PATENT CLAIMS FOR BIOLOGICS IN CANADA: IT'S A QUESTION OF FUNCTION

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On January 17th 2014, in a rare patent infringement case involving a relatively new class of drug products known as "biologics", the Federal Court of Canada upheld the validity of a patent owned by AbbVie Deutschland GmbH & Co. KG ("AbbVie), relating to human antibodies, and found that said patent was infringed by Janssen Inc's ("Janssen") STELARA® human antibody drug treatment for psoriasis [*AbbVie Corporation et al. v. Janssen Inc*., 2014 FC 55, January 17th 2014, Hughes].

Biologic Drugs

Biologics are products made from biological processes which are manufactured from the use of animals or microorganisms. For example: antibodies, hormones and gene therapy products. These products are regulated in a similar way as other classes of drugs in Canada, are considered patentable subject matter, and are rarely the subject of infringement proceedings such as in the present case.

The Patent

Janssen's STELARA® drug product involves the use of a human antibody, derived from transgenic mice, for the treatment of psoriasis. AbbVie alleged that this product was within the scope of the protection granted by claims 143 and 222 of its Canadian 2,365,281 patent ('281), which are directed to human antibodies binding (or having an affinity for) a protein known as IL-12, also for the treatment of psoriasis. These claims were drafted so as to be functionally defined by at least their binding affinities, binding partners and potencies.

An example found in the description of '281 described the results of a human test subject who had been suffering from psoriasis at the time the study was conducted and who reported an overall improvement in his skin condition after receiving the "AbbVie Treatment" claimed in this patent.

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Following its study of the patent, the Court construed the relevant claims as being i) directed to the use human antibodies, however created, ii) which antibodies bind and dissociate from IL-12; iii) at a defined "stickiness or affinity", iv) which antibodies have a defined minimum potency, v) to treat psoriasis.

Infringement

On the issue of infringement, Janssen essentially conceded that since the Court's construction covered human antibodies that are made by any method, therefore including a transgenic mouse method, their STELARA® product would fall within the scope of the claims, subject to an assessment of the stickiness (affinity) and potency of the antibodies. AbbVie had conducted such tests and it was established that the STELARA® antibody was within the scope of the claimed affinity and potency.
As such, the Court found that Janssen's STELARA® product infringed claims 143 and 222 of the '281 patent.

Invalidity

Once infringement was established, the Court then studied the question of the alleged invalidity of patent '281. Janssen had argued that the claims were obvious in light of the prior art, but the main ground of contention was that the scope of the claims directed to human antibodies were allegedly too broad and covered more than what was actually invented, or what could be properly claimed.

On the question of obviousness, the court asked itself "*what, if any, are the differences between the Prior Art and the Invention Claimed*"? The answer was the difference between "hope and certainty". Of the prior art cited, the experts were in agreement that: "before the invention was made, there was a *hope* that, among the "soup" of cytokines in the human body, if an antigen was found to bind to one or more of them, then certain human diseases *might be treatable"*.

The inventive concept of '281 was, with reference to the antibodies, *that if a particular cytokine was bound by an antigen with certain properties,* psoriasis would be treatable. The Court did not agree that this concept was "self evident", as Janssen argued, and distinguished the "worth a try" approach, from the Canadian "more or less self-evident" one, stating that Abbvie may have gotten lucky, but that does not make the invention was self-evident with respect to the prior art and therefore obvious.

Concerning the alleged broadness of the claims, Janssen argued that the claims exceeded the scope of the invention, as only one specific antibody was alleged to have been specifically described in the patent, while any antibody binding IL-2 was being claimed. The claims were drafted using functional language, that is, the invention was described on the basis certain functional characteristics, which

Janssen argued did not describe, nor provide guidance, as to the structure of the antibodies.

The use of functional language in patent claims is an allowable practice in Canada, so as long as those claims don't "merely relate to a desired result". For example, simply claiming "an elixir for curing baldness", would be insufficient unless further characteristics of this elixir are provided. In the present case, the Court found that, contrary to Janssen' arguments, AbbVie was not claiming all antibodies that treat psoriasis:

> there may be many ways to treat psoriasis, but AbbVie's way is to have an antibody that does so by binding to IL-12 with at least a certain level of stickiness and potency ", That is very different from saying - we have a particular antibody (J695), and we put it into people, and it treats their psoriasis; therefore, we want a patent claiming any antibody that does that.

Furthermore, Janssen did not provide evidence of "non-working" or "non-useful" antibodies that would fall within the scope of the claims. The Court reiterated that there is no universal rule or principle that can be applied to the issue of over-breadth. The fact that a description contains only one or two working examples does not preclude claiming everything that has the same function, and doing so does not make a claim indeterminate. A patentee can therefore validly claim more than the embodiments that are specifically disclosed in the specification. Functional language is therefore permissible in cases where the specification and the claims provide exclusion criteria for non-useful entities (for example, to carve out non-working antibodies), as well adequate support and guidance to a person versed in the art.

Conclusion

The Court was therefore of the opinion that the claims at issue were valid and infringed. A bifurcation order was in place so the Court did not provide guidance as to damages; however, on February 13th 2014, Janssen filed a Notice of Appeal and it therefore remains to be seen how the Federal Court of Appeal will side with regards to this matter.

Notwithstanding appeal, Canadian case law has so far consistently been to the effect that functional language in claim drafting is permissible, if what is being claimed is not merely a desired result. It is clear, at least at the time of writing of the present article, that these principles are transposable to the field of "biologics", where the subject matter, as it relates to antibodies, can validly be defined by their affinity and potency characteristics.

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