Federal Court Considers “Functionally” - Limited Claims in a Biologic Case

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The Federal Court of Canada recently issued a decision in *AbbVie Corporation v. Janssen Inc.*, 2014 FC 55, involving infringement and validity of a biologic patent. Such cases are rare in Canada, and this is the first major biologic patent to go to a trial decision in the Federal Courts since 2001[1]. Biologics are medicinal products having an active ingredient which is manufactured from, or through the use of, animals or microorganisms. Examples of biologics include therapeutic proteins, such as hormones and therapeutic antibodies.

AbbVie v. Janssen involves a patent infringement action brought by AbbVie against Janssen, alleging that Janssen's biologic product, Stelara® (ustekinumab), infringes Canadian patent no. 2,365,281 ('281 patent). Stelara® is a human antibody that binds and neutralizes interleukin-12 ("IL-12"), which is a naturally occurring cytokine in the human body. At the time of filing, IL-12 was known to be associated with inflammatory conditions, and was one of 22 cytokines identified in psoriatic lesions. Both AbbVie and Janssen independently developed human antibodies against IL-12 as possible treatments for psoriasis using different techniques. AbbVie's antibody, known as J695 (briakinumab), has not received regulatory approval and is not marketed in Canada. A Notice of Compliance from Health Canada was granted for Janssen's Stelara® product in 2008.

Specifically at issue in the case were two use claims of the '281 patent (claims 143 & 222) which described use of an antibody, "functionally" defined in terms of binding partner, binding affinity, and neutralization potency, for treatment of psoriasis. The principal ground of contention was whether the claims, which encompass use of *any* human antibody with particular characteristics as to affinity and potency, regardless of specific structure or method of preparation, exceeded the scope of the actual invention. In the patent application, AbbVie disclosed only a single human antibody (J695 and its related lineage), which it had developed using phage display technology. In comparison with J695, Janssen's Stelara® product was developed using a different technology (transgenic mice), was structurally distinct (<50 percent sequence similarity), and bound to a different site in IL-12.

Ultimately, Justice Hughes upheld the validity of the "functionally" limited use claims and found Stelara® infringed these claims. In finding the claims were not overly broad, Hughes J. held that "techniques used to create [human antibodies], in particular, phage display and transgenic mice, were well known in the art" as of March 1999 and there was no evidence "a person skilled in the art, given the patent, could not have created an antibody that meets the parameters of either of these two claims" (at 146-147). Hughes J. further rejected arguments that “functional” claiming was not allowable on policy grounds.

In his decision, Hughes J. also considered the issue of obviousness. He emphasized that there is a difference "between hope and certainty", providing some welcome clarification concerning the "obvious to try" test in Canada. While it was known in the art that a number of cytokines were involved in various diseases and that a neutralizing antibody might be useful as a treatment, this knowledge was seen as a "hope" or "speculation" that treatment *might* be possible. Hughes J. emphasized the serendipity of the discovery that a patient in a clinical trial, who had been administered J695 by chance, experienced dramatic clearance of psoriasis. This discovery that psoriasis *is* treatable by administration of an antibody targeting a particular cytokine and having certain characteristics was itself determined to be inventive.

Caution should be taken in extending this decision to other fact situations, as the Court noted that sufficiency of the disclosure must be addressed on a case-by-case basis. In particular, the Court emphasized "there is no simple principle that can be universally applied that would say, for example, that you have shown only one or two antibodies in your disclosure; you cannot claim all that will do the particular trick that you have in mind" (at 178). Nevertheless, this ruling should be encouraging for patentees seeking protection for human antibodies, and may provide some basis for arguing against an Examiner's objections that the claimed subject matter is broader in scope than the teaching of the application or obvious to try.

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1 *Kirin-Amgen Inc. v. Hoffmann-La Roche Ltd.*, [2001] 2 F.C. D-27 (FCA)