

# Crafting Claims in the Life Sciences for an International Application

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“The world is flat,” says Thomas Friedman in his bestseller of the same name, and it’s getting flatter every day. Just a few years ago, no one would ever think of filing a patent application in China or India. Yet today, with manufacturing leaving the United States and foreign markets opening to advanced medical technology, the U.S. remains an important, yet shrinking, part of a global patent portfolio. When drafting applications, U.S. patent practitioners typically draft claims with the U.S. market in mind. While there is continuing discussion about harmonizing patent systems, recent developments in patent law have accentuated the differences between the systems. Although a “foreign” associate can revise the claims to comply with the particular requirements of each jurisdiction, these jurisdictions often have their own particular requirements regarding the disclosure necessary to support claims. This article provides guidance on adequate support and proper claim coverage in jurisdictions outside of the United States. First, the article reviews the requirements for the major jurisdictions, then provides some suggestions for use when drafting applications under the Patent Cooperation Treaty (PCT).

A major consideration for building a patent portfolio is whether or not to pursue protection in countries outside the United States. National and/or regional filing outside of the United States is expensive, often requiring costly translations and yearly annuity payments. Additionally, the value of filing in certain jurisdictions remains questionable. Nevertheless, companies continue filing applications outside of the United States. Indeed, nearly 90 percent of the world’s patents are issued through the U.S., European, and Japan patent offices. Although there are many similarities between drafting claims for a U.S. application and those for an international application, there are also significant differences. Understanding these differences can ultimately improve examination, and ensure both support for your claims and proper claim coverage, resulting in cost savings.

Because of the difficulty in summarizing all the legal differences that exist in each country, we will concentrate on filing for medical technology inventions in the most popular countries or regions: the European Patent Office (EPO), Japan, China, Canada, and Australia. First, we briefly summarize differences in claiming medical methods, including the patentability of treatment and diagnostic claims. Next, we will provide suggestions for preparing claims for an application under the PCT.

## Overview

### Method of Treatment vs. Use of

In the United States, you can claim a method of treating a human. In most of the rest of the world, such methods of treatment claims, particularly those focused on humans, are not allowed. The typical way that such a subject is claimed is by “use of” claims.

However, such claims do not comply with U.S. practice.

### Multiply Dependent Claims

In the United States, you can have a claim depend upon more than one claim, but you cannot have a claim that depends upon more than one claim (a multiply-dependent claim) depend upon another multiply-dependent claim. In most of the rest of the world, multiply-dependent claims can depend upon multiply-dependent claims. As will be explained below, this is important for support purposes in Europe.

## European Patent Convention

Under the European Patent Convention, European patents are granted for any invention that has industrial application, i.e., can be made or used in any kind of industry and is new and involves an inventive step.<sup>1</sup> Similar to the patentability of subject matter in the United States, there are exceptions to patentable subject matter in the EPO, such as scientific theories, mathematical methods, schemes, rules, and methods for mental acts. A major difference between the U.S. and EPC law is that the EPC excludes methods for treatment of and diagnostic methods practiced on the human or animal body. EPC Article 52(4) states that, “Methods for treatment ... and diagnostic methods practiced on the human or animal body ... shall not be regarded as inventions susceptible of industrial

application within the meaning of paragraph 1 [of EPC Article 52]. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.”

Thus, for example, the following claims would not be allowed:

1. A method of treating disease X by administering compound Y (nonpatentable)
2. A method of measuring R (a marker for disease Q) by taking a sample from a subject and analyzing the concentration of substance R.

The second sentence in Article 52(4) EPC provides, however, that substances or compositions for use in any of these methods referred to in the first sentence are not excluded. Therefore, applicants can claim substances or compositions for use in a medical treatment. The EPC allows first medical-use claims for substances, such claims can be written as, for example: “the use of compound X or pharmaceutically acceptable salt thereof as a medicament.”

Further, second medical-use claims, i.e., claims directed to a specific medical use, have been granted if written in “Swiss style,” which generally has the following format: “the use of X (known drug) for the preparation of a medicament for the treatment of Y.”

The patentability of first medical-use claims has never been in question. There has been some question, however, regarding the patentability of second medical-use claims written in Swiss-style form for known compounds with a new medical use. Such second medical-use claims are not explicitly authorized in the EPC articles, and debate has existed as to whether or not such claims are valid if the composition claimed is not novel.

A revision to the current EPC, EPC 2000, went into force in December 2007. The revised law explicitly confirms and provides that second and subsequent medical uses of a known substance or composition are not excluded from patentability, provided that inventive step is involved.<sup>2</sup> Under the revised law the following forms of medical use claims are patentable:

1. Product X for use as a medicament (first medical use)
2. Product X for the treatment of disease Y (second medical use)

The traditional Swiss style, second medical-use claim, i.e., a method for manufacturing a medicament using product X, should also still be allowable. Thus, after December 2007, applicants will be able to choose which style better suits their needs.

Strategies for claiming medical technologies related to diagnostic methods remain unclear, because the European courts have been inconsistent in defining “diagnostic method.” Hence, it remains advisable to claim diagnostics through their compositions or otherwise follow the Swiss style.

Finally, regarding patentable subject matter, the EPO will not grant patents for inventions that are contrary to public order or morality.<sup>3</sup> For example, processes for cloning human beings would be considered contrary to morality.

In the EPO, great emphasis has been placed on finding literal support for a claim. Two recent EPO cases illustrate this. In one case, a claim was not allowed because the exact support for that combination of elements could not be found. In the second case, because the applicant had used a style of having multiply-dependent claims depend upon multiply-dependent claims, it was held that a combination not explicitly discussed in the specification was supported by the claims.

## Japan

In Japan “high-grade creation among creations of technical ideas using natural rules” or “the creation of a technological idea that exploits principles of nature” are patentable. The Japanese definition of patentable subject matter is essentially coextensive with that of the EPC and also excludes processes in the fields of medicine, diagnosis, therapy, and pharmacology in which the human body is an indispensable element. The Japanese Patent Office holds that method inventions in the field of therapeutic or diagnostic treatment of humans are not being part of “industry.”

The legal precedence relating to diagnostics is unclear at this time: In some instances, claims relating to a step in diagnosis short of a full diagnosis or final indication have been allowed in some cases, but not in others. As with the EPC, patent protection is open to

the materials that are used in the excluded methods or the products of those methods. Unpatentable inventions are those “likely to injure the public health.”<sup>4</sup> Typically, the subject matter is claimed as “a composition for doing something.”

## People’s Republic of China

In China, inventions possessing novelty, inventiveness, and practical applicability are patentable.<sup>5</sup> As with the EPO and Japan, an important exception is that methods for diagnosis or medical treatment are not patentable. Swiss format claims to second medical uses are patentable. In China, there is a clear distinction, however, regarding allowable claims relating to diagnostic methods. Claims directed to live humans or animals, to the immediate purpose of obtaining a diagnosis, or to the entire process of diagnosis are not patentable. In contrast, claims directed to obtaining intermediate information or to testing tissue or biological samples *in vitro* are patentable.

## Australia

Australian law with respect to methods of treatment, surgery, and diagnostics is similar to the U.S. law in terms of patentable subject matter. Section 6 of Australia’s Statute of Monopolies provides that a manner of manufacture is patentable as long as the invention is novel and has an inventive step. Human beings and their biological processes for their generation are not patentable.

Accordingly, methods of treatment and diagnostic methods directed to both humans and other animals are patentable subject matter in Australia. In addition, the requirements for support, enablement, and utility are less stringent than those found in the United States, and it is easier to obtain broader methods of treatment claims in Australia versus the United States.

Although methods of treatment and diagnostic methods are patentable subject matter in Australia and it is often easier to obtain such claims, Swiss-style claims, which differ in their scope, are also accepted. Therefore, it may be desirable to include both method-of-treatment claims as well as Swiss-style claims for maximum coverage. It bears noting, however, that unlike what will be accepted in Europe, Australia will view a claim that is in

the format “product X for the treatment of disease Y (second medical use),” as being “suitable for use” in treating a disease, thus, such a claim will likely not be viewed as novel.

With respect to diagnostic-kit claims in Australia, diagnostic-kit claims styled as in the United States are often rejected as merely specifying a collection of known reagents and not being directed to a novel article of manufacture. For example, a claim drafted as “a kit for diagnosing disease Y comprising reagent A and B,” is not patentable in Australia if reagent A and B are known. Diagnostic-kit claims comprising known reagents can be amended upon filing in Australia to recite a kit “when used in a particular diagnostic method” to circumvent a rejection.

## Canada

Any new and useful art, process, machine, manufacture, or composition of matter or any new and useful improvement in any art, process, machine, manufacture, or composition of matter is patentable. Methods of medical treatment and surgery are not patentable, as they are considered by Canadian courts to produce no economic result relating to trade, commerce, or industry.

However, Swiss-style claims are patentable under Canadian law. The following styled claims are acceptable in Canadian practice:

1. Use of X in preparation of a medicament for the treatment of disease Y
2. Use of X for Y
3. Use of X for treatment of Y

Importantly, if the use claim includes any active method step, the Canadian Patent Office will consider the claim to be a method claim and unpatentable. For example:

1. Use of device X for making an incision in tissue Y (acceptable)
2. The use of claim 1, wherein following the incision, device X is inserted into the incision site (not acceptable)
3. The use of claim 1, wherein the incision is semicircular and at least 2 cm in length (acceptable)

The action of inserting device X in claim 2 above would be considered to be a method step and would render claim 2 into a method claim directed to surgery. Claim 3 would be acceptable, as it introduces no method steps, only limitations regarding the shape and size of the incision.

With respect to diagnostic claims, methods of diagnosis are patentable in Canada. The recited method steps must not comprise a treatment or a surgery step, however.

## Drafting International Patent Applications and Claims

It is important for practitioners to understand the differences in style between different countries. Thus, in drafting PCT applications, care should be taken to include claims drawn to all these differing styles. For example, including both method-of-treatment and use-of claims. You should have multiply-dependent claims depend upon multiply-dependent claims to help with support for various combinations. It is also advisable to copy the claim set into the specification to ensure for such combinations in the event that claims are cancelled or amended.

It is also advantageous in your PCT application to place the claims with the most import first. This is because if the PCT issues a lack-of-unity rejection, the claims that will be automatically examined are the first set. If you want additional claims examined, you have to pay additional fees. Also, if the EPO is the designated search authority, it is better to avoid listing method-of-treatment claims first as such claims are not patentable in Europe.

## Conclusions

The necessitated differences in claim drafting between foreign countries arise mainly due differences in unpatentable versus patentable subject matter in the respective countries. Although it is not possible to draft a claim set that meets every requirement of all countries without some amendment, a claim set can be drafted that requires relatively few amendments at the time of submission to the national patent office, e.g., only deletion of inappropriate claims. Applicants may adopt different claim-format styles depending on what countries the applicants wish to enter.

**Acknowledgements:** The authors wish to thank Mary Webster, Nixon Peabody LLP, Washington, D.C., for her assistance with this article. We also wish to thank David Brown, Haseltine Lake & Co., Bristol, United Kingdom; Nick Finnie, Pizzeyes, Australia; Jung-Kay Chiu, Ogilvy Renault, Toronto, Canada; and Hatsushi Shimizu, Shimizu Patent Office, Japan.

## Notes

1. Paragraph 1 of Article 52 EPC.
2. Art 54(5).
3. EPC Article 53(a)
4. See, e.g., Miyako Okada-Takagi, 6 Eubios J. Asian & Int'l Bioethics, 166-68 (1996).
5. *Patents throughout the World*, Thomson West, 2007.