

**Patents Registry**  
**Intellectual Property Department**  
**Hong Kong SAR Government**  
**Patents Examination Guidelines**

**Section 5: Medical or Diagnostic Use Claims**

**General principles**

- 5.1. Under section 9A(4) of the Ordinance, methods for the treatment of the human or animal body by surgery or therapy, or diagnostic methods practised on the human or animal body, are not regarded as inventions that are susceptible of industrial application, and thus not patentable.
- 5.2. The purpose of this exclusion from patentability is set out in *Bristol-Myers Squibb Co. v Baker Norton Pharmaceuticals Inc.* [1999] RPC 253 by Jacob J at para. 51 as follows:  
  
*“The purpose of the limitation is much narrower, merely to keep patent law from interfering directly with what the doctor actually does to the patient. Patent monopolies are permitted to control what he administers to, or the implements he uses on, the patient.”*
- 5.3. This exclusion applies to any method claim comprising at least one feature defining a physical activity or action that constitutes a method for treatment of the human or animal body by surgery or therapy, or a diagnostic method practised on the human or animal body. This contrasts with the exclusion under section 9A(2) of the Ordinance which is only applicable to the extent to which a patent or patent application relates to the excluded subject-matter or activities *as such*.
- 5.4. The phrase “practised on the human or animal body” in this exception only relates to diagnostic methods, and not methods for the treatment of human or animal body by surgery or therapy (*Schultz’s Application* BL O/174/86). In other words, therapeutic methods for the treatment of the human or animal body, whether practised on the body or not, essentially remain to be unpatentable.

used to relieve pain but was subsequently found to be useful as an anticoagulant (blood-thinner).

- 5.41. Section 9B(5) of the Ordinance addresses the novelty issue concerning the second or further medical use, under which a specific use of a known substance or composition in a method of treatment of the human or animal body by surgery or therapy, or a diagnostic method practised on the human or animal body is not prevented from being regarded as new, provided that such specific use is new.
- 5.42. In view of the above, for the purpose of substantive examination of standard patent (O) applications and short-term patents, the Registrar of Patents generally accepts direct purpose-limited product claims relating to second or further medical uses in straightforward/undisputed cases, having the following general format:

*Substance X or composition comprising X for use in the treatment of Y (medical condition)*

- 5.43. It is important to note that the absence of the term “for use” in ~~the above example~~ an independent or dependent claim may render the claim unacceptable because it is not evident if/whether the claim is directed to ~~the~~ product suitable for ~~the~~ specified use or ~~if~~ the claim is limited by ~~the~~ medical use.
- 5.44. A claim relating to a medical use specifying a disease or medical condition in the form “*substance X for use in the treatment of disease Y*” is only anticipated by the use of X for the specific purpose of treating disease Y, and is considered to be novel over a broad first medical use claim in the form “*substance X for use in therapy*”.

### **Swiss-type claims**

- 5.45. In the Hong Kong SAR, prior to the commencement of the *Patents (Amendment) Ordinance 2016*, it was recognized in *Abbott GMBH & Co KG & Another v Pharmareg Consulting Co Ltd. & Another* [2009] 3 HKLRD 524 that patent protection of second or further medical uses could be obtained by using a specific type of claim drafting known as the “Swiss-type claim” which is usually drafted in the format as: