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United Kingdom's highest court provides guidance on how to disclose inventions over large classes of products

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Did the inventor of the very first wheeled vehicle invent *all* vehicles with wheels because they all work in the same way? From a legal standpoint, would this inventor's patent claiming cars, bicycles and airplanes be valid even if the patent did not disclose how to make *all* of these vehicles? The answer to this legal question depends on what the invention is understood to be, which dictates how it should be disclosed in a patent.

In *Regeneron Pharmaceuticals Inc v Kymab Ltd*, [2020] UKSC 27, the Supreme Court of the United Kingdom held that a claim directed to a large number of products is insufficient if the patent does not teach how to make substantially all of them. The whole scope of product claims must essentially be enabled: if the skilled person using the disclosure could make only some of the claimed products, then the claims are invalid because they exceed the scope of the inventor's contribution to the technical art.

This landmark U.K. decision casts new light on the Canadian requirement of sufficiency: it provides persuasive authority that a Canadian patent claiming a large number of products or compounds may be challenged if its claims are not enabled across their full scope.

Background

Regeneron Pharmaceuticals held two patents directed to modified (transgenic) mice used to produce hybrid human-murine (chimeric) antibodies. It was known before the patents that mice used to make the antibodies develop immunological sickness, thereby reducing the production of antibodies used as drugs. Regeneron's patents focused on this problem; they disclosed chimeric antibodies with a murine (i.e., mouse) constant region and a variable region (technically, V, D and J segments) that had been at least partially modified with human segments. This hybrid gene structure was known as "reverse chimeric locus." The patent claims were directed to an entire range of transgenic mice for producing a large number of different chimeric antibodies using the technique disclosed.

Kymab challenged the patents on the grounds that they did not disclose the information necessary to "make" the whole range of transgenic mice to produce the chimeric antibody variants. At the priority date of the patents, the relevant date under U.K. law, it was not possible to make the whole range of transgenic mice, including the gold standard: mice having the whole of the human variable region gene locus.

Reversing the trial judge's decision, the U.K. Court of Appeal had held the claims to be sufficiently enabled. In the Court of Appeal's view, an invention may be enabled, even if the patent does not provide sufficient information for the skilled person to make all the products of the claims, provided that it can be seen that all products deliver the same benefit. In this

case, the claims were sufficiently enabled because every transgenic mouse would avoid immunological sickness even if, at the priority date, it was not possible to make many of them. Plainly, the Court of Appeal was moved by policy considerations; as the U.K. Supreme Court put it, "[i]n a fast-moving field, where new products quickly outperform their predecessors so as to render them obsolete, the reward of a monopoly limited to those immediately capable of being made would be short-lived and illusory." Still, the Supreme Court asked, was the Court of Appeal's holding "part of the law or, perhaps, a legitimate development of it"?

Sufficiency of disclosure requires the full enablement of product claims

The Supreme Court noted that the requirement of sufficiency exists to ensure that the exclusivity conferred by a patent corresponds with the contribution it makes to the art. For product claims, the inventor's contribution is teaching the skilled person how to make the new products. Patent claims will therefore exceed the inventor's contribution if the skilled person could not make substantially all of the claimed products. To establish sufficiency, a patentee may teach in the disclosure how to make substantially all claimed products, or it may rely upon a principle of general application that enables the making of the products. In the latter case, however, the patentee runs the risk that this supposed general principle does not in fact enable the entire range of the products claimed.

In *Regeneron*, the U.K. Supreme Court held by a majority that the two patents did not enable the skilled person to make mice with a reverse chimeric locus containing more than a very small subset of variations of the human variable region. It was understood that the amount of the human variable gene locus included in the hybrid antibody gene structure was a very important factor affecting the usefulness of the transgenic mice. The most beneficial transgenic mouse to make was one with the reverse chimeric locus comprising the entire human variable region gene locus. Yet, the making of such mice depended upon further inventions made separately and only years after the priority date. As the Supreme Court noted, the reverse chimeric locus was not a principle that enabled the claimed products to be made; it rather was the result of successfully making the products. The product claims were insufficient and therefore invalid.

Two observations may help grasp the Supreme Court's reasons. First, the claims at issue were directed to products, and not to a process, which could not have been challenged on the same grounds. Second, the requirement to demonstrate enablement across the whole scope of a claim only applies to a range denominated by a factor affecting the value or utility of the claimed products. A range denominated by an irrelevant factor (the length of a mouse's tail, for example) would not cause a patent claim to be insufficient. Still, the Supreme Court held a patentee cannot establish enablement merely by showing that all claimed products deliver the same general benefit if the patent does not teach how to make them.

What does *Regeneron* mean for Canadian patent law?

Given the historical similarities in the laws of the two countries, Canadian courts have often turned to U.K. courts for guidance on challenging patent law questions. Canadian courts are therefore likely to find the *Regeneron* case persuasive on similar questions of sufficiency and, more specifically, of overbreadth.

In Canada, patent claims will be found to be invalid if they are overbroad in the sense that they claim more than what is disclosed in the patent's specification or more than what was actually invented. In some cases, overbreadth overlaps other grounds of patent invalidity,

notably anticipation, obviousness, lack of utility in fact, or lack of demonstrated and soundly predicted utility of the products made. In contrast, Canadian courts have rarely commented on the alleged overbreadth of patent claims based on an alleged lack of enablement across the full scope of the claims. The U.K. Supreme Court's decision in *Regeneron* offers a persuasive framework to analyze this type of overbreadth argument in situations where there is an alleged difference between what invention was made, what the Canadian patent specification discloses, and what the patent claims.

All vehicle wheels may turn the same way, but it is the Wright brothers, not the Mesopotamians, who are generally credited with inventing the airplane.