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Supreme Court of Canada Finds Biolyse Not Caught by Linkage Regulations

On May 19, 2005, the Supreme Court of Canada announced its decision in *Biolyse Pharma Corporation v. Bristol-Myers Squibb Company et al* (2005 SCC 26). Biolyse's appeal was allowed in a 6:3 decision of the Court.

The issue addressed was whether Biolyse's submission to Health Canada for approval to sell its prescription drug (paclitaxel) was within the scope of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*"). If so, Biolyse was required to comply with the *Regulations* and address certain patents on the Patent Register. If not, Biolyse could obtain its notice of compliance ("NOC") as soon as its submission met the safety and efficacy requirements of the *Food and Drug Regulations*.

Bristol Myers Squibb ("BMS") has three patents listed on the Patent Register for TAXOL, BMS's paclitaxel product, which cover formulations and methods of administration of paclitaxel. Paclitaxel is not a patented product.

Health Canada decided that Biolyse's product was not caught by the *Regulations*. Both the Federal Court (2002 FCT 1205) and the Federal Court of Appeal (2003 FCA 180) disagreed and quashed Biolyse's NOC. Satisfying the *Regulations* would require Biolyse to await patent expiry or make an allegation. Upon BMS's application, the latter would result in an automatic 24-month statutory stay, prohibiting Health Canada from issuing a NOC for Biolyse's paclitaxel.

Biolyse appealed to the Supreme Court of Canada, which reversed the decision of the Federal Court of Appeal and freed Biolyse from the requirements of the *Regulations*. The Court was strongly influenced by the fact that paclitaxel was not a patented product.

The Decision

The case turned on whether Biolyse was caught by section 5(1.1) of the *Regulations*. Section 5(1.1) provides:

> (1.1) Subject to subsection (1.2), where subsection (1) does not apply and where a person files or has filed a submission for a notice of compliance in respect of a drug that contains a medicine found in another drug that has been marketed in Canada pursuant to a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the person shall, in the submission, with respect to each patent included on the register in respect of the other drug containing the medicine, where the drug has the same route of administration and a comparable strength and dosage form,
>
> (a) state that the person accepts that the notice of compliance will not issue until the patent expires; or
>
> (b) allege that …

Health Canada required Biolyse to present its regulatory submission for its paclitaxel product as a new drug submission ("NDS"), and not an abbreviated drug submission ("ANDS"), because "the different botanical source and additional medical claims prevented any reliance on BMS's Taxol as a 'Canadian reference product'". Biolyse submitted independent clinical studies and received its NOC in 2001 without addressing the BMS patents.

Before the Supreme Court, BMS argued that "submission" in section 5(1.1) must include *any* submission, including an NDS for an innovator drug. Biolyse countered that "submission" should apply only to submissions for generic "copycat" drugs that use a "Canadian reference product" and are applied for under an ANDS.

In considering the "general context" of section 5(1.1), and referring solely to Canada's submissions to the WTO in the context of a complaint made by the European Communities, the majority held that "[i]t seems clear that the NOC Regulations were introduced to help generic drug companies and at the same time curb potential patent abuse by them".

Turning to the scheme of the *Regulations*, the majority held, "The Federal Court has consistently held that the word "submission" in section 4(1) does not include all submissions. It does not include a [supplementary NDS (SNDS)]" on the basis that "to include all NDSs would allow innovator companies to sidestep the time limits applicable to patent lists by the simple expedient of submitting an SNDS making corporate or technical changes to their filing... Such a result would not be consistent with the scheme of the NOC Regulations as a whole. In my view, this purposive approach is correct".

The majority held that section 5(1.1) should receive a similarly purposive interpretation. It held that the stated purpose of the provision is to prevent generic manufacturers from hiding their reliance on innovator drugs by putting forward another generic manufacturer's product as their reference drug in circumstances where both generic drugs are simply copies of the innovator drug.

The majority objected to BMS's interpretation based on "the fundamental objection that on such a view a "first person" could extend its monopoly far beyond the scope of any possible *quid pro quo* its own skill and ingenuity have contributed to the public". They interpreted section 5(1.1) as follows:

> 69 In my view, s. 5(1.1) does not apply to innovative drugs. It should be confined to applications for generic copies of patented drugs in the circumstances contemplated by the regulator, i.e. where a manufacturer makes a submission for a NOC for a drug which contains a medicine that it purports to copy from another generic but in fact copies from the innovator company that has filed the patent list.

However, in a strong dissent, three judges fundamentally disagreed with the majority's approach to interpretation, concluding:

> 182 Having examined the words in s. 5(1.1) in their grammatical and ordinary meaning, having considered them in their broader and external context, I must reject the arguments presented by Biolyse. In my view, it is clear that the entire context of the litigious provision is in harmony with its ordinary meaning. The addition of words to the provision is not grammatically required to make the subsection intelligible, especially when it is neither ambiguous nor incoherent. Furthermore, even when read in context, the impugned provision cannot reasonably be restricted to ANDS. Biolyse is asking our Court to perform legislative redrafting, a task that is beyond this Court's role in giving a judicial interpretation. I cannot accept Biolyse's view of unwarranted consequences of a proper application of s. 5(1.1) as an excuse to place an unreasonable construction on words and alter the meaning of this provision.

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The question decided by the Supreme Court was a narrow one. As the Government has proposed to repeal section 5(1.1), the significance of the specific finding of the majority may be minimal. However, the principles of interpretation applied by the majority are potentially wide-ranging.

The extent to which the Supreme Court's decision will affect the Federal Court's interpretation of the *Regulations* (apart from section 5(1.1)) remains to be seen. We will report on any developments in future issues of *Rx IP Update*.

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