Protecting personalized medicine innovation in China and India: Are diagnostic methods patentable?

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The agreement on Trade Related Aspects of Intellectual Property (TRIPS), Section 5, Article 27, provides that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” However, there are exceptions to the phrase “any invention,” and one of them particularly concerns inventions related to diagnostic methods. Specifically, Article 27(3)(a) of TRIPS provides that “members may also exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals.” This exception has been taken by two important markets, namely, China and India, limiting the possibility to protect personalized medicine-related diagnostic inventions in these countries.

Specifically, Article 25(3) of the Chinese Patent Law excludes patent protection for “methods for the diagnosis or for the treatment of diseases”. The Examiner Guidelines particularly note that methods of diagnosis are not patentable if: (1) it takes a live human or animal body as the object on which diagnosis is carried out; (2) its immediate purpose is to obtain the diagnosis of a disease; and (3) it covers the entire process of diagnosis. However, methods to treat or test tissue, body fluids or a discharge that has already been extracted from a human body or animal body, are in principle patentable. Thus, diagnostic tests are not patentable—only a method which provides an intermediate step in obtaining a diagnostic result can be protected. For example, a method for obtaining treatment information (e.g., increase or decrease of a level of a biomarker), rather than a final diagnostic result (e.g., does the subject have cancer or not). The Guidelines note that even if the claim and/or description does not satisfy all of conditions (1) to (3), it may still be excluded if the Examiner considers that it relates to the above in substance. For example, if a claim refers to measurement of a biomarker in a blood or urine sample and the Examiner knows that that biomarker can be used to directly diagnose a disease on the basis of medical knowledge, or if the specification sets forth that the biomarker can be used for diagnosis of one or more diseases, then the application will be rejected as containing non-patentable subject matter.

Therefore, only an invention for a novel biomarker or a novel method of detection could be considered patentable subject matter in China. However, one must be careful in drafting the
specification to avoid any reference of the potential use of the method or marker for any direct diagnostic method.

Similarly, Section 3(j) of the Indian Patents Act 1970, as amended in 2005 to comply with the TRIPS agreement, states that patentable inventions do not include “any process for the medicinal, surgical, curative, prophylactic [diagnostic therapeutic] or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.” Further, Section 3(d) states that “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use of a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.”

These sections apparently differ from the European Patent Convention (EPC) Article 52(4), that EPC excludes patents only for methods that are practiced on the human or animal body, such as surgical methods or diagnostic methods directly applied on the body, but does not exclude in vitro methods performed on samples that have already been taken outside from the body.

However, interpretation of Sections 3(j) and 3(d) in India appears to be somewhat non-uniform. When we asked three different Indian associates whether an in vitro diagnostic method, such as a method of diagnosing a viral disease from a blood or urine sample, is patentable in India, we received three different answers.

According to one of the associates, in vitro diagnostic methods can be patented in India. One should use a claim format that clearly sets forth in the claim that the method is intended for in vitro use only. The suggested claim format would be:

An in vitro diagnostic method to diagnose…comprising the steps of…

According to another one of the associates, in vitro methods should, in theory, be patentable. However, many times they report having come across objections from the patent Examiners and Controllers under Section 3(j), even if the method clearly sets forth that it is performed in vitro. Their counter argument is that “in vitro diagnostic methods which do not involve treatment of the body and are therefore allowable.” This associate advocated that the “claims may be drafted in such a way that they are not clearly directed to a method for diagnosis”, for example:

An in vitro method for the detection of (the biomarker) in (the sample) comprising the steps of ……(give the method steps here) wherein the presence of (the biomarker) indicates the (disease condition) and the absence of (the biomarker) indicates the absence of the (disease condition).

However, the associate reported also receiving rejections under Section 3(d) of the Act. Thus, for example, if the biomarker, as well as its detection method in the sample are already known and if the invention only lies in identifying the use of the said marker in the detection of a disease, the method would not be patentable. Therefore, the advice this associate gave was that to preclude Section 3(d), the claimed method should involve novel and inventive method steps, i.e., the invention should not
be a mere use of a known process. This seems to bring the patentable subject matter closer to that in China.

According to yet another one of the associates, diagnostic methods, whether in vivo or in vitro, are clearly not patentable in view of Section 3(i).

In conclusion, it appears that obtaining patent protection for diagnostic methods faces some difficulties in both China and India. However, if the invention includes a novel biomarker or a novel detection method, there seems to be ways of pursuing such claims in both China and India.

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