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Pharma in brief - Canada

Minister's decision to issue NOC without notice to first person for cross-referenced drug submission held reasonable by the FCA

Case:	*Teva Canada Limited et al v Pfizer Canada Inc et al*, 2016 FCA 248
Drug:	AROMASIN® (exemestane) and REMICADE® (infliximab)
Nature of case:	Appeal from a judicial review setting aside a decision of the Minister of Health to not require notice under section 5 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133
Successful party:	Teva Canada Limited, Hospira Healthcare Corporation and The Minister of Health
Date of decision:	Oct. 12, 2016

Summary

This appeal relates to two generic drug submissions for two different products: exemestane and infliximab. Both submissions cross-referenced the submission of another generic company that had received a Notice of Compliance (**NOC**). The Minister of Health (**Minister**) issued NOCs for the two generic products without requiring notice to the innovator company in the form of a Notice of Allegation (**NOA**).

In both cases, the innovator companies brought an application for judicial review and the Minister's decisions were set aside. The Minister and the respective generic manufacturers appealed. The appeals were allowed by the Federal Court of Appeal. The FCA held that in the circumstances the generic companies were not required to serve NOAs.

Background

This decision results from a consolidation of four appeals arising from the Federal Court setting aside the Minister's decision to issue NOCs to two generic companies relating to exemestane and infliximab. The issue in both appeals is whether the Minister was permitted to issue NOCs to the generic companies without requiring them to address relevant patents on the Patent Register pursuant to section 5 of the *Patented Medicines (Notice of Compliance) Regulations* (**Regulations**).

Exemestane. Pfizer Canada Inc. manufactures exemestane under the name AROMASIN®. Generic Medical Partners Inc. (**GMP**) filed a submission seeking approval to market a generic version of exemestane and served an NOA on Pfizer. Pfizer did not seek a prohibition order and an NOC subsequently issued to GMP.

After GMP received an NOC, Teva Canada Limited filed a submission for a generic version of exemestane that cross-referenced GMP's submission. Teva's submission included a certification that all aspects of its product were identical to GMP's, except for the names of the manufacturer and the product, and an authorization from GMP to access GMP's submission.

The Minister issued an NOC to Teva without requiring it to serve an NOA on Pfizer. As we reported, Pfizer successfully brought an application for judicial review, and the Minister's decision was set aside.

Infliximab. Janssen Inc. manufactures infliximab under the name REMICADE®. Celltrion Healthcare Co. Ltd. filed a submission seeking approval to market a biosimilar under the name INFLECTRA®. At that time, no patent was listed on the Patent Register in respect of REMICADE® and the NOC issued. Janssen subsequently listed a patent on the register for infliximab.

After Celltrion received an NOC and Janssen listed its patent on the Register, Hospira Healthcare Corporation filed a submission that cross-referenced Celltrion's submission. Hospira's submission certified that it had entered into a licensing agreement with Celltrion, that all aspects of Hospira's product were identical to Celltrion's except for the manufacturer's name and included an authorization from Celltrion to cross-reference Celltrion's submission.

The Minister issued the NOC to Hospira without requiring that an NOA be served on Janssen. The Minister's decision was set aside by the Federal Court on consent, to allow the appeals to be heard with those for exemestane.

The standard of review is reasonableness

The FCA reversed the Federal Court's holding that the applicable standard of review was correctness. The FCA agreed with the Federal Court that the presumptive standard of review is reasonableness. Whether section 5 is engaged, the FCA held, is a question of mixed fact and law within the expertise of the Minister, and reasonableness applies where, as in this case, the statute or regulations at issue are closely related to the decision maker's function.

Furthermore, the FCA disagreed with the Federal Court that the presumption was rebutted in these cases, holding that there was no evidence of an intention by Parliament to have the Minister's decisions reviewed on a less deferential standard. Therefore, the Minister's decisions should be reviewed on the standard of reasonableness.

The Minister's decision was reasonable

Having determined the correct standard of review, the FCA went on to review the reasonableness of the Minister's decision.

The FCA found that it is relevant to consider whether the generic company took advantage of the early working exception. This is particularly relevant to infliximab as there was no patent listed when Celltrion obtained its NOC, and therefore as a matter of law there could be no early working.

The FCA also considered the interpretation of the word "submission," which requires consideration of each individual submission. Consistent with jurisprudence interpreting the term "submission" in the context of section 4 of the Regulations, the FCA held that the focus should be on the drug product itself and whether the changes reflected in the submission give rise to a new or different basis for asserting that a particular product is infringing. In both cases, the generic companies sought approval for products that were identical to a previously approved generic product and any potential infringement could be addressed in infringement proceedings.

The FCA found that on the facts of these cases, the generic companies did not need to serve NOAs on the innovator companies.

Links:

Teva Canada Limited et al v Pfizer Canada Inc et al, 2016 FCA 248
Federal Court decision (exemestane): *Pfizer Canada Inc v Canada (Health)*, 2014 FC 1243

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