

Under ideal circumstances an applicant generally tries to obtain a patent that claims the underlying invention as a substantive and definitive object or composition. In doing so, the claims extend protection from the invention itself to essentially any use or production thereof. However, such broad coverage is not always achievable, particularly in the medical field where methods of treatment can change more frequently than devices and compositions. While method of treatment claims face some challenges in enforcement, such as divided infringement, the exception of medical practitioners from liability in certain circumstance, and judgement proof defendants, these challenges can be overcome while preserving significant economic value.

At the United States Patent and Trademark Office (USPTO), method of treatment claims must meet requirements related to subject matter eligibility, written description and enablement, as well as novelty and non-obviousness to reach allowance. Recent decisions by the Federal Circuit have shown that the determination of subject matter eligibility in method of treatment claims turns on the use of specific, concrete, physical steps that practically apply natural relationships. In contrast, diagnostic methods that include only observations of natural relationships without steps applying the observations are not patent eligible.

A challenge for meeting the requirements of written description and enablement in method of treatment claims is the need to explain in the application what makes the treatment effective and why. This requirement may lead applicants to delay filing of an application until sufficient experimental results are available to support the claimed invention. Additionally, the requirements of novelty and non-obviousness require applicants to establish that the method of treatment was not necessarily performed in the prior art – as a newly discovered benefit alone does not render a new use patentable. If the above conditions are met, patents including claims directed to methods of treatment can be granted at the USPTO.

Outside of the USPTO, many jurisdictions place limits on the patenting of methods of treatment. Generally speaking, method of treatment claims are not eligible for patenting in Europe, Canada, China, Japan, South Korea, and many other jurisdictions. However, first medical use claims, second medical use claims, and swiss-style claims can avoid the

prohibition on methods of medical treatment in many jurisdictions.