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# Canadian courts are interpreting supplementary pharmaceutical patent protection more broadly than their EU counterparts

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For nearly 30 years, pharmaceutical patent policy in Canada has been designed to strike a balance between rewarding pharmaceutical innovation and enabling affordable drug access. This balance has evolved over time. From entry into the original North American Free Trade Agreement (NAFTA) in 1993 until entry into the Canada-EU Comprehensive Economic and Trade Agreement (CETA) in 2014, the Canadian government has successfully resisted trade obligations and pressures that, had it acceded, would have forced this delicate balance to tip in favour of intellectual property (IP) protection for pharmaceuticals.

With CETA, the Canadian government agreed to measures to enhance pharmaceutical IP protection, including the extension of patent terms to reflect delays in regulatory approval. This form of protection is called supplementary protection certificates (SPCs) in the European Union. In agreeing to implement SPC-like measures, Canadian trade negotiators introduced safeguards to limit extended patent terms to two years and to exempt pharmaceutical manufacturing that is for the purposes of export. An apparent premise of Canada's agreement to introduce SPC-like measures was that the protection would be similar to (and not broader than) SPC protection but balanced with the negotiated safeguards.

In September 2017, Canada ratified this CETA obligation to provide at least an additional two years of supplementary protection beyond the term of the "basic patent" protecting a drug product. The new form of protection is called a "certificate of supplementary protection," or CSP. There was never any indication during trade negotiations or ratification that the scope of protection conferred by a CSP would be broader than the SPCs upon which they were based. As the purpose for implementing CSPs was to meet an EU demand in pursuit of a broader CETA compromise, there is no clear policy rationale for expansive Canadian protection.

Despite this background, in the first two court decisions to interpret the scope of CSPs, the court ruled in favour of broad CSP protection where the very same protection was denied after due consideration in the EU:

- **Adjuvant as basis for combination CSP:** In *Glaxosmithkline Biologicals SA v Canada (Health)*, 2020 FC 397 (GSK), the Federal Court considered whether a CSP could be granted for a patent covering the combination of an antigen and adjuvant.[1] Despite a decision of the Court of Justice of the European Union finding against an SPC in similar circumstances,[2] the Federal Court found that it was unreasonable to deny protection for this combination on the premise that an adjuvant is biologically active and thus forms a protectable combination of medicinal ingredients with the antigen.[3] We previously

commented on the *Glaxosmithkline Biologicals* case.

- **Single-ingredient patent CSP for combination drug:** Shortly after that, in *ViiV Healthcare ULC v. Canada (Health)*, 2020 FC 756 (Viiv), the Federal Court considered whether a CSP for a patent directed to one medicinal ingredient could be granted in respect of a product containing two medicinal ingredients.[4] EU law provides that in such circumstances, the patent must "necessarily and specifically" relate to the combination of medicinal ingredients,[5] and SPC protection was denied when it was found that each active ingredient was not specifically identifiable in the patent by a person skilled in the art.[6] In Viiv, however, the Court found that the decision to refuse a CSP was unreasonable.[7] The Court held that the Minister failed to consider the meaning of the applicable CSP provisions in the wider context and purpose of the legislative scheme in relation to CETA.[8]

In both the GSK and Viiv cases, the application judge found the denial of a CSP to be unreasonable because Health Canada had not adequately considered Canada's domestic CSP provisions in light of CETA. Neither application judge made mention of the EU SPC cases that had been adjudicated consistently with Health Canada's position. Unlike in the GSK case, the Viiv application judge did not pronounce on what result was dictated by a proper consideration of CETA.

It is of course proper to consult an underlying international trade agreement to interpret a Canadian statute or regulation implementing a trade agreement obligation, particularly to resolve an ambiguity, whether patent or latent.[9] However, where the trade obligation in question, here relating to CSPs, is modelled on a trade agreement counterparty's law, it should be clear that rights granted in Canada need not be more expansive than the rights granted by the counterparty. Yet, in finding Health Canada's CSP interpretations unreasonable, Canadian judges may now force Health Canada to grant CSPs in a broader set of circumstances than in the EU. This interpretation would arguably itself be unreasonable, creating a Canada-EU divergence where harmonization was the entire intent.

Notably, a third application judge in a matter pertaining to the scope of pharmaceutical data protection under the *Food and Drug Regulations* found that underlying trade agreements (NAFTA and TRIPS, the Agreement on Trade-Related Aspects of Intellectual Property Rights) should be treated subordinately to the language of domestic provisions. In *Natco Pharma (Canada) Inc v Canada (Health)*, 2020 FC 788 (Natco), the application judge considered it reasonable for Health Canada to consider obligations under trade agreements as a guide to interpretation, but the assessment of such obligations could not be used to undercut the implementing language.[10]

In Natco, the Court concluded that the filing of an application for a generic combination drug product involving a comparison to a single product possessing data protection was prevented by the data protection on the single product.[11] The basis for this result was regulatory language preventing applications that involved a "direct or indirect comparison" to an innovative drug, regardless of whether the generic applicant has formally relied on the regulatory dossier supporting approval of the innovative drug.[12] The application judge noted that the manner in which the Governor in Council has chosen to implement a trade obligation and the words used are critical and that an international treaty cannot be used to override the clear words of a statutory provision.[13]

The GSK case is before the Federal Court of Appeal, and a decision is pending. The Viiv matter

was not appealed. The matter was remanded back to the Minister, and the CSP was again refused, with the Minister taking the position that her interpretation is consistent with CETA. ViiV Healthcare ULC has sought judicial review of Health Canada's re-determination.

The availability of CSPs has a significant impact on affordable access to medicines because CSPs typically extend IP protection at the height of a drug's revenues, as patents are set to expire and prices fall as a result of generic or biosimilar competition. The authors are hopeful that the Federal Court of Appeal in GSK duly considers the EU's treatment of SPCs and the limitations on their availability that underpinned CETA, so that Canada's obligations are harmonized with the EU approach as originally intended.

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[1] *Glaxosmithkline Biologicals SA v Canada (Health)*, 2020 FC 397 at para 23.

[2] *Glaxosmithkline Biologicals SA v Comptroller-General of Patents, Designs and Trade Marks*, [2014] RPC 17 at paras 38, 45.

[3] *Supra* note 1 at paras 43, 46.

[4] *ViiV Healthcare ULC v. Canada (Health)*, 2020 FC 756 at para 6.

[5] *Teva UK and Others v Gilead Sciences Inc*, [2018] EUECJ C-121/17 (25 July 2018) at para 58.

[6] *Teva UK Ltd and others v Gilead Sciences Inc*, [2018] EWHC 2416 at para 38.

[7] *Supra* note 4 at para 30.

[8] *Supra* note 4 at para 26.

[9] *National Corn Growers Assn. v. Canada (Import Tribunal)*, [1990] 2 SCR 1324 at p 1372.

[10] *Natco Pharma (Canada) Inc v Canada (Health)*, 2020 FC 788 at para 52.

[11] *Ibid* at paras 2-4.

[12] *Supra* note 10 at para 11.

[13] *Supra* note 10 at para 52.