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Pharma in brief - Canada

Federal Court of Appeal upholds prohibition order against generic DOVOBET®, dismisses inutility and insufficiency challenges

Case:	*Teva Canada Limited v Leo Pharma Inc*, 2017 FCA 50 (A-508-15), aff'g 2015 FC 1237 (T-1791-13)
Drug:	DOVOBET® (calcipotriol/betamethasone dipropionate ointment)
Nature of case:	Appeal from application for prohibition order granted pursuant to section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133
Successful party:	Leo Pharma Inc. and Leo Pharma A/S (collectively **Leo**)
Date of decision:	March 14, 2017

Summary

Teva asked the Court of Appeal (**FCA**) to overturn the Federal Court's findings (reported here) on utility and insufficiency of disclosure. The FCA, dismissing Teva's appeal on both counts and upholding the prohibition order, addressed the role of inventors' evidence in proving sound prediction and the use of trial-and-error testing to support sufficiency of disclosure.

Background

Leo Pharma Inc. markets DOVOBET® (calcipotriol/betamethasone dipropionate ointment) in Canada for the treatment of psoriasis. Teva Canada Limited sought approval for a generic version of DOVOBET® and was opposed by Leo. Leo's application was successful, and Locke J issued an order prohibiting the Minister of Health from approving Teva's proposed generic until the expiry of Canadian Patent No. 2,370,565 (the **565 Patent**).

The 565 Patent is listed on the patent register against DOVOBET®. It relates to a combination formulation of: at least one vitamin D or vitamin D analogue (Component A); at least one corticosteroid (Component B); and a solvent (Component C). Components A and B were both known to be useful in the treatment of psoriasis but believed to be incompatible for co-formulation in an ointment due to stability issues. The invention of the 565 Patent lay in the addition of Component C, which resolved these stability issues.

Utility: Inventors' evidence not required to prove sound prediction

Teva argued that the Federal Court erred by dismissing its inutility allegation without evidence from Leo regarding the factual basis and logic or reasoning used by the inventors to support their sound prediction of the invention's utility. Teva framed this issue as a question of law, i.e., whether Locke J reformulated the test for inutility.

The FCA rejected Teva's argument that, as a matter of law, subjective proof of the inventors' prediction must be made through evidence directly from the inventors, not an expert witness. The FCA held that in *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77, the Supreme Court did not limit the means of proving the facts required to establish a sound prediction. The court below did not err in law.

As a result, the FCA found that the main issue was whether Locke J committed a palpable and overriding error by inferring the inventors' factual basis and line of reasoning from the 565 Patent, aided in his interpretation by Leo's expert witness. The FCA found no basis to interfere with this inference on the facts.

Insufficiency: Trial-and-error testing permissible

Teva also argued that the Federal Court erred in law because it did not find that the 565 Patent fails to correctly and fully disclose the invention as contemplated by the inventors. The FCA held that the question was whether the skilled person would consider the disclosure given to be sufficient to work the invention. Contrary to Teva's assertion, the issue on appeal was therefore a question of fact.

The FCA held that one must always consider the nature of the invention to determine what needs to be included in the disclosure. Furthermore, the FCA accepted that non-inventive trial-and-error experimentation is permissible when determining whether a skilled person would be able to work the invention. The FCA held that the Supreme Court's decision in *Teva Canada Limited v Pfizer Canada Inc*, 2012 SCC 60 [*sildenafil*], had not changed this law. Rather, the FCA distinguished permissible routine testing, of the kind also permitted under the enablement branch of the test for anticipation, from the "minor research project" that the Supreme Court found impermissible in *sildenafil*.

The FCA also distinguished the nature of the insufficiency alleged in this case from the Supreme Court's decision in *sildenafil* that the invention itself had not been properly disclosed. Here, no experimentation of any kind was required to identify the invention.

Links:

This decision: *Teva Canada Limited v Leo Pharma Inc*, 2017 FCA 50

Underlying Federal Court decision: *Leo Pharma Inc v Teva Canada Limited*, 2015 FC 1237 (Pharma in Brief here)

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