A-549-05

2006 FCA 335

Hoffmann-La Roche Limited (*Appellant*)

v.

The Minister of Health and **The Attorney General of Canada** (*Respondents*)

INDEXED AS: HOFFMANN-LA ROCHE LTD. v. CANADA (MINISTER OF HEALTH) (F.C.A.)

Federal Court of Appeal, Noël, Sharlow and Pelletier JJ.A.—Ottawa, September 6 and October 18, 2006.

Patents — Practice — Appeal from Federal Court judgment dismissing application for judicial review of Minister of Health's decision not to list Canadian Patent No. 2141964 (′964 patent) on patent register — Appellant seeking to have ′964 patent, issued on October 21, 2003, listed against drug Bondronat — Notice of compliance for Bondronat issued to Boehringer Mannheim Canada Ltd. in August 1997 — After Boehringer Canada, appellant consolidating in 1998, Minister accepting appellant as de facto corporate successor thereof, owner of listed drug products, related documentation — Appellant subsequently filing submission (administrative submission) for change in manufacturer's name regarding Bondronat, receiving notice of compliance therefor in own name — Although appellant submitting first application to list ′964 patent within prescribed time limit, application rejected because submission to which application relating merely administrative submission, and as such could not be used for patent listing application under NOC Regulations, s. 4(4) — Appellant's second application rejected for untimeliness — Minister correct in characterizing first submission as supplement within Food and Drug Regulations, s. C.08.003 that did not engage his obligation to assess safety, effectiveness of drug, as submission reflecting proposed name change of entity marketing Bondronat and notice of compliance for Bondronat already issued to Boehringer Canada — When appellant submitted application to list ′964 patent with respect to Bondronat, appellant continuation of Boehringer Canada given amalgamation — Because supplement to new drug submission supporting patent listing application made only to reflect change in manufacturer's name, supplement not submission capable of supporting filing of new or amended patent list — This conclusion established by Court's case law — Minister also correctly rejecting appellant's second application because filed outside 30-day time limit — Appeal dismissed (Pelletier J.A. dissenting).

This was an appeal from a Federal Court judgment dismissing the appellant's application for judicial review of the Minister of Health's decision not to list Canadian Patent No. 2141964 (′964 patent) on the patent register maintained under the *Patented Medicines (Notice of Compliance) Regulations* (NOC Regulations).

Pursuant to section C.08.002 of the *Food and Drug Regulations*, no drug can be marketed in Canada unless the Minister has issued a notice of compliance for that drug under those Regulations. A notice of compliance is obtained by filing a new drug submission or an abbreviated new drug submission containing prescribed information that is intended to enable the Minister to assess the safety and effectiveness of the drug. If certain significant changes relating to a drug for which a notice of compliance has been issued (i.e. drug's description, labels used in connection with the drug, drug's brand name, etc.) are made, a supplement to a new drug submission is required under section C.08.003 of the *Food and Drug Regulations*. Some supplements to new drug submissions are referred to as "administrative" new drug submissions. Such supplements do not directly engage the Minister's obligation to ensure the safety or effectiveness of a drug. The "patent register" is an important part of the NOC Regulations and is a collection of patent lists. Each patent list relates to a particular drug for which a notice of compliance has been issued. Section 4 contains the rules for the creation and maintenance of those lists. Under subsection 4(5) of the NOC Regulations, a new or amended patent list submitted under subsection 4(4) must identify the submission to which the patent list relates and the date on which that submission was filed. The word "submission" in section 4 of the Regulations refers to a submission made under the *Food and Drug Regulations*. A patent list filed under subsection

4(1) of the NOC Regulations or a new or amended patent list filed under subsection 4(4) must have as its foundation a specific submission made under the *Food and Drug Regulations*.

On July 26, 1996, Boehringer Mannheim Canada Ltd. (Boehringer Canada) filed a new drug submission (submission number 044900) under section C.08.002 of the *Food and Drug Regulations* in order to obtain a notice of compliance for the drug Bondronat, which notice was issued on August 27, 1997. Boehringer Canada notified the Minister in a letter dated March 31, 1998, that it had consolidated with the appellant, giving the appellant full right of access and ownership to the drug products listed therein (including Bondronat) and to related documentation on file with the Minister. Thereafter, for the purposes of the *Food and Drug Regulations*, the Minister accepted the appellant as the *de facto* corporate successor of Boehringer Canada with respect to Bondronat and all Bondronat files maintained by the Minister. The appellant later notified the Minister that the resulting consolidated corporation would operate under its name and that changes in the manufacturer's name would be made shortly. After the appellant filed a submission on April 30, 1998, relating to Bondronat (submission number 056442) for a change in the manufacturer's name, a notice of compliance was issued on June 8, 1998, allowing the appellant to market Bondronat in its own name. As legally required, articles reflecting that amalgamation were subsequently registered, thereby giving legal effect to the *de facto* corporate succession that had been previously recognized by the Minister.

When the ′964 patent was issued on October 21, 2003, the 30-day period referred to in subsection 4(4) of the NOC Regulations during which the appellant was entitled to submit an application to list that patent on the patent register began to run. On November 18, 2003, the appellant submitted an application to list the ′964 patent with respect to Bondronat and referred to submission number 056442 on its application. On December 2, 2003, the Minister rejected the appellant's application on the basis that that submission was merely an administrative submission for a change of name and was not the kind of submission that could properly be used as a reference for a patent listing application under subsection 4(4) of the NOC Regulations. The appellant's new application filed on December 22, 2003, in which both submission numbers 056442 and 044900 were indicated, was rejected for being out of time.

The issue was whether the Federal Court was correct in concluding that a new patent list could not be filed on the basis of the supplement to a new drug submission filed by the appellant in the above circumstances.

Held (Pelletier J.A. dissenting), the appeal should be dismissed.

Per Sharlow J.A. (concurring reasons by Noël J.A.): With respect to the November 18, 2003 patent listing application, the Minister's characterization of the April 30, 1998 submission as a supplement within the scope of section C.08.003 of the *Food and Drug Regulations* that did not engage his obligation to assess the safety or effectiveness of the drug was correct. On that date, there was an existing notice of compliance for Bondronat that had been issued to Boehringer Canada. The April 30, 1998 submission reflected a proposed change in the name of the entity that would be marketing Bondronat. The Court's case law has established that a supplement to a new drug submission, if made only to reflect a change in the name of the drug or the manufacturer, is not a submission that can support the filing of a new or amended patent list. If the patent listing application had identified the original new drug submission filed by Boehringer Canada in 1996 (submission number 044900), the ′964 patent would have been accepted for listing in respect of Bondronat because in November 2003, as a result of the amalgamation in July 1998, the appellant was a continuation of Boehringer Canada and stood in its shoes *vis-à-vis* the Minister.

With respect to the appellant's second patent listing application, dated December 22, 2003, the application was filed outside the 30-day time limit prescribed in subsection 4(4) of the NOC Regulations and was correctly rejected by the Minister.

Per Pelletier J.A. (dissenting): This was a case of the issuance of an NOC on the basis of a change of ownership of the drug referred to in the NOC. The fact that the Minister treated this as a matter of limited significance, based upon his administrative policy, was irrelevant. The principle underlying the Minister's rejection of the appellant's November 18, 2003, patent list submission was that a change in the name of a drug manufacture "c[ould not] possibly be relevant to any potential claim for infringement of a patent for a medicine found in the drug." This proposition was too broadly stated. The presence of a patent on the patent register is the trigger for the anti-infringement aspects of the NOC Regulations. A person acquiring ownership of a drug for which an NOC has

been issued in someone else's name must make a submission for an NOC with respect to that drug in its own name in order to market that drug. Therefore, a submission for the issuance of an NOC on the basis of a change in the ownership of that drug must be considered a submission for the purpose of filing a patent list.

Treating a submission to reflect a change of ownership as sufficient to support the filing of a patent list is consistent with the purpose of the NOC Regulations and is not inconsistent with the Federal Court of Appeal's case law, which has not previously addressed the distinction between a change of name and a change of ownership. It was no answer for the Minister to say that the appellant could file its patent list the next time it makes a submission that is relevant to the issue of infringement. That would simply be inviting it to concoct a transaction for the purpose of working around those Regulations. The line of authority on which the Minister relied came into being precisely to prevent manufacturers from manipulating the system on the basis of transactions whose sole object was to work around the system.

statutes and regulations judicially considered

Canada Business Corporations Act, R.S.C., 1985, c. C-44, ss. 1 (as am. by S.C. 1994, c. 24, s. 1(F)), 186.

Food and Drug Regulations, C.R.C., c. 870, ss. C.08.001.1 "Canadian reference product" (as enacted by SOR/95-411, s. 3), C.08.002 (as am. by SOR/93-202, s. 24; 95-411, s. 4), C.08.003 (as am. *idem*, s. 6).

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, ss. 4 (as am. by SOR/98-166, s. 3), 5 (as am. *idem*, s. 4; 99-379, s. 2).

cases judicially considered

applied:

Bristol-Myers Squibb Canada Inc. v. Canada (Attorney General) (2001), 10 C.P.R. (4th) 318; 199 F.T.R. 142 (F.C.T.D.); affd (2002), 16 C.P.R. (4th) 425; 2002 FCA 32; *Hoffmann-La Roche Ltd. v. Canada (Minister of Health)*, [2006] 1 F.C.R. 141; (2005), 253 D.L.R. (4th) 644; 40 C.P.R. (4th) 108; 336 N.R. 383; 2005 FCA 140; affg (2004), 38 C.P.R. (4th) 47; 263 F.T.R. 234; 2004 FC 1547; *AstraZeneca Canada Inc. v. Canada (Minister of Health)* (2004), 36 C.P.R. (4th) 58; 253 F.T.R. 195; 2004 FC 736; affd (2005), 39 C.P.R. (4th) 366; 335 N.R. 6; 2005 FCA 175; *Toba Pharma Inc. v. Canada (Attorney General)* (2002), 21 C.P.R. (4th) 232; 227 F.T.R. 261; 2002 FCT 927; *Ferring Inc. v. Canada (Attorney General)* (2003), 26 C.P.R. (4th) 155; 242 F.T.R. 160; 310 N.R. 186; 2003 FCA 274; leave to appeal to S.C.C. refused [2003] S.C.C.A. No. 396 (QL).

considered:

Apotex Inc. v. Canada (Minister of Health) (1999), 87 C.P.R. (3d) 271; 165 F.T.R. 42 (F.C.T.D.); affd (2001), 11 C.P.R. (4th) 538 (F.C.A.); *Abbott Laboratories v. Canada (Minister of Health)* (2004), 239 D.L.R. (4th) 627; 31 C.P.R. (4th) 321; 320 N.R. 37; 2004 FCA 154.

APPEAL from a Federal Court judgment ((2005), 45 C.P.R. (4th) 439; 2005 FC 1415) dismissing the appellant's application for judicial review of the Minister of Health's decision not to list Canadian Patent No. 2141964 on the patent register maintained under the *Patented Medicines (Notice of Compliance) Regulations*. Appeal dismissed, Pelletier J.A. dissenting.

appearances:

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Frederick B. Woyiwada for respondents.

solicitors of record:
Gowling Lafleur Henderson LLP, Ottawa, for appellant.

Deputy Attorney General of Canada for respondents.

The following are the reasons for judgment rendered in English by

[1] SHARLOW J.A.: This is an appeal by Hoffmann-La Roche Limited (Roche) of a judgment of the Federal Court ((2005) FC 1415, 45 C.P.R. (4th) 439) dismissing Roche's application for judicial review of the decision of the Minister of Health not to list Canadian Patent No. 2141964 (the '964 patent) on the patent register maintained under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the NOC Regulations). The '964 patent was issued on October 21, 2003, from a patent application dated August 19, 1993. Roche seeks to have the '964 patent listed against the drug Bondronat (1 mg/ml ampoules).

Section 4 of the NOC Regulations

[2] The relevant parts of section 4 [as am. by SOR/98-166, s. 3] of the NOC Regulations read as follows:

4. (1) A person who files or has filed a submission for, or has been issued, a notice of compliance in respect of a drug that contains a medicine may submit to the Minister a patent list certified in accordance with subsection (7) in respect of the drug.

. . .

(3) Subject to subsection (4), a person who submits a patent list must do so at the time the person files a submission for a notice of compliance.

(4) A first person may, after the date of filing of a submission for a notice of compliance and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date that precedes the date of filing of the submission, submit a patent list, or an amendment to an existing patent list, that includes the information referred to in subsection (2).

(5) When a first person submits a patent list or an amendment to an existing patent list in accordance with subsection (4), the first person must identify the submission to which the patent list or the amendment relates, including the date on which the submission was filed.

(6) A person who submits a patent list must keep the list up to date but may not add a patent to an existing patent list except in accordance with subsection (4).

Statutory scheme

[3] To put this part of the NOC Regulations in context, it is necessary to understand certain elements of the regulatory scheme for the approval of drugs.

[4] Pursuant to section C.08.002 [as am. by SOR/93-202, s. 24; 95-411, s. 4] of the *Food and Drug Regulations*, C.R.C., c. 870, no drug can be marketed in Canada unless the Minister has issued a notice of compliance for that drug under the *Food and Drug Regulations*. A notice of compliance is obtained by filing with the Minister a new drug submission or an abbreviated new drug submission containing prescribed information that is intended to enable the Minister to assess the safety and effectiveness of the drug.

[5] Generally, a "new drug submission" is filed by the innovator or creator of a new drug. An "abbreviated new drug submission" is filed by a generic drug manufacturer who proposes to market a new drug on the basis of certain permitted comparisons to a "Canadian reference product" (as defined in section C.08.001.1 [as enacted by SOR/95-411, s. 3] of the *Food and Drug Regulations*).

[6] A supplement to a new drug submission is required under section C.08.003 [as am. *idem*, s. 6] of the *Food and*

Drug Regulations to reflect certain significant changes relating to a drug for which a notice of compliance has been issued. A supplement must be filed to reflect a change in any of the following:

· the description of the drug: paragraph C.08.003(2)(*a*),

· the brand name of the drug or its identifying name or code: paragraph C.08.003(2)(*b*),

· the specifications of the ingredients of the drug: paragraph C.08.003(2)(*c*),

· the plant and equipment used in the manufacturing, preparation and packaging of the drug: paragraph C.08.003(2)(*d*),

· the method of manufacture and the controls used in manufacturing, preparation and packaging the drug: paragraph C.08.003(2)(*e*),

· the tests applied to control the potency, purity, stability and safety of the drug: paragraph C.08.003(2)(*f*),

· the labels used in connection with the drug: paragraph C.08.003(2)(*g*),

· the representations made with regard to the drug respecting the recommended route of administration, the dosage, the claims made, the contra-indications and side effects, or the withdrawal period: paragraph C.08.003(2)(*h*), or

· the dosage form: paragraph C.08.003(2)(*i*).

[7] The Minister refers to certain supplements to new drug submissions as "administrative" new drug submissions. I understand that to be a functional description, intended to refer to a supplement that does not engage directly the Minister's obligation to ensure the safety or effectiveness of a drug. An administrative submission normally would include, for example, a supplement that is required to reflect a change in the brand name of a drug or a change of manufacturer.

[8] There are many kinds of commercial transactions that could involve or affect the holder of a notice of compliance that do not require the filing of a supplement under section C.08.003 of the *Food and Drug Regulations*. For example, that provision does not require a supplement to be filed if there is a reorganization of the corporate group of which the holder is a member, if there is a change in the corporate control of the holder, if the assets of the holder are acquired by another entity, or if there is an amalgamation or merger of the holder with another entity. However, if such a transaction requires or results in a change of the brand name of a drug, a change of labelling, or a change of manufacturer, then a submission would be required under paragraph C.08.003(2)(*b*), (*d*) or (*g*), as the case may be, although the *Food and Drug Regulations* do not require the Minister to be notified of the particulars of the underlying transaction.

[9] The NOC Regulations link the regulatory process for drug products to the law relating to patented medicines. The NOC Regulations provide a process for identifying and providing a provisional determination of certain patent-related disputes between the holder of a notice of compliance for a drug (if that person also has certain rights in relation to a patent containing a claim for a medicine in the drug, or for the use of that medicine), and a generic drug manufacturer that files an abbreviated new drug submission making specified comparisons to that drug.

[10] An important aspect of the NOC Regulations is the "patent register". The patent register is a collection of patent lists. Each patent list relates to a particular drug for which a notice of compliance has been issued. Each patent listed for a particular drug must contain a claim for the medicine in the drug, or for the use of that medicine. If a generic drug manufacturer files an abbreviated new drug submission making one of the specified comparisons to a drug for which a notice of compliance has been issued, each patent on the patent list for that drug must be addressed under section 5 [as am. by SOR/98-166, s. 4; 99-379, s. 2] of the NOC Regulations before the Minister may issue a notice of compliance for the generic drug manufacturer's product.

[11] Section 4 of the NOC Regulations contains the rules for the creation and maintenance of patent lists. Pursuant to subsection 4(1), a person who files or has filed a submission for, or has been issued, a notice of compliance for a

drug that contains a medicine may submit a patent list in respect of the drug. Subject to certain conditions that are not relevant to this appeal, the patent list may include any patent that contains a claim for the medicine itself, or a claim for the use of the medicine (subsection 4(2) of the NOC Regulations). Subsection 4(3) of the NOC Regulations provides that the submission for a notice of compliance and the patent list must be submitted to the Minister at the same time, subject to the exception in subsection 4(4).

[12] Subsection 4(4) of the NOC Regulations applies if a patent that contains a claim for a medicine in a drug, or for the use of that medicine, is issued after the submission for a notice of compliance for that drug is filed. Such a newly issued patent may be included on a new or amended patent list for that drug if two conditions are met. First, the patent application must have been made before the submission for the notice of compliance was filed. Second, the new or amended patent list must be submitted to the Minister within 30 days after the issuance of the patent.

[13] Subsection 4(5) of the NOC Regulations states that a new or amended patent list submitted under subsection 4(4) must identify the submission to which the patent list relates and the date on which that submission was filed.

The jurisprudence

[14] The word "submission" in section 4 of the NOC Regulations refers to a submission made under the *Food and Drug Regulations*. A patent list filed under subsection 4(1) of the NOC Regulations, or a new or amended patent list filed under subsection 4(4), must have as its foundation a specific submission made under the *Food and Drug Regulations* (see subsection 4(5) of the NOC Regulations).

[15] In a number of cases, the Minister and the generic drug manufacturers have taken the position that section 4 of the NOC Regulations should be construed narrowly, so that a supplement to a new drug submission should not be considered to be a "submission" for the purposes of section 4 of the NOC Regulations. That argument has been accepted in the Federal Court and in this Court in certain circumstances, but not in others. The result is that a supplement to a new drug submission may or may not be found to be a sufficient foundation for the filing of a new or amended patent list, depending upon why the supplement is filed. The relevant jurisprudence is reviewed below.

[16] The earliest case on this point is *Apotex Inc. v. Canada (Minister of Health)* (1999), 87 C.P.R. (3d) 271 (F.C.T.D.); affd (2001), 11 C.P.R. (4th) 528 (F.C.A). In that case, a supplement to a new drug submission had been filed to reflect a new indication for an existing drug. That supplement was held to be a sufficient foundation for the filing of a new patent list naming a patent for a new formulation of the medicine in the drug.

[17] *Apotex* involved the NOC Regulations as they read in 1993, before they were substantially amended in 1998. The jurisprudence in relation to the current version of the NOC Regulations begins with *Bristol-Myers Squibb Canada Inc. v. Canada (Attorney General)* (2001), 10 C.P.R. (4th) 318 (F.C.T.D.); affd (2002), 16 C.P.R. (4th) 425 (F.C.A.).

[18] In *Bristol-Myers Squibb*, a supplement to a new drug submission filed to reflect a change in the brand name of a drug was not permitted to support the filing of a new patent list. It was found as a fact in that case that the applicant, having previously made the mistake of omitting a patent from an earlier patent list, was attempting to use the device of a supplement, and the principle from the *Apotex* case referred to above, to avoid the time limitations in section 4 of the NOC Regulations. The same conclusion was reached on similar facts in *Toba Pharma Inc. v. Canada (Attorney General)* (2002), 21 C.P.R. (4th) 232 (F.C.T.D.), and in *Ferring Inc. v. Canada (Attorney General)* (2003), 26 C.P.R. (4th) 155 (F.C.A.) (leave to appeal to the Supreme Court of Canada denied [[2003] S.C.C.A. No. 396 (QL)]).

[19] On the other hand, in *Abbott Laboratories v. Canada (Minister of Health)* (2004), 239 D.L.R. (4th) 627 (F.C.A.), a supplement to a new drug submission was found to be a sufficient basis for the filing of a new patent list. Abbott had a notice of compliance permitting it to sell Biaxin (clarithromycin) in combination with amoxicillin and omeprazole for use as a triple drug therapy for the treatment of H. pylori infections. It wished to obtain a new notice of compliance to sell a different drug combination, using lansoprazole instead of omeprazole. A subsidiary of Abbott called TAP Pharmaceuticals had obtained a notice of compliance for the combination of clarithromycin, amoxicillin and lansoprazole. However, Abbott could not sell that combination in its own name without obtaining from the

Minister a new notice of compliance. To that end, Abbott filed a supplement to its new drug submission to change its product monograph by adding a cross-reference to the product monograph of TAP Pharmaceuticals. At the same time, Abbott filed a patent list that included a patent that made certain claims in relation to clarithromycin. Some years later, a generic drug manufacturer filed an abbreviated new drug submission comparing its proposed combination product to Abbott's combination product. Abbott responded with an application under the NOC Regulations for an order prohibiting the Minister from issuing a notice of compliance to the generic drug manufacturer until after the expiry of its patent. The generic drug manufacturer argued that the patent should not have been listed on the basis of a supplement to a new drug submission that merely amended the product monograph. That argument failed because the changes reflected in the supplement were substantive (referring to subparagraph C.08.003(2)(*h*)(iii) of the *Food and Drug Regulations*) and because there had been no attempt to circumvent the time limitations in section 4 of the NOC Regulations.

[20] The *Abbott* case was interpreted by some as authority for the proposition that a supplement to a new drug submission would support the filing of a new patent list as long as the supplement was not filed in an attempt to circumvent the time limitations in section 4 of the NOC Regulations. That proposition was rejected in *Hoffmann-La Roche Ltd. v. Canada (Minister of Health)*, [2006] 1 F.C.R. 141 (F.C.A.); affg (2004), 38 C.P.R. (4th) 47 (F.C.). In that case, a supplement to a new drug submission had been filed to reflect an additional manufacturing site. The filing of that supplement was not an attempt to circumvent a time limitation. Nevertheless, the supplement was found to be incapable of supporting the filing of a new patent list because it did not reflect a change that could possibly be relevant to any potential claim for infringement of a patent claiming a medicine in the drug or the use of that medicine.

[21] The same result was reached in *AstraZeneca Canada Inc. v. Canada (Minister of Health)* (2004), 36 C.P.R. (4th) 58 (F.C.); affd (2005), 39 C.P.R. (4th) 366 (F.C.A.). That case involved a supplement to a new drug submission that was required to reflect a change in the name of the manufacturer of the drug following a merger between Astra Pharma Inc. and Zeneca Pharma Inc. The original notice of compliance had been issued to one of the merged corporations. The supplement was held to be incapable of supporting a new patent list.

[22] That is the current state of the jurisprudence. In this case, the issue is whether the Federal Court Judge was correct when he concluded that a new patent list could not be filed on the basis of the supplement to a new drug submission filed by Roche on April 30, 1998, in the circumstances described below.

Facts

[23] On July 26, 1996, Boehringer Mannheim Canada Ltd. (Boehringer Canada) filed with the Minister a new drug submission (submission number 044900) under section C.08.002 of the *Food and Drug Regulations* in order to obtain a notice of compliance for a drug called Bondronat. On August 27, 1997, the Minister issued a notice of compliance to Boehringer Canada for Bondronat. It appears that no sales of Bondronat were reported in respect of that notice of compliance.

[24] In a letter to the Minister dated March 31, 1998, Boehringer Canada advised the Minister that Roche had acquired "all of the divisions of Boehringer Mannheim (BM) International", and that the acquisition was "legally complete". The letter further advised the Minister that Boehringer Canada granted Roche "full right of access and ownership to the following drug products and corresponding product-related documentation presently on file" with the Minister. Bondronat was one of the drug products listed in the letter.

[25] It is not clear from the March 31, 1998 letter, or anything else in the record, exactly what the "acquisition" involved, except that it seems that Roche had acquired control of Boehringer Canada. I assume that it acquired that control by acquiring the shares of Boehringer Canada or the shares of its parent corporation. However, the reference in the March 31, 1998 letter to "ownership of drug products", coupled with the "granting" of "full right of access" to documents, could suggest that Roche had also acquired some rights in relation to Bondronat, perhaps including some proprietary interest. Alternatively, it may be that Roche did not acquire a direct proprietary interest in any of Boehringer Canada's property but wished only to be recognized by the Minister as being in a position to control the regulatory aspects of Bondronat and its marketing in Canada.

[26] In the material submitted by Roche in support of its application in the Federal Court, Roche provided no further particulars of the transaction referred to in the March 31, 1998 letter, perhaps because neither Roche nor the Minister considered those particulars to be relevant. In any event, I infer that the Minister was intended to understand, and did understand, that Boehringer Canada was asking the Minister to permit Roche, in effect, to stand in the shoes of Boehringer Canada in all matters relating to the application of the *Food and Drug Regulations* to Bondronat. I also infer that the Minister acceded to that request. That is, for the purposes of the *Food and Drug Regulations*, the Minister accepted Roche as the *de facto* corporate successor of Boehringer Canada with respect to Bondronat and all Bondronat files maintained by the Minister.

[27] By letter dated April 20, 1998 (and for reasons that are not clear), Roche informed the Minister that the "consolidation" of Roche and Boehringer Canada was in progress, that the resulting consolidated corporation would have the same name as Roche, and that applications for changes in the manufacturer's name would be made in the near future. I assume that the word "consolidation" was intended to refer to a statutory amalgamation.

[28] On April 30, 1998, Roche filed a submission in relation to Bondronat (submission number 056442). The submission was entitled "Administrative NDS—Change in Manufacturer's Name", and read in part as follows:

In 1998, [Roche] purchased [the Boehringer parent corporation]. As of March 31, 1998, all business activities of the Canadian affiliates [including Boehringer Canada] and [Roche] were consolidated under the corporation [Roche] . . . .

Therefore, the following [Boehringer Canada] products will in future be sold under the [Roche] name/label. [Roche] would like to retain the identical DIN [drug identification] numbers already assigned to each of the products listed below. [The list includes Bondronat.].

In support of this administrative NDS and as per the April 24, 1998 policy entitled "Changes in Manufacturer's Name and/or Product Name", we are submitting the following information (for each of the products listed above).

[29] Again, this letter is vague as to the particulars of the transaction to which it refers. In any event, the Minister responded to the April 30, 1998 submission by issuing to Roche a notice of compliance dated June 8, 1998 permitting Roche to market Bondronat in its own name.

[30] On July 3, 1998, articles reflecting the amalgamation of Roche and Boehringer Canada were registered under the *Canada Business Corporations Act*, R.S.C., 1985, c. C-44 [s. 1 (as am. by S.C. 1994, c. 24, s. 1(F))]. On that date, the consolidated corporation would, as a matter of law, be entitled to stand in the shoes of Boehringer Canada with respect to Bondronat and its related documentation filed with the Minister under the *Food and Drug Regulations* (section 186 of the *Canada Business Corporations Act*). That gave legal effect to the *de facto* corporate succession that, on March 31, 1998, the Minister had been asked to recognize, and had recognized, for the purposes of the *Food and Drug Regulations*.

[31] On October 21, 2003, the ′964 patent was issued. That marked the beginning of the 30-day period referred to in subsection 4(4) of the NOC Regulations (quoted above) during which Roche was entitled to submit an application to list the ′964 patent on the patent register. It is undisputed for the purposes of this appeal that Bondronat is a product against which the ′964 patent could have been listed, if a valid application had been submitted on time.

[32] On November 18, 2003, within the 30-day period, Roche submitted an application to list the ′964 patent in respect of Bondronat. The application form includes a space in which the applicant must identify the submission to which the application relates. That requirement conforms to subsection 4(5) of the NOC Regulations. Roche completed that space on the form by referring to submission number 056442, the submission it had filed on April 30, 1998.

[33] The Minister, by letter dated December 2, 2003, advised Roche that its application to list the ′964 patent was rejected on the basis that submission number 056442, being merely an administrative submission for a change of name, was not the kind of submission that could properly be used as a reference for a patent listing application under

subsection 4(4) of the NOC Regulations.

[34] On December 22, 2003, Roche filed a new application at the suggestion of a Health Canada official, this time naming both submission number 056442 and submission number 044900 (relating to the original new drug submission filed by Boehringer Canada). The Minister rejected that application for listing on the basis that it was out of time.

[35] Roche applied for judicial review of the Minister's decision not to list the '964 patent in respect of Bondronat, but was not successful. Roche now appeals to this Court.

Discussion

(1) The November 18, 2003 patent listing application

[36] Roche argues that the Minister erred in law in concluding that the patent listing application Roche submitted on November 18, 2003 was not properly supported by the submission it had filed on April 30, 1998 (submission number 056442).

[37] There is a debate between the parties as to the proper characterization of the April 30, 1998 submission. Counsel for Roche characterizes it as a new drug submission and not a supplement to a new drug submission, because it was filed to obtain a notice of compliance that would permit Roche for the first time to market Bondronat. Counsel for the Minister argues that the April 30, 1998 submission is what it purports to be, an "administrative" submission or, in other words, a supplement to the new drug submission originally filed by Boehringer Canada, reflecting a change in the name of the corporation that would market Bondronat. The Minister treated the April 30, 1998 submission as a supplement within the scope of section C.08.003 of the *Food and Drug Regulations* but not a supplement that engaged the Minister's obligation to assess the safety or effectiveness of the drug.

[38] I can find no fault with the Minister's characterization of the April 30, 1998 submission. On that date there was an existing notice of compliance for Bondronat that had been issued to Boehringer Canada. The April 30, 1998 submission reflected a proposed change in the name of the entity that would be marketing Bondronat, which would require that the labels be changed to identify Roche rather than Boehringer Canada as the source of the drug (see paragraph C.08.003(2)(*g*) of the *Food and Drug Regulations*).

[39] Counsel for Roche argues that the April 30, 1998 submission cannot be considered a supplement to the original new drug submission of Boehringer Canada because Roche and Boehringer Canada were separate corporations on April 30, 1998. While it is true that they were separate corporations at that time, it is also true that, as far as the Minister was concerned, Roche was the successor to Boehringer Canada and was to be treated as standing in the shoes of Boehringer Canada, just as Boehringer Canada had requested. Roche does not suggest that the Minister was wrong in law in acceding to the request of Boehringer Canada. Nor is it necessary in this case to express any opinion on whether the Minister was obliged to accede to that request.

[40] The jurisprudence of this Court has established that a supplement to a new drug submission, if made only to reflect a change in the name of the drug or the manufacturer, is not a submission that can support the filing of a new or amended patent list. The Minister correctly treated the supplement filed by Roche on April 30, 1998 as falling into the same category.

[41] The facts of this case are similar to the facts in *AstraZeneca* (cited above). Counsel for Roche has made a number of submissions in an attempt to distinguish *AstraZeneca*, or to establish that the principle in *AstraZeneca* should not be applied in this case, or to establish that the principle is incorrect. I need not discuss those submissions in detail. It is enough to say that I am unable to discern a relevant distinction between this case and *AstraZeneca*, and I am not persuaded that there is any error in the principle applied in *AstraZeneca* or, for that matter, in *Hoffmann-La Roche*, *Ferring*, *Toba*, or *Bristol-Myers Squibb* (cited above). I see no reason why the result in this case should not be the same as the result in those cases.

[42] Roche argues that if the principle in the *AstraZeneca* line of cases is applied in this case, the result will be to

deny Roche its right to list the ′964 patent on the first opportunity it had to do so after the ′964 patent was issued in 2003. In my view, there is no merit to that argument. It seems to me, and indeed the Minister concedes, that if the patent listing application filed by Roche on November 18, 2003 had identified the original new drug submission filed by Boehringer Canada in 1996 (submission number 044900), the ′964 patent would have been accepted for listing in respect of Bondronat. That must be correct, because in November of 2003, as a result of the amalgamation in July of 1998, Roche was a continuation of Boehringer Canada, and as a matter of law stood in the shoes of Boehringer Canada *vis-à-vis* the Minister.

[43] Roche also submits that the principle based on the *AstraZeneca* line of cases should not apply to Roche in this case because the Minister's refusal to list the patent rests solely on the fact that Roche chose its April 30, 1998 change-of-name submission, rather than Boehringer Canada's initial new drug submission in 1993, as the reference for its patent listing application.

[44] Unfortunately for Roche, the regulatory scheme (particularly subsection 4(5) of the NOC Regulations) requires an applicant for a patent listing to choose a correct reference, if not at the time the application is made, at least within the 30-day period specified in subsection 4(4) of the NOC Regulations. The Minister should be entitled to assess a patent listing application based on its contents. I see no justification for interpreting the NOC Regulations in a manner that imposes a duty on the Minister to suggest or make corrections, particularly once the 30-day time limit has expired.

(2) The December 22, 2003 patent listing application

[45] Roche's second patent listing application was filed outside the 30-day time limit in subsection 4(4) of the NOC Regulations, and for that reason, was correctly rejected by the Minister.

Conclusion

[46] I would dismiss the appeal with costs.

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The following are the reasons for judgment rendered in English by

[47] NOËL J.A.: I agree with Sharlow J.A. that Roche became entitled to sell the product in issue as a result of an amalgamation and that, as a result, this case must suffer the same fate as *AstraZeneca Canada Inc. v. Canada (Minister of Health)* (2005), 39 C.P.R. (4th) 366 (F.C.A.).

[48] Pelletier J.A. has expressed the view that the principle underlying the Minister's practice with respect to so called "administrative" submissions would also apply to a person acquiring ownership of a drug by way of a direct acquisition. In my view, whether this would be the effect of the Minister's practice and if so, whether this practice could operate to exclude an acquirer from the benefits of the NOC Regulations, is better left to be decided if and when the issue arises.

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The following are the reasons for judgment rendered in English by

[49] PELLETIER J.A. (dissenting): I regret that I am unable to agree with the disposition of this matter proposed by my colleague Sharlow J.A.

[50] The present controversy arose when Roche, in filing a patent list with respect to Canadian Patent No. 2141964 (the ′964 patent) in relation to the drug Bondronat on November 18, 2003, referenced its April 30, 1998 submission with respect to Bondronat (a reference to a submission being a requirement of subsection 4(5) of the Regulations). The Minister rejected Roche's patent list on the ground that the April 30, 1998 submission, having

been submitted to indicate a change of name of manufacturer, did not support the filing of a patent list. When Roche subsequently re-filed its patent list, this time referencing Boehringer- Mannheim's original submission for an NOC, the Minister rejected the patent list on the ground that it was filed outside the 30-day time limit provided in subsection 4(4) of the Regulations. Roche's application for judicial review was filed shortly thereafter.

[51] My colleague has reviewed the circumstances surrounding the issuance of the NOC to Roche in respect of Bondronat. My view of these transactions is that the Minister was told that Roche had become the owner of Boehringer-Mannheim's drug Bondronat. Roche then asked the Minister to issue it an NOC for the drug and he did so. Roche stands upon the fact that these transactions occurred prior to the amalgamation of the two companies. In my view, this is a case of the issuance of an NOC on the basis of a change of ownership of the drug referred to in the NOC. The fact that the Minister treated this as a matter of limited significance, based upon his administrative policy, is simply irrelevant.

[52] The principle underlying the Minister's rejection of Roche's November 18, 2003 patent list submission is that a change in the name of a drug manufacturer "cannot possibly be relevant to any potential claim for infringement of a patent for a medicine found in the drug": *Hoffmann-La Roche Ltd. v. Canada (Minister of Health)*, [2006] 1 F.C.R. 141 (F.C.A.), at paragraph 25.

[53] In my view, this proposition is too broadly stated. The presence of a patent on the patent register is the trigger for the anti-infringement aspects of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/ 93-133, as amended (the Regulations). A person acquiring ownership of a drug for which an NOC has been issued in someone else's name must make a submission for an NOC with respect to that drug in its own name in order to market that drug (see paragraph C.08.002(1)(*b*) of the *Food and Drug Regulations*, C.R.C., c. 870). If that submission (and the resulting NOC) will not support the filing of a patent list (because it is merely a submission for a name change), then that acquirer cannot claim the benefit of the Regulations with respect to its newly acquired drug. As a result, a generic manufacturer can enter the market by obtaining an NOC for its competing product without having to address the claims of the acquirer's patent, thereby denying the acquirer (and patent holder) the benefit of the Regulations. I am therefore of the view that a submission for the issuance of an NOC on the basis of a change in the ownership of that drug must be considered a submission for the purpose of filing a patent list.

[54] I do not dispute that Roche could have avoided this problem by referencing Boehringer's submission rather than its own when submitting its patent list, particularly since the amalgamation was effective at the time it sought to add the ′964 patent to the patent register. However, the principle underlying the Minister's position applies where there is no amalgama-tion, and therefore no alternate means of avoiding its consequences. The effect of the Minister's position is that an acquirer of a drug cannot become a "first person" with respect to that drug except by filing a supplemental new drug submission designed to look substantial without necessarily being so. With the greatest of respect for my colleagues, I do not believe that it is appropriate to work around this problem by means of an informal substitution of one party for another.

[55] Treating a submission to reflect a change of ownership as sufficient to support the filing of a patent list is consistent with the purpose of the Regulations, and is not inconsistent with the jurisprudence of this Court which has not previously addressed the distinction between a change of name and a change of ownership. It is no answer to say that Roche can file its patent list the next time it makes a submission which is relevant to the issue of infringement. This is simply inviting Roche to concoct a transaction for the purpose of working around the Regulations. The line of authority on which the Minister relies came into being precisely to prevent manufacturers from manipulating the system on the basis of transactions whose sole object was to work around the system.

[56] I would therefore allow the appeal, allow the application for judicial review and direct the Minister to reconsider Roche's November 18, 2003 patent list application on the basis that Roche's submission dated April 30, 1998, was a submission for the purpose of filing a patent list.