Federal Court finds Minister of Health's refusal of BELSOMRA CSP unreasonable, remits for redetermination

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For the third time since the Canadian Certificate of Supplementary Protection (CSP) regime came into force, the Federal Court has reviewed the decision to refuse a CSP application. In *Merck Canada Inc v Minister of Health* (2021 FC 1015), Merck sought judicial review of the Minister of Health's refusal to issue a CSP for suvorexant, the medicinal ingredient in Merck's drug product BELSOMRA. In this case, the Minister's failure to consider the context and purpose of the CSP regime in the interpretation of CSP eligibility requirements was fatal, resulting in Merck's CSP application being remitted for redetermination. The Federal Court's decision highlights the critical importance of considering the objectives underlying the CSP Regime during the application process.

Two CSP eligibility requirements as set out in s 106(1) of the *Patent Act* were at issue in this decision. The first is the "authorization for sale requirement" (s 106(1)(c)), which requires an authorization for sale to have been issued for the medicinal ingredient, or combination of medicinal ingredients, after the CSP provisions came into force in September 2017. The definition of "authorization for sale" includes a Notice of Compliance (NOC), but also covers any authorizations under the *Food and Drugs Act*, save for certain exclusions.

The second eligibility requirement at issue is the "timely submission requirement" (s 106(1)(f)), which requires a Canadian New Drug Submission (NDS) to be filed within 12 months after authorization is first sought in a prescribed country (the US, UK, the EU or any member country, Japan, Switzerland, and Australia). The goal of the timely submission requirement is to incentivize the early introduction of innovative drugs into the Canadian market (*CSP Regulations* Regulatory Impact Statement).

Merck first filed an NDS for Canadian approval of BELSOMRA on November 15, 2012, which was within 12 months after authorization was first sought in the US. Health Canada issued a Notice of Deficiency, citing concerns that the NDS contained insufficient information about the benefit/risk profile of suvorexant, and that additional clinical trial data were required to satisfy these concerns. Merck withdrew this NDS in February 2014. After Health Canada indicated that other post-market data could satisfy the need for additional safety evidence, Merck filed a second NDS in 2016. It was as a result of this second NDS that the NOC for BELSOMRA was issued in November 2018. In 2019, Merck applied for a CSP, identifying the NOC to fulfill the "authorization for sale requirement", and the first NDS filed in 2012 to fulfil the "timely submission requirement".

Health Canada, on behalf on the Minister, gave the preliminary view that Merck was not eligible to receive a CSP, because it did not meet those two requirements. In response, Merck filed submissions including statutory interpretation arguments that it met the authorization for sale requirement since it obtained an NOC for BELSOMRA in November 2018. Further, Merck met the timely submission requirement since it filed an NDS in Canada within 12 months of the first filing for authorization in the US. Merck also argued that the preliminary decision was contrary to the object and purpose of the

Patent Act and *CSP Regulations*, which was to promote innovation and investment in new drugs in Canada by compensating innovators for patent term lost during research and while obtaining market authorization.

In August 2019, the Minister refused Merck's application, finding that the first NDS, which was withdrawn and did not receive an NOC for BELSOMRA, could not satisfy the authorization for sale requirement. Further, the second NDS, which did receive an NOC, was not filed within the prescribed time and did not meet the timely submission requirement. However, in its decision, the Minister did not address the context or purpose of the CSP regime set out in the *Patent Act* and *CSP Regulations*.

At the Federal Court, the only issue raised in Merck's application for judicial review was whether the Minister's decision to deny Merck's application for a CSP for BELSOMRA was reasonable. Ultimately, the Federal Court lost confidence in the Minister's decision due to the Minister's failure to consider the context and purpose of the provisions, as well as the central role of *the Comprehensive Economic and Trade Agreement* (*CETA*) in the context and enactment of the provisions. The Federal Court emphasized that it was not approving or disapproving of either the Minister's interpretations and arguments or those of Merck. Rather, the Minister's decision was unreasonable because it failed to meaningfully account for a key argument raised by Merck pertaining to a relevant issue of statutory interpretation. The Minister's decision was set aside, and Merck's CSP application was remitted for redetermination.

This decision, along with *ViiV Healthcare ULC v. Canada (Health)* 2020 FC 756 [JULUCA] and *Canada (Health) v. GlaxoSmithKline Biologicals S.A.*, 2021 FCA 71; rev'g 2020 FC 397 [SHINGRIX], emphasizes the importance of the policy and intent behind the CSP regime, along with Canada's international obligations underlying the CETA, in the consideration of CSP eligibility.