Federal Court of Appeal | Cour d'appel fédérale

Date: 20150415

Dockets: A-452-14
A-453-14

Citation: 2015 FCA 93

CORAM: **RYER J.A.**
NEAR J.A.
RENNIE J.A.

Docket:A-452-14

BETWEEN:

ViiV HEALTHCARE ULC,
ViiV HEALTHCARE UK LTD
AND GLAXO GROUP LIMITED

Appellants

and

TEVA CANADA LIMITED
AND THE MINISTER OF HEALTH

Respondents

Docket:A-453-14

BETWEEN:

ViiV HEALTHCARE ULC,
ViiV HEALTHCARE UK LTD
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and

APOTEX INC
AND THE MINISTER OF HEALTH

Respondents

Heard at Toronto, Ontario, on April 13, 2015.

Judgment delivered at Toronto, Ontario, on April 15, 2015.

REASONS FOR JUDGMENT OF THE COURT BY: NEAR J.A.

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REASONS FOR JUDGMENT OF THE COURT
(Delivered from the Bench at Toronto, Ontario, on April 15, 2015)

NEAR J.A.

[1] Before us are two appeals, A-452-14 and A-453-14, that were consolidated and heard together in accordance with the Order of Justice Boivin dated November 21, 2014.

[2] These appeals concern the eligibility for listing of Canadian Patent No. 2,289,753 (the '753 Patent) against KIVEXA, a drug marketed by ViiV Healthcare ULC, ViiV Healthcare UK Ltd., and Glaxo Group Limited (collectively, the appellants) under paragraph 4(2)(*a*) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (Regulations).

[3] For Reasons cited at 2014 FC 328, Prothonotary Milczynski (the Prothonotary) found that the '753 Patent was not eligible for listing against KIVEXA. She issued orders to this effect in separate proceedings involving the respondent Teva Canada Limited (Teva) and the respondent Apotex Inc. (Apotex). In a decision made in respect of both Teva and Apotex, Justice

Hughes of the Federal Court (the Federal Court judge) upheld the decisions of the Prothonotary (2014 FC 893). The appellants have appealed from that decision.

[4] The facts underlying these appeals are largely not in dispute and were set out in some detail by both the Prothonotary and the Federal Court judge. There is no need to extensively repeat them. KIVEXA is an anti-retroviral fixed-dose combination (FDC) drug that contains two medicinal ingredients: abacavir hemisulfate and lamivudine. The Minister of Health (Minister) issued a Notice of Compliance (NOC) for KIVEXA on July 25, 2005.

[5] The '753 Patent was issued on January 23, 2007. The invention described in the '753 Patent relates to a novel salt of abacavir. Claim 2, the claim at issue, expressly claims abacavir hemisulfate. On February 23, 2007, after reviewing the patent list filed by the appellants, the Minister added the '753 Patent to the register against KIVEXA.

[6] Teva and Apotex each served a Notice of Allegation on the appellants advising that they had filed an Abbreviated New Drug Submission using KIVEXA as the Canadian reference product. Teva's proposed drug is "TEVA-abacavir/lamivudine" and Apotex's proposed drug is "APO-Abacavir-Lamivudine".

[7] The appellants commenced prohibition applications against both Teva and Apotex under subsection 6(1) of the Regulations. In their respective proceedings, both Teva and Apotex brought motions under paragraph 6(5)(*a*) of the Regulations arguing that the '753 Patent was not eligible for listing against KIVEXA.

[8] The Prothonotary allowed both motions. In her Reasons, she explained that, under the interpretation of paragraph 4(2)(*a*) given in *Gilead Sciences Canada Inc. v. Canada (Health)*, 2012 FCA 254, [2012] F.C.J. No. 1259 (QL) [*Gilead*], the '753 Patent did not have the degree of product specificity required to be listed against KIVEXA.

[9] The Federal Court judge heard the appeals from these motions jointly, and dismissed both. In his Reasons, the Judge provided a thorough review of the legislative framework and canvassed the relevant jurisprudence. While his decision (and the decisions of the Prothonotary) concerned multiple issues, the scope of these appeals is limited to one: the eligibility for listing of the '753 Patent against KIVEXA under paragraph 4(2)(*a*) of the Regulations based on claim 2. On this issue, the Judge concluded that:

> [89] ... The decision of the Federal Court of Appeal in *Gilead* is sufficiently clear. A patent claim for only one medicinal ingredient cannot support a listing under the NOC Regulations where the underlying NOC is for a combination (synergistic or otherwise) of two or more medicinal ingredients.

[10] The issue in these appeals is whether Justice Hughes erred in holding that the '753 Patent is not eligible for listing against KIVEXA under paragraph 4(2)(*a*) of the Regulations. Crucial to this determination is whether *Gilead* is distinguishable, and, if not, whether *Gilead* was correctly decided.

[11] The parties agree that the question at issue – the eligibility for listing on the register of a claim to a single medicinal ingredient against an FDC drug containing more than one medicinal ingredient – is a question of law. Thus, it is reviewable on the standard of correctness (*Housen v. Nikolaisen*, 2002 SCC 33 at para. 8, [2002] 2 S.C.R. 235).

[12] The appellants submit that the Federal Court judge erred in three respects: he failed to appreciate the distinctions between the case at bar and *Gilead*; he misinterpreted *Bayer Inc. v. Canada (Health)*, 2009 FC 1171, [2009] F.C.J. No. 1471 (QL); and he failed to apply the principles of interpretation set out in *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533.

[13] The respondents Teva and Apotex ask this Court to dismiss the appeals. They submit that the Federal Court judge properly held that *Gilead* is applicable to the case at bar, and that, as a result, the '753 Patent is not listable against KIVEXA under paragraph 4(2)(*a*).

[14] The Minister is also a party to these appeals. The Minister's position is that the '753 Patent may be listed. The Minister submits that *Gilead* is distinguishable, or alternatively, wrongly decided.

[15] In our view, both the Prothonotary and the Federal Court judge correctly concluded that *Gilead* applies to the facts of this case. In *Gilead*, this Court found that paragraph 4(2)(*a*) of the Regulations sets an exacting threshold of specificity between what is claimed in the patent and what has been approved in the NOC—a patent that does not explicitly claim all of the medicinal ingredients contained in the drug for which the NOC was issued cannot be listed against that drug.

[16] In *Gilead*, the Court considered the policy arguments put forward by the appellants and the Minister in this matter with respect to the interpretation of paragraph 4(2)(*a*) and did not

accept them. Despite counsel's submissions that the Court in *Gilead* was dealing with a different, more complex situation, and not a simple compound claim, we do not see how this alters the pivotal holding in *Gilead* with respect to paragraph 4(2)(*a*). Further, the Federal Court judge, starting at paragraph 50 of his Reasons, dealt extensively with the policy arguments advanced by the appellants and the Minister and rejected the submission that they in any way affect the applicability of the conclusion reached in *Gilead* to this case. We agree with his analysis.

[17] The Court in *Gilead* comprehensively addressed subsection 4(2) as a whole, and came to a conclusion inconsistent with the position of the appellants in this case and inconsistent with the policy of the Minister. Both the appellants and the Minister note in their materials that the Minister has indicated for several years that she may amend the Regulations to address the *Gilead* decision. The possibility of amendment does not serve as a basis upon which to find that the interpretation given to paragraph 4(2) as a whole, and to 4(2)(*a*) specifically, by the Court in *Gilead* can be distinguished on the facts, as urged on us by the appellants.

[18] The Minister submitted an alternative argument that *Gilead* was wrongly decided, but did not specifically argue that *Gilead* was manifestly wrong in the way contemplated by *Miller v. Canada (Attorney General)*, 2002 FCA 370, 293 N.R. 391 [*Miller*]. In *Miller*, the Court found that to overrule a decision of another panel of this Court, the previous decision must be "manifestly wrong, in the sense that the Court overlooked a relevant statutory provision, or a case that ought to have been followed" (at para. 10). Accordingly, the question of whether *Gilead* is manifestly wrong was not before us.

[19] The appeals will therefore be dismissed, with costs fixed in the amount of $5,000 in each appeal to be awarded to Teva Canada Limited and $2,500 in each appeal to be awarded to Apotex Inc.

[20] A copy of these reasons shall be placed on each file.

"D.G.Near"

J.A.

I HEREBY CERTIFY that the above document is a true copy of the original issued out of / filed in the Court on the 15

day of APRIL A.D. 20 15

Dated this 15 day of APRIL 20 15

MAGGIE LAU
REGISTRY OFFICER
AGENT DU GREFFE