

# SUFFICIENCY TEST FOR SELECTION PATENTS TIGHTENED



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In the recent decision of *Eli Lilly v. Novopharm*, 2007 FC 596, a Federal Court judge in Canada revisited the issue of sufficiency for disclosure for “selection patents”. The court dismissed Eli Lilly’s application against the generic company Novopharm for a prohibition order under the *Patented Medicines (Notice of Compliance or NOC) Regulations* relating to olanzapine, the pharmaceutically active ingredient of Eli Lilly’s drug ZYPREXA.

The decision related to Lilly’s application seeking to prohibit the Minister of Health in Canada from issuing a Notice of Compliance to Novopharm, in respect of various tablets for the oral administration of drugs containing olanzapine, until the expiry of Eli Lilly’s Canadian patent no. 2,041,113 (the 113 patent). At the centre of the litigation was the issue of validity relating to the 113 patent as a selection patent.

Generally speaking, a selection patent is a selection from members of a previously known class of substances. A selection patent may be patentable if the substance selected is unobvious and affords a new and useful result.

In this case, the 113 patent was considered a selection patent, as a group of compounds containing olanzapine had been previously disclosed. With respect to its allegation that the 113 patent is invalid, Novopharm raised the issue of lack of sufficiency.

The disclosure of the 113 patent stated: “We have now discovered a compound which possesses surprising and unexpected properties by comparison with flumazepine and other related compounds.”

Novopharm argued that the insertion in the descriptive portion of the 113 patent of certain pieces of information, but not others, meant that Lilly had failed to meet the provision of section 27(3) (b) of the *Canadian Patent Act*, which requires that the patent specification must clearly set out the invention in such full, clear, concise and exact terms so as to enable a person skilled in the art to make, construct, compound or use the invention.

In considering the law as to sufficiency in regard to selection patents, the court concluded:

1. A valid selection patent may be obtained where the invention lies in selecting a member or members from a previously disclosed group where the member or members selected possess a particular advantage not previously to be found or predicted in a large number of members of the class by a person skilled in the art.
2. The advantage may also be a disadvantage to be avoided.
3. The advantage must be clearly set out in the specification. A statement that the selected group possesses advantages or lack of disadvantages is not in

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itself sufficient; the advantage must be plainly and fully set out in sufficient detail so as to enable a person skilled in the art to know and appreciate what they are.”

In view of the above, the court framed the issue relating to sufficiency of disclosure as whether the advantages of the selected compound were sufficiently stated in the 113 patent specification.

Justice Hughes concluded that the specification must set out, with clarity, the advantage claimed by the selection. The patentee cannot merely state that the selected compound or group has advantages; these must be identified. Justice Hughes noted that there was no comparative data to support the statement of invention, which said that olanzapine has “surprising and unexpected properties by comparison with flumazepine and other related compounds”.

The court found that the only comparative data given was an incomplete description of a dog study. The comparison was not to flumazepine but to ethyl olanzapine, which, presumably, is one of the “other related compounds”.

Novopharm argued that there was much more data that Lilly had recorded that ought to have been presented, and that, in looking at all the data, a person skilled in the art may have come to different conclusions as to the effectiveness of olanzapine, not only in respect of cholesterol but other things as well.

In the end, the court concluded that Lilly has not provided “clear and explicit disclosure to what the invention is, if any, in the properties of olanzapine alone that merit a further monopoly in a separate further patent.”

This case appears to suggest that the court has ‘tightened’ the sufficiency test for selection patents in Canada, in particular, with the requirement for “comparative data” in a selection patent.

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