Patent Information Initiative for Medicines (Pat-INFORMED)

Background Information

The Patent Information Initiative for Medicines (Pat-INFORMED) is a program developed by twenty leading research-based biopharmaceutical companies[1], supported by the World Intellectual Property Organization (WIPO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

Pat-INFORMED seeks to make it easier for national and international drug procurement agencies to access a basic body of patent information. The program is built upon the industry's firm belief that a properly implemented patent system should not only work to sustainably incentivize innovation, but should also strive to make information about patented inventions available, and accessible, to the public to inform and educate others, to add to the body of scientific and technological knowledge, and to promote the further advancement and improvement of technology.

The initiative is based on the concept of a "global version" of the US Orange Book[2]. It will at first provide information on granted patents for small molecule products within oncology, hepatitis C, cardiovascular, HIV, diabetes, and respiratory therapy areas; and any products on the WHO Essential Medicines List that are not within these therapy areas. In addition, a facility for follow on enquiries will also provide a channel for procurement agencies to seek additional clarification regarding the patent status of the products they wish to procure.

Participants will endeavor to have the database relating to these therapy areas ready by mid 2018.

Why have pharmaceutical companies decided to do this now?

Information about granted patents and, in many cases, patent applications is already public, but resources that directly link patents to marketed medicines are more limited (generally available publicly only in select countries (e.g. the US Orange Book or through private databases). Some companies already self-publish this sort of linking patent information, but there is no consistent approach to doing so. As other companies have decided to do the same, it was decided that setting up a common platform would ensure a more consistent approach and best serve the needs of users.

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[1] Abbvie Inc, Astellas Pharma, Boehringer-Ingelheim, Bristol Myers Squibb, Daiichi Sankyo, Eisai Co., Ltd, Eli Lilly and Company, Gilead Sciences, GlaxoSmithKline, Ipsen, LEO Pharma, Merck KGaA, Merck Sharp & Dohme, Novartis, Novo Nordisk Inc, Pfizer Inc., Roche Group, Shionogi, Takeda Pharmaceutical Company, UCB,

[2] The "Orange Book," formally the FDA Approved Drug Products List with Therapeutic Equivalence Evaluations, is available at www.fda.gov/cder/orange/default.htm.

The pharmaceutical industry relies on the patent system, which is based on public disclosure of inventions, and supports the patent system by facilitating access to patent information through Pat-INFORMED.

Why is IFPMA collaborating with WIPO?

The World Intellectual Property Organization (WIPO) is the specialized UN agency with a specific mandate in the field of intellectual property. WIPO has expertise and work programs in global databases as well as collaborative, multistakeholder platforms in the fields of global health, environment, and copyrighted materials. WIPO has the technical capacity, expertise, and confidence of the international community as an objective and independent body with experience managing and reporting patent information. As such, WIPO is a natural organization to facilitate access to patent data from pharmaceutical companies.

Why didn't IFPMA and the pharmaceutical companies do this alone?

Partnership between the public and private sectors is fundamental to success in the field of development. The United Nations Sustainable Development Goals, particularly SDG 17, identify partnerships as both a means to attain development objectives, and an end in itself. Pat-INFORMED fits squarely within the UN's own framework for partnership, and responds to an important need for accessible and available patent information for medicines.

Which countries stand to benefit most from Pat-INFORMED and which ones the least?

Pat-INFORMED will not distinguish in any way between countries. All countries will benefit.

Why is it planned that the Pat-INFORMED will consist of a database and a facility for follow-on inquiries?

The database, which is open to anyone, provides information such as the key patents that are likely to be most relevant to a procurement agency interested in supplying generic products for an approved indication. For example, it will disclose the patent relating to the active ingredient.

In addition to the database, participants have committed to respond in good faith to a procurement agency's *bona fide* and reasonable requests for additional patent information related to a product of interest. For example, it might disclose patents that fall into one of the excluded Orange Book categories, or basic patent information concerning alternative versions of a product that the participant does not presently market. What and whether any additional information will be disclosed is at the discretion of the participant.

We believe that this system will enable a procurement agency to identify key granted patents of interest more easily than would be the case if all granted patents were simply listed in the database, as it creates a channel to provide more comprehensive information.

Why do you need an initial phase which doesn't cover all therapy areas? What is the reason for limiting the information to certain therapeutic area products in the pilot?

An initial phase is needed to see how this initiative works in practice. Depending on the results, participants will decide whether or not to modify or expand the initiative in the future. In the meantime, we believe that the therapy areas covered by the initial phase, including all medicines on the essential medicines list, address significant public health needs.

What will I have to do if I want to find out about a product that is not in the Pat-INFORMED database?

If a procurement agency is interested in finding out more about a medicine that is not included in the therapeutic areas covered by the database, it can make an inquiry to the manufacturer of that medicine through the Pat-INFORMED platform. Answers to such queries are strictly voluntary. If the medicine belongs to a company that has not signed up to Pat-INFORMED, the procurement agency will have to contact that company directly.

Why is the Pat-INFORMED information limited to small molecule pharmaceuticals? What are your plans for the future?

Pat-INFORMED is based on the concept of a “global version” of the US Orange Book. This approach was taken because the Orange Book format is familiar to many users searching medicine patent information, and it has set the standard for listing what are generally considered “core” or “key” patents.

The Orange Book does not include complex therapeutics like vaccines and biologics. The template for vaccines and biologics is still evolving, and Pat-INFORMED participants will explore the possibility of including them as the initiative progresses. In the meantime, once Pat-INFORMED goes live, it will have a facility for follow-on inquiries that allows procurement agencies to request additional information from pharmaceutical companies.

Why is the facility for follow-on inquiries limited to addressing questions from procurement agencies?

The principal purpose of the initiative is to facilitate requests from procurement agencies to obtain information that could enable them to form a preliminary view about whether they can lawfully obtain a generic product without infringing patents. Procurement agencies may not have the expertise, tools, or resources enabling them to make this assessment, and Pat-INFORMED is primarily aimed at facilitating this process.

What happens if there is a mistake in the information in the database?

The database is intended to assist users (procurement agencies) to obtain a preliminary impression of patent status. It should not be the sole source of information in making a decision in such cases as: whether or not to manufacture, purchase, or supply a particular product in a particular country. Before any such decision is made, further due diligence should be done. Pat-INFORMED is not intended to provide a basis for complete freedom-to-operate analyses or other legal determinations. Such analyses would need to be done by professional advisors. This is made clear in the disclaimer section of the website.

Pat-INFORMED participants will attempt to be as accurate as possible. However, mistakes can occur, and sometimes the question of whether something should be entered in the database is a matter of interpretation, where reasonable opinions can differ. As per the disclaimer, mistakes will not affect the legal rights of participants.

If a Pat-INFORMED participant becomes aware of a mistake, it will have the opportunity to correct it.

Will Pat-INFORMED provide freedom to operate guarantee to procurement agencies? If not, why?

No. It will identify patents that Pat-INFORMED participants have the right to enforce and may be relevant to the supply of generic products. It cannot provide – and must not be seen as providing – any guarantee of freedom to operate for a number of reasons.

Can other organizations such as universities and generic companies join?

Any organization that has rights to enforce patents on marketed products and is willing to comply with the Pat-INFORMED Guiding Principles may and is welcome to join.