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First decision on CSPs: SHINGRIX refusal remanded to Health Canada.

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The first decision considering the scope and meaning of the provisions in the *Patent Act* relating to Certificates of Supplementary Protection (CSPs) has now been released. Justice Barnes of the Federal Court in *GlaxoSmithKline Biologicals SA v The Minister of Health*, 2020 FC 397 found the decision of the Minister of Health (the Minister) refusing to issue a CSP in respect of Canadian Patent No. 2,600,905 (905 patent) and SHINGRIX unreasonable.

The decision is important insofar as it considers:

i) the meaning of "medicinal ingredient" for the purposes of the CSP provisions in the *Patent Act* and related *Certificate of Supplementary Protection Regulations* (*CSP Regulations*), and

ii) whether a claim to a formulation—and specifically a vaccine—may be eligible for a CSP.

The interpretation of "medicinal ingredient" may have broader implications, as the term is also found in the *Patented Medicines (Notice of Compliance) Regulations* and the data protection provisions of the *Food and Drug Regulations*.

The Court ultimately did not decide these issues, returning the matter to the Minister to redetermine the CSP application on the merits and in accordance with the Court's reasons. The Minister has advised it intends to appeal the decision to the Federal Court of Appeal.

CSPs in context

The CSP provisions of the *Patent Act* came into force on September 21, 2017 together with the related *CSP Regulations* (see here). To date, 41 CSPs have been granted, and only 8 CSPs have been refused (see here and here).

CSPs were introduced to comply with commitments under the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union. While there are a number of parallels between Canada's CSP regime and Europe's Supplementary Protection Certificate (SPC) regime, there are notable differences (see here).

A CSP application must comply with several requirements, including that the "patent pertains in the prescribed manner to a medicinal ingredient, or combination of medicinal ingredients" contained in a drug (see section 106(1)(c) of the *Patent Act*). The "prescribed manner" in which a patent may pertain is set out in section 3(2) of the *CSP Regulations*; namely, that the patent include:

- a claim for the medicinal ingredient or combination of all the medicinal ingredients in the drug, per se or in product by process form; or
- a claim for the use of the medicinal ingredient or combination of all the medicinal ingredients in the drug.

When the *CSP Regulations* were published, the accompanying Regulatory Impact Analysis Statement (RIAS) expanded on the foregoing, noting that formulation claims are not eligible:

Also, claims that are directed to a formulation containing the medicinal ingredient, including compositions, preparations or similar claim types, do not make a patent eligible for a CSP. A claim to a formulation does not protect the medicinal ingredient or combination of medicinal ingredients *per se*. A claim to a formulation may be directed, for example, to the improvement of the stability of medicinal ingredients. This is consistent with CETA, which only requires the protection of the medicinal ingredient or combination of medicinal ingredients when claimed "as such."

The refusal

Health Canada's refusal of the SHINGRIX CSP was based on a finding that the patent did not meet the requirements of section 106(1)(c) of the *Patent Act* and section 3(2) of the *CSP Regulations*.

Broadly stated, the patent claims an immunogenic composition or vaccine comprising a Varicella Zoster Virus (VZV) gE antigen in combination with an adjuvant, as well as a use thereof. GSK had provided evidence to Health Canada that the antigen and the adjuvant claimed by the 905 patent were both biologically active and that the adjuvant was necessary to achieve clinical efficacy.

According to Health Canada, the medicinal ingredient is the antigen, and not a combination of an antigen and adjuvant, and the claims pertained to a formulation or a use of the formulation, rather than to the medicinal ingredient or combination of medicinal ingredients or a use thereof.

The reasonableness of the decision

The Court found that the Minister had not adopted a purposive approach to interpreting the CSP provisions in the *Patent Act* or the *CSP Regulations*. In reaching this conclusion, the court notably commented on:

CETA Commitments under Article 20.27: Article 20.27 of CETA defines an eligible patent as one that protects "an 'active ingredient or combination of active ingredients' of, *inter alia*, a vaccine" (see para. 21).

Patent Act and CSP Regulations: "there is nothing in the relevant *Patent Act* CSP provisions or in the *CSP Regulations* that expressly supports a requirement that an eligible claim is one that protects a medicinal ingredient or a combination of medicinal ingredients *per se*... CETA does not refer at all to 'medicinal ingredients' and nowhere in Canadian legislation is that term defined" (see para. 26).

Canada-European Union Comprehensive Economic and Trade Agreement Implementation Act[CETA Act], section 3: "The absence of any statutory definition for 'medicinal ingredient' is significant because the [*CETA Act*] at section 3 directs that, unless otherwise stipulated, matters of statutory interpretation are to be resolved harmoniously with CETA" (see para. 27).

The Court also had specific concerns regarding vaccines.

The Court expressed "concern that the Minister's decision offers no justification for adding the requirement that vaccine adjuvants do not qualify as medicinal ingredients because they do not independently cause an immune response" (see para 38) and the possible exclusion of CSP protection for many novel vaccines which "is at least doubtful that such a result was intended by CETA" (see para 39).

Further, as there is "nothing in the CSP provisions of the *Patent Act* or in the *CSP Regulations* that expressly excludes from eligibility patent claims directed to a formulation ... the disqualification of a novel and useful vaccine on the basis that it is made-up from a unique and necessary combination of two biologically active components is hard to justify where the

applicable regulations do not expressly and clearly apply and where the language of CETA suggests otherwise" (see para 44).

As noted above, the Court ultimately found that the Minister's decision was unreasonable as it "failed to take appropriate account of Canada's CETA commitments and the full scope and purposes of the applicable statutory provisions, most notably Article 20.27 of CETA and section 3 of the *CETA Act*" and sent the matter back to the Minister for redetermination (see para 46).

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