# PATENT INFORMATION INITIATIVE FOR MEDICINES (PAT-INFORMED) TERMS OF USE / DISCLAIMERS

## I. General

The Patent Information Initiative for Medicines ("Pat-INFORMED" or "the Initiative") is a program developed by a number of global research-based biopharmaceutical companies, 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 global drug procurement agencies to access a basic body of patent information. As a part of its support for Pat-INFORMED, WIPO hosts and administers this patent information database ("Database"), and provides all necessary IT infrastructure for its operation.

IFPMA and WIPO are pleased to provide you with access to and use of this Database for purposes of accessing the information contained therein. These Terms of Use and Disclaimers govern your use of the Database, your use of the information contained therein, and your use of any and all additional features or programs of Pat-INFORMED that you may undertake as a User of the Initiative, including but not limited to any bona fide inquiries that you may make as set forth below, and any activities that you may undertake on any associated portals, websites, Social Media Sites, or any other affiliated media (all of the foregoing collectively hereinafter referred to as the "Pat-INFORMED Services"). The Pat-INFORMED Services are provided solely for your noncommercial use, are intended for informational purposes only, and do not create any legal duty, obligation, or liability on or for WIPO, IFPMA or any listing entity.

YOU MUST READ AND AGREE TO THESE TERMS OF USE AND DISCLAIMERS BEFORE USING THE DATABASE OR ANY OTHER PAT-INFORMED SERVICES. Your use of any of the provided Pat-INFORMED Services constitutes your acknowledgement that you have read and agree to these Terms of Use and Disclaimers, and further constitutes due consideration for your acceptance of these Terms of Use and Disclaimers. If you do not agree to and accept these Terms of Use and Disclaimers, you are not authorized to use any of the Pat-INFORMED Services. These Terms of Use and Disclaimers describe the limited basis on which the Pat-INFORMED Services are available and supersede any prior agreements, arrangements, or understandings between you, WIPO, IFPMA and/or any listing entity concerning Pat-INFORMED or the Pat-INFORMED Services.

The following additional terms and disclaimers also apply:

# II. Pat-INFORMED Database

The Database is a voluntary platform that, subject to the limitations, definitions and restrictions set forth in these Terms of Use and Disclaimers, the Guiding Principles, and other official Pat-INFORMED materials, provides basic information for certain granted patents that listing entities ("Participants"), or any of their affiliates, own or have the legal right to enforce. You acknowledge and agree that Pat-INFORMED is not intended, and shall not be relied upon, as a comprehensive inventory of patent information, as an official record of patent grant or ownership, as a substitute for any information that may be available from national patent offices, regulatory agencies, or any other

source, database or system, or as a replacement to any extent or degree for a freedom-to-operate analysis.

**PARTICIPATION AND LISTING:** Any entity or individual that owns, or has the legal right to enforce, one or more patents that fall within the scope of the Initiative may join as a Participant<sup>1</sup> and list such patents in the Database. You acknowledge that any Participant who lists patents or provides information or other Pat-INFORMED Services does so on a purely voluntary basis, and that such participation shall remain voluntary at all times. You further acknowledge that Participants may voluntarily withdraw their participation and information at any time in accordance with procedures set forth in the Guiding Principles, or in other official documents governing Participation.

**SCOPE OF PATENTS AND INFORMATION:** The Database contains Basic Information for Qualifying Patents, subject to the following definitions, exclusions and further limitations:

- **Basic Information:** Basic Information means, for each Qualifying Patent, the jurisdiction of grant, grant number, and the name of the listing Participant.
- **Qualifying Patents**: A Qualifying Patent is a patent granted anywhere in the world that meets each and all of the following criteria:
  - 1. The patent relates to at least one product marketed and/or approved in at least one country, as determined by applying a theoretical "global Orange Book" standard. In the United States of America, a patent is listable in the "Orange Book" if it (1) claims a small molecule-based drug product or method of use that is approved in the United States and (2) does not fall into one of the excluded patent categories. Similarly, under Pat-INFORMED's theoretical "global Orange Book" standard, a patent granted anywhere in the world meets this listing criterion if it (1) claims a small molecule drug product approved or marketed anywhere in the world and (2) does not fall into one of the categories excluded in the (US) Orange Book.
  - 2. The listing Participant (including all affiliates) either legally owns or has the legal right to enforce the patent in the subject jurisdiction, and is not restricted from publicly disclosing its ownership or right to enforce the patent by any contractual, legal, or other third-party restriction.

<sup>1</sup> Participants of the Initiative may serve the sole role of listing information in the Database for its subsidiary or affiliated companies. In such instances the Participant may have neither ownership or enforcement rights for any of the listed patents, nor be involved in the sale or marketing of the listed product

<sup>2</sup> The "Orange Book," formally the *FDA Approved Drug Products List with Therapeutic Equivalence Evaluations*, is available at <a href="https://www.fda.gov/cder/orange/default.htm">www.fda.gov/cder/orange/default.htm</a>.

<sup>3</sup> Peptides, polynucleotides or other non-small molecule products that are listable in the Orange Book may also be listed in the Database on a voluntary basis

<sup>4</sup> Patents are not listable if they are solely directed to metabolites, intermediate products, packaging, or methods of making (manufacturing process patents).

- 3. The patent relates to a small molecule product, *or*, in the sole discretion of each Participant, to other products that are listable in the US Orange Book.
- **Additional information:** In addition to Basic Information, the following additional information may be provided under the terms and conditions specified below:
  - O Participants may, where available and at their sole discretion, provide additional information relating to a Qualifying Patent, such as the publication number, publication date, application filing date, or grant date.
  - O WIPO may also list additional information derived from public databases, such as Abstracts from listed patents, and links to other databases such as PATENTSCOPE ("WIPO Information"). WIPO Information shall designate WIPO as the source of such information in the Database. You acknowledge and agree that WIPO Information is provided as a further convenience directly by WIPO, has not been reviewed or approved by Participants, and shall not be attributed to any Participant.
- **Exclusions:** In addition to and notwithstanding the above, you acknowledge that the following are expressly excluded from Basic Information and from the Database:
  - a. Pending patent applications that have not yet granted;
  - b. Pending patent applications whose grant has not yet been timely communicated to the Participant before the time of the last Database update;
  - c. Patents owned or controlled by third parties (unless the Participant has a legal right to enforce the patent and is not restricted from publicly disclosing it by legal or other third-party restrictions);
  - d. Patents solely directed to manufacturing processes, or any of the other categories of patents excluded from the US Orange Book;
  - e. Patents that do not read on a product that is approved somewhere in the world;
  - f. Utility models; non-utility patents such as "innovation patents" and design patents; and any other form of intellectual property that is not a utility patent (e.g. copyrights, trademarks, trade secrets, know-how, regulatory exclusivities, etc.).

**LISTING OF BASIC INFORMATION:** Qualifying Patents and the Basic Information for each are listed in the Database according to the international non-proprietary name (INN) to which the Qualifying Patent pertains.\_\_

**LISTING OF PATENTS UNDER EXTENDED EXCLUSIVITY:** Qualifying Patents that have been granted an extension, such as a Patent Term Extension (PTE), Patent Term Adjustment (PTA), Pediatric Extension, or a Supplemental Protection Certificate (SPC) or similar sui generis extension right, will remain listed until the first scheduled update after the expiry of the extension. Alternatively, Participants may, at their sole option, list extensions on Qualifying Patents as separate entries within the patent family.

FREQUENCY OF UPDATES; AVAILABILITY OF INFORMATION: The Database is being populated in a phased approach, prioritized for those disease areas of greatest public health need (as determined in the sole discretion of IFPMA and Participants), until all Qualifying Patents in all fields are ultimately listed. Once fully populated, information in the Database will be updated at least annually except for information on Qualifying Patents that relate to products on the World Health Organization's Essential Medicines List (EML), which will be updated at least every six (6) months. You acknowledge that during the phased implementation, between updates, and at various other times, information, including Basic Information, may not be immediately available in the Database for all Qualifying Patents and/or may be incomplete, inaccurate, or out-of-date, including patents which may have expired and which, due to the frequency of updates or for other reasons, have not yet been removed from the Database. While WIPO and Participants will make reasonable efforts to populate and update the Database in a timely manner and within the stated timeframes, neither WIPO nor Participants make any guarantees as to the timely availability of information in the Database.

# III. Bona Fide Follow-on Inquires

In addition to the Database, Pat-INFORMED includes an online platform through which genuine procurement agencies may initiate bona fide and reasonable requests for additional patent information related to a product of interest. The bona fide follow-on inquiry platform is an additional feature of Pat-INFORMED, separate from the Database, that is only available to genuine procurement agencies and their representatives. Participants are committed to providing a good faith response to any bona fide and reasonable request submitted through this platform, provided that you are or represent a genuine procurement agency, and subject to the following additional terms and conditions:

- **A.** You must register as a procurement agency or as an official representative thereof and create a Pat-INFORMED account before receiving access to the online bona fide follow-on inquiry platform.
- **B.** Each Participant will make its own determination as to whether a particular request made through the platform is bona fide and reasonable, and its own determination as to the nature, content and scope of any response, taking into account the totality of the circumstances. As a general matter, what constitutes "bona fide and reasonable" will be determined by reference to the purpose of Pat-INFORMED, though other factors may apply. Although Participants commit to respond to all bona fide and reasonable inquiries in good faith, Participants generally will not provide information that is not publicly available, or legal opinions or advice of any nature, such as whether a particular patent may or may not read on a particular product. All decisions as to whether, and in what manner, to respond to an inquiry are in the sole discretion of each Participating company.
- **C.** In addition to creating a Pat-INFORMED account, as a pre-condition to any response, you will be required to identify yourself, the genuine procurement agency that you represent, your role or relationship to such agency, and any real-party-in-interest. By submitting an

inquiry and otherwise availing yourself of the Pat-INFORMED Services, you acknowledge and agree that the details of your request and of the information you provide will <u>not</u> be held confidential, and may become public. Although any bona fide inquiry that you make to a Participant will only be received by the Participant, you further authorize WIPO, IFPMA and Participants to use, refer to, and publish the fact or details of any inquiry for purposes of documenting, reporting upon, publicizing, or promoting Pat-INFORMED, or for any other non-commercial purpose. At all times, each Participant in its sole discretion reserves the right to accept or reject your inquiry on the basis of the information you provide, and to determine whether you are or represent a genuine procurement agency for purposes of providing a response. In the event that a Participant rejects your inquiry, you will be notified of the decision, but you acknowledge that Participants are under no obligation to provide a reason for the rejection.

- **D.** Participants will make reasonable efforts to respond to bona fide and reasonable requests from genuine procurement agencies in a timely manner, but make no guarantee of responding in any set period of time.
- **E.** You acknowledge that any response to a bona fide inquiry is purely voluntary, and that a decision to respond is not a guarantee that any particular type or scope of information will be provided.

#### IV. Disclaimers

No warranty for information, content, or services: All information provided on this Database and through the Pat-INFORMED Services, including any communications in the form of any social media, e-mail message, text message, short message service ("SMS"), and/or other media, or any related microsites and/or derivative works of any of the above, is entered manually and is subject to human error. Although effort has been made to provide complete, accurate and timely information, PARTICIPANTS, WIPO AND IFPMA MAKE NO WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, ABOUT THE SUITABILITY, RELIABILITY, AVAILABILITY, QUALITY, MERCHANTABILITY, FITNESS, CONTENT, CURRENCY, TIMELINESS, ACCURACY, COMPLETENESS, OR USEFULNESS OF ANY INFORMATION, CONTENT OR SERVICE PROVIDED THROUGH THE PAT-INFORMED SERVICES. All such information, content and services are provided on a strictly "AS IS" basis, and you are fully and solely responsible for your use of them and for any results or consequences of your use. YOUR USE OF THE PAT-INFORMED SERVICES IS AT YOUR SOLE RESPONSIBILITY AND AT YOUR OWN RISK. WIPO, IFPMA and Participants neither endorse, support, warrant nor expresse any opinion on any User, any Technology, service, product, organization name or other information.

**NO RELIANCE, NO LICENSE TO USE:** You further acknowledge and agree that information provided through the Pat-INFORMED Services is for general, noncommercial, informational purposes only, and shall not be understood or relied upon in any way or form as commercial, investment-related, or legal advice, a legal opinion, a legal determination, or any other type of binding statement or representation with regard to any patent's validity, meaning, scope, enforceability, ownership,

listability in other resources or databases, or any other subject matter. Moreover, you acknowledge and agree that neither information provided through the Pat-INFORMED Services, nor any omission therefrom, shall be understood or relied upon in any way or form as an indication of a Participant's intent to enforce or not enforce any patent. You further acknowledge and agree that neither the use of the Pat-INFORMED Services nor anything in these Terms of Use and Disclaimers constitutes or entails the grant of any license, express or implied, nor any other form of authorization or consent to practice or use any of the patents listed or described in any of the Pat-INFORMED Services, or any other patents or intellectual property rights.

**CORRECTIONS:** You acknowledge and agree that WIPO, IFPMA and Participants reserve the right to amend, remove or correct any information provided in the Database or through the Pat-INFORMED Services at any time in their sole discretion, for any reason, and without prior notification, and will not be liable for any such amendment, correction or removal.

## V. Limitations of Liability

NO LIABILITY FOR INFORMATION, CONTENT OR SERVICES: You acknowledge and agree that any error, omission, inaccuracy, or incompleteness in any of the information provided in the Database, or through or in any of the Pat-INFORMED Services, will not create any liability against WIPO, IFPMA, or any Participant. UNDER NO CIRCUMSTANCES, INCLUDING NEGLIGENCE, SHALL WIPO, IFPMA OR PARTICIPANTS BE LIABLE FOR ANY DAMAGES OF ANY KIND, WHETHER DIRECT, INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, CONSEQUENTIAL, OR OTHER DAMAGES, INCLUDING COSTS, EXPENSES (INCLUDING ATTORNEYS' FEES), LIABILITIES, AND LOSSES OF ANY KIND WHATSOEVER THAT MAY RESULT USE OR INABILITY TO USE THE PAT-INFORMED FROM THE SERVICES, INTERRUPTIONS, ERRORS, DEFECTS, MISTAKES, OMISSIONS, DELETIONS OF FILES OR INFORMATION, DELAYS IN OPERATION OR TRANSMISSION, NON-DELIVERY OF INFORMATION, DISCLOSURE OF COMMUNICATIONS, OR ANY OTHER FAILURE, ACTION, INACTION, OR PERFORMANCE. You further acknowledge and agree that any error, omission, inaccuracy, or incompleteness in any of the information provided through any of the Pat-INFORMED Services will not in any way limit or impair any legal right of any Participant, affiliate, patent owner, assignee or licensee. Moreover, any error, omission, inaccuracy, or incompleteness in information shall not be relied upon in any way to challenge, limit or impair any legal right or right to enforce any legal right of any Participant or third party in any forum whatsoever.

**NO LIABILITY FOR RELIANCE:** In addition to the above, you acknowledge and agree that WIPO, IFPMA and Participants will not be responsible for any damages of any kind, whether direct, indirect, incidental, special, punitive, consequential, or other damages, including costs, expenses (including attorneys' fees), liabilities, and losses of any kind whatsoever, that may result from any conclusions, opinions, or inferences that you or any third party may or may not draw or derive, or any actions that you or any third party may or may not take, from or as a result of the use of the Pat-INFORMED Services. Reliance on the information, content and services provided is solely AT YOUR OWN RISK.

## VI. Indemnification

You agree to defend, indemnify and hold WIPO, IFPMA and each and every Participant and any listed patent owner, assignee or licensee, harmless from and against any claims, liabilities, damages, losses, and expenses arising out of or in any way connected with any of the following:

- A. Your access to or use of the Pat-INFORMED Services for any purpose not authorized by these Terms of Use and Disclaimers;
- B. Your breach, attempted breach, or alleged breach of these Terms of Use and Disclaimers;
- C. Your violation of any right of a Participant or third party, including but not limited to any intellectual property right;
- D. Your violation of any law, rule, or regulation; or
- E. Any misinformation that you make, provide or cause to be provided.

You agree that you will cooperate to the maximum extent required in the defense or indemnification of any claim arising out of or in any way connected with any of the above. WIPO, IFPMA, Participants, and any listed patent owner, assignee, or licensee, as applicable, reserve the right to assume the defense and control of any matter subject to indemnification by you, and you will not in any event settle any claim without the prior written consent of the relevant aforementioned party.

#### VII. Other Terms and Conditions of Use

SERVICE INTERRUPTIONS/EVENTS BEYOND CONTROL: Although WIPO intends to provide continuous access to the Database and the other Pat-INFORMED Services, there will be occasions when the Pat-INFORMED Services may be interrupted for maintenance, updates, repairs, or due to other events beyond its control including, without limitation, internet failures, equipment failures, electrical power failures, computer viruses, strikes, labor disputes, riots, insurrections, civil disturbances, shortages of labor or materials, fires, floods, storms, earthquakes, explosions, acts of God, war, terrorism, pandemics, outbreaks, intergalactic struggles, governmental actions, orders of courts, agencies or tribunals or non-performance of third parties. WIPO, IFPMA and Participants will not be liable in any way for any suspension or discontinuation of the Pat-INFORMED Services as a result of any of these interruptions, no matter the cause or circumstances. The provisions of this paragraph are in addition to, and not intended to limit or modify, the limitation of liabilities provisions of these Terms.

**PROHIBITED USES:** Automated queries, bulk downloads of information from Pat-INFORMED, and sharing data from Pat-INFORMED in bulk with others are expressly forbidden. You agree not to engage in these prohibited uses.

**ABUSIVE USE:** WIPO reserves the right to block access for abusive use of the Pat-INFORMED Services. Abusive use of the Pat-INFORMED Services includes, but is not limited to, any of the following:

- importing emails addresses into contact databases, etc.;
- sending unsolicited emails;

- defaming, abusing, harassing, stalking, threatening or otherwise violating the legal rights (such as rights of privacy and publicity) of others;
- publishing, posting, distributing or disseminating any defamatory, infringing, obscene, indecent or unlawful material or information;
- uploading or attaching files that contain software or other material protected by intellectual property or other rights unless the User owns or controls the rights thereto or has received all consents therefore as may be required by law;
- uploading or attaching files that contain viruses, corrupted files or any other similar software or programs that may damage the operation of another's computer;
- deleting any author attributions, legal notices or proprietary designations or labels in any file that is uploaded;
- falsifying the origin or source of software or other material contained in a file that is uploaded; or
- downloading any file uploaded by another User that the User knows, or reasonably should know, cannot be legally distributed.

USER INTERFERENCE AND SYSTEM INTEGRITY: You agree not to use any device, software or routine to interfere with the proper working of the website, the Database, or any other aspect of the Pat-INFORMED Services, or which is intended to damage, interfere with, surreptitiously intercept or expropriate any system, data or personal information. You further agree not to take any action that imposes an unreasonable load on WIPO's infrastructure; to knowingly or recklessly introduce a virus or other harmful component, or otherwise tamper with, impair or damage the Database or any other Pat-INFORMED Service; or interfere with any person or entity's use or enjoyment of any Pat-INFORMED Service. Additionally, you agree not to access, monitor or copy, or permit another person or entity to access, monitor or copy, any element of the Database or Pat-INFORMED Services using a robot, spider, scraper or other automated means or manual process without the express written permission of WIPO and IFPMA.

**RESPONSIBILITY FOR LOGIN CREDENTIALS:** You acknowledge and agree that you are responsible for maintaining the confidentiality of any login name and password for any account that you open to access any of the Pat-INFORMED Services. You may not disclose or share your login name or password for any unauthorized purposes. You agree to notify WIPO promptly of any unauthorized disclosure of your login information or password.

**TERMINATION:** These Terms of Use and Disclaimers remain in full force and effect while you use and as long as you use any of the Pat-INFORMED Services. You may terminate your use of the Pat-INFORMED Services at any time. WIPO may terminate or suspend your use of and access to the Database or any of the other Pat-INFORMED Services at any time, for any reason, and without warning. WIPO may also terminate or suspend your use of and access to any and all of the Pat-

INFORMED Services immediately, without prior notice or liability, if you breach, threaten to breach, or attempt to breach of any of these Terms of Use and Disclaimers, or if WIPO is obligated to suspend or terminate your access or use under any applicable law, rule or regulation. Upon termination of your access to the Pat-INFORMED Services, your privilege to use the Pat-INFORMED Services, including the Database, will immediately cease. All provisions of these Terms of Use and Disclaimers which, by their nature, should survive termination, shall survive termination, including, without limitation, ownership provisions, disclaimers and limitations of liability.

**SEVERABILITY:** If any term of these Terms of Use and Disclaimers is deemed to be in any way invalid, illegal, or incapable of being enforced, such term shall be excluded to the extent of such invalidity, illegality or unenforceability. All other terms shall remain in full force and effect, and, to the extent permitted and possible, the invalid or unenforceable term shall be deemed replaced by a term that is valid and enforceable and that comes closest to expressing the intention of such invalid or unenforceable term.

# VIII. Privileges and immunities

Nothing in or relating to these Terms of Use and Disclaimers shall be deemed a waiver of any of the privileges and immunities of WIPO in conformity with the Convention on the Privileges and Immunities of the Specialized Agencies approved by the General Assembly of the United Nations on November 21, 1947 and with the provisions of the Agreement between the Swiss Federal Council and WIPO to determine the organization's juridical status in Switzerland of December 9, 1970, and of the Implementation Arrangement of the same date related thereto.

# **IX.** Settlement of Disputes

## A. DISPUTES WITH WIPO

Any dispute, controversy or claim between you and WIPO arising out of or relating to the use of the Pat-INFORMED Services that cannot be resolved by negotiation shall be submitted to conciliation in accordance with the UNCITRAL Conciliation Rules. The place of conciliation shall be Geneva. The language to be used in the conciliation shall be English.

If, and to the extent that any such dispute, controversy or claim has not been settled pursuant to the conciliation within sixty (60) days of the commencement of the conciliation, it shall, upon the filing of a Request for Arbitration by either party, be referred to and finally determined by arbitration in accordance with the UNCITRAL Arbitration Rules. There shall be a sole arbitrator. The place of arbitration shall be Geneva. The language to be used in the arbitral proceedings shall be English.

WIPO shall not have any responsibility, obligation or reliability whatsoever with respect to any disputes between you and other Users, and/or between you and IFPMA, Participants or third parties.

# **B. Disputes with IFPMA**

Any dispute, controversy or claim between you and IFPMA arising out of or relating to the use of the Pat-INFORMED Services that cannot be resolved by negotiation shall be governed by the laws of Switzerland and settled in the Courts of Geneva.

# **C.** Disputes with Participants

Any dispute, controversy or claim between you and any Participant arising out of or relating to the use of the Pat-INFORMED Services that cannot be resolved by negotiation shall be submitted to the International Court of Arbitration of the International Chamber of Commerce and shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. This contract shall be governed by the substantive law of Switzerland. The seat of arbitration shall be Switzerland. The language to be used in the arbitral proceedings shall be English.