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The Current Frame Work and Expected Trends in Canadian Disputes About Biosimilar Drugs

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A biologic drug typically includes a large or complex bioactive molecule that is produced using animals or microorganisms. A biosimilar drug is a biologic drug that is similar to but not equivalent to a prior biologic drug that has already received regulatory approval for use in humans. The prior biologic drug is often called a reference biologic.

Here we discuss the current framework for disputes between owners of reference biologics and owners of biosimilar drugs. We also summarize some expected trends in Canadian legal disputes between these entities.

Current Framework for Disputes

Disputes that relate to biosimilar drugs and patented reference biologics are subject to the *Patented Medicines (Notice of Compliance) Regulations* (*PMNOC* Regulations).[1] Litigation under the *PMNOC* Regulations involves a summary procedure to determine whether allegations of invalidity or non-infringement are justified as between the parties. Apart from obtaining the regulatory submission from the biosimilar drug in dispute, there are limited discovery rights, such as examination for discovery, available for proceedings under the *PMNOC* Regulations.

If the owner of the reference biologic drug has filed a qualifying patent on the Patent Register established under the *PMNOC* Regulations, the owner of the biosimilar drug will not be able to obtain regulatory approval until after the listed patents have expired or until a proceeding launched under the *PMNOC* Regulations is decided in favor of the owner of the biosimilar product.

The process of the *PMNOC* Regulations is put in motion when the owner of the biosimilar drug serves a Notice of Allegation alleging that the patent for the reference biologic is invalid, not infringed, or was improperly listed on the Patent Register. In response, the owner of the reference biologic can

[1] *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (*PMNOC* Regulations).

apply within a fairly short time period to the Federal Court seeking a prohibition order that prevents the Minister of Health from issuing a Notice of Compliance for the biosimilar product until after expiration of the relevant patent.

Through the proceeding, the parties exchange evidence including expert testimony by way of affidavits, and cross examinations on the affidavits that take place outside of the court. An oral hearing before a judge takes place to determine whether the allegations of invalidity or non-infringement are justified. In the event that the owner of the reference biologic drug prevails, a prohibition order is issued by the court. If the owner of the biosimilar product prevails, a Notice of Compliance is issued by the Minister of Health and the biosimilar owner can launch their product. Additionally, they may be entitled to claim damages that they suffered as a result of being delayed by reason of the proceedings under the *PMNOC* Regulations.

If the court issues a prohibition order or dismisses the proceedings, neither of these are a final determination of the dispute between the parties. The unsuccessful party can commence a separate legal action, outside of the *PMNOC* Regulations, to determine validity or non-infringement of the patent for the reference biologic. These subsequent actions are decided after full discovery takes place and on the basis of *viva voce* testimony before a trial judge. In Canada, unlike in the United States, patent matters are not decided by a jury.

One of the first Canadian legal cases that relates to a dispute between the owner of a biosimilar drug and the owner of a reference biologic is *Amgen Canada Inc. et al. v. Teva Pharmaceutical Industries Ltd. et al.* (T-989-12). Briefly, Amgen had an approved biologic drug called filgrastim that was marketed under the name NEUPOGEN®. NEUPOGEN® can be used for treating low levels of white blood cells in cancer patients. Reportedly, Amgen received billions of dollars of revenue generated by NEUPOGEN® around the world. Teva developed a biosimilar drug to NEUPOGEN® and sought regulatory approval for its biosimilar drug. Amgen sought a prohibition order through the *PMNOC* Regulations to block the approval of Teva's product. In the end, this dispute was settled privately between the parties on confidential terms. However, subsequent cases have confirmed that the *PMNOC* Regulations are an appropriate procedure for determining disputes relating to biologic drugs and biosimilar drugs. At least for the time being.

Potential Changes to the Current Framework

Canada's obligations with the European Union under the Comprehensive Economic and Trade Agreement (CETA) may impact how disputes over biosimilar drugs are addressed in Canada. In particular, CETA is likely to lead to changes in Canadian law that will impact on the Canadian biotech industry.

For example, CETA will likely replace the current dual-track framework of patent litigation for drugs where proceedings can occur under both the *PMNOC* Regulations and the subsequent court actions discussed above. Under CETA, *PMNOC Regulations* proceedings will likely be replaced with full legal actions that will result in a final determination of patent validity and infringement. These full legal actions will also include an opportunity for the unsuccessful party to appeal.

Additionally, CETA is expected to lead to the restoration of the duration of patents covering pharmaceutical products where "unreasonable curtailment" of the patent term occurs during the marketing approval process of the pharmaceutical products. The concept is referred to as a Supplementary Protection Certificate. The objective is to provide additional patent protection to permit

the patentee to recover some of the expensive research and development costs associated with developing new drugs.

This extension of patent term may result in further litigation between the owners of reference biologics and the owners of biosimilar drugs because the biosimilar owners are likely to object to having to wait longer than the current patent term of twenty years before they can bring their product to market, particularly if proceedings under the *PMNOC* Regulations are no longer available. As such, there may be an increased occurrence of owners of biosimilar drugs seeking declarations of invalidity or non-infringement of the term-extended reference biologic patents.

In summary, the current framework provides two procedural tracks for legal disputes between the owners of reference biologics and the owners of biosimilar drugs. However, Canada's international treaty obligations may result in one of those procedural tracks being dismantled. It is possible that losing one procedural track could result in further full legal actions for a final determination of patent validity and infringement of reference biologic patents.

*This article provides information only and does not provide any legal advice.