Date: 20100210

Docket: T-2009-09

Citation: 2010 FC 120

TORONTO, ONTARIO, February 4, 2010

PRESENT: Madam Prothonotary Milczynski

BETWEEN:

EPICEPT CORPORATION

Applicant

and

THE MINISTER OF HEALTH

Respondent

REASONS FOR ORDER AND ORDER

[1] This is the second motion brought by the Applicant, EpiCept Corporation for an order under Rule 151 of the *Federal Courts Rules*. For the purposes of this application for judicial review, the Applicant seeks to maintain the confidentiality of:

(i) the identity of the Applicant company;

(ii) the identity of any employee of the Applicant company;

(iii) the brand name of the drug product;

(iv) the medicinal ingredient and variations of the medicinal ingredient;

(v) other drug products containing the medicinal ingredient or its variations;

(vi) the disease at issue in the new drug submission ("NDS") filed by the Applicant; and

(vii) otherwise, the entire contents of the NDS.

[2] The only difference between this motion and the first which was dismissed in its entirety without prejudice to the Applicant bringing a further motion for a confidentiality order, is that the Applicant is no longer pursuing the further relief that the very existence of a judicial review of a decision of the Minister of Health ought also be kept from the public record. The Minister takes no position on this motion, having opposed in part the first.

Background

[3] In the ordinary course, an innovator drug manufacturer seeking approval may file a confidential NDS and apply to have any patent applicable to the drug product on the Patent Register pursuant to sections 3 and 4 of the *Patented Medicines (Notice of Compliance) Regulations* ("*PMNOC Regulations*"). The innovator would also seek protection of its data under s.C.08.004.1 of the *Food and Drug Regulations*. In these cases, even the fact that an NDS has been filed is confidential and would not become known unless and until a Notice of Compliance ("NOC") has been issued. At that time, if the drug is an eligible innovative drug, it is listed on the Register of Innovative Drugs, and if the patent is eligible, it is listed on the Patent Register (s.3(7) of the *PMNOC Regulations*).

[4] Thus, only when a NOC is issued, would the public know that a drug manufacturer has sought approval to market a particular drug, that approval has been granted, that the data supporting the approval is protected by virtue of section C.08.004.1(3) of the *Food and Drug Regulations*, and that the drug is protected by a patent for the purposes of the *PMNOC Regulations*.

[5] By virtue of C.08.004(3) of the *Food and Drug Regulations*, if the innovator's drug is eligible for data protection, a generic manufacturer may not file its submission for approval of a copy of the drug until at least six years after the NOC was issued to the innovator for the drug, and may not receive an NOC until at least eight years after the NOC has issued – even if the innovator's drug is not protected by a patent. Finally, if the innovator's drug has a patent listed against on the Patent Register, the generic manufacturer must, pursuant to the *PMNOC* Regulations, address that patent by way of Notice of Allegation, submitting that the patent is invalid and/or would not be infringed by the generic drug product. In the event a proceeding is commenced by the innovator to prohibit the Minister of Health from issuing an NOC to the generic, unless the Court is satisfied that the patent would not be infringed, the generic manufacturer must also await the expiry of the patent before obtaining its NOC.

[6] In the present case, EpiCept Corporation filed a NDS with Health Canada on August 5, 2009 for the approval of CEPLENE (histamine dihydrochloride) for remission maintenance in acute myeloid leukemia. As part of its NDS, EpiCept requested that CEPLENE be designated as an innovative drug pursuant to the data protection provisions of the *Food and Drug Regulations*. As

noted above, the data protection provisions provide an eight year term of market exclusivity for eligible “innovative drugs” listed on the Register of Innovative Drugs.

[7] EpiCept also submitted one patent for listing on the Patent Register with respect to CEPLENE. This patent will expire in 2010, and as acknowledged at paragraph 8 of its written submissions, EpiCept is relying on the market exclusivity provided by data protection to protect its product in Canada for eight years following the issuance of a NOC.

[8] On August 27, 2009, the Office of Patented Medicines and Liason, on behalf of the Minister, expressed its “preliminary view” that CEPLENE is not an “innovative drug” and would not be added to the Register of Innovative Drugs. EpiCept sought reconsideration of this decision by submitting responding submissions and affidavit evidence to the Minister.

[9] On November 2, 2009, the Minister rejected EpiCept’s arguments and maintained its decision that CEPLENE was not eligible for listing on the Register of Innovative Drugs, and on December 1, 2009, EpiCept commenced the within application for judicial review.

Confidentiality

[10] EpiCept seeks a confidentiality order to prevent the disclosure of its NDS for CEPLENE, and argues that to protect the confidentiality of the NDS, it is necessary to use neutral designations on any public documents: “Company X”, “Employee X”, “Drug Product A”, “Medicinal Ingredient A”, and “Human Disease A”. The Applicant also seeks leave to file an amended notice of

application incorporating these neutral designations, and further submits that this relief is necessary to protect the confidentiality of the NDS and would cause only minimal impairment to the public court system.

[11] EpiCept submits that it does not have approval to sell any products in Canada, and that CEPLENE is its only marketed product around the world. EpiCept further submits that its competitors have no way of knowing if CEPLENE is eligible for data protection, as this information would only be made available to the public by Health Canada after a NOC is issued.

[12] While the fact of EpiCept's filing of an NDS would have been confidential in the ordinary course unless and until a NOC was issued, EpiCept issued a press release on November 9, 2009 announcing:

> EpiCept Corporation (Nasdaq and OMX Nordic Exchange: EPCT) today announced that Health Canada has accepted for review the Company's New Drug Submission (NDS) for Ceplene (histamine dihydrochloride) for the remission maintenance of acute myeloid leukemia (AML) patients in first complete remission. Health Canada's performance target for the completion of review and a decision is within 300 days.
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> ****
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> This news release and any oral statements made with respect to the information contained in this news release, contains forward-looking statements within the meaning of the Private Securities Litigation Regorm Act of 1995. Such forward- looking statements include statements which express plans, anticipation, intent, contingency, goals, targets, future development and are otherwise not statements of historical fact. These statements are based on our current expectations and are subject to risks and uncertainties that could cause actual results or developments to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Factors that may cause actual

> results or developments to differ materially include: the risk that Ceplene will not receive regulatory approval or marketing authorization in the United States or Canada…
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> ****
>
> You are cautioned not to place undue reliance on any forward-looking statements, any of which could turn out to be wrong due to inaccurate assumptions, unknown risks or uncertainties or other risk factors.

[13] Thus the fact that EpiCept sought marketing approval for CEPLENE is information that is public, as is the medicinal ingredient and human disease. I would also note, however, that for whatever reasons it has, this information contained in the press release was made public by EpiCept after it had already been informed of the Minister's decision that CEPLENE was not eligible for data protection. The Court can only surmise that it is the decision denying data protection and its judicial review application that EpiCept is most concerned be kept confidential.

Confidentiality and the Public Interest

[14] The test to be met for the issuance of a confidentiality order pursuant to Rule 151 of the *Federal Courts Rules* is a high one. In accordance with the Supreme Court of Canada's decision in *Sierra Club of Canada v. Canada (Minister of Finance)* [2002] 2 SCR 522, the party requesting such order must satisfy the Court that the information sought to be sealed "should be treated as confidential, notwithstanding the public interest in open and accessible court proceedings". The public interest is in the open and transparent administration of justice – not some narrow view of the public's perception or interest in the particular subject matter of a particular proceeding. Only in

exceptional cases, and where circumstances warrant can the public interest in open courts be outweighed by the need to prevent a serious risk of harm or prejudice to an important interest, which may include a commercial interest. In that regard, some degree or element of public interest will also be identified in protecting the confidentiality of information and restricting access to the court process and file. For example, in *Apotex Inc. v. Canada* [1993] FCJ No. 427, Justice McGillis noted that it was in the public interest to protect the confidentiality of information contained in new drug submissions, arguably to encourage full and complete information disclosure to regulatory agencies and continued research and development:

> The perceived confidentiality of information flowing from a drug manufacturer to the Department of National Health and Welfare is a cornerstone of the system pertaining to the processing of new drug submissions and the issuance of notices of compliance. For this system to function effectively, the confidential nature of the relationship ought to be honoured and maintained to the extent possible.

[15] By issuing the press release, it can be said that EpiCept put its competitors on notice:

(i) that any competitor interested in producing a generic copy of the CEPLENE will have had the opportunity to consider whether it will be eligible for data protection;

(ii) that in accordance with the legislative requirement for eligibility for innovative drugs, the drug must not contain either a medicinal ingredient contained in a previously approved drug, or a variation of such medicinal drug;

(iii) that the medicinal ingredient in CEPLENE is histamine hydrochloride; and

(iv) that informed competitors could come to some determination as to whether histamine hydrochloride is likely to qualify CEPLENE for data protection.

[16] Nonetheless, EpiCept submits that if the current application for judicial review of the decision to deny data protection is made public, it would be harmed by the "head start" its competitors would enjoy to prepare regulatory submissions to enter the market themselves. It seeks to keep secret the negative decision regarding data protection, its application for judicial review, and the entire content of the application, which coincidentally would also allow EpiCept to maintain the impression left by its press release, notwithstanding the disclaimer contained therein.

[17] I cannot see the concerns and risks identified by EpiCept as any reasonable basis to order the breadth of confidentiality sought, which would essentially result in a secret proceeding being conducted in this Court. EpiCept has failed to identify any interest, other than the most narrow and private of commercial interests in support of its proposed order that in no way outweighs or should sweep aside the public interest in open and accessible court proceedings.

[18] In any event, if it is successful in the within application EpiCept will not lose its competitive advantage – its competitors will be prohibited from filing any regulatory submissions for six years. If EpiCept is unsuccessful, competitors may or may not enter the market sooner, but not because of having received any "confidential" information through this proceeding.

[19] Accordingly, this motion is dismissed with the exception of the granting of the protection sought for the NDS filed with the Minister, which may be filed confidentially. The parties may submit a draft confidentiality order consistent in that respect with these reasons.

ORDER

THIS COURT ORDERS that:

1. Leave is granted to the parties to file the New Drug Submission filed by EpiCept Corporation on August 5, 2009 on a confidential basis pursuant to Rule 151 of the *Federal Courts Rules*.

2. The balance of the motion is dismissed.

"Martha Milczynski"
Prothonotary

FEDERAL COURT

Names of Counsel and Solicitors of Record

DOCKET:	T-2009-09
STYLE OF CAUSE:	EPICEPT CORPORATION Applicant and THE MINISTER OF HEALTH Respondent

MATTER CONSIDERED AT TORONTO, ONTARIO PURSUANT TO RULE 369

REASONS FOR ORDER AND ORDER BY:	MILCZYNSKI P.
DATED:	FEBRUARY 4, 2010

WRITTEN SUBMISSIONS BY:

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Ms. Lindsay Ellis	FOR THE RESPONDENT

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