香港特別行政區政府知識產權署
Intellectual Property Department
The Government of the Hong Kong Special Administrative Region

知識產權署
Intellectual Property Department

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16 July 2015

Dear Sir/Madam,

Re: Consultation on patent protection of inventions relating to second or further medical use

We are writing to seek your views on our proposed amendments to the Patents Ordinance (Cap 514) to address the captioned topic. Please find attached hereto a consultation note setting out the material issues and legislative proposals for your attention.

The proposed amendments are intended to form part of the legislative package for, amongst others, introducing an "original grant" patent system and refining the existing short-term patent system for implementing the strategic recommendations of the Advisory Committee on Review of the Patent System in Hong Kong ("Advisory Committee"). A copy of the Report of the Advisory Committee setting out its recommendations is available at http://www.ipd.gov.hk/eng/intellectual_property/patents/review_report.pdf.

In view of the tight legislative time-table, we look forward to receiving your written submissions ***on or before the close of play on 14 August 2015 (Friday)***.

Should you have any question about the consultation, please feel free to contact our Mr. Thomas TSANG (Tel: 2961 6920; E-mail: thomastsang@ipd.gov.hk).

Yours sincerely,

(Ms. Ada Leung)
Director of Intellectual Property

Encl.

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CONSULTATION ON PATENT PROTECTION OF INVENTIONS RELATING TO SECOND OR FURTHER MEDICAL USE

This note seeks your view on a proposal to amend the Patents Ordinance, Cap. 514 ("PO") to specifically address the issue of novelty of inventions relating to second or further medical use.

Background

2. Section 93(1) of the PO sets out the patentability requirements, including the requirement that the invention be new (i.e. the novelty requirement). Section 94(4) of the PO addresses the novelty issue concerning the patenting of a known substance or composition used in medical treatment or diagnosis ("medical use")[1] and provides that such substance or composition is still regarded as new for medical use provided that it has not been known for any medical use before.[2]

3. While the scope of the material statutory provisions is confined to first medical use of a substance or composition and does not cover second or further medical use thereof (collectively referred to as "second medical use")[3], the local court (Court of First Instance) has recognized that patent protection of second medical use can be obtained by using a specific type of claim drafting known as the "Swiss-type claim"[4] which is usually drafted in the format as "*the use of substance ABC for the manufacture of a medicament to treat disease/condition Y*".[5]

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[1] Medical treatment or diagnosis by itself is not patentable but this restriction of patentability does not apply to a product, notably substance or composition, for use in such medical treatment or diagnosis. Section 93(4) PO provides that "[a] *method for treatment of the human or animal body by surgery or therapy and a diagnostic method practised on the human or animal body shall not be regarded as an invention which is susceptible of industrial application for the purposes of subsection (1), but this subsection shall not apply to a product, and in particular a substance or composition, for use in any such method.*"

[2] Section 94(4) PO states that section 94(1)-(3) "*shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in section 93(4) where its use for any method referred to in that subsection is not comprised in the state of the art*".

[3] The existing legal position can be illustrated by the following examples -

(a) A known substance or composition (ABC) for medical use in the treatment/diagnosis of disease/condition X can still be regarded as novel provided that ABC has not been known for any previous medical use.

(b) Where ABC is subsequently found (by means of further researches or clinical applications) to be capable of a new medical use (i.e. second medical use, e.g. in the treatment/diagnosis of disease/condition Y), a direct claim on such second or further medical use is not considered as novel under section 94 of PO mainly because ABC and its previous use in medical treatment/diagnosis has already been known.

[4] It is so called since such type of claim was first allowed by the Swiss Federal Intellectual Property Office in its decision in 1984.

[5] *Abbott GMBH & Another v Pharmareg Consulting Company Ltd & Another* [2009] 3 HKLRD 524.

Overseas practice

4. Section 94(4) of the PO is similarly worded as the repealed section 2(6) of the UK Patents Act 1977 and the then Article 54(5) of the European Patent Convention 1973 under which Swiss-type claims used to be accepted by the UK Intellectual Property Office (UKIPO) and the European Patent Office (EPO) for seeking patent protection of inventions relating to second medical use.[6] The relevant provisions in the aforesaid enactments were subsequently amended to specifically address the novelty of inventions relating to second medical use.[7]

5. We note that following the EPO Enlarged Board of Appeal decision in *G 02/08 Abbott Respiratory/Dosage regime* on 19 February 2010, both EPO and UKIPO considered that Swiss-type claims were no longer necessary. Instead, protection of inventions relating to second medical use should be sought through a direct claim. On the other hand, no similar legislative amendment has been introduced into the Mainland and the State Intellectual Property Office (SIPO) continues to accept Swiss-type claims as an indirect drafting approach for seeking patent protection for inventions relating to second medical use.

Proposal

6. Under our existing patent regime, while patent protection of inventions relating to second medical use can be obtained through the indirect claim drafting of "Swiss-type claims", in light of the overseas developments as briefly stated in paragraphs 4 and 5 above which specifically addresses the novelty of inventions relating to second medical use, we see merit in updating the PO to the same effect. To facilitate consideration, a possible draft of the relevant provisions is attached at Annex.

7. It should be noted that the proposal does not change what is and is not patentable as far as inventions relating to second medical use are concerned, given that patent protection of such inventions is recognized under our existing local patent regime through Swiss-type claims. In this regard, the technical disclosure in terms of the therapeutic substance/compound/composition and the medical use in Swiss-type claim is essentially the same as a direct claim which seeks patent protection for invention relating to second medical use. However, the proposed new provision would enable patent applicants to seek

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[6] In *G05/83* EISAI/*Second medical use*, the EPO Enlarged Board of Appeal allowed the Swiss-type claim.

[7] The revised provisions addressing the novelty of inventions relating to second medical use are section 4A(4) of the UK Patents Act 1977 and Article 54(5) of the European Patent Convention 2000. The revised provisions have confirmed that an invention consisting of a known substance and composition for any "specific use" in a medical method does not prevent such invention from being regarded as new provided that such specific use does not form part of the state of the art.

protection of inventions relating to second medical use through a simpler and more direct claim form.

8. The proposed provision, which has taken into account the corresponding up-to-date enactments in the European Patent Convention 2000 and UK Patents Act 1977, does not prescribe how patent claims, including claim(s) for inventions relating to second medical use, should be drafted in future. Such matters will be dealt with in the examination practice manual of the Patents Registry which will be drawn up having regard to the prevailing practice of other established patents offices outside Hong Kong.[8]

Application

9. It is proposed that the new provision would apply to new patent applications received after commencement of the legislative amendment, as well as applications received before commencement which are pending before the Registrar of Patents. Patents already granted in Hong Kong before commencement would remain governed by the existing law.

Consultation

10. You are cordially invited to provide your views on the above proposals ***on or before the close of play on 14 August 2015 (Friday)*** through post, email or fax -

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25th Floor, Wu Chung House,
213 Queen's Road East,
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Email : 2nd_medical_use@ipd.gov.hk

Fax : 2838 6315

11. We may publish your submission or a summary in response to this consultation for public viewing, together with your name or your affiliation (or both). If you do not wish to disclose your identity in such a way, please state so when making your submission.

12. Any party providing personal data in the submission will have the rights of access and correction with respect to such personal data. Any requests for data access or correction

[8] For example, it is noted that currently SIPO, EPO and UKIPO, the three designated patent offices under our existing "re-registration" system for grant of standard patents, differ in their practice of accepting or rejecting Swiss-type claims.

should be made in writing.

13. This consultation focuses on the issue of second medical use. The Government will keep other issues relating to substantive patent law issues including the patentability requirements under review, and will engage the stakeholders for discussion and consultation in due course.

Intellectual Property Department
July 2015

ANNEX

In order to specifically address the issue of novelty of inventions relating to second or further medical use, we propose to introduce the following new subsections into a consolidated set of provisions concerning "novelty" under the PO which will mirror and supplement the existing section 94 PO:

[s.94] Novelty

...

(5) If an invention consists of a substance or composition for a specific use in a method referred to in section [93(4)][9], the fact that the substance or composition and the use of the substance or composition in any such method form part of the state of the art does not prevent the invention from being regarded as new if that specific use does not form part of the state of the art.

(6) Subsection (5) does not apply to an invention that is the subject of a patent granted before the commencement date of the Patents (Amendment) Ordinance 201[ ] (of 201[ ]).

[9] See footnote 1 above on the existing s.93(4) PO.