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25 April 2017

Mr Keith WONG
Clerk to Establishment Subcommittee
Legislative Council Secretariat
Legislative Council Complex
1 Legislative Council Road, Central

Dear Mr WONG,

Legislative Council Establishment Subcommittee

Meeting on 10 April 2017

Proposed Creation of one Permanent Directorate Post of Assistant Director of Intellectual Property in the Intellectual Property Department

At the meeting of the Establishment Subcommittee on 10 April 2017, Members requested the Government to provide supplementary information on the supernumerary directorate post of Assistant Director of Intellectual Property in the Intellectual Property Department. The relevant information is enclosed for Members' reference.

Yours sincerely,

(Mr Kevin LI)
for Secretary for Commerce and Economic Development

c.c. Director of Intellectual Property
(Attn: Mr Thomas TSANG)

Establishment Subcommittee
Follow-up to Meeting held on 10 April 2017

Proposed Conversion of a supernumerary post of Assistant Director of Intellectual Property to a permanent post to continue with the duties and responsibilities pertinent to the patent portfolio
(EC(2016-17)24)

Supplementary information

At the meeting of the Establishment Subcommittee held on 10 April 2017, Members supported the submission of the proposal on converting a supernumerary Assistant Director of Intellectual Property (ADIP) post to a permanent post to the Finance Committee. This paper provides the supplementary information in response to Members' discussion at the meeting.

(a) The effectiveness of the tasks accomplished by the supernumerary ADIP post for the past 3 years; a list of regular tasks of the permanent post upon conversion from the supernumerary post; and the criteria for measuring the work effectiveness of the permanent post

2. We have explained the effectiveness of the tasks accomplished and the tasks to be accomplished by the Intellectual Property Department (IPD) in implementing the new patent system in our respective papers submitted to the Establishment Subcommittee (vide LC Paper No. EC(2016-17)24) and the Panel on Commerce and Industry (vide LC Paper Nos. CB(1)90/16-17(05) and CB(1)311/16-17(03)). The relevant information is summarised below for Members' reference.

Tasks accomplished by the supernumerary ADIP post in the past 3 years

3. With the assistance of the supernumerary ADIP, IPD has undertaken the following major preparatory tasks for rolling out the new patent system -

(i) in December 2013, IPD signed a Co-operation Arrangement with the State Intellectual Property Office of the Mainland (SIPO) under which SIPO has agreed to provide IPD with technical assistance and support on substantive examination of patent applications and personnel training;

(ii) the Government, having completed the drafting of the legislative exercise for the necessary legal framework of the new patent system, introduced the Patents (Amendment) Bill 2015 (the Bill) into the Legislative Council in November 2015; and

(iii) by assisting the Bills Committee of the Legislative Council in scrutinizing the Bill, the Government promoted support and passage of the Bill by the Legislative Council in June 2016, leading to the enactment of the Patents (Amendment) Ordinance 2016.

4. As the new law and the new patent system can only be brought into effect upon completion of all preparatory work, the supernumerary ADIP had, before the lapse of his time-limited post on 1 April 2017, started to assist IPD in initiating other critical preparatory work, including drawing up proposals on amending the subsidiary legislation to provide for the relevant procedural framework under the new patent system, drawing up the practice guidelines for the examination of patent applications, recruiting patent examiners, and setting up an electronic system to support the new patent system (vide paragraph 7 of LC Paper No. EC(2016-17)24).

5. In the course of the aforesaid preparatory work, the supernumerary ADIP had assisted IPD in communicating with the stakeholders and collecting their views, and reporting on the progress of the implementation of the new patent system and explaining the policies to the public in different conferences and seminars, such as the Business of IP Asia Forum held in December 2016. Moreover, the ADIP had led the Patents Team to draw up publicity plan for promoting the new patent system before and after its implementation.

A list of regular tasks after the supernumerary post is made permanent

6. In paragraph 8 of and Annex 4 to the LC Paper no. EC(2016-17)24, we gave an account of the duties of the proposed permanent ADIP post. The on-going duties of the ADIP are not limited to completing the remaining preparatory tasks for implementing the new patent system. As the operation of the new patent system will become a regular duty of the Government, the proposed permanent post will be held responsible for monitoring, streamlining and enhancing the overall operation of IPD's Patents Registry under the new patent system on a permanent basis. The permanent ADIP is also required to ensure that the new patent system is capable of evolving and improving, which includes keeping track of the developments of patent law and

practice in the international community, regularly reviews of the local patent law (e.g. studying the applicability of the Bolar exemption to Hong Kong), and ensuring the local patent law is on par with and consistent with the international developments and standards by proposing necessary legislative amendments. Furthermore, the permanent ADIP will assist IPD in building up in-house substantive examination capability in the medium to long-term, starting with niche areas where Hong Kong has an edge in research and development in the longer run, establishing a full-fledged regulatory regime for local patent practitioners, and drawing up further publicity plan to promote the new patent system to be implemented etc. The above are all long-term and ongoing tasks.

Criteria for measuring work effectiveness of the permanent post

7. The legal, technical and administrative issues involved in the patent reform are broad and complicated. In view of the increasing workload of IPD in recent years, and having reviewed and examined the current organizational structure of IPD and the manpower need at directorate level, we see an actual operational need to set up a permanent post of ADIP for leading the Patents Team to take on and promote the work pertinent to the patent portfolio in the long term.

8. The proposed permanent ADIP is accountable to his supervisor (the Deputy Director of Intellectual Property (Directorate Legal 3)), the former's work progress and performance will be monitored and assessed in accordance with the existing assessment criteria and procedures under the civil service mechanism. In continuing the reform of the patent system (e.g. tabling the legislative proposal to amend the subsidiary legislation referred to in paragraph 4 above), the Government will report the overall work progress to the Legislative Council as appropriate.

(b) Research progress and preliminary research findings on the inclusion of Bolar exemption principles to the "Original Grant" Patent System by the Government

9. The Government was requested to provide information about its preliminary research findings on the Bolar exemption being an exception to patent infringement available under certain jurisdictions outside Hong Kong.

10. A patent owner has an exclusive right to manufacture and sell a patented drug, and prevent any generic drug manufacturer from entering into the market to sell

the corresponding generic drug during the term of the patent in question. Even after the patent has expired, a generic drug manufacturer has to obtain prior approval from the relevant drug regulatory authorities for putting the generic drug on market (i.e. marketing approval).[1]

The Bolar exemption

11. Following *Roche Products, Inc. v Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (1984)[2] in which the U.S. Court of Appeals for the Federal Circuit held that the use of a patented drug in experiments for obtaining approval from the U.S. Food and Drug Administration before the expiry of the patent did not fall within the defense of experimental use, the US Congress passed the Hatch-Waxman Act in 1985 which made it easier for generic drugs to enter the market. The above Act provides, inter alia, that:

> *"It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."*

12. By virtue of this statutory exemption (also known as the "Bolar exemption") and as far as the jurisdiction in the USA is concerned, generic drug manufacturers no longer have to wait until the relevant patents have expired for conducting tests and experiments solely required for the development and submission of information to the regulatory authorities for approval. In other words, the exemption may enable the entry of generic drugs into the market as early as practicable after the lapse of the relevant patents.

13. Similar exemption has also been introduced into several other jurisdictions including Australia, Canada, Mainland China, European Union, New Zealand, Singapore and the United Kingdom in addition to the USA. An extract of the

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[1] Although the marketing approval procedures for a drug that is bioequivalent to an approved drug are generally simpler and shorter than those for a new drug, the generic drug manufacturer may still have to submit data to show that the generic product is bioequivalent to the approved drug, and conduct additional trials of the generic drug in support of its application.

[2] A copy of the decision is available at http://law.justia.com/cases/federal/appellate-courts/F2/733/858/459501/

relevant statutory provisions on the Bolar exemption under these major jurisdictions are set out in the **Annex**.

Applicability of the Bolar exemption to Hong Kong

14. At present, tests or experiments solely for obtaining marketing approval for generic drugs do not fall within the existing permitted acts under the Patents Ordinance, Cap 514 ("PO").[3] In other words, generally speaking, tests or experiments solely for obtaining marketing approval of generic drugs can only be initiated or conducted after expiry of the patent of the originator drug. As a result, manufacturers of generic drugs would not be able to put their products on the market for sale and distribution immediately upon the expiry of the patent.

15. Further studies have to be conducted followed by stakeholders' consultation, particularly on the following major issues, before we are in the position to reach an informed policy decision on whether and how the existing law should be amended to cater for the Bolar exemption:

(a) Scope of the Bolar exemption

The experience of other jurisdictions indicates that there is no hard and fast rule for the Bolar exemption, i.e. the scope of the exemption is not necessarily the same in every jurisdiction where the exemption is available. This is because the overall underlying circumstances (such as the stakeholders' interest and expectation and the public policy consideration) vary from one jurisdiction to another. In this connection, any policy decision on adopting the Bolar exemption should require careful consideration of the overall underlying circumstances and proper public consultation in order to define the appropriate parameter of the exemption, e.g. whether the exemption should cover pre-clinical testing in addition to the safety and effectiveness testing on human at the later stage, whether the exemption should cover inventions relating to medical devices apart from

[3] The most relevant existing permitted act under consideration is s.75(b) of PO which provides -
"(t)*he rights conferred by a patent shall not extend to—*
(b) acts done for experimental purposes relating to the subject-matter of the relevant patented invention;"

The general principle as stated in paragraph 14 is derived from the UK case law in which the equivalent provision under the *UK Patents Act 1977* (i.e. s.60(5)(b)) was construed by the UK courts (e.g. *Auchincloss v Agricultural & Veterinary Supplies Ltd.* [1999] RPC 397 by the English Court of Appeal) in the absence of local case precedent.

drugs, and whether the exemption should also encompass any post-approval activity (e.g. those relating to retention of data, samples or records that is not submitted to the drug regulatory authority but is required by such authority for potential inspection).

(b) Compliance with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The Bolar exemption, while bringing benefits to the public by expediting the entry of the generic drugs into the market, will inevitably affect the exclusive rights of the patent owner under the existing patent laws in Hong Kong. Given that Hong Kong is a WTO member, any policy decision on whether, and if so how best, any exemption and limitation to patent rights should be introduced into the local patent regime must not only specifically cater for the local circumstances but also has to be in compliance with the test under Article 30 of TRIPS,[4] having regard to the contemporary international landscape and development.

16. Our focus and priority at this stage is to first set up the basic infrastructure that is required to roll out the "original grant" patent system as early as practicable. As a long term commitment, we shall sustain our efforts to run, maintain and enhance the new patent system by reference to the development of the patent law and practice in the international community. Bolar exemption will be one of the study topics. The proposed permanent ADIP(Patents) will be responsible for providing dedicated strategic inputs at the directorate level in this regard.

Commerce and Economic Development Bureau
Intellectual Property Department
April 2017

[4] Article 30 of TRIPS provides that -
"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

Annex

Jurisdiction	Statutory provisions on the Bolar exemption
Australia	Section 119A of the Patents Act 1990 : *"(1) The rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for:* *(a) purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods … ; or* *(b) purposes connected with obtaining similar regulatory approval under a law of a foreign country…"*
Canada	Section 55.2(1) of the Patent Act : *"It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product."*
China	《专利法》**第六十九条：** "有下列情形之一的，不视为侵犯专利权 … （五）为提供行政审批所需要的信息，制造、使用、进口专利药品或者专利医疗器械的，以及专门为其制造、进口专利药品或者专利医疗器械的。" English translation : *"The following shall not be deemed to be patent right infringement:…* *(5) Any person produces, uses, or imports patented drugs or patented medical apparatus and instruments, for the purpose of providing information required for administrative examination and approval, or produces or any other person imports patented drugs or patented medical apparatus and instruments especially for that person."*

Jurisdiction	Statutory provisions on the Bolar exemption
European Union[5]	Article 10, paragraph 6 of the Directive on Medicinal Products for Human Use (Directive 2001/83/EC) : *"Conducting the necessary studies and trials with a view to the application of paragraphs 1,2,3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products."* Article 13, paragraph 5 of the Directive on Veterinary Medicinal Products (Directive 2001/82/EC) : *"Conducting the necessary studies, tests and trials with a view to the application of paragraphs 1 to 5 and the consequential practical requirements shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for medicinal products."*
New Zealand	Article 145 of the Patents Act 2013 : *"It is not an infringement of a patent for a person to make, use, import, sell, hire, or otherwise dispose of the invention solely for uses reasonably related to the development and submission of information required under any law (whether in New Zealand or elsewhere) that regulates the manufacture, construction, use, importation, sale, hire, or disposal of any product."*
Singapore	Section 66(2)(h) of the Patents Act : *"An act which … would constitute an infringement of a patent for an invention shall not be so if … it consists of the doing of any thing set out in subsection (1) in relation to the subject-matter of the patent to support any application for marketing approval for a pharmaceutical product, provided that any thing produced to support the application is not — (i) made, used or sold in Singapore; or (ii) exported outside Singapore, other than for purposes related to meeting the requirements for marketing approval for that pharmaceutical product …"*

[5] The European Union enacts directives which set out the goals to be achieved by the EU member countries. It is for the individual countries to decide on the form and methods in devising its own laws to reach the goals.

Jurisdiction	Statutory provisions on the Bolar exemption
United Kingdom	Sections 60(5) and 60(7) of the Patents Act 1977 : *"An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –* *(a) – (h) …* *(i) it consists of –* *(i) an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs 1 to 5 of article 13 of Directive 2001/82/EC or paragraphs 1 to 4 of article 10 of Directive 2001/83/EC, or* *(ii) any other act which is required for the purpose of the application of those paragraphs."*
United States	Section 271(e)(1) of the 35 U.S. Code (also referred to as "Hatch-Waxman exemption") : *"It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."*