

Federal Court



Cour fédérale

**Date: 20150715**

**Docket: T-259-14**

**Citation: 2015 FC 864**

**Toronto, Ontario, July 15, 2015**

**PRESENT: The Honourable Mr. Justice Hughes**

**BETWEEN:**

**SHIRE CANADA INC.**

**Applicant**

**and**

**PHARMASCIENCE INC. AND THE  
MINISTER OF HEALTH**

**Respondents**

**and**

**SHIRE LLC**

**Respondent Patentee**

**ORDER AND REASONS**

[1] This is an appeal from the decision of the Case Management Judge dated June 26, 2015 with Reasons cited as 2015 FC 798. I am setting aside that decision and issuing an Order which is an amended form of an Order different from that submitted to the Case Management Judge.

[2] This proceeding is brought under the provisions of the *Patented Medicines (Notice of Compliance) Regulations* SOR/93-133 by way of an application with evidence provided by way of affidavits, exhibits to those affidavits, transcripts of cross-examination upon those affidavits and exhibits identified in the cause of those cross-examinations.

[3] The Case Management Judge has issued a Confidentiality Order in these proceedings, largely directed to the Abbreviated New Drug Submission (ANDS) of the Respondent Pharmascience, and a Protective Order directed to “Confidential Information” defined in paragraph 1(d) of the Protective Order as follows:

*(d) “Confidential Information” shall mean any document, evidence, correspondence, record, thing or any other information, designated by any Party as confidential in accordance with the procedure described herein, whether or not embodied in any physical medium, Confidential Information may include any document, evidence, correspondence, record, thing or information produced or disclosed, as the case may be, on any Examination, motion, hearing, or pursuant to any provision of the Federal Courts Rules, or pursuant to the Patented Medicines (Notice of Compliance) Regulations, or Order of the Court, which contains non-public and confidential or proprietary information, whether personal or business-related, except information not described as confidential.*

[4] The Protective Order contains at paragraph 3 a provision that a Party may challenge the designation of a document or other material as confidential

3. *A Party who reasonably believes it will be disclosing or has disclosed confidential information, shall have the right, through its counsel, to designate such information as “Confidential Information” pursuant to this Order in which event such information shall thereafter be governed by the terms of this Order, subject to the right of the non-producing Party to challenge the designation (“Challenged Information”).*

[5] Paragraph 16 of the Order provides that the Court may, upon application of an Party, vary the Order:

16. *Any Party shall also have the right to apply to the Court for any modification or variation of the restrictions on disclosure imposed by any term of this Order as applied to any specific item or items of Confidential Information.*

[6] Paragraph 18 provides that at the hearing the Court seized with the matter has full power to deal with whether the material should be treated as Confidential or not.

18. *The terms and conditions of the use of Confidential Information, the issuance of Confidential Orders enabling parties to file into Court Confidential information under seal and the maintenance of the Confidential Information during any hearing of this proceeding shall be matters in the discretion of the Court seized of this matter. In any event, the terms of this Order do not apply to the hearing of this application on its merits or to the manner in which the final Judgment is to be written and treated, unless specifically ordered by the Application Judge.*

[7] Thus, the scheme of the Protective Order is that a Party may designate a document or other material as Confidential, that designation may be challenged in the Court and the Judge who is hearing the matter on the merits has full discretion as to whether the designation is appropriate.

[8] In this case Pharmascience wishes to provide, as an exhibit to one of its affidavits, data compiled and provided by a United States organization called IMS which, as described by the Case Management Judge at paragraph 2 of her Reasons, makes it its business to gather, compile and sell pharmaceutical and healthcare information as to pharmaceutical sales data, prescription data, medical claims data and other related data.

[9] In this case the data at issue has been provided by IMS to Pharmascience pursuant to what is described as a Litigation Agreement. That Agreement requires Pharmascience to obtain from this Court an Order ensuring the confidentiality of the data. Pharmascience sought to do so by providing to the Case Management Judge a draft Order, consented to by the Parties. Therein lies the problem.

[10] The draft Order contained a provision as follows:

*CONSIDERING that the Court is satisfied that the confidential information and documents of IMS found in the IMS Report containing sales data for Attention Deficit Hyperactivity Disorder (“ADHD”) drug products in the United States attached as Exhibit “F” to the Affidavit of Dr. Levinson sworn January 27, 2015 (the “IMS Data”) and any document or transcript referring to the IMS Data, meet the criteria for the protection of a confidentiality order under Rule 151, and that the information disclosed in these documents also merits protection.*

[11] Undoubtedly prompted by this provision which states that the Court is satisfied that the information and documents of IMS meet the criteria for the protection of confidential information, that the information is confidential, the Case Management Judge embarked on her own determination in that regard the result of which is the decision and reasons under appeal.

[12] The Case Management Judge in making the determination under appeal did not have before her representations from IMS as to the documents and information provided by it to Pharmascience. The Judge did not have before her all the necessary information to arrive at a reasoned decision respecting the Litigation Agreement as the documents and information governed by that Agreement. The reasons are not based on adequate information or representations.

[13] The Case Management Judge should not have embarked on this determination without giving all interested parties an opportunity to provide evidence and argument. The Case Management Judge should have requested an amendment to the draft Order such that the Order does not say that the Court has found the information and documents to meet the criteria for confidential information. The Order should say only that Pharmascience asserts that the information and documents meet the criteria. Thus a challenge may be raised at a later date and the Judge hearing the application will be free to make a determination if needed, at that time, as to whether the information and documents are truly confidential or not.

[14] I will sign an amended Draft of the Order different from that presented to the Case Management Judge which does not refer to a Court determination as to confidentiality but, rather to an assertion by Pharmascience to that effect.

**ORDER**

**THIS COURT ORDERS that:**

1. The appeal is allowed;
2. The Order and Reasons of the Case Management Judge dated June 26, 2015 are set aside;
3. A new Order respecting the IMS material will be signed contemporaneous with these Reasons and Order.

"Roger T. Hughes"

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Judge

**FEDERAL COURT**  
**SOLICITORS OF RECORD**

**DOCKET:** T-259-14

**STYLE OF CAUSE:** SHIRE CANADA INC. v PHARMASCIENCE INC. AND  
THE MINISTER OF HEALTH AND SHIRE LLC

**PLACE OF HEARING:** TORONTO, ONTARIO

**DATE OF HEARING:** JULY 14, 2015

**ORDER AND REASONS:** HUGHES J.

**DATED:** JULY 15, 2015

**APPEARANCES:**

No Appearance	FOR THE APPLICANT SHIRE CANADA INC.
Carol Hitchman Rosamaria Longo	FOR THE RESPONDENTS PHARMASCIENCE INC. AND THE MINISTER OF HEALTH
No Appearance	FOR THE RESPONDENT THE MINISTER OF HEALTH
No Appearance	FOR THE RESPONDENT PATENTEE SHIRE LLC
Adrian Howard	FOR IMS HEALTH INCORPORATED (INTERVENER ON MOTION)

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