IP law changes coming after Europe deal

BY MICHAEL MCKIERNAN
For Law Times

After seven years of talks, delays and drama, changes to Canada's intellectual property laws as a result of the nation's free trade deal with the European Union are finally coming into view.

On Oct. 31, the federal government introduced in Parliament Bill C-30, an Act to implement the Comprehensive Economic and Trade Agreement, which includes proposed amendments to both the Patent Act and the Trade-Marks Act.

The first reading came mere hours after Prime Minister Justin Trudeau and European Commission president Jean-Claude Juncker added their signatures to the deal's final text at a ceremony in Brussels, which marked a change in pace for an agreement that has been in the works since 2009.

An agreement in principle was struck in 2013, but negotiations did not end until a year later, and then things slowed even further as CETA worked through the approvals process in each of the EU's 28 nations.

A last-minute hitch involving the provincial assembly of Wallonia, a region of Belgium, looked set to sink the agreement altogether, before scrambling trade officials were able to pull together an addendum that addressed local concerns.

Bill C-30's introduction came not a moment too soon for Daphne Lainson, partner in the Ottawa office of intellectual property law boutique Smart & Biggar.

Her pharmaceutical patent practice stands to feel the biggest impact from the CETA-related amendments.

"It's really exciting stuff for a pharma person to see the bill at first reading, and think about it being in force maybe by the end of the year," she says.

"It's been very hard getting to this point. There has been so much political turmoil in Europe and elsewhere that it's going to be nice to actually move forward, instead of remaining sort of stuck where we are," adds Lainson.

Some of the most controversial changes under CETA involve patent term restoration or extensions to patent terms to account for regulatory delays.

The concept has two decades of history in Europe, but it is brand new to Canada, so while European patentees can get an extra five years on top of a 20-year drug patent term, the negotiators settled on a compromise that will see a maximum extension of two years for companies issued a supplementary protection certificate in this country.

Daphne Lainson says Bill C-30 leaves plenty of holes to be filled in by regulations to come later under the new legislation.

"Two years is better than zero, so that's great news for innovators," Lainson says. "It does account at least in part for the lengthy process of bringing a drug to market."

Still, she says C-30 leaves plenty of holes to be filled in by regulations to come later under the new legislation. Uncertainty remains about how cases involving more than one patentee will be treated, and whether the CPLs will apply retroactively to products that have already received regulatory approval or are currently mired in the process.

Alan Macek, an IP litigation and patent prosecution partner with DLA Piper (Canada) LLP in Toronto, says generic drug producers have long opposed any kind of patent term restoration in this country.

"The fear that people have raised is that by extending patent terms, it will be longer before generics come into the market, and costs will be higher," Macek says.

No matter how the final rules shake out, Scott Foster, an intellectual property lawyer with Gowling WLG, says they will result in plenty of litigation for the foreseeable future.

"I can see a lot of litigation around the Certificates of Supplementary Protection; the rules about what you need to get one, who is entitled to one and how it can be lost. The same thing happened in Europe around similar principles there," says Foster, who leads the firm's IP litigation practice in Vancouver.

"There's always a lot of controversy when patent rights are amended, because you have one side who has spent a lot of time and money developing drugs and medicinal products, and on the other side, you've got generic producers who think they have already had to wait too long to start selling."

CETA implementation also necessitates a major change to the Patented Medicines (Notice of Compliance) Regulations, which govern the process by which generic producers introduce their versions of patented drugs to market.

As it stands, the summary process allows generic producers to challenge patents and start marketing their own products before innovators' patents expire.

However, when generics are successful, the system effectively denies innovators a right of appeal by forcing the minister of Health to immediately approve the generic drug.

Instead of appealing, innovators must turn to the Federal Court of Canada, where they can launch a patent infringement action against the generic producer.

"The whole process starts again, and now you've got two sets of proceedings dealing with the same issues," Foster says.

Bill C-30 proposes "full actions that will result in final determinations of patent infringement and validity" to replace the current summary proceedings held under the PM(NOC) Regulations.

"Having these two routes was putting too much of a burden on the court," Foster says. **LT**