Federal Court of Appeal interprets CSP regulations and denies patent term restoration

April 16, 2021

In a recent case, the Federal Court of Appeal (FCA/the Court) overturned a decision of the Federal Court (FC) and held that that the Minister of Health (the Minister) made a reasonable decision in refusing a Certificate of Supplementary Protection (CSP) to GlaxoSmithKline (GSK) for its SHINGRIX vaccine product.[1] This was the Court of Appeal's first interpretation of the terms “medicinal ingredient” and “claim for the medicinal ingredient or a combination of all the medicinal ingredients” found in the *Certificate of Supplementary Protection Regulations* (CSP Regulations).

GSK sought patent term restoration (a CSP) with respect to a patent claiming an immunogenic composition relating to its SHINGRIX vaccine product. The Notice of Compliance (NOC) for the SHINGRIX product identifies the antigen as the only medicinal ingredient. Similarly, the register of innovative drugs lists only the antigen as the medicinal ingredient. In the CSP application, the antigen was listed as the single medicinal ingredient.

The Court stated that the patent claims an immunogenic composition comprising an antigen, an adjuvant, and excipients; the use of that composition, and a kit comprising the composition.

History of the case

The Minister’s preliminary decision was that the patent claimed a formulation, not a medicinal ingredient or combination of medicinal ingredients as required by the CSP Regulations. Furthermore, the antigen was not novel, as it had been the subject of two prior patents.

GSK argued that the adjuvant was also an active ingredient, and that therefore, the patent was directed to a combination of medicinal ingredients. It also argued the claims were not formulation claims. The Minister’s final decision refused the CSP, as the patent did not contain a claim for the approved medicinal ingredient. Health Canada holds the position that adjuvants are not medicinal ingredients. The Minister held that an adjuvant is not responsible for the vaccine’s desired effect, as it only improves the immune response induced by the antigen itself. Further, the Minister confirmed that as the claims are directed to a formulation, they are not eligible for a CSP.

Upon judicial review of the Minister's decision, the FC held that it was unreasonable. In the FC's view, the term "active ingredient" used in the Comprehensive Economic Trade Agreement between Canada and the European Union (CETA) would include an adjuvant. Furthermore, the FC held that the Minister adopted "administrative tunnel vision" by requiring that a medicinal ingredient have an independent desired effect on the body (para 16). The FC also held that only the Regulatory Impact Analysis Statement (RIAS) could support the Minister's interpretation of "claim for the medicinal ingredient", and this did not justify excluding novel and useful vaccines such as SHINGRIX.

The FCA decision

The FCA discussed the legislative background of CSPs and the CSP Regulations in the context of the CETA and its implementation act.

The Court held that it "is not disputed that while the antigen induces the immune response in humans to prevent shingles, it could not do so in the absence of the adjuvant, which enhances the immune response to the level necessary for its use in a vaccine to prevent or ameliorate shingles." (para 5)

In consideration of the definition of "medicinal ingredient," the FCA commented that there was no definition in the *Patent Act* or any regulations issued under it. The Court held that while it must consider whether the Minister's interpretation is consistent with the CETA, "one should be careful not to put aside a regulator's interpretation of a term that is used across the regulatory system … solely because of a seemingly logical alternative interpretation." (para 51)

The Court held that "active ingredient" and "medicinal ingredient" refer to the same thing. The Court then considered law from the European Union interpreting similar phrasing with respect to their patent term restoration provisions. The Court was satisfied that the Minister's construction of "medicinal ingredient" is consistent with the CETA and with the interpretation of the phrase under other domestic legislation pertaining to pharmaceutical products.

The FCA further held that it is unfair to characterize the Minister's approach as unwarranted tunnel vision, as it is reasonable to desire consistency between regimes when interpreting "medicinal ingredient." In addition, it was reasonable for the Minister to determine that the adjuvant was not a medicinal ingredient, as it does not have independent therapeutic effect on the body.

While there can be more than one reasonable interpretation of "medicinal ingredient", the FCA held that its role is not to choose the one they prefer, but rather to decide whether the interpretation of the Minister was reasonable.

A second issue before the Court was whether that patent claimed a formulation. The FCA considered the historical case law interpreting the different types of claims found in patents related to pharmaceuticals and biologics. The Court held it was reasonable for the Minister to conclude that "a claim for the medicinal ingredient refers only to a claim for the antigen and not a mixture of ingredients in an approved drug." (para 101)

Thus, the appeal was allowed. As the FC Order sent the matter back to the Minister for redetermination, such redetermination is no longer necessary, and the Minister's refusal to grant the CSP will stand.

[1] Canada (Health) v. GlaxoSmithKline Biologicals S.A., 2021 FCA 71; rev'g 2020 FC 397.

By

Beverley Moore

Expertise

Intellectual Property, Intellectual Property Litigation, Life Sciences

---