In the recent Photocure decision the Federal Court has once again sided with Canada's Minister of Health in denying data protection for a new medicinal ingredient. In Photocure, the medicinal ingredient was labelled "a variation" of a previously approved medicinal ingredient. While Photocure presented expert evidence to the contrary, the Court refused to consider the evidence, refusing data protection in the process and opening the door to generic copying of Photocure's data filed with its New Drug Submission. This case presents an opportunity to examine the Minister's unbeaten track record in data protection judicial review applications and consider how we arrived at the present state of affairs.

**Background on Data Protection**

In 2006, Canada amended the data protection provisions of the Food and Drug Regulations to grant eight years of market exclusivity to manufacturers of "innovative drugs." These amendments were intended to clarify and effectively implement Canada's obligations under the North American Free Trade Agreement and the Agreement on Trade-Related Aspects of Intellectual Property Rights to protect undisclosed data necessary to determine the safety and efficacy of a new pharmaceutical product containing a new chemical entity. As determined by the Federal Court of Appeal, the clear policy behind Canada's data protection regulations is to encourage the development of new drugs.²

The eight years of market exclusivity is enforced through a six-year "no filing" period and an eight year "no approval" period. In the first six years, no one may file a drug submission making
a direct or indirect comparison to the innovator’s data.

In the last two years, a drug submission may be filed but the approval (i.e., the Notice of Compliance or NOC) cannot issue until the expiry of the eight-year term. This eight year "no approval" period is extended an additional six months if pediatric studies are filed. The "no approval" period is also engaged when later-filed amendments to a drug submission make reference to an innovator’s data. Drugs that qualify for data protection are listed on Health Canada’s Register of Innovative Drugs.

Eligibility for data protection is governed by the definition of "innovative drug" under the Food and Drug Regulations. The definition sets out what is not an innovative drug: an innovative drug contains a medicinal ingredient that is not (1) previously approved in a drug by the Minister and (2) a variation of a previously approved medicinal ingredient, such as a salt, ester, enantiomer, solvate or polymorph.

The Food and Drug Regulations do not provide further guidance regarding the meaning of "previously approved" or "a variation." Therefore, these terms are left for the Minister and the Courts to interpret and apply. Since 2006, a series of decisions from the Federal Court and Federal Court of Appeal have tackled the meaning of these terms.

Three decisions of the Federal Court and Federal Court of Appeal have addressed the meaning of "previously approved":

- In Epicept (histamine dihydrochloride), the Federal Court determined that "previously approved in a drug" includes approvals in any drug (e.g., natural health products) and is not limited to approvals of "new drugs" through the drug submission and NOC procedures. This decision is reflected in the Minister’s data protection analysis, where the Minister searches a number of databases for previously approved medicinal ingredients, such as the Drug Product Database and the Licensed Natural Health Products Database. Notably, the Minister’s search is not limited to the NOC Database, which lists approvals of "new drugs."
- In Teva (oxaliplatin), the Federal Court of Appeal determined that authorizations under Canada’s Special Access Programme do not constitute "approvals" and therefore do not act as a bar to later data protection.
- In Celgene (thalidomide), the Federal Court of Appeal determined that "previously" does not mean "currently" and therefore it is irrelevant if the approval of the "previously approved" drug was subsequently revoked. The medicinal ingredient at issue in Celgene, thalidomide, was approved in the 1960s, but was subsequently pulled from the market for serious side-effects in pregnant women. This subsequent removal from the market did not impact thalidomide's "previously approved" status.
The Federal Court has also addressed the meaning of "a variation." In Takeda (dexlansoprazole), notwithstanding a strong dissent to the contrary, the majority of the Federal Court of Appeal found that the enumerated variations (i.e., salt, ester, enantiomer, solvate or polymorph) of previously approved medicinal ingredients are automatically excluded from data protection, irrespective of the nature of the underlying data or what it demonstrates with respect to the medicinal ingredient under review.

This restrictive interpretation of "innovative drug" puts Canada at odds with the law of the United States and the European Union. In the US, data protection is available for drugs that "demonstrate substantial evidence of effectiveness of a previously approved drug product for any indication or of safety for a new patient population." Similarly, in the EU, data protection is available for drugs that are variations of previously approved drugs but differ "significantly in properties with regard to safety and efficacy."

In Canada, while the regulatory basis (and clearly the policy basis) exists for an analysis of safety and efficacy, medicinal ingredients labelled as one of the enumerated "variations" have not to date benefitted from such a review.

Recent Application of "a variation" in Photocure

This restrictive interpretation of "variations" was recently illustrated in the Federal Court's decision in Photocure. The drug at issue was Photocure's new drug CYSVIEW, an optical imaging agent designed to enhance detection of bladder cancer. The medicinal ingredient in CYSVIEW is hexaminolevulinate hydrochloride (referred to in the decision as "HAL HCl").

The Minister found CYSVIEW ineligible for data protection because HAL HCl was deemed to be an ester variation of a previously approved medicinal ingredient, aminolevulinic acid hydrochloride (referred to in the decision as "ALA HCl"). The Minister understood that the structure of HAL HCl is identical to ALA HCl, but with the addition of an ester group. Accordingly, CYSVIEW was automatically excluded from data protection, irrespective of the clinical data contained in the drug submission.

Photocure challenged the Minister's finding in a judicial review application to the Federal Court, arguing that the material issue was one of interpretation of "innovative drug." However, the Court disagreed and found that the issue before the Court was the narrow question of whether HAL HCl is an ester of ALA HCl, declaring the issue to be the proper application of the regulations and not the meaning of the regulations.
Different Standard of Review Applied

The Court considered the standard of review in Photocure to be the deferential standard of reasonableness. This case is the first data protection judicial review to apply such a standard; all prior cases have applied the standard of correctness. The Court distinguished the established line of authority on the basis that questions of statutory interpretation were raised in those cases, while this case dealt merely with a question of fact.

It should be noted that even more recently, in Hospira, the Federal Court reverted to the logic of previous decisions, finding that the standard of review is correctness. It may be that the Court's decision in Photocure is an outlier in terms of standard of review.

Subsequently-Filed Evidence found Inadmissible

Prior to assessing the merits of the application, the Court applied an evidentiary rule unique to judicial review proceedings and rejected expert affidavit evidence filed by Photocure and also responding evidence filed by the Minister. The evidence related to issues of science. For example, Photocure's expert stated that chemists would regard HAL HCI as first a salt of HAL and secondly as an ester of ALA.

The Minster objected to Photocure's expert evidence, arguing that evidence in judicial review applications must be limited to the evidence before the administrative decision-maker. There are exceptions to this rule, including an exception allowing general background evidence, and Photocure argued that its expert evidence was permissible under this exception.

The Court disagreed, noting that Photocure's expert "opines on the very issue the Minister was asked to determine" and "attempts to impugn the decision after the fact with information that was not provided to the decision-maker." For this reason, Photocure's expert evidence was struck, as was the Minister's responding evidence.

Minister's Decision Found Reasonable

The Court in Photocure went on to find the Minister's denial of data protection for CYSVIEW to be reasonable. Without the impugned, but contradicting, expert evidence in hand the Court found that the Minister's decision fell within a range of possible, acceptable outcomes, and was therefore reasonable.

To date, the Federal Court's decisions have reflected the Minister's restrictive interpretation of
the definition of "innovative drug" and the Minister's restrictive approach to data protection. Nevertheless, the precise scope of the Regulations, and of data protection in Canada, remains to be determined.

---

1 Photocure ASA v Canada, 2015 FC 959.
2 Apotex Inc v Canada (Health), 2010 FCA 334.
3 Hospira Healthcare Corporation v Canada (Health), 2015 FC 1205.
5 Epicept Corporation v Canada (Health), 2010 FC 956.
6 Teva Canada Limited v Canada (Health), 2012 FCA 106.
7 Canada (Health) v Celgene Inc, 2013 FCA 43.
9 Photocure ASA v Canada, 2015 FC 959.
10 Hospira Healthcare Corporation v Canada (Health), 2015 FC 1205.
Gowling WLG is an international law firm comprising the members of Gowling WLG International Limited, an English Company Limited by Guarantee, and their respective affiliates. Each member and affiliate is an autonomous and independent entity. Gowling WLG International Limited promotes, facilitates and co-ordinates the activities of its members but does not itself provide services to clients. Our structure is explained in more detail on our Legal Information page.

© 2020 Gowling WLG International Limited. All rights reserved.