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Pharma in brief - Canada

Federal Court construes single overarching promise of the patent: s. 6 application for dasatinib dismissed for lack of utility

Case:	*Bristol-Myers Squibb Canada et al v Apotex et al*, 2017 FC 296
Drug:	SPRYCEL® (dasatinib)
Nature of case:	Prohibition application pursuant to section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the ***Regulations***)
Successful party:	Apotex Inc. (**Apotex**)
Date:	March 21, 2017

Summary

The Federal Court dismissed Bristol-Myers Squibb's prohibition application, finding that one of the patents had an overarching promise and lacked utility, and the other patent was "obvious to try." The court also assessed double patenting at the priority date of the later filed patent.

Bristol-Myers Squibb Canada distributes and sells SPRYCEL® (dasatinib) in Canada to treat chronic myelogenous leukemia (**CML**). Apotex sought approval for Apo-dasatinib and was opposed by Bristol-Myers Squibb Canada and Bristol-Myers Squibb Holdings Ireland (collectively **BMS**), which asserted Canadian Patents No. 2,366,932 (the **932 Patent**) and No. 2,519,898 (the **898 Patent**) under section 6 of the *Regulations*.

Justice Manson dismissed BMS's application, holding that Apotex's allegations of inutility (against the 932 Patent) and obviousness and double patenting (against the 898 Patent) were justified.

The 932 Patent

The 932 Patent claims cyclic compounds and the use of these compounds in treating various cancers. Only the claim for dasatinib or a salt thereof was at issue in the proceeding.

The description included various references to use of the compounds of the invention in treatment, including:

- "The present invention relates to …compounds…, to methods of using such compounds in treating protein tyrosine kinase-associated disorders such as immunologic and oncologic disorders…"
- "The compounds of the invention inhibit protein tyrosine kinases … and are thus useful in the treatment …of protein kinase-associated disorders such as immunologic and oncologic disorders."
- "The compounds … are therefore useful in the treatment of proliferative disorders such as… cancer…"

Based on the entire patent, Justice Manson found that the 932 Patent had an overarching promise that the compounds will inhibit specific enzymes and be therapeutically useful in treating a protein tyrosine kinase-associated disorder or be

useful as anti-angiogenic agents. Justice Manson distinguished this patent from others in which different claims had different promised utilities (in particular, Justice Snider's decision in *Teva Canada Limited v Novartis AG*, 2013 FC 141 relating to GLEEVEC® [imatinib mesylate]). He held that as the 932 Patent included "numerous instances" where the inventors state the compounds "are" useful for treatment. In contrast to the patent before Justice Snider, which stated that the compounds "can be used" for a therapeutic purpose, the language in the 932 Patent is not equivocal when referring to the therapeutic purpose.

Justice Manson held that the overarching promise was not soundly predicted because BMS did not challenge the allegation that there was no sound prediction of dasatinib's therapeutic utility. He also held that if the promise was only inhibition of specific enzymes, there was still no sound prediction, as the inventors did not have a factual basis or a sound line of reasoning that dasatinib would inhibit all of the enzymes promised, nor was there disclosure of either in the patent.

Apotex's allegation of insufficiency was an alternative allegation if the court held there was no overarching promise. Justice Manson held that had he not found an overarching promise, he would have found that the 932 Patent is sufficient.

The 898 Patent

The claims at issue in the 898 Patent claimed the oral use of dasatinib for treating CML and imatinib-resistant CML.

The court found Apotex's allegations of obviousness were justified. Although the parties agreed that it would not be obvious at the relevant date that dasatinib would be an "effective oral treatment," Justice Manson held that, given the motivation in the field, the state of the art and the routine nature of the work done, it would have been "more or less self-evident that trying to treat CML and imatinib-resistant CML with dasatinib ought to work."

Justice Manson also found that the 898 Patent was invalid for obviousness-type double patenting in light of the 932 Patent. He stated that, based on the Court of Appeal's decision in *Apotex Inc v Eli Lilly Canada Inc*, 2016 FCA 267 (reported here), the state of the law on the appropriate date to assess double patenting is inconclusive. He referred to Justice Gleason's reasoning in *Eli Lilly Canada Inc v Apotex Inc*, 2015 FC 875 and applied the priority date of the later filed patent.

Link to decision:

Bristol-Myers Squibb Canada et al v Apotex et al, 2017 FC 296

For more information, please contact your IP/Life sciences or healthcare practice professional at Norton Rose Fulbright Canada LLP.

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