NOC Regulations do not apply to biosimilars when reference products are not marketed

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The Federal Court recently denied AbbVie's application for judicial review of two decisions of the Minister of Health (the Minister) relating to JAMP Pharma's SIMLANDI product, which is a biosimilar version of AbbVie's HUMIRA adalimumab product. The Court held that the Minister's decision interpreting the *Patented Medicines (Notice of Compliance) Regulations* (the *NOC Regulations*) as applying only to a single version of a drug with a drug identification number (DIN) that is marketed in Canada was reasonable (para 5).

Is JAMP a second person?

The first question to be considered by the Court was whether the Minister's decision determining that JAMP is not a "second person" for the purposes of the *NOC Regulations* could be upheld. The Minister had decided that JAMP was not a second person, meaning that it was not required to send AbbVie a Notice of Allegation (NOA) pursuant to the *NOC Regulations*. As a result, it did not have to clear non-infringement or invalidity proceedings prior to being granted regulatory approval.

JAMP's biosimilar new drug submission (bNDS) relied on comparisons to three HUMIRA products that were not marketed in Canada by AbbVie at the time JAMP's bNDS was filed. JAMP'S SIMLANDI product was the same strength and dosage form as the three AbbVie products.

When JAMP filed its bNDS, it was deemed administratively incomplete. JAMP filed a Form V and served AbbVie with a NOA but indicated that these were filed without prejudice in order to avoid delay, as JAMP's position was that it did not need to comply with the *NOC Regulations*. The Office of Submissions and Intellectual Property at Health Canada (OSIP) gave both JAMP and AbbVie time to make submissions on this issue.

After a preliminary decision, and an opportunity to make further submissions, the Minister confirmed their preliminary decision that "another drug" in the *NOC Regulations* must refer to the Canadian Reference Product (CRP) or the Reference Biologic Drug (RBD) as identified by the Biologic and Radiopharmaceutical Drugs Directorate (BRDD), as the case may be. This meant that the product must be marketed in Canada and have

a DIN. The Minister indicated that the RBD was DIN-specific. As, at the time JAMP's bNDS was submitted, there was no RBD, and thus, JAMP was not a second person.

The Court held that the Minister's decision that the *NOC Regulations* require the patent list to be specific to the medicinal ingredient, brand name, dosage form, strength, route of administration, and use, and that that specificity meant that the patent list contained a description of the drug at a DIN-specific level – was reasonable. Furthermore, the decision requiring the RBD to be marketed was reasonable. The Court held that the marketing requirement was intended to prevent a patentee who obtains an NOC but does not make their drug available to Canadians, from relying on the benefits conferred by the *NOC Regulations*.

Thus, the Court dismissed the judicial review on the question of whether the Minister's decision that JAMP was not a second person could be upheld.

Could the Minister issue a NOC to JAMP?

The second question before the Court was whether the Minister's decision to issue a Notice of Compliance (NOC or regulatory approval) to JAMP on the basis of its bNDS could be upheld.

As a result of the Minister's decision that JAMP was not a second person pursuant to the *NOC Regulations*, JAMP was issued a NOC when its drug was approvable. JAMP was not required to follow the procedures in the *NOC Regulations*. The Court held that this decision was reasonable.

Standard of review

It is worth noting that AbbVie argued pursuant to the SCC's recent decision in *Rogers* that the standard of review was correctness, as both the executive and judicial branches of government have concurrent jurisdiction over this issue of statutory interpretation. The Court held that the Federal Court of Appeal had rejected this interpretation of the *NOC Regulations*. Thus, the Ministerial decisions at issue are to be reviewed on a standard of reasonableness.

Key Takeaway

Innovative companies need to carefully manage their products in Canada. As with this decision, when a drug is removed from the market, or submitted but not marketed, it can lead to an opportunity for a biosimilar filer to circumvent the *NOC Regulations*. A patent infringement suit will remain an option in such instances. However, it will be extremely difficult for an innovator to obtain an interlocutory injunction during the pendency of such a proceeding.

By

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