GUIDELINES FOR FILING OF PCT APPLICATIONS

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INDIAN COUNCIL OF MEDICAL RESEARCH

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Preamble

The Indian Council of Medical Research (ICMR) is the premier autonomous organization of the Department of Health Research, Government of India, for planning, promoting, coordinating and conducting biomedical research in India through a network of 33 Institutes and extramural support system. The ICMR (estd. 1911) has a broad mandate to generate new knowledge in all areas in biomedical research that would have a bearing on improving the health of Indian people. The scientists of the Council are encouraged to create new knowledge and protect through appropriate IPR systems. For this purpose, the Council has created the Intellectual Property Rights (IPR) Unit in the ICMR Headquarters for the protection, maintenance and exploitation of new IPR generated. The IPR Unit helps scientists to identify innovative component of their research and seek patent protection before publication and provides all techno-legal and other support for bringing the products into the market. The IPR Unit is also charged with the responsibility for the technology transfer and licensing to the industry for quick and efficient development of new medical technologies developed by its scientists. There are also 26 Translational Research Units established in all major institutes of ICMR to assist this process.

Mission

Major thrust and focus of the ICMR, New Delhi, is to work towards improving the health of the Indian people. The Council promotes biomedical research through its research institutes/centres and also by sponsoring and supporting extramural research so that the various technologies developed could be transferred to the industries for commercialization thereby making them accessible to the society. ICMR thus recognizes and supports new intellectual property development and technology transfer as integral components of its mission and asserts that the guiding principle governing the conduct of these activities shall be the prompt and efficient availability of the products developed indigenously for the service of its mission.

Major concerns for filing PCT applications from the ICMR

1. *Diseases/areas with limited and/or non-availability of health products:* It is well known that the pharma industry is not interested in drugs, diagnostics and vaccines for diseases of the poor as there is not enough market for these drugs and therefore not enough profits for the industry. Most of such drugs are purchased by the govt. for public sector use and therefore the price is not market-driven. Any new knowledge that would lead to a new health product and/or process in the area of neglected diseases.

2. *New products in the area of non-communicable diseases (NCDs):*
There is a steady increase of non-communicable diseases (NCD) like cardiovascular diseases (such as heart attack and stroke), cancers, chronic respiratory diseases (such as chronic obstructive pulmonary disease and asthma), and diabetes. Roughly 80 percent of NCD related deaths occur in low- and middle-income countries, where fragile health systems often struggle to meet the population's most basic health needs primarily due to the cost of health products like for cancer, diabetes, heart diseases as these drugs need to be taken often for lifetime. Any NCD interventions that are relevant from the local context based on country and region-specific priorities and burden of disease considerations could be considered for PCT filing. Also, such products are likely to have global markets.

3. *Technology that would lead to platform technologies*

Platform technologies enable the creation of products and processes that support present or future development of new drugs, vaccines or diagnostics. They could be structural or technological form from which various products can emerge without the expense of a new process/technology introduction. Any such creation of platform technologies could be considered for PCT filing.

4. *Knowledge that substantially contributes to the future development new products and processes.*

Any new patentable invention that substantially contributes to new knowledge that would lead to a new product even at a later date for the creation of process or method for public health use could be considered even though it may not immediately lead to the product/process.

Patent filing system in the Council

The Council has an existing policy framework for filing applications for Indian patents (both from intra and extramural). But so far there are no specified guidelines for international filings, especially for PCT filings route which is considered the most appropriate approach. Currently, PCT filings are done through the system of expert committee(s) on a case to case basis. As the PCT filing and the subsequent identification of countries for filing and maintenance is an expensive process, it is proposed to formulate a policy that would help the Council in the process of standardization and harmonization of PCT filings. Therefore there is need to formulate robust, transparent and less restrictive/ more inclusive PCT guidelines for development of low cost medicines and other health products like vaccine, diagnostics, devices for the diseases prevalent in the country.

The contextual references of previous studies are also supporting the requirement of balance between IPR and public health.

1. Studies conducted jointly by WHO, WIPO and WTO on *Promoting Access to Medical Technologies* (2012) states that **an Intersection is required between public health, intellectual property and trade** which may improve understanding of the options available to policymakers in developing effective public health strategies that address the balance between IP and access.

2. WHO Policy Perspectives on Medicines- Equitable access to essential medicines: a framework for collective action (2004), also refers **that global trade agreements can threaten access to newer essential medicines in low- and middle-income countries**. Although the total number of people with access to essential medicines has increased from around 2.1 billion in 1977 to an estimated 3.8 billion in 1997, but still it is very low in relation to population of Low & Middle Income Countries.

3. WIPO Development Agenda (2007) Adopted 45 Recommendations also refers that **public policy should be inclusive and member-driven; take into consideration a balance between costs and benefits**; consider the preservation of the public domain within WIPO's normative processes and deepen the analysis of the implications and benefits of a rich and accessible public domain.

"*There is a vast area of practical cooperation, which is very important in the achievement of the balance between creation, on the one hand, and diffusion of the social benefit of creation, on the other hand*." Francis Gurry, Director General, WIPO

WIPO is the specialized agency of the United Nations dedicated to developing a balanced and accessible IP system which rewards creativity, stimulates innovation and contributes to economic development in the public interest.

In light of international studies there is need to devise guidelines to consider applications for PCT filing and these guidelines should be more inclusive and robust, less restrictive and encourage more filing with special reference to the neglected diseases.

What is PCT system?

The Patent Cooperation Treaty (PCT), an international patent law treaty that provides a unified procedure for filing patent applications to protect inventions in each of its contracting states. The PCT makes it possible to seek patent protection for an invention simultaneously in a large number of countries by filing a single "international" patent application instead of filing several separate national or regional patent applications. The granting of patents remains under the control of the national or regional patent offices in what is called the "national phase".

The PCT procedure includes:

Filing: An international application with a national or regional patent Office or WIPO, complying with the PCT formality requirements may be filed in one language, and one set of fees.

*International Search***:** An "International Searching Authority" (ISA) (from one of the identified WIPO patent offices) conducts a prior art search to ascertain whether the invention is patentable, and establishes a written opinion on the invention's potential patentability.

International Search Report: The search report with written opinion is transmitted by ISA to International Bureau of WIPO after 16 months from date of priority.

International Publication: As soon as possible after the expiry of 18 months from the earliest filing date, the content of the international application is disclosed to the world.

National Phase: After the end of the PCT procedure, usually at 30 months from the earliest filing date of the initial application, from which one claim priority and start to pursue the grant of the patents directly before the national (or regional) patent Offices of the countries in which one want to obtain them.

Advantages: The PCT System offers several advantages for international filings such as:

(a) It provides 18 months for seeking protection in foreign countries, to appoint local patent agents in each foreign country, to prepare the necessary translations and to pay the national fees;

(b) If the international application is in the form prescribed by the PCT, it cannot be rejected on formal grounds by any PCT Contracting State patent Office during the national phase of the processing of the application;

(c) The international search report and written opinion contain important information about the potential patentability of the invention, providing a strong basis to make business decisions about how to proceed;

(d) It offers the possibility during the optional international preliminary examination to amend the international application, enter into dialogue with the examiner to fully argue the case and put the application in order before processing by the various national patent Offices;

(e) The search and examination work of patent Offices in the national phase can be considerably reduced, the written opinion and, where applicable, the international preliminary report on patentability that accompany the international application;

(f) The examination procedures could be fast tracked in the national phase in Contracting States that have PCT-Patent Prosecution Highway (PCT-PPH) agreements or similar arrangements;

(g) Since each international application is published together with an international search report, third parties are in a better position to evaluate the potential patentability of the claimed invention;

(h) For an applicant, international publication online puts the world on notice of invention;

(i) To achieve other savings in document preparation, communication and translations because the work done during the international processing is generally not repeated before each Office; and

(j) If the invention appears to be not patentable at the end of the international phase, one may abandon the PCT application and can save the cost that could otherwise have incurred by directly seeking protection in foreign countries, appointing local patent agents in each foreign country, preparing the necessary translations and paying the national fees.

Guidelines:

To meet its objectives of improving public health through research and balance between IP and public health, the ICMR will pursue guidelines to ensure the most rapid and efficient development of new significant medical technologies developed by its scientists through seeking IP rights via PCT route.

Criteria for PCT filing:

- The criteria/ responsibilities broadly should be inclusive for maximizing the PCT filings to encourage innovations within the ICMR system.
- The responsibilities should be clearly defined for inventor and ICMR.
- The draft proposal prepared by IPR Unit along with the check list will be used by the Expert Committee for arriving at a decision for PCT filing.
- The International Search Report (ISR) is the basis for filing applications in national phase. In case of clear ISR wherein novelty, inventiveness and utility are recognized, the inventor will be consulted to suggest about the potential countries of interest for national phase filing duly recommended by the Director/Head of concerned ICMR/Non-ICMR institute.

- Check list be of simple YES/NO type. (Annexure)
- The inventor must send a write up on the invention with justification for answers given in the check list.

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Annexure

Checklist of criteria

S.no	Checklist	Yes	No
	Commercial Prospective (to be addressed by ICMR in consultation with inventor)		
1.	Identify and name the countries other than India proposed invention for PCT filing/ if in case PCT is not possible then convention application filing. Where are the major manufacturing centers in different countries for proposed invention for PCT filing/if in case PCT is not possible then convention application filing		
2.	Where are the emerging markets and the estimated market size for the invention?		
3.	When any immediate or future commercial potential could be expected in the PCT countries?		
4.	Any landscape analysis for proposed PCT filing done to assess the potential in terms of competing products		
5.	Name of interested potential collaborators to take forward the invention for PCT filing in those countries.		
6.	Status of Indian filing of the invention.		
7.	Is this patent application carried out through joint R&D/collaboration - joint patent? If so names of other assignees non-ICMR only)		
8.	Potential to make the product affordable for the National /Regional /Public health programs of the proposed invention for PCT filing?		

	Public Health Perspective (to be answered by inventor)		
9	Has the approval of the Director/HOD/ Competent authority been taken for this PCT filing?		
10	Strength of invention over the existing prior art in term of enhanced efficacy, advantages etc.		
11	Describe the extent and form of disclosure of your invention made public (including publication/presentation at seminar).		
12	Status of your technology: a. Lab Scale: At Bench/Lab to product the product in small quantity b. Pilot Scale: Performed at small industrial setup for validation of large quantity c. Platform technology: That enables the creation of products and processes that support present or future or development or knowledge that substantially contributes to the future development new products and processes.		
13	To which category does the invention belong: diagnostic, device, formulation, drug, vaccine, technique, others (please specify)		
14	Does the invention cater to the neglected diseases?		
15	Details on competing available products closely related to your technology with special reference to disease specific and cost		

	effectiveness.		
16	Details on countries of interest for national phase filing duly forwarded by Director/Head of organization.		
17	Synopsis of 200 words enclosed.		