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Crafting claim strategies in animal and human therapeutics

There are varying national eligibility requirements that distinguish between treatments of and diagnostics for animals and humans; it's just a question of reformatting 'method of treatment' claims, write lawyers from Sterne Kessler.

Companies seeking patent protection for methods of treatment related to their therapeutic programmes face different challenges depending on the national laws of the patent office in which they seek patent protection.

For example, some prohibit issuance of patent claims that encompass treating diseases in animals or in humans (e.g., "a method of treating disease X comprising the administering of therapeutic Y.") as being against public policy, while others impose no such restrictions.

However, a handful of countries have different rules depending on whether a claim encompasses treatment of an animal or a human and the purpose of the treatment (e.g., therapeutic versus economic purpose).

The distinction between the eligibility requirements of the US and Europe for claiming treatment of animals and humans is illustrative.

The US permits claims to methods of medical treatments for animals and humans (35 U.S.C. § 101, "Whoever invents or discovers any new and useful process…or composition of matter…may obtain a patent therefore…").

In contrast, the European Patent Convention (EPC) explicitly excludes treatment methods and diagnostic methods directed to animals and humans (Eur. Pat. Conv., Art. 53(c), "European patents shall not be granted in respect of:…methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body").

However, consistent with other patent offices, the European Patent Office (EPO) accepts alternative claim formats to protect medical treatments for animals and humans.

Below, we introduce a sample of strategies to reformat 'method of treatment' claims to meet eligibility requirements in a number of countries, as well as country-specific exceptions that distinguish between treatments of and diagnostics for non-human animals and humans.

I. Claim format workaround strategies

Despite prohibitions on claiming methods for medical treatments of animals and humans, certain countries permit workarounds by adopting specific claim formats.

'Use' claims

As noted above, the EPC explicitly prohibits claiming methods of treating animals and humans. Id. However, the EPO generally permits claim formats for first and second medical indications of a substance or composition.

First medical use claims (e.g., "Product X for use as a medicament") provide an acceptable format when a product is not known for use in medicine and the use in medicine is inventive. [https://www.epo.org/en/legal/guidelines-epc/2025/g_vi_6_1.html].

Likewise, the use-limited product claim format (e.g., “Product X for use in the treatment of disease Y”) of a second or subsequent medical use for a compound provides a useful alternative to a method treatment if the claim involves an inventive step over what was already known about the use of the product as a therapeutic. Id.

'Swiss-type' claims

Several countries permit the so-called Swiss-type claim format (e.g., “Use of substance X for the manufacture of a medicament for the treatment of disease Y”) as a substitute for claims to methods of treating animals and humans.

For example, the Brazilian patent office (Instituto Nacional da Propriedade Industrial) accepts this specific claim format for claims to otherwise prohibited methods of treatment.

Brazil’s prohibition extends to claims specifying uses related to operating techniques, surgical techniques, and therapeutic or diagnostic methods for use on the animal or human.

However, companies can obtain protection for such uses in Brazil by drafting their patent claims in a Swiss-type claim format specific to Brazilian practice that requires the additional phrase “characterised by” (e.g., “Use of a compound of formula X, characterised by being for the preparation of a medicine to treat disease Y.”).

II. Country-specific exceptions to prohibitions on eligibility of treatment claims for non-human animals and humans

Some countries offer different options to capture methods related to treatment of non-human animals versus humans that do not require an alternative claim format.

For example, while New Zealand prohibits methods of treatment of and diagnosis performed on the human body as ineligible for patent protection, New Zealand permits claims to such methods for non-human animals.

Companies seeking to claim methods related to non-human animal therapeutics in New Zealand should be aware, however, that the New Zealand Intellectual Property Office considers terms including “animal,” “mammal,” “primate,” or “hominid” to include humans as well.

Thus, companies should consider preparing patent applications that provide support for non-human animal therapeutics that exclude humans from the scope of the treatment methods.

And as many therapeutics have utility in non-human animals, as well as humans, New Zealand permits the Swiss-type claim format for human therapeutic applications, as the New Zealand Intellectual Property Office does not consider Swiss-type claims to be method of treatment claims.

In contrast, claims to methods of treatment for non-human animals are generally patentable in New Zealand.

As another example, South Korea also prohibits methods for the treatment of or diagnosis performed on the human body but permits claims to such methods for non-human animals, so long as humans are excluded from the claim scope.

Thus, preparing patent applications that provide support for non-human animal therapeutics that exclude humans from the scope of the treatment methods presents opportunities for claiming in South Korea, as well as New Zealand.

Further, South Korea also permits alternative claim formats to protect a first medical or veterinary use of a substance or composition already known, as well as second or subsequent uses of a substance or composition for the treatment of different disease by using one of several claim formats (e.g., "A medicine for the treatment of disease Y… containing a substance X…as an active ingredient").

III. Purpose-specific exceptions to subject matter eligibility

Finally, at least one country that otherwise prohibits method of treatment claims for non-human animals and humans allows an exception in specific circumstances.

For example, the Canadian Intellectual Property Office presents several particularly noteworthy examples of specific eligibility exceptions.

Canadian patent law prohibits methods for medical treatment of living humans or non-human animals. However, Canadian patent law does allow for exceptions for claimed methods directed to certain nonmedical purposes.

These exceptions include treatment directed to non-medical conditions—such as cosmetic treatments—and to animal treatments that are for essentially economic purposes distinct from treating disease.

The eligibility of animal treatments for essentially economic purposes is of particular importance for companies seeking patent protection for therapies that may impact, for example, the efficiency of producer livestock species (e.g., those that are used for production of dairy, meat, or textiles).

IV. Conclusions

The eligibility requirements for method claims involving animal and human treatments are complex and vary depending on the country targeted for patent protection and the specifics of the kinds of treatment claimed.

Companies seeking to develop patent portfolios to protect uses of their therapeutics to treat diseases in non-human animals and humans should develop a global patent protection strategy early to maximise opportunities for claim scope across countries and markets important for animal and human health, as well as non-human animal production.

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