



INTERNATIONAL GENERIC AND  
BIOSIMILAR MEDICINES ASSOCIATION

26 February 2019

Mr. Francis Gurry  
Director General  
World Intellectual Property Organization (WIPO)  
34, chemin des Colombettes  
CH-1211 Geneva 20, Switzerland

### Re: Patent Information Initiative for Medicines (Pat-INFORMED)

Dear Mr. Gurry,

I am writing on behalf of the International Generic and Biosimilar Medicines Association (IGBA) to express concern that the Patent Information Initiative for Medicines (Pat-INFORMED) could unnecessarily delay patient access to more affordable medicines. The IGBA would appreciate the opportunity to engage with you and your staff in a productive discussion of potential solutions.

As you are aware, the Pat-INFORMED database was launched on September 28, 2018. The joint news release issued by the World Intellectual Property Organization (WIPO) and the International Federation of Pharmaceutical Manufacturers Association (IFPMA) describes Pat-INFORMED as “an online tool designed to help procurement agencies better understand the global patent status of medicines.”

The news release also includes comments attributed to you which share WIPO’s views regarding the initiative: “WIPO is committed to increasing the transparency of the patent system and ensuring it works to benefit humankind. As a public-private partnership focusing on access to key patent information, Pat-INFORMED will facilitate the procurement of important medicines and thereby support better health outcomes for people across the globe. Such partnerships are critical to success in the field of public health.”

Given the importance of both access to affordable medicines and competition in pharmaceutical markets worldwide, we are very disappointed that WIPO did not consult with the generic and biosimilar medicines industries during the development of this initiative. It is our view that WIPO



\*\*\*For full details on each association see the respective website\*\*\*



missed the opportunity of valuable insights that has led to a misapprehension of both the utility and potential impact of Pat-INFORMED.

The following is a short summary of some of the IGBA's concerns:

### **1. Pat-INFORMED is a tool for patent linkage**

Pat-INFORMED is an inappropriate tool for medicines procurement. A database that purports to link patents with procurement serves as a tool for patent linkage.

As you are aware, most national governments have not implemented patent linkage systems because they can pose a major barrier to pharmaceutical competition and delay access to cost saving generic and biosimilar medicines. Any form of patent linkage is considered unlawful under EU competition law. In countries where patent linkage provisions are present, provisions are limited as to the scope of the patents that are covered and are balanced by appropriate safeguards to prevent abuse.

There may be a long list of irrelevant patents in the Pat-INFORMED database that may easily mislead procurement agencies and unduly delay access to generic and biosimilar medicines, providing a disservice to public health.

No limitations or safeguards to protect users are included in Pat-INFORMED.

### **2. There is no mechanism to insure the accuracy of the information contained in Pat-INFORMED**

While the information in the Pat-INFORMED database can be accessed from the WIPO website, the information is uploaded directly by the originator companies who are the patent/Supplementary Protection Certificate (SPC) holders, without any controls or verification by WIPO. As such, incorrect information can easily be uploaded to the database, and outdated information may not be revised or removed in a timely manner. This could easily mislead public authorities and delay the opportunity for generic medicines to participate in competitive tenders.

WIPO staff have informed IGBA that a model for Pat-INFORMED is FDA's Orange Book. They are indeed similar in the sense that they both are tools for patent linkage. Yet the FDA has established a way to referee disputes regarding the accuracy of listings in the Orange Book, and such listings by originator drug companies are made under penalty of federal law which includes criminal liability for providing false information to the U.S. government.<sup>1</sup> In addition, the FDA's Orange Book is counter-balanced by incentives to challenge patents. WIPO has created no such means to ensure that Pat-INFORMED contains only accurate patent listings.

As discussed at our meeting with WIPO officials in October 2018 the IGBA has already identified an example of incorrect information in the database. The example we provided at that meeting was in regard to Truvada (emtricitabine) – on 18 September 2018, the UK Supplementary Protection Certificate (SPC/GB05/041) was invalidated with no possibility of appeal by Mr. Justice Arnold of the UK Court.

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<sup>1</sup> See Ashley M. Winkler, et al., *Requirements, Benefits, and Possible Consequences of Listing Patents in FDA's Orange Book*, BNA's Pharmaceutical Law & Industry Report (2018), available at <https://www.finnegan.com/en/insights/requirements-benefits-and-possible-consequences-of-listing-patents-in-fdas-orange-book.html>.



### **3. It is inappropriate for a UN agency to lend legitimacy to such an initiative**

The hosting of the Pat-INFORMED database on the WIPO website provides the public with the perception that WIPO and the United Nations more broadly views the information as being accurate and useful, even though the Pat-INFORMED database can easily be transformed by originator companies into a tool for anti-competitive delays for generic medicines access worldwide as well as for biosimilar medicines, in the event that larger molecules are added to the database in the future.

Given the many issues the IGBA has identified with respect to its potential impact on pharmaceutical competition, procurement and public health, we believe WIPO should reassess its involvement in this initiative and whether the inclusion of a link to the database on its website is appropriate for a United Nations agency.

Thank-you for reviewing these important concerns of the generic and biosimilar medicines industries. We look forward to engaging in a constructive dialog on this issue.

Sincerely,

Jim Keon  
Chair, IGBA

Cc: Dr. Tedros Adhanom Ghebreyesus, Director General, World Health Organization (WHO)  
Mr. Roberto Azevêdo, Director General, World Trade Organization (WTO)

#### **About IGBA**

The International Generic and Biosimilar Medicines Association (IGBA) was founded to strengthen cooperation between associations representing manufacturers of generic and biosimilar medicines from around the world. The IGBA is at the forefront of preserving sustainable competition within our industry, by stimulating competitiveness and innovation in the pharmaceutical sector; thereby, ensuring millions of patients around the world have access to high quality, pro-competitive medicines. For more details see the IGBA website at: [www.igbamedicines.org](http://www.igbamedicines.org).