NORTON ROSE FULBRIGHT

Pharma in brief - Canada

Federal Court grants prohibition order for methylphenidate extended release product

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Case: *Janssen Inc v Actavis Pharma Company*, 2016 FC 1361
Drug: CONCERTA® (methylphenidate extended release)
Nature of case: *Prohibition application pursuant to section 6 of the Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the ***Regulations***)
Successful party: Janssen Inc.
Date of decision: January 9, 2017

Summary

The Federal Court granted Janssen's application for a prohibition order relating to Actavis' generic version of its CONCERTA® product, finding that Actavis' allegations of invalidity (including obviousness, lack of utility and overbreadth) and non-infringement were not justified.

Claims construction

The patent relates to the use of compositions that release methylphenidate in a "sustained-ascending dose over time." In a previous proceeding between Janssen and Novopharm relating to the same patent (*Janssen-Ortho Inc v Canada (Health)*, 2010 FC 42), Justice Zinn had construed the phrase "sustained-ascending dose over time" as meaning methylphenidate is released from the tablet at an increasing rate, and not that plasma concentrations increase at an ascending rate. Justice O'Reilly followed this construction.

Actavis argued that the increasing rate of release had to occur over the entire dosing period. Justice O'Reilly disagreed, and held that although "over time" means an extended period, a skilled person would not interpret this as the entire dosing period, as efficacy is sustained for a period of time beyond the point when methylphenidate is last released from the tablet.

Justice O'Reilly also disagreed with Actavis that the inclusion of specific amounts in one of the claims meant that the claim covered dosage forms with those amounts of active ingredients. Rather, he held that the patent claimed dosage forms in which the claimed amounts may be contained in one of its components.

Invalidity

Invention not obvious. Justice O'Reilly held that the inventive concept of the patent was the use of a formulation that delivers a sustained-ascending dose of active ingredient over time to address acute tolerance (i.e., when a patient becomes tolerant to the drug within a single dosing period), and that this was an advantage over what was known at the relevant date, namely: an immediate release formulation that required frequent dosing (a problem given that it often needed to be given to children during the school day) and a sustained release dosing form that did not overcome the problems with the immediate release formulation.

Although acute tolerance was mentioned as a potential cause of the known sustained release formulation's lack of success, Justice O'Reilly held that prior to the patent there was nothing in the art showing that acute tolerance was a problem to be solved. It was therefore not obvious to try a sustained-ascending dosage form.

No lack of utility. Justice O'Reilly found that the examples in the patent demonstrated utility and that given his construction regarding specific dosages, Actavis' allegation that the claims covered inoperable products (namely, tablets containing as little as 100 ng of active ingredient) was not justified.

Claims not overbroad. Actavis argued that the specific dosages of 100 ng and 500 mg included in one of the claims would be ineffective and lethal, respectively. Justice O'Reilly held that the patent did not claim a dosage form with the lower dose and he had insufficient evidence to show that the higher dose would be fatal.

Infringement

Actavis alleged that its product does not infringe the patent as the methylphenidate is not released at a "sustained-ascending release rate over time." Given his construction that the claims do not require a sustained-ascending release rate over the entire dosing period, his preference for Janssen's expert's analysis and his finding that Actavis' product monograph indicates that the Actavis product provides a sustained-ascending dosage form for methylphenidate that can overcome acute tolerance, Justice O'Reilly disagreed and held that this allegation was not justified.

Link:

Janssen Inc v Actavis Pharma Company, 2016 FC 1361.

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