

# Misleading disclosure invalidates patent: *Ratiopharm*

Full, frank and fair disclosure of an invention is an essential part of the bargain for a patent. A patent is void if any material allegation in the petition is untrue or if the specification contain omissions or additions that are wilfully made for the purpose of misleading.

This long-standing rule has only rarely been applied to invalidate a patent. The decision of Justice Roger Hughes of the Federal Court released on August 12 in *Ratiopharm Inc. v. Pfizer Ltd.*, [2009] F.C.J. No. 967 will undoubtedly be used in the future to measure the adequacy of the disclosure patentees give as consideration for a statutory monopoly.

The decision involved Ratiopharm's challenge to the validity of Canadian Letters Patent 1,321,393 (the "393 Patent"), which claims amlodipine besylate, the active pharmaceutical ingredient in NORVASC, Pfizer's brand of high blood pressure medication. The 393 Patent was previously attacked by Ratiopharm in proceedings under the *Patented Medicines (Notice of Compliance) Regulations*. In the earlier decision, Justice Konrad von Finkenstein ruled that Ratiopharm's allegations that the 393 Patent was invalid were justified. The Federal Court



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of Appeal reversed, held that Ratiopharm's allegations of invalidity were not justified, and issued an order prohibiting Ratiopharm from marketing its competing generic product.

Ratiopharm renewed its challenge to the 393 Patent in the impeachment action heard by Justice Hughes. It is a quirk of the present legal regime relating to patented medicines that the earlier decisions, in which many of the same issues were considered, are only "instructive" and did not prevent this subsequent, repetitious litigation.

Justice Hughes found that the 393 Patent was invalid because:

- the selection of the besylate salt was obvious;
- it was not a valid selection patent (assuming such a class of patents exists);
- it lacked utility;
- the disclosure was insufficient; and
- there were false material allegations that had been wilfully made for the purpose of misleading.

Justice Hughes construed the

393 Patent as promising that "the besylate salt has a unique combination making it 'particularly suitable' and 'outstandingly suitable' for preparation of pharmaceutical formulations of amlodipine."

In assessing the validity of the 393 Patent against that promise, Justice Hughes repeated the admonition against considering each particular ground of invalidity in watertight compartments. He found that Pfizer had developed amlodipine besylate through a routine pre-formulation procedure known as a salt-screen. The salt-screen involved seven salts and as a result of those tests, the besylate was selected as the preferred salt.

However, the besylate was not actually clearly superior to three or four other salts tested. Stressing the importance of having direct evidence from the inventors, Justice Hughes found that, contrary to the inventors' recommendation to seek patent protection for several of the salts, the patent department singled out and filed the patent in respect of the besylate only. In doing so, it drafted a patent that mixed data from some tests with data from other tests, put in data that could not be found anywhere in the evidence and left out data favourable to other salts. Despite these undisclosed evidentiary problems, Pfizer filed a patent that

characterized the besylate salt as "unique" and "outstanding."

In assessing the sufficiency of the 393 Patent, Justice Hughes remarked that this case presented a rare opportunity in which the court had an opportunity to compare what the inventors contemplated with the disclosure of the patent itself. Justice Hughes concluded that, because of the "many serious errors, omissions, insertions from elsewhere and departures in the 393 Patent," the specification for the 393 Patent did not, as required by para. 34(1)(a) of the "old" *Patent Act*, disclose the invention as contemplated by the inventors.

Section 53 of the *Patent Act* states that a patent is void if any material allegation in the petition of the applicant in respect of the patent is untrue, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made and the omission or addition is wilfully made for the purpose of misleading. Justice Hughes found that alleging a breach of s. 53 comes close to alleging fraud and that such allegations must be pleaded with particularity. Ratiopharm alleged that Pfizer breached s. 53 by:

- omitting to mention the stability of the mesylate monohydrate and adding that it might be unsuitable

for tablet formulations;

■ omitting certain test data relating to the stability of other salts; and

■ adding that certain salts had been found not to satisfy the four criteria for pharmaceutically acceptable salts.

Justice Hughes found that the evidence showed that these misstatements were made, they were untrue and they served to enhance the alleged uniqueness and outstanding characteristics of the besylate salt. The court was left with the clear impression that Pfizer knew that there were problems with the patent as drafted and took no steps to do anything about it except to mount a vigorous defence to the action.

Justice Hughes repeated the admonition that, for at least the last 60 years, there has been an obligation of good faith on those seeking patents. That obligation requires that the disclosure set out in the specification be full, frank and fair. Hughes found that Pfizer breached its obligation of good faith and that the 393 Patent was invalid under s. 53 of the *Patent Act*. ■

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## IP lawyers comment on *Ratiopharm*

DONALEE MOULTON

The Federal Court of Appeal's decision in *Ratiopharm v. Pfizer* could mean savings of up to \$180 million a year for Canadians, according to the plaintiff, Ratiopharm Canada.

"What is significant about this decision is that it is not in the context of patented medicine notice of compliance. We commenced an action in federal court to impeach the patent. That is a full trial with live witnesses before a judge," said David Aitkin, a partner with Osler, Hoskin & Harcourt LLP in Ottawa, who represented Ratiopharm Canada.

Indeed, said Kent Major, vice president of research and development with Ratiopharm Canada in Mississauga, "if you win... you may enter the market. The patent doesn't exist."

The court found the patent invalid under s. 53 of the *Patent Act*.

"To some extent, it's forging new ground," said Euan Taylor, head of the patent practice group with Davis LLP in Vancouver.

"It's an approach the judge has taken in other decisions," he added. "He's given teeth to a sec-

tion that is largely ignored."

The s. 53 argument hinges on whether patent documents contain willfully misleading statements. "This is the first decision, to my knowledge, that has held a patent to be invalid on s. 53 of the *Patent Act*," said Aitkin. "Justice [Roger] Hughes noted this clause is very close to a fraud provision," he added.

"In recent years, people have said, 'don't use the patent document as a promotional vehicle.' This case is an example of what happens when you do that," noted Taylor.

"I don't think I've seen any other case in Canada that has specifically addressed this point," he said.

There is a caution here for patent lawyers, noted Sarah Dale-Harris, an IP lawyer with Davis LLP in Toronto. "Under the *Patent Act*, you're being granted a monopoly. This forces people to be careful what they say."

This decision, she noted, demonstrates the "marketing business inserting themselves in the process. This is a technical document. Marketing information should not have been included."

"One of the impressions that comes out of this is that the inventor submitted a disclosure

and the patent documents did not go back to the inventor for a validity check," said Taylor.

Ratiopharm's five-year legal battle against Pfizer is not yet over. The pharmaceutical giant, which is "extremely disappointed" by the decision, told *The Lawyers Weekly* it will be appealing. "Generic manufacturers continually challenge our patents and Pfizer must work tirelessly to protect our intellectual property rights and to ensure the long-term viability of our research and development initiatives," said spokesperson Rhonda O'Gallagher.

The implications of the Federal Court's decision remain to be seen. On the one hand, noted Ratiopharm's president, "it was one of the few times generics have used the *Patent Act* to gain entry. It sends a ripple."

That impact may be in direct relation to the market share of the drug. Amlodipine, the highest selling medication in its class, is an important cardiovascular medication with more than 7,869,000 prescriptions written to Canadian patients each year.

Offsetting the ripple effect, however, is the time and cost involved in patent litigation of this nature. ■