seven years.<sup>23</sup> As cited in the Administration's own budget proposal, in U.S. federal programs alone, reducing data exclusivity for biologics by five years would result in savings of nearly \$7 billion over ten years.<sup>24</sup>

### *The TPP's overall negative impact on health and access to medicines*

The overall negative public health impact of the TPP has been recognized by many others, including but not limited to the World Health Organization,<sup>25</sup> UNITAID,<sup>26</sup> the Holy See<sup>27</sup> and the World Medical Association.<sup>28</sup>

The negative impact of TRIPS-plus provisions that expand protections for pharmaceutical companies at the expense of affordable access to medicines, beyond what is currently required by international trade rules through the WTO's TRIPS Agreement has been well documented.<sup>29</sup> For example, a 2009 study evaluating the impact that just two TRIPS-plus provisions like those included in the TPP would have on Peru if implemented in a different trade agreement estimated that they "would lead to an increase of 459 million USD in Peru's total pharmaceutical expenditure in 2025 and a cumulative increase in expenditure of 1267 million dollars (at present value, PV) for the same year."<sup>30</sup>

One analysis of the TPP's overall potential impact on the cost of health care found that in Vietnam HIV treatment access would be significantly affected. The results indicated that "82% of the HIV population eligible for treatment would receive ARVs under a full TRIPS flexibility scenario, while only 30% of Vietnam's eligible HIV patients would have access to ARVs under the US 2014 TPPA proposals" as

identified in leaked versions of TPP negotiating texts. That is less than half of the HIV-treatment eligible population receiving treatment in Vietnam as of November 2014, according to the study. As the study also highlighted, “similar price impacts can be expected for other countries participating in the TPPA.”<sup>31</sup>

### **The TPP is bad for biomedical innovation**

MSF recognizes the need to reward innovation and finance research and development (R&D). We are a humanitarian medical organization that welcomes innovations that improve medical outcomes. However, the TPP will also fail to address the urgent need for reform in the biomedical innovation system. The sole reliance on high medicine prices, backed by monopolies expanded and further entrenched by the TPP, is a flawed paradigm for funding innovation. This leads to unaffordable prices while failing to stimulate innovation for diseases disproportionately affecting developing countries, where patients have limited purchasing power.

In fact, the current innovation model is failing patients in all countries, as we see with antibiotic resistance. As the President’s Council of Advisors on Science and Technology highlighted in their Report to the President on Combating Antibiotic Resistance, we are now facing a crisis of growing antibiotic resistance that outpaces the development of new antibiotics.<sup>32</sup> In spite of the need for new antibiotics that must be affordable and used sparingly, pharmaceutical companies, including Pfizer, the world’s largest, have abandoned antibiotic drug development.

Governments are already funding innovation and providing drug companies with tax incentives and subsidies to promote innovation while paying record prices. In some cases, governments are paying twice – first by paying a significant percentage of the R&D costs and second by paying high prices.

Seeking longer and stronger monopoly protection for pharmaceutical companies not only does little for innovation, but it perpetuates a failed innovation business model that is hurting U.S. patients as well as patients abroad. We believe new approaches to promote medical innovation, including approaches that MSF and others have supported, are demonstrating that significant medical breakthroughs with access are possible – in particular, when incentives break the link between the cost of R&D and the price of the end product.<sup>33</sup> Instead of doubling down on a broken model, the U.S. government should collaborate with other governments to introduce new approaches that promote both innovation and access. In this sense, TPP is a missed opportunity to promote biomedical innovation.

### **Conclusion: the TPP is a bad deal for medicine**

The TPP is a bad deal for medicine; it’s bad for humanitarian medical treatment providers such as MSF, and it’s bad for people who need access to affordable medicines around the world, including here in the United States.

The White House fiscal year 2017 budget proposal highlights that “the Administration is deeply concerned about rapidly growing prescription drug prices.”<sup>34</sup> The U.S. government is not alone in this concern; MSF has for more than fifteen years highlighted the challenges of high prices for our medical operations. As the U.S. and other governments around the world are under pressure from patients, payers and medical providers to address exorbitant drug pricing as barriers to effective medical care and sustainability of health programs, it is incomprehensible that at the same time the TPP terms will lock in high prices and keep price-lowering generic medicines off the market for years to come.

Every country has the right and the obligation to take steps to increase access to medicines and implement a patent and regulatory system in line with its public health needs; the TPP will take away key components of that flexibility and limit the tools that governments and civil society have to try to ensure access to affordable medicines.

The negative impact of the TPP on public health will be enormous, be felt for years to come, and will not be limited to the 800 million people living in the current 12 TPP countries. It is a dangerous blueprint for future agreements and aims at being a standard-setting agreement and to create new global trade norms.

Pharmaceutical companies already enjoy some of the highest profit margins and strongest monopoly protections of any industry. Granting them extended and additional market exclusivity and power is unnecessary to promote innovation and it will cause needless death and suffering. We urge the U.S. government to uphold its obligations to protect public health and fight back against unjust profiteering.

It is not too late to prevent further restrictions on access to affordable medicines that would be created through the TPP. MSF urges the United States government to protect the right to health of millions of people that will be negatively impacted if the TPP is approved in its current form. The TPP should be modified or rejected.



**Annex - Examples of new TPP intellectual property obligations that will keep medicines prices high**

<b>TRIPS-Plus Provision</b>	<b>Description and Impact</b>	<b>2007 New Trade Policy</b>
<p><b>Lowering the standards for patentability</b> – creating new patent monopolies for existing medicines.</p>	<p>The TPP requires countries to grant secondary patents on modifications of existing medicines for at least one of the following: new uses, methods of use or new processes of a known product. This provision is designed to prevent countries from using public health safeguards in their national patent laws and judicial decisions that limit abusive patent evergreening. The effect will keep medicine prices high by delaying the availability of price-lowering generics.</p>	<p>Not mentioned – TRIPS flexibilities allowed</p>
<p><b>Creating data/market exclusivity</b> – preventing drug regulatory authority (DRA) from approving any generic or biosimilar drug formulation during the period of exclusivity.</p>	<p>The TPP requires countries to protect clinical test data with a period of market exclusivity for at least 5 years for small molecules and at least 3 years for modifications on existing medicines, or 5 years for combinations, which facilitates abusive data evergreening. Furthermore, the TPP contains, for the first time in a US trade agreement, a data protection obligation for a class of products called biologics, already expensive products which are used to treat and prevent cancer, diabetes and many other conditions. The protection for biologics is for at least 8 years of market exclusivity or 5 years with other measures that provide a comparable outcome. These data obligations grant a distinct monopoly protection to medicines, even when patents no longer apply or exist, giving companies a new way to keep prices high for longer and further delaying competition.</p>	<p>Mandatory TRIPS+ data protection with exclusivity for small molecules, but permanent limits and public health safeguards created</p>
<p><b>Mandating patent term extensions</b> – extending 20 year patent terms.</p>	<p>The TPP requires countries to create two mechanisms to extend patent terms. At present, patents on drugs in most countries last for 20 years from the date of filing. The extra years added to the patent are extra years in which the patent holder can maintain a monopoly position and continue to charge artificially high prices for the drug, free from competition.</p>	<p>No obligation - Optional for governments</p>
<p><b>Requiring new forms of intellectual property enforcement</b> – granting customs officials new powers to detain trade of medicines, requiring mandatory injunctions for alleged IP infringements; raising damages amounts.</p>	<p>The TPP contains a variety of obligations that increase the risk of unwarranted interruptions and delays in the flow of legitimate trade in generic medicines, and limits countries’ judicial systems’ capacity to balance commercial interests and public health interests in intellectual property disputes. These provisions strip away the ability of governments to define their own enforcement provisions as allowed by international law.</p>	<p>Not mentioned – TRIPS flexibilities allowed</p>

MSF is also concerned about other provisions included in the TPP, including:

- Provisions in the “Transparency and Procedural Fairness Chapter” that could restrict the ability of governments to use reimbursement or price control systems to reduce healthcare costs.
- Provisions in the “Investment Chapter” that give pharmaceutical companies the right to sue governments for regulations and decisions that reduce their expected profits in private, supra-national investor-state dispute settlement (ISDS) tribunals, the decisions of which can usually not be appealed.
- Provisions in the “Technical Barriers to Trade Chapter” that prohibit governments from requiring pharmaceutical companies’ “sale or related financial data concerning the marketing of the product” as well as “pricing data” as part of approval for marketing determinations.

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<sup>1</sup> Médecins Sans Frontières. International Activity Report 2014. Available from: <http://www.msf.org/msf-international-activity-report-2014>.

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<sup>3</sup> UNAIDS. Fact sheet 2015. [Online]. June 2015 [Cited 2016 Feb 16]. Available from: <http://www.unaids.org/en/resources/campaigns/HowAIDSchangedeverything/factsheet>.

<sup>4</sup> US Department of State. PEPFAR Blueprint: Creating an AIDS-free generation. [Online] 29 Nov 2012 [Cited 2016 Feb 16]. Available from: <http://www.pepfar.gov/documents/organization/201386.pdf>.

<sup>5</sup> Holmes C, Coggin W, Jamieson D, et al. Use of generic antiretroviral agents and cost savings in PEPFAR treatment programs. [Online] Journal of the American Medical Association 2010; 304(3):313. [Cited 2014 Oct 22]. Available from: <http://jama.jamanetwork.com/article.aspx?articleid=186252>.

<sup>6</sup> Holmes C. PEPFAR: Making smart investments to save more lives. [Online] US Department of State Official Blog, 2011 Feb 18 [Cited 2014 Oct 22]. Available from: <https://blogs.state.gov/stories/2011/02/18/pepfar-making-smart-investments-save-more-lives>

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<sup>8</sup> World Health Organization. Hepatitis C, factsheet no. 164 [Online] Updated July 2015. [Cited 2016 Feb 16]. Available from: <http://www.who.int/mediacentre/factsheets/fs164/en/>.

<sup>9</sup> Centers for Disease Control and Prevention. Hepatitis C FAQs for the Public. [Online] Updated 8 Jan 2016 [Cited 2016 Feb 16]. Available from: <http://www.cdc.gov/hepatitis/hcv/cfaq.htm#statistics>.

<sup>10</sup> US Senate Committee on Finance. The Price of Sovaldi and Its Impact on the U.S. Healthcare System. [Online] Prepared by the staffs of Ranking Member Ron Wyden and Committee Member Charles E. Grassley. December 2015 [Cited 2016 Feb 16]. Available from: <http://www.finance.senate.gov/download/the-price-of-sovaldi-and-its-impact-on-the-us-health-care-system-full-report>.

<sup>11</sup> Van de Ven N, Fortunak J, Simmons B, Ford N, Cooke G, Khoo S, et al. Minimum Target Prices for Production of Direct-Acting Antivirals and Associated Diagnostics to Combat Hepatitis C Virus. Hepatology [Internet]. 2015 [cited 2015 Aug 13]; 61(4): 1174-1182

<sup>12</sup> For example, Pricing of Indian generic sofosbuvir (30th Jan, 2016) <http://hepcasia.com/2016/02/16/pricing-of-indian-generic-sofosbuvir-30th-jan2016/>

<sup>13</sup> Médecins Sans Frontières. Strategies to Secure Access to Generic Hepatitis C Medicines. [Online] May 2015. [Cited 2016 Feb 16]. Available from: <http://www.msfaccess.org/content/strategies-secure-access-generic-hepatitis-c-medicines>

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<sup>16</sup> For example, Mayo v. Prometheus and Association for Molecular Pathology v. Myriad Genetics

<sup>17</sup> Kapczynski, Park and Sampat. “Polymorphs, prodrugs and salts (oh my!): an empirical analysis of ‘secondary’ pharmaceutical patents.” PLOS One [Online] 5 December 2012 [Cited 11 April 2014] Available from: <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0049470>

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