

## **Public Consultation on Proposed Changes to Singapore's Patents Regime**

### **1. Introduction**

- 1.1 The Ministry of Law ("MinLaw") and the Intellectual Property Office of Singapore ("IPOS") are seeking feedback on proposed changes to Singapore's patents regime. The period of public consultation is from **5 July 2017 to 1 August 2017.**

### **2. Background**

- 2.1 Since the implementation of the Patents Act in 1995, Singapore has made significant progress towards building a forward looking and robust patents regime that supports innovative individuals and businesses and our future economy. This includes developing our own search and examination capability and transitioning to a positive grant regime. These developments have increased the level of confidence that stakeholders and investors have in our patent system.
- 2.2 During the public consultation period stated at paragraph 1.1, we are consulting on the following:
- (a) Proposed amendments to IPOS's patent examination guidelines on isolated products from nature;
  - (b) Policy concerning two proposed new patents mechanisms (Proposed formal process for the submission of Third Party Observations and proposed new Re-Examination option);
  - (c) Proposed amendments to IPOS's patent examination guidelines on the new patents grace period arising from the Patents (Amendment) Act 2017; and
  - (d) Proposed amendments to Patents Rules concerning patentable subject matter and supplementary examination.

### **3. Proposed amendments to IPOS's patent examination guidelines on isolated products from nature**

- 3.1 The biomedical and biotechnology sector is one of the key pillars of Singapore's economy, and the strength of our patents regime has been a contributory factor. The government has also committed \$4 billion over the period 2016 – 2020 to fund health and biomedical sciences research to improve health outcomes in Singapore. On the other hand, patent protection necessarily affects competition and as a result may inhibit access. Therefore, it is important to have a balanced patents regime which considers the interests of all stakeholders in order to maximise the overall benefit to society.
- 3.2 After consultation with a wide range of local stakeholders, including relevant government agencies, research institutes, academia, patent professionals and companies, we propose to amend Chapter 8 of IPOS' Examination Guidelines

(“Guidelines”) to clarify the distinction between inventions and discoveries<sup>1</sup> as applied to the issue of isolated products found in nature<sup>2</sup>.

- 3.3 More specifically, isolated or purified materials or microorganisms that can be found in nature would represent a discovery and would not be an invention. However if a new use of the isolated or purified material or microorganism is found, then the new use can be claimed. In the case of an isolated material or microorganism which has been modified such that the modified material or microorganism can be clearly distinguished from the isolated or purified naturally occurring material or microorganisms, then not only can the modified material or microorganism be claimed but also any new use of the modified material or microorganism. The scope of the claim, however, must not encompass the isolated or purified naturally occurring material or microorganism.
- 3.4 Likewise, a claim directed at a process that occurs in nature would not be allowable but if a new application of the process is found, then the specific application can be claimed. For example, a method of growing a plant with a particular trait comprising selection and breeding steps would be considered as directed to a process that is found in nature, despite the selection and breeding being performed by man. However, it may be possible to claim the process of selection if the claimed process is a new application, comprising technical steps that clearly distinguishes the process from the natural process. In the same way, an *in vitro* diagnostic method based on novel biomarkers performed on blood samples obtained from patients is an invention if it represents a specific application of a discovery which allows the diagnosis of a disease to be made.
- 3.5 The objective is to support innovation by allowing *access* and providing *rewards* at the appropriate points.
- i. Access. If isolated natural materials cannot be patented, they remain in the public domain as “building blocks”. This enables access and use for all inventors. This facilitates innovation by allowing many to continue working on developing applications relating to the discovery, as the discovery is not monopolised by one party.
  - ii. Rewards. Only allowing patent protection downstream of the discovery means that the subsequent new process or application is rewarded. This incentivises innovation by spurring competition in translational research and development, for example, developing a new process for mass production of the isolated natural material, or developing new downstream products such as a diagnostic kit to detect the specific gene mutation. These can be patented and bring in commercial rewards. Therefore, patent protection at this point can encourage competition to continually develop new processes and products, and improve upon them.
- 3.6 A copy of the proposed revisions to Chapter 8 of the Guidelines is set out in [Annex A](#). We welcome your feedback on the proposed amendments to the Guidelines.

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<sup>1</sup> The Singapore Court of Appeal in *Merck & Co, Inc v Pharmaforte Singapore Pte Ltd*<sup>1</sup> has already made a distinction between a discovery and an invention.

<sup>2</sup> Isolated products from nature refers to naturally-occurring compounds that are isolated or extracted from their natural environments. Examples of isolated natural materials include bacteria, fungi (including yeast), cell organelles, gene sequences as well as chemical compounds such as morphine and penicillin.

**4. Policy concerning two proposed new patents mechanisms (Proposed formal process for the submission of Third Party Observations and proposed new Re-Examination Option)**

4.1 We would like to seek your feedback on the policy for two proposed new patents mechanisms, namely:

- i. A formal process for the submission of Third Party Observations (before patent grant); and
- ii. A new ex parte binding Re-Examination Option (after patent grant).

4.2 The purpose of these initiatives is to have low-cost procedures to reduce the risk of patents being granted that do not meet the requirements for the obtaining of the patent, and for any such patents which should not have been granted, to be revoked in a cost-effective manner. These measures would consequently reduce the cost of patent litigation or avoid it completely.

4.3 A description of the proposed initiatives are set out in [Annex B](#) (Proposal to Formalise Submission of Third Party Observations) and [Annex C](#) (Proposed New Re-Examination Option). We welcome your feedback on the policy for these two proposed new patents mechanisms.

**5. Proposed amendments to IPOS's patent examination guidelines on patents grace period**

5.1 The Patents (Amendment) Act 2017, which broadens the scope of the grace period for patent applications, was passed in Parliament on 28 February 2017 and gazetted in the Government Gazette on 11 April 2017, after a round of public consultation held in October to November 2016 on the proposed primary and subsidiary legislative amendments.

5.2 In this round of public consultation, we would like to seek your feedback on IPOS's proposed examination practice in relation to patents grace period, in light of the expanded scope of the grace period arising from the Patents (Amendment) Act 2017.

5.3 As background:

- i. The new primary and subsidiary legislation amendments (i.e. Patents Act and Patents Rules amendments) relating to patents grace period are intended to come into operation sometime in 4Q 2017;
- ii. Section 2 of the Patents (Amendment) Act 2017 amends Section 14 of the Patents Act and expands the scope of the grace period for patent applications. A copy of the Patents (Amendment) Act 2017 can be found at [Annex D](#). For the full text of the current Patents Act, please refer to Singapore Statutes Online at [statutes.agc.gov.sg](http://statutes.agc.gov.sg); and
- iii. The proposed amendments to be made to the Patents Rules concerning patents grace period can be found in the proposed Rules 3 and 6 of the draft Patents (Amendment) No. 2 Rules 2017 in [Annex E](#), which seek to amend the current Rules 8 and 86(4) of the Patents Rules. Please note that the wording of the proposed draft Patents Rules changes in [Annex E](#) has not been finalised

and is subject to change after legislation drafting by the Attorney General's Chambers. For the full text of the current Patents Rules, please refer to Singapore Statutes Online at [statutes.agc.gov.sg](http://statutes.agc.gov.sg)

5.4 The proposed revisions to the Guidelines concerning patents grace period can be found in [Annex F](#). We welcome your feedback on the proposed revisions to the Guidelines in [Annex F](#).

6. **Proposed amendments to Patents Rules concerning patentable subject matter and supplementary examination**

6.1 We are proposing to amend the Patents Rules such that an examiner may raise an objection relating to patentable subject matter under the supplementary examination route (under Section 29(1)(d) Patents Act).

6.2 The intention is to ensure consistency across all the routes of examination under Section 29 of the Patents Act (whether under the local, mixed or foreign routes) to allow an examiner to raise an objection relating to patentable subject matter. At present, an examiner may only raise an objection relating to patentable subject matter when conducting an examination under the local or mixed routes.

6.3 The proposed Rules amendments are described in the proposed Rule 2 and Rule 5 of the draft Patents (Amendment) No. 2 Rules 2017 in [Annex E](#), which are intended to amend Rule 2A(3) and Rule 46(1A) of the Patents Rules. The intention is to allow an examiner to raise an objection relating to patentable subject matter under the supplementary examination route where the invention in the claims does not constitute an invention. As for the savings and transitional provisions relating to the proposed Rule 2 and Rule 5, we intend to have provisions as described at the box at the end of [Annex E](#). Please note that the wording of these proposed Rules changes in [Annex E](#) have not been finalised and is subject to change after legislation drafting by the Attorney General's Chambers. We welcome your feedback on these proposed Rules amendments.

7. **Conclusion**

7.1 We look forward to your feedback and suggestions in relation to the proposals indicated above.

7.2 Your views are important and will help us in improving the patents regime. The feedback may be submitted in electronic or hardcopy form, with the subject "Public Consultation on Proposed Changes to Singapore's Patents Regime" to:

Intellectual Property Office of Singapore (IPOS)  
51 Bras Basah Road #01-01, Manulife Centre  
Singapore 189554  
Email: [ipos\\_consultation@ipos.gov.sg](mailto:ipos_consultation@ipos.gov.sg)

7.3 IPOS reserves the right to disclose feedback or suggestions and make them available to the general public, in whole or in part, through its website or other means. However, the identity of the respondents will not be disclosed, if so requested.

7.4 Please submit your feedback by **1 August 2017**. Thank you.