Canadian court interprets CETA drug patent extensions more broadly than EU equivalent

APRIL 24, 2020 7 MIN READ

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Authors: J. Bradley White, Nathaniel Lipkus, Jaymie Maddox

It is a delicate balance between promoting pharmaceutical innovation and ensuring affordable access to pharmaceuticals. Every decade or so, the Canadian government seeks to recalibrate the balance, most recently with entry into the Canada-EU Comprehensive Economic and Trade Agreement (CETA) in 2014. One of Canada's CETA obligations, ratified in September 2017, was to provide at least an additional two years of supplementary protection beyond the term of the "basic patent" protecting a drug product.

Prior to CETA, Canada had never recognized any form of patent term extension. The best blueprint available to show how supplementary protection would work was the EU's supplementary protection certificate (SPC) regime, which has been in place for several decades. EU courts have grappled with many challenging questions regarding how and when a party should be entitled to an SPC.

Canada's Federal Court just ruled in its first case that considers the Canadian supplementary protection scheme. The case addressed whether a certificate of supplementary protection (CSP) could be granted for a patent covering the combination of an antigen and an adjuvant. The Court of Justice of the European Union had previously dealt with the same question in respect of a different product and found that no supplementary protection was permitted. The Federal Court came to the opposite conclusion, finding Health Canada to be unreasonable in concluding that no protection was available for the adjuvant.

Federal Court finds denial of CSP for adjuvant patent to be unreasonable

Justice Barnes of Canada's Federal Court found for GlaxoSmithKline (GSK) in *Glaxosmithkline Biologicals SA v Canada (Health)*, 2020 FC 397, a decision issued on April 7, 2020. GSK had applied to the Court to challenge an August 2018 decision of Health Canada, which had refused to issue a CSP respecting Canadian Patent No. 2,600,905 (905 Patent) and the shingles vaccine, SHINGRIX®. The Court found that Health Canada had unreasonably restricted the definition of a medicinal ingredient in refusing GSK's application for a CSP and directed that the matter be redetermined.

Health Canada deemed the 905 Patent ineligible for a CSP because the 905 Patent claims a formulation consisting of an antigen and an adjuvant. The Regulatory Impact Analysis Statement (RIAS) introducing CSPs expressly excluded CSP protection for patents directed to formulations. In evaluating the argument that the claims were directed to a combination of medicinal ingredients (the antigen and the adjuvant), Health Canada based its conclusion that the adjuvant was not a medicinal ingredient as required under subsection 3(2) of the *CSP*

Regulations on its licensing guidelines, which characterize adjuvants as inactive excipients whether they are biologically active or not. Health Canada determined that the *CSP Regulations* do not apply to patents claiming a composition of medicinal and non-medicinal ingredients, or the use thereof.

On judicial review of Health Canada's decision, the Court considered the origins of Canada's CSP regime in view of CETA, specifically noting that CSPs were intended to be available for eligible vaccine patents. The Court recognized that neither the pertinent Canadian legislation nor CETA define a "medicinal ingredient." However, the Court stated that, unless otherwise stipulated, matters of interpretation were to be resolved in harmony with CETA and its definition of a protected product.[1] The Federal Court considered CETA protected "products" as "the *active* ingredient or combination of *active* ingredients" in an approved drug or vaccine.

In the context of regulatory approval, Health Canada treats all adjuvants as inactive ingredients. Health Canada chooses for administrative reasons to categorize vaccine adjuvants as excipients and to treat them for licensing purposes in the same way as stabilizers, fillers and preservatives. This approach was applied in the patent context, in assessing GSK's CSP application. However, the Federal Court found that given that adjuvants enhance biological activity when paired with an antigen, potential inconsistency with Health Canada's regulatory guidelines was not persuasive and did not weigh against a broader interpretation of "medicinal ingredient." The Court found no practical purpose for excluding adjuvanted vaccines from the CSP regime, which serves very different purposes from pharmaceutical licensing. Instead, the Court considered the adjuvant in SHINGRIX® an active and necessary ingredient of the vaccine, finding it eligible for protection under Canada's CSP regime.

Rather than direct the Minister to issue a CSP to GSK, the Court set the decision aside and ordered the Minister of Health to redetermine the matter on the merits and in accordance with the Court's reasons. In light of the detailed independent assessment provided by Justice Barnes, the Minister will have very limited flexibility in arriving at a decision different from the one dictated by the Court.

EU courts have refused SPCs for adjuvant patents

The Federal Court's decision rests on an interpretation of Canada's CETA commitments to arrive at the appropriate scope of CSP protection. It is therefore noteworthy that the EU Court of Justice has considered the very same issue, and in stark contrast, declined protection in similar circumstances.

A 2014 decision of the EU Court of Justice, *Glaxosmithkline Biologicals SA v Comptroller-General of Patents, Designs and Trade Marks*, [2014] RPC 17, came to the opposite conclusion than the Federal Court on the eligibility of analogous adjuvant patent claims for supplementary protection. Between October 2008 and August 2011, GSK filed applications for two SPCs, relying on its marketing authorization for a pre-pandemic influenza vaccine called PREPANDRIX. GSK sought SPCs for two European patents, one for a vaccine adjuvant (0,868,918) and the other for a vaccine containing an antigen and that same adjuvant (1,618,889).

GSK's applications for SPCs were refused by the U.K.'s Patent Office because the Patent Office did not consider the adjuvant a "product" within the meaning of the applicable SPC regulation. The Patent Office found that the adjuvant did not meet the regulatory definition of a "product" because it was not an active ingredient of PREPANDRIX on its own, or in combination with an antigen. The enhanced therapeutic effect of the antigen when combined with the adjuvant was insufficient to enable the adjuvant itself to be regarded as

an active ingredient.

GSK appealed the Patent Office's refusal of its SPC applications to the U.K. Patents Court. The U.K. Court referred the following two questions to the EU Court of Justice due to a lack of clarity in prior pertinent case law and divergent findings on equivalent SPC applications by various EU patent offices:

1. if an adjuvant that only has a therapeutic effect when combined with an antigen in a vaccine could be considered an "active ingredient" within the SPC regulation, and ***if no***,
2. if the combination of an adjuvant, which has a therapeutic effect when paired with an antigen, and that antigen, could be considered a "combination of active ingredients" subject to the SPC regulation?[2]

Though not defined within the SPC regulation, the EU Court found that based on its general context and use in everyday language, the term "active ingredient" did not encompass an adjuvant. Unlike Canada's Federal Court, the EU Court considered the distinction between "active ingredient" and "adjuvant" in a directive regarding marketing authorization instructive and weighed in favour of this narrow interpretation. Even though the GSK adjuvant enhanced the therapeutic effect of another active ingredient, it was still not considered an active ingredient itself, and thus did not fall within the meaning of a "combination of active ingredients" protected by the SPC Regulation.

A *sui generis* approach to the CSP regime

When the Canadian government took steps to implement its CETA obligation to expand pharmaceutical patent protection, it did so based on its understanding of how the EU SPC system worked. The RIAS clearly delineated that it would protect medicinal ingredients but not formulations, as CETA did not require protection to be so broad. This policy was driven by the fact that CSPs almost uniformly accrue to the benefit of foreign (often European) corporations.

Despite the Canadian government's attempt to implement CSP protection only as broadly as necessary, subject to how Health Canada ultimately redetermines the issue, the Federal Court's decision in *Glaxosmithkline Biologicals SA v Canada* has reached beyond both the RIAS and the protections afforded in the EU. The decision may result in patentees who are doing business in Canada getting more than the EU bargained for.

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[1] S. 3 of the *CETA Implementation Act*, SC 2017, c 6.

[2] *Glaxosmithkline Biologicals SA v Comptroller-General of Patents, Designs and Trade Marks*, [2013] EWHC 619 (Pat).