

CANADA / JUDGMENT

Abbvie Corporation v. Samsung Bioepis Co., Ltd.

2017 FC 675

COURT
Federal CourtDECIDED
12 July 2017

Source: decisions.fct-cf.gc.ca · Research copy typeset by Esheria. Not court-issued or certified.

Abbvie Corporation v. Samsung Bioepis Co., Ltd. Court (s) Database Federal Court Decisions Date 2017-07-12 Neutral citation 2017 FC 675 File numbers T-598-17, T-599-17, T-600-17, T-601-17, T-602-17, T-603-17, T-604-17, T-605-17 Decision Content Date: 20170712 Dockets: T-598-17 T-599-17 T-600-17 T-601-17 T-602-17 T-603-17 T-604-17 T-605-17 Citation: 2017 FC 675 Ottawa, Ontario, July 12, 2017 PRESENT: The Honourable Mr. Justice Manson BETWEEN: ABBVIE CORPORATION AND ABBVIE BIOTECHNOLOGY LTD. Applicants and SAMSUNG BIOEPIS CO., LTD. AND THE MINISTER OF HEALTH Respondents ORDER AND REASONS I. Introduction [1] This is a motion on behalf of the Respondent, Samsung Bioepis Co., Ltd. (“Bioepis”), seeking a protective order regarding documents that will be disclosed pursuant to an underlying action, in which the Applicants, AbbVie Corporation and AbbVie Biotechnology Ltd. (together, “AbbVie”), are seeking orders prohibiting the Minister of Health from issuing notices of compliance pursuant to the Patented Medicines Notice of Compliance Regulations, SOR/93-133 [Regulations]. II. Background [2] On March 13, 2017, Bioepis served Notices of Allegation (“NOAs”) on AbbVie in relation to its proposed adalimumab product, HADLIMA, and Canadian Patent Nos. 2,494,756; 2,385,745; 2,847,142; and 2,504,868 (collectively, the “AbbVie Patents”). Bioepis alleged in its NOAs that HADLIMA will not infringe any of the AbbVie Patents. In response, AbbVie commenced the underlying applications.

[3] Adalimumab is a biologic medicine, specifically an antibody. Unlike other generic medicines, biosimilars are not simple generic versions of the originator biologic because, unlike small molecule drugs, biologics are made by living organisms or cells, which make them inherently potentially variable. It is the view of many originator companies that it is not possible to create an identical copy of an originator biologic. As such, the process through which a biologic is made can make a significant difference in the structure of the resultant biologic. This variability and the effects of the process through which they are made are important factors to consider when dealing with biologics and intellectual property.

- [4] As is common in proceedings under the Regulations, the Parties have agreed that it is appropriate to have a protective order, which will keep their respective sensitive business information from being disclosed to the public. In addition to the agreed upon confidentiality provisions, Bioepis has requested that an additional layer of information protection be instituted in this action, consisting of provisions that would prevent outside counsel and in-house counsel for both Parties from engaging in activities concerning patent prosecution, relating to the in-suit patents or patents related to adalimumab, for one year after the conclusion of the underlying action or any other “relevant litigation”, whichever is later (the “Proposed Prosecution Bar”). AbbVie objects to the inclusion of the Proposed Prosecution Bar.
- [5] At the hearing, counsel for Bioepis limited the Proposed Prosecution Bar to only Canadian Patent No. 2,494,756, in Court applications T-603-17 and T-605-17. III. Issues [6] The issues are: Is the Counsel Eyes Only (“CEO”) test the appropriate test to use to determine whether the Proposed Prosecution Bar should be granted? Should the Proposed Prosecution Bar be granted? IV. Conclusion [7] Since the purpose of the Proposed Prosecution Bar is different from the purpose of a CEO order, I find that the CEO test is not the appropriate test to determine whether the Proposed Prosecution Bar should be granted. I also find that Bioepis has not adduced sufficient evidence to show that the Proposed Prosecution Bar is necessary or reasonable in the context of this action. V. Analysis A. Is the Counsel Eyes Only (“CEO”) test the appropriate test to use to determine whether the Proposed Prosecution Bar should be granted? [8] Bioepis suggests that the Proposed Prosecution Bar is less restrictive than a CEO designation. It asserts that the public’s interest in open courts is not engaged by the Proposed Prosecution Bar, given that the Proposed Prosecution Bar is not a confidentiality order for use in Court, and that these additional provisions would not interfere with the Parties’ ability to instruct counsel or with the normal solicitor-client relationship. Therefore, Bioepis asserts that the circumstances warranting the issuance of a CEO protective order would also warrant the issuance of the less intrusive Proposed Prosecution Bar.
- [9] AbbVie argues that the test for the inclusion of provisions barring counsel from engaging in certain activities after they have been privy to specific confidential information should be different from the test for a CEO protective order. Since the fundamental purpose of the Proposed Prosecution Bar is to restrain counsel or persons entitled to information under the protective order from future activities, and not to limit who can see certain confidential information, use of the CEO test is inappropriate. AbbVie suggests that a more appropriate legal parallel to the Proposed Prosecution Bar provisions is a restrictive covenant.
- [10] I agree with AbbVie that the Proposed Prosecution Bar is more similar to a restrictive covenant or a restraint of trade than it is to a CEO protective order. For example, one of the clauses that Bioepis wishes to insert into the protective order reads: After any persons listed in subparagraph 13(b) (except Counsel for the Minister), (c) or (d) obtains, receives, has access to, or otherwise learns, in whole or in part, of the designated Confidential Information that person shall not:

- a) Prosecute a Prosecution Bar Patent or Application; or
 - b) Substantively perform, participate in, contribute to, provide input on, or otherwise assist in the drafting, amending or modifying of the scope of any patent claim in any Post-Grant Patent Office Proceeding concerning a Prosecution Bar Patent or Application, including without limitation providing advice or input concerning whether to amend or modify the scope of any patent claim. This paragraph shall not prevent persons listed in subparagraph 13(d) from supervising a lawyer or patent agent engaged in the activities specified in subparagraphs (a) or (b) with respect to a Prosecution Bar Patent or Application, so long as such a person does not herself or himself engage in the activities specified in subparagraphs (a) and (b).
- [11] The Supreme Court of Canada, in *Shafron v KRG Insurance Brokers (Western) Inc.*, 2009 SCC 6 [Shafron] at paragraphs 15 to 17, summarize the law on restrictive covenants as follows: A restrictive covenant in a contract is what the common law refers to as a restraint of trade. Restrictive covenants are frequently found in agreements for the purchase and sale of a business and in employment contracts. A restrictive covenant precludes the vendor in the sale of a business from competing with the purchaser and, in an employment contract, the restrictive covenant precludes the employee, upon leaving employment, from competing with the former employer. Restrictive covenants give rise to a tension in the common law between the concept of freedom to contract and public policy considerations against restraint of trade. In the seminal decision of the House of Lords in *Nordenfelt v. Maxim Nordenfelt Guns and Ammunition Co.*, [1894] A.C. 535, this tension was explained. At common law, restraints of trade are contrary to public policy because they interfere with individual liberty of action and because the exercise of trade should be encouraged and should be free. Lord Macnaghten stated, at p. 565: The public have an interest in every person's carrying on his trade freely: so has the individual. All interference with individual liberty of action in trading, and all restraints of trade of themselves, if there is nothing more, are contrary to public policy, and therefore void. That is the general rule. However, recognition of the freedom of the parties to contract requires that there be exceptions to the general rule against restraints of trade. The exception is where the restraint of trade is found to be reasonable...
- [12] The effects of the Proposed Prosecution Bar are analogous to restraint of trade in the employer/employee context, since the affected parties are employees of their respective firms or companies. Therefore, it would be more appropriate to approach the Proposed Prosecution Bar provisions as if they were provisions restraining trade, where there is "the presumption that restrictive covenants are prima facie unenforceable, [however] a reasonable restrictive covenant will be upheld" (Shafron at para 17). The onus of showing the reasonableness of a restrictive covenant is on the party seeking to enforce it (Shafron at para 27).

- [13] Moreover, although I have found that the CEO test is inappropriate for these circumstances, I agree with AbbVie that Bioepis has not satisfied the CEO test (*Apotex Inc v Wellcome Foundation Ltd*, [1993] FCJ No 1117 at paras 14 to 16):
- 1) the terms reflect the terms of protective orders granted upon consent in parallel litigation in the US, in which the parties are directly or indirectly involved;
 - 2) the terms of the order provide opportunity to a receiving party to object to the classification of certain documents as confidential; and
 - 3) the party requesting the CEO order believes in good faith that its commercial business or scientific interests may be seriously harmed by disclosure.
- [14] There is no parallel litigation involving the same confidential information. The mere fact that AbbVie has agreed to a protective order containing provisions similar to the Proposed Prosecution Bar provisions in a different action in the United States of America (“US”) involving adalimumab, does not satisfy this condition. The US litigation involves parties, legislation, patents, and issues that are different from the case here. The fact that the US courts and AbbVie have found provisions similar to the Proposed Prosecution Bar provisions reasonable in that context is not, without evidence demonstrating that this litigation and the US action are actually comparable, evidence that they would be reasonable in this action.
- [15] Although Bioepis also argues that their commercial business or scientific interests may be seriously harmed by conscious or unconscious misuse of their confidential information, they have provided no evidence to support the conclusion that this is a reasonably held belief. All individuals included within the protective order have a serious obligation not to disclose or otherwise use confidential information originating from this action for purposes other than this litigation. Therefore, it is not reasonable for the Court to find that the Proposed Prosecution Bar should be granted, without concrete evidence to prove, on a balance of probabilities, that these individuals are at risk to misuse the confidential information disclosed to them. B. Should the Proposed Prosecution Bar be granted? [16] Bioepis argues that once AbbVie’s employees have had access to Bioepis’ proprietary information, they can no longer be expected to have an “empty head” with respect to such information. This knowledge could lead them to misuse Bioepis’ confidential information in the prosecution of AbbVie’s Canadian and foreign patent applications.
- [17] I agree with AbbVie that these assertions are mere speculation of a nebulous future wrongdoing. For example, Bioepis asserts that AbbVie’s knowledge of its proprietary information may lead an AbbVie employee to amend pending patent claims in applications not at issue in these proceedings to “read on” Bioepis’ processes, or to file new patent applications over processes, products, or formulations that are disclosed in Bioepis’ NDSs. However, Bioepis has not provided any evidence to demonstrate that there is an actual risk that the information disclosed in this action could or would be used inappropriately. As such, this is not a concrete harm.

- [18] While I acknowledge that the decision of the United States Court of Appeals, Federal Circuit in *Re Deutsche Bank Trust Company America's and Total Bank Solutions, LLC*, 605 F 3d 1373, held that: We therefore hold that a party seeking imposition of a patent prosecution bar must show that the information designated to trigger the bar, the scope of activities prohibited by the bar, the duration of the bar, and the subject matter covered by the bar reasonably reflect the risk presented by the disclosure of proprietary competition information. We further [xxx1405] hold that the party seeking an exemption from a patent prosecution bar must show on a counsel-by-counsel basis: (1) that counsel's representation of the client in matters for the PTO does not and is not likely to implicate competitive decisionmaking related to the subject matter of the litigation so as to give rise to [**20] a risk of inadvertent use of confidential information learned in litigation, and (2) that the potential injury to the moving party from restrictions imposed on its choice of litigation and prosecution counsel outweighs the potential injury to the opposing party caused by such inadvertent use. (Emphasis in original)
- [19] The evidence filed by Bioepis in this case falls short of meeting the initial burden of showing that the risk presented by the disclosure of proprietary competitive information—in terms of the scope and the activities prohibited by the bar, the duration of the bar, and the subject matter covered by the bar—justifies such a bar in this case.
- [20] Given all of the above, I find that the Proposed Prosecution Bar should not be granted. ORDER in T-598-17, T-599-17, T-600-17, T-601-17, T-602-17 T-603-17, T-604-17, T-605-17 THIS COURT ORDERS that:
1. The motion is dismissed with costs to AbbVie, calculated at the midrange of Column 4 of Tariff B.
 2. The Protection Order previously agreed to by the parties, as attached as schedule A hereto, is hereby so ordered. "Michael D. Manson" Judge SCHEDULE "A" FEDERAL COURT SOLICITORS OF RECORD DOCKETS: T-598-17, T-599-17, T-600-17, T-601-17, T-602-17, T-603-17, T-604-17, T-605-17 STYLE OF CAUSE: ABBVIE CORPORATION AND ABBVIE BIOTECHNOLOGY LTD. v SAMSUNG BIOEPIS CO., LTD. AND THE MINISTER OF HEALTH PLACE OF HEARING: Toronto, Ontario DATE OF HEARING: July 5, 2017 ORDER AND ORDER: MANSON J. DATED: July 12, 2017 APPEARANCES: Peter Wilcox Jason Markwell For The ApplicantS Vincent De Grandpre Geoffrey Langen For The Respondent, SAMSUNG BIOEPIS CO., LTD. SOLICITORS OF RECORD: BELMORE NEIDRAUER LLP Toronto, Ontario For The ApplicantS OSLER, HOSKIN & HARCOURT LLP Ottawa, Ontario For The Respondent, SAMSUNG BIOEPIS CO., LTD. Nathalie G. Drouin Deputy Attorney General of Canada Toronto, Ontario FOR THE RESPONDENT, THE MINISTER OF HEALTH

Source & reproduction note

Judgment wording, source notices and original paragraph numbers are retained. Esheria supplies the layout and this PDF's page numbers; these are not the source pagination. This is a research copy, not an official or certified court document. Check quotations, citations and publication restrictions against the original source before relying on it.

ORIGINAL SOURCE <https://decisions.fct-cf.gc.ca/fc-cf/decisions/en/item/232782/index.do>

CASE PAGE <https://chat.esheria.ai/case-law/canada/abbvie-corporation-v-samsung-bioepis-co-ltd-2017>

Prepared on 28 October 2026 · Esheria