Legal challenges hit data protection law amendments

BY DEREK HILL
For Law Times

The future of the sweeping amendments made to the data protection provision of the food and drug regulations enacted last October may still be in doubt.

The Canadian Generic Pharmaceutical Association, an industry association representing most Canadian manufacturers of generic drugs, has filed the first of two legal challenges to the provision, which grants an eight-year period of data exclusivity to brand-name manufacturers when they issue a notice of compliance for a new drug, and contains a no-filing rule for new generic drug submissions of any sort for the first six years.

The CGPA is seeking a declaration that the provision is *ultra vires* the government to legislate.

A second challenge filed by the generic manufacturer Apotex Inc. also attacks the provisions, arguing that as they are designed to protect the unfair commercial use of trade secrets and undisclosed data they are beyond federal authority.

"It's almost like a new kind of intellectual property," says Edward Hore, of Hazzard & Hore LLP, and counsel for the CGPA, describing the overall effect of the amendments. "Yet it's been passed not in the form of a statute, but entirely by regulations, under a statute which in fact has a very different purpose — the protection of health and safety. These regulations aren't intended to protect health and safety, they're all about conferring monopoly powers on a powerful industry segment."

"Clearly we believe they [the provisions] are harmful to the business interests of our member companies," says Jim Keon, president of the CGPA. "Secondly, we think they're also harmful to the Canadian public in terms of access to lower cost generics. The government estimated that the new data protection provisions could delay up to a quarter of all generic products for some period of time, keeping them off the market."

Russell Williams, president of Canada's Research-Based Pharmaceutical Companies (Rx&D), says he couldn't comment on the specific grounds of the application as it's before the courts. However, in a written statement to *Law Times*, he says: "However, we believe that eight years of clinical trial data protection, as adopted in the new data protection regulations, is a powerful tool for our research-based pharmaceutical community in its continuing efforts to attract international R&D investments to Canada, and will ultimately benefit Canadian patients.

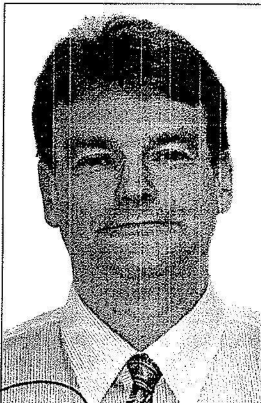
"We also believe that the new regulations are essential to fulfill Canada's international trade treaty commitments. Although the regulations will allow our community to be more competitive internationally, Canada still falls short of the 10 years of data protection offered by the European Union."

This, though, is precisely the bone of contention.

In its legal challenge to the provisions, the CGPA argues s. 30(3) of the FDA only conferred the power on the governor-in-council to make such regulations it deemed necessary for the purpose of implementing art. 1711 of NAFTA and paragraph 3 of art.39 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), and the impugned regulations are unnecessary and can't be deemed necessary to implement Canada's obligations under those provisions.

"Both TRIPS and NAFTA do not require eight years of data protection," says Keon. "TRIPS is a very general provision that we believe is met by the previously existing regulations, and NAFTA talks about five years of protection, which Canada already had."

Hore says the other argument is that they're dealing with a matter of exclusive jurisdiction because the regulations deal with the protection of confidential information, a matter of property and civil rights in the province, not of federal jurisdiction.



Ed Hore says it's unusual that data protection provisions have been added as regulations to a statute designed to protect health and safety.

"Probably, if the government wanted to introduce that form of regulation, it should have bit the bullet and revised the legislation, brought it to Parliament, had committee hearings, and gone through a legislative public-policy review process," Keon adds.

"We believe there's no reason to amend these data protection regulations," he says. "Canada already had data protection regulations. They've already been interpreted by the courts. The Federal Court of Appeal has already said explicitly that the regulations were consistent with NAFTA."

Nevertheless, the regulations have been some time in the making, in part in response to perceived shortcomings in the prior provisions.

"The previous data protection provision was construed very narrowly, so that it was almost never applied — indeed I'm not aware of any circumstances when it was applied," says Nancy Pei, of Smart and Biggar LLP, adding it's a long-standing concern.

A version of the amended regulations was first published in 2004 under the previous Liberal government, which published them and later pulled them back. Informal consultations with both the brand name and generic industries followed, and the package of amendments underwent several iterations. After the Harper government was elected, the revised amendments were published in June, again with a call for comments.

"The provinces were quite concerned about it," says Keon, "because under the National Pharmaceutical Strategy, part of the health accord signed between the federal government and the provinces, one of the elements was faster access to non-patented medicines. That was one of their objectives. Well, lengthening data protection is clearly going in the directly opposite direction in terms of policy."

The provinces had consultations with the government between June and October, and in the end decided to go ahead. In the government's regulatory impact analysis statement, it states it "believes that these proposed changes made in response to stakeholders' comments will achieve a greater balance between the need for innovative drugs and the need for competition in the marketplace in order to facilitate the accessibility of those drugs. Introducing a six-year no-filing period within the eight-year term of data protection will allow innovators to enjoy market exclusivity without the threat of any challenges that might be brought against them during that six-year period. During this period, it is anticipated that innovator and generic litigation, and the costs associated with that litigation, would decrease significantly while providing increased predictability, a result which is desirable to stakeholders on both sides of the industry."

The CGPA's challenge was filed in November 2006, and since then the association has filed its evidence and is awaiting the government's response. LT