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Overbroad patent claims: Canadian law may draw strength from policy behind U.S. and U.K. Supreme Court rulings

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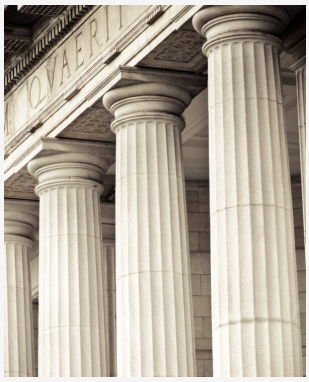

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A recent U.S. Supreme Court decision serves as a reminder that, in the United States as in Canada, a bargain underlies the issuance of a patent: an applicant must fully and clearly disclose the invention to obtain a 20-year exclusivity. In *Amgen v Sanofi* [PDF], the Supreme Court invalidated patent claims to millions of antibodies because the patents failed to enable a person skilled in the art to make and use the entire class of claimed antibodies. For Canadian applicants and litigants, the *Amgen* decision provides further authority that a patent may be invalid if its claims are overbroad.

What happened in *Amgen*?

Amgen owned two patents for antibodies that bind and block the PCSK9 protein involved in maintaining LDL or "bad" cholesterol. The patents fully described the structure of 26 antibodies specific to a target region or "sweet spot" on PCSK9. The patents also purported to describe two methods of making additional antibodies that performed the same functions. On the evidence these methods were routine and well-known in the art, but substantial time and effort would be required to generate and identify the full class of claimed antibodies.

On these facts, the Supreme Court affirmed the rulings of the courts below that Amgen's claims were not properly enabled. Under 35 USC §112, a patent applicant is required to describe the invention in full, clear, concise and exact terms to enable any skilled person in the art to make and use it. Below, the District Court [PDF] had analogized the disclosure in Amgen's patent to providing "a lock and a ring with a million keys on it": a skilled person who sought to work the invention would have to try every key to see if it fit. In fact, taking this analogy a bit further, the skilled person would have needed to first make a million keys to see if they worked.

Amgen's predicament arose from claiming the invention in functional terms: it claimed all antibodies that bound to the "sweet spot" on the PCSK9 protein, regardless of their configuration or whether Amgen had made them. From this perspective, Amgen disclosed comparatively little while claiming a lot. Importantly, Amgen did not describe any common general quality or principle to suggest which antibodies would work – perhaps in relation to their folded structure or the location of key amino acids with a particular charge or hydrophobicity – leaving scientists with little useful disclosure to work with.

In dismissing Amgen's action, the U.S. Supreme Court thus confirmed two principles:

- **"The broader the monopoly [a patent] demands, the more it must enable"**. The patent bargain requires that the public receive the benefit of a full disclosure. For claims to a broad class of antibodies, the description must enable the entire class.
- Inventors need not describe every possible embodiment of the invention, and enablement may be satisfied with only a few examples **provided that the specification discloses "some general quality … running through the class that gives it a peculiar fitness for the particular purpose"**. If claiming a broad class, an applicant must also describe or identify a quality common to every functional embodiment. Revisiting the analogy, if claiming a class of keys, the common quality of working keys must be identified rather than merely identifying the keyhole.

How would a U.K. court deal with *Amgen*-type claims?

The validity of claims like those at issue in *Amgen* has also arisen in the U.K. In the 2020 *Regeneron* [PDF] case, the Supreme Court of the United Kingdom invalidated a claim to a range of genetically modified mice on the ground of excessive claim breadth, a type of insufficiency. The court held that the claim failed because a skilled person reading the patent would not have been able to make all of the mice covered by the claim. In so doing, the court held that a patentee's monopoly must not exceed the scope of its contribution to the art. Paralleling the reasons in *Amgen*, the court noted that claims to a range of embodiments could instead rely on a 'principle of general application' to enable the whole range of embodiments within the scope of the claim.

And what about Canada?

In Canada, parties challenging overly broad patents may do so on two grounds: insufficiency and overbreadth. A patent's disclosure is insufficient if it does not fully describe how to make or use the claimed invention. A claim may also be overbroad if it claims embodiments that the inventor did not invent or disclose. Thus, insufficiency and overbreadth may be considered two sides of the same coin, with the former relating to "under-describing" relative to what is claimed and the latter to over-claiming relative to what is disclosed. Both legal issues are heavily fact-dependent.

Canadian law relating to patent overbreadth seemed unsettled until 2021 when the Federal Court of Appeal in *Seedlings* reiterated that the patent bargain underscores the need for patent claims to be commensurate with the invention that was made and disclosed in the patent. Despite the Court of Appeal's guidance, questions remain about how to assess whether claims are well proportioned to an invention.

The *Amgen* and *Regeneron* decisions signal potential Canadian law developments. The principles articulated by the top courts in these customarily influential jurisdictions bolster the principle that broad patent claims insufficiently tethered to an inventor's contribution and disclosure undermine the patent bargain and make for bad policy. For patent applicants, the lessons are clear: claim both narrowly and broadly and ensure that broad claims to classes of products are supported by a full disclosure, including of a common feature that would allow a skilled person to practice the entire range of embodiments covered by the invention