Bayer Inc. v. The Attorney General of Canada and the Minister of Health (1998), Federal Court of Canada, 84 C.P.R. (3d) 129.

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Summary

This case dealt with the interpretation of the Canadian Food and Drug Regulations, subsection C.08.004.1(1) concerning data exclusivity protection. The Federal Court of Canada (hereinafter "the Court") ruled that the five-year data protection to originator manufacturers is not triggered if the subsequent manufacturer, generally a generic manufacturer, can establish the safety and effectiveness of its product on the basis of bioequivalence or bioavailability studies without the Minister having to consult the confidential data filed by the innovator.

The facts

Bayer Inc. (hereinafter "Bayer"), the plaintiff, filed a new drug submission (hereinafter "NDS") with the Minister, which is responsible for regulatory approval of medicines. As the drug in question was not patented, Bayer tried to obtain assurance from the Minister that its NDS would have the effect of blocking approval of a competing generic product given the five-year period of data protection for pharmaceutical products.

The Minister was not in agreement with Bayer's interpretation of the data protection laws. In practice, when approving generics by a so-called "notice of compliance" (hereinafter "NOC"), the Minister usually does not consult the clinical data submitted by the originator innovators. Accordingly, when the Minister does not rely on the innovator's information, the latter is not entitled to the period of data exclusivity. The regulator examines the submission by the generic producer, who only needs to prove that its product is the pharmaceutical and bioequivalent of the originator's product. An examination of the safety, efficacy and quality of an equivalent drug is therefore not required, as these criteria are already established through the originator's clinical data.

Bayer therefore sought summary judgment against the Minister declaring that Canada's Food and Drug Regulations provided automatically a five-year period of protection for originators *vis-à-vis* generic approvals.

The relevant provision in the Canadian Food and Drug Regulations reads as follows:

> "**Food and Drug Regulations (C.R.C., c. 870)**
> **C.08.004.1.**
>
> (1) Where a manufacturer files a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or a supplement to an abbreviated new drug submission for the purpose of establishing the safety and effectiveness of the new drug for which the submission or supplement is filed, and the Minister examines any information or material filed with the Minister, in a new drug submission, by the innovator of a drug that contains a chemical or biological substance not previously approved for sale in Canada as a drug, and

the Minister, in support of the manufacturer's submission or supplement, relies on data contained in the information or material filed by the innovator, the Minister shall not issue a notice of compliance in respect of that submission or supplement earlier than five years after the date of issuance to the innovator of the notice of compliance or approval to market that drug, as the case may be, issued on the basis of the information or material filed by the innovator for that drug."

One of the objectives of the Canadian Food and Drug Regulations was to implement a NAFTA obligation, which provides:

"**North American Free Trade Agreement**
Chapter Seventeen: Intellectual Property
Article 1711: Trade Secrets

[…]

5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products."

The legal issues

The legal issue related to the interpretation of subsection C.08.004.1(1) of the Food and Drug Regulations. Bayer and the Minister *inter alia* disagreed on whether the Minister, by approving generic versions of originator drugs on the basis of an abbreviated new drug submission ("ANDS"), invariably *relies* on data contained in the information or material filed by the innovator within the meaning of Section C.08.004.1. (1) of the Food and Drug Regulations. If the Minister relies on the data supplied by the innovator, it would not issue an NOC and the five-year protection from competition for the innovator would apply.

According to Bayer, the Minister necessarily relies on the safety and efficacy information filed by the innovator when a competitor seeks approval, as only the data submitted by the originator contain the relevant information. The Minister disagreed, pointing to the fact that, in general, the Minister does not consult the originator files as such, but bases its decision on the bioequivalence information provided by the generic producer. Bayer countered that such an abbreviated procedure is made possible only through the innovator's clinical test data and thus constitutes an indirect form of reliance.[1]

The Court disagreed with Bayer's interpretation, holding that section C.08.004.1. (1) of the Food and Drug Regulations does not prevent the Minister from approving generic versions during the five-year period of protection for the information contained in the NDS. The Court noted that the preponderant purpose of the Food and Drug Regulations was the promotion of generic competition. In the words of the Court:

> "At first blush, the Minister's argument may seem very formalistic, in the sense that, in granting approval to a generic drug manufacturer because its product is the functional equivalent of a drug for which the Minister has already issued an NOC on the basis of the information supplied by the innovator, the Minister is indirectly, at least, "relying" on that information to establish the safety and effectiveness of the generic drug manufacturer's product. The NOC, on which the Minister says that he relies, was itself issued on the basis of the confidential test data compiled by the innovator-manufacturer. However, it is also important that this provision of the Regulations be read in the context of the overall scheme, which is to facilitate the approval process for new drugs when sought by manufacturers other than the innovators, and thus to reduce the cost of drugs to provincial governments and members of the public: see the Regulatory Impact Analysis Statement filed with the Regulations in *Canada Gazette Part II*, vol. 129, No. 18. If Bayer's contention were accepted, then it would effectively undermine the efficacy of the ANDS provisions by imposing a delay of five years on the issue of an NOC to a generic manufacturer. The scheme of the Regulations does not suggest that the issue of an NOC is normally so delayed: if this had been the intended result, the wording of C.08.004.1 is a very oblique way to express it."[2]

The other legal issue related to the obligation in NAFTA Article 1711.6 that provides for the protection of "data exclusivity" and that was implemented by Section C.08.004.1 of the Food and Drug Regulations. Bayer alleged that there is no need for "direct" reliance on originator test data by the Minister (i.e. in the form of a direct consultation of the data) for data protection to arise under Article 1711.6 of the NAFTA. In Bayer's view, Article 1711.6 of the NAFTA imposes an obligation on the Minister to not issue NOCs during the five-year period of data protection.

The Court rejected this view, arguing that the NAFTA obligation applies when a competitor benefits from the drug regulator's failure to keep the data secret. Moreover, the Court opined that NAFTA contained no obligation for the drug regulator to delay

[1] For a summary of these arguments by the parties, see under Question 2 of the Court's decision.
[2] See under Question 2 in the Court's decision.

generic drug approvals based on its own marketing approval previously granted to an innovator. With respect to Article 1711.6 of NAFTA, the Court observed:

> "If paragraph 6 were intended also to apply the five years' delay to a situation where a Party relies on a marketing approval that it had itself previously issued to a manufacturer that had been required to submit its undisclosed data in order to obtain approval, the text would surely have said so much more clearly. Indeed, it is significant in my opinion that paragraph 6 concludes by stating that, "Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products." […] My conclusion is, therefore, that the Minister will only "examine" the data supplied by Bayer in connection with drug X, within the meaning of C.08.004.1, if, in the exercise of the discretion contained in C.08.003, for example, departmental officials go back to consult that material in the course of considering an ANDS submitted by another company seeking approval for a drug that is the functional equivalent of Drug X. Moreover, this interpretation of C.08.004.1(1) does not deprive Bayer of any legal protection to which it is entitled by virtue of Article 1711."[3]

Points of Significance:

- The Federal Court's decision was subsequently upheld on appeal by the Canadian Federal Court of Appeal on May 19, 1999.[4]
- According to the Court, data exclusivity provisions under Canadian law should be interpreted under the overall objective of promoting generic competition and lowering the costs of medicines for the public health budget.
- The Court considered that the Canadian test data provision, which provides a five-year term of protection, applies in cases where the regulatory authority has failed to keep the originator's data secret. Marketing approvals in these cases shall not be granted to a competitor that uses the leaked data to support its own request for marketing approval.
- In the context of approving generics that are bioequivalent to originator drugs, the drug regulator is not barred from relying on the fact that the safety and efficacy of the generic drug has already been established through the safety and efficacy information provided by the innovator (indirect reliance).
- By contrast, according to the Court, the five-year protection from competition for the innovator applies when a drug regulator physically opens and consults the material previously filed by the innovator (direct reliance by the drug regulator).
- The decision reflects the political priorities of a country that is home to many generic, but not many originator companies. Other jurisdictions have adopted data exclusivity approaches more favorable to originator firms (see the Court of Justice of the European Union in *ex parte Generics* in this database). Language similar to the Canadian legislation and NAFTA has been employed in a number of free trade agreements between developed and developing countries to the contrary effect, i.e. to create broad exclusive rights in pharmaceutical test data. Developing country's Courts should examine to what extent their domestic provisions on test data and any bilateral commitments would allow an approach similar to that of the Canadian Courts.

[3] See under Question 3 in the Court's decision.
[4] Bayer Inc. v. Canada (Attorney General), Canadian Federal Court of Appeal, A-679-98, 1999.

Key words: Pharmaceutical test data, new drug submission (NDS), abbreviated new drug submission (ANDS), data protection, data exclusivity, direct reliance, indirect reliance, notice of compliance, competition between generic and branded drugs.

Available at:
https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/32108/index.do?q=Bayer
(only the decision of the Federal Court of Appeal[5])

[5] The decision of the Federal Court no longer appears to be available as of December 2020.