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# I Want a New Drug: Developments in Data Protection for Innovative Drugs

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In the highly competitive market for pharmaceuticals, the market exclusivity provided to the manufacturers of innovative drugs by the data protection regime of the *Food and Drug Regulations* (the Regulations) is important, and has the potential to be extremely lucrative. Two recent federal court decisions highlight some of the ambiguities in the Regulations and provide guidance on how courts interpret the Regulations.

## OVERVIEW OF DATA PROTECTION REGIME IN CANADA

In order for a new drug to be sold in Canada, it must be approved by the Minister of Health (the Minister) in the form of a Notice of Compliance (NOC). The approval process is different for brand name drugs, many of which are also "innovative drugs", as compared to their generic counterparts. An "innovative drug" is defined in the Regulations as "a drug that contains a medicinal ingredient *not previously approved* in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph." (emphasis added)

In Canada, manufacturers of innovative drugs are required to file a New Drug Submission (NDS) with the Minister, containing safety and efficacy information. The Minister issues an NOC only after determining that the benefits of the drug outweigh the risks, and that the risks can be mitigated and/or managed. Generic manufacturers, on the other hand, generally obtain drug approval by filing an Abbreviated New Drug Submission (ANDS), which is intended to establish bioequivalence with an existing "reference product", usually a previously approved innovative drug. Instead of providing clinical data to demonstrate safety and efficacy, generic manufacturers rely on the data provided by the innovator at the time the innovative drug was approved.

In this context, and in keeping with its international treaty obligations, Canada provides protection to the safety and efficacy data submitted by the innovator. Specifically, the Regulations prohibit the Minister from issuing an NOC to a manufacturer that makes a direct or indirect comparison to an innovative drug until at least eight years have passed from the issuance of the NOC for the innovative drug at issue. The eight-year period of protection may be extended by six months if, within the first five years of the protection period, the results of pediatric clinical trials designed and conducted for the purpose of increasing knowledge of the use of the drug in pediatric populations, are submitted and found acceptable.

The Regulations also provide for a "no filing" period, whereby the generic manufacturer is prohibited from filing its ANDS for the first six years of the eight-year data protection period. The Minister maintains a Register of Innovative Drugs (the Register) to track the dates on which the six-year, eight-year and, where applicable, pediatric extension periods, will expire.

## NO SPECIAL ACCESS TO DATA PROTECTION

In *Teva Canada Limited v. Canada (Health)*, the Federal Court of Appeal (FCA) confirmed that drugs made available pursuant to Health Canada's Special Access Programme (the SAP) are not considered "previously approved" under the Regulations and are therefore eligible for data protection.

Teva Canada wanted to market a generic version of ELOXATIN but was being prevented from doing so because it was listed on the Register and therefore benefited from the data protection provisions of the Regulations. In 2010, Teva Canada requested that the Minister remove ELOXATIN from the Register on the basis that it did not meet the definition of "innovative drug" under the Regulations. Teva Canada argued that because ELOXATIN had been available under the SAP (a program designed to provide exceptional access to unapproved drugs on a compassionate or emergency basis to patients with serious or life-threatening conditions) since 1999, it has been "previously approved" by the Minister. The Minister rejected Teva Canada's request and an appeal to the Federal Court of Canada (FCC) was dismissed. Teva Canada made a further appeal to the FCA.

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In denying Teva Canada's appeal, the FCA considered the issue of whether authorizations under the SAP could make a drug "previously approved" for the purposes of the data protection provisions of the Regulations. The court in this case focused on the primary purpose of the Regulations themselves and found that they are directed to the safety and efficacy of drugs. Specifically, the court noted that a drug is only "approved" by the Minister when it has been found to be safe and effective. The Minister does not determine the safety and effectiveness of a drug under the SAP. Accordingly, drugs under the SAP are not "approved" by the Minister.

Furthermore, the court noted that the data protection regime under the Regulations was designed to implement specific treaty obligations. Those treaty provisions repeatedly refer to the concept of market approval. Since, in Canada, marketing approval requires the issuance of an NOC, sale under the SAP did not mean market approval. To find otherwise might put Canada offside its treaty obligations.

## NEW USES FOR OLD DRUGS

In *Celgene Inc. v. The Minister of Health*, the FCC considered what data protection, if any, was available to a drug whose medicinal ingredient had previously been approved for sale in Canada. The medicinal ingredient at issue, *thalidomide*, was approved for sale in Canada in 1960 and was used to treat sleeplessness, minor ailments, and morning sickness in pregnant women. By 1962, data linking *thalidomide* with serious birth defects and deaths prompted Health Canada to order its permanent withdrawal from the market.

Despite its history, further research found that *thalidomide* was effective in treating various conditions, including leprosy and cancer. Celgene began offering *thalidomide* in association with the trade-mark THALOMID and in 1995 it was made available in Canada through the SAP.

In 2009, Celgene sought approval to sell THALOMID in Canada outside of the SAP and an NOC was issued in 2010. However, when the NOC was issued, the Minister advised Celgene that because *thalidomide* had been previously approved by the Minister, THALOMID was not eligible for data protection. Celgene appealed that ruling to the FCC.

The court was tasked with interpreting the meaning of "innovative drug" and determining whether the Minister's prior approval of *thalidomide* constituted an approval within the meaning of "approved" in the definition of "innovative drug". The Minister took the position that the intent of the data protection provisions of the Regulations is to reserve the special market exclusivity period for genuinely new and innovative medicinal ingredients. According to the Minister, new uses of ingredients that had been previously approved for a different use should not qualify for data protection.

The FCC did not accept the Minister's position and held that THALOMID was eligible for data protection. A key aspect of the court's decision was its finding that the purpose and intent of the Regulations is to encourage innovation and the development of drugs that can be used by Canadians. In that context, the court concluded that Celgene's innovation was to take something that had been banned as dangerous and show it to be a useful, potentially lifesaving drug. In doing so, Celgene could not rely on data from the prior approval for *thalidomide* and had to produce entirely new data. The court held that it would be inconsistent with Canada's international treaty obligations to refuse data protection when a medicinal ingredient is put to an entirely new use based on extensive and genuinely new data demonstrating its safety and efficacy.

On that basis, the court concluded that the Minister's decision was incorrect and that *thalidomide* qualified as a medicinal ingredient not previously approved. It was therefore eligible for listing on the Register.

Due to the exceptional circumstances surrounding the use of *thalidomide* in Canada, the future impact of the *Celgene* decision may be limited. However, the case provides a useful example of the types of legal considerations that may arise in a research environment where old drugs essentially become new again. Indeed, one of the growing trends in pharmaceutical research is to identify new therapeutic uses for existing compounds that are not currently being marketed.

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For example, in May 2012, the National Institutes of Health in the U.S. launched a pilot program called *Discovering New Therapeutic Uses for Existing Molecules*. The program matches biomedical researchers with a selection of compounds that have been developed by industry and that have already undergone significant testing, including safety testing in humans. Successful applicants will have the opportunity to work with the compounds (deemed unsuitable for their intended therapeutic indication or not pursued for business reasons) to see if they can develop new treatments or therapies. To date, eight major pharmaceutical companies are participating in the program and 58 compounds have been made available for further study. Grants are expected to be awarded by summer 2013.

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