NORTON ROSE FULBRIGHT

Pharma in brief - Canada

Top headlines of 2016

Summary

Happy New Year from Pharma in Brief!

Pharma in Brief reported on many legal and regulatory developments of interest to the pharmaceutical industry in 2016. Looking back on 2016 as the new year begins, we have compiled our list of the past year's top headlines below. These include, in no particular order, key developments that affect the pharmaceutical industry and we will continue to monitor in 2017.

Top headlines of 2016

Canada signs on to CETA. On October 30, Canadian and European Union leaders signed the Comprehensive Economic and Trade Agreement (**CETA**). On October 31, the Canadian government tabled Bill C-30, which is intended to implement CETA into Canadian law. Bill C-30 provides for certificates of supplementary protection for patents relating to pharmaceutical products and for proceedings under the *Patented Medicines (Notice of Compliance) Regulations* (***Regulations***) to proceed as full actions that will result in final determinations of patent infringement and validity.

Utility and the promise of the patent were front and center in patent cases again in 2016. In September, two back-to-back Federal Court of Appeal (**FCA**) decisions affirmed that the "promise" doctrine will hold an inventor to an elevated standard of utility "only where a clear and unambiguous promise has been made" and that where validity is challenged on the basis of an unfulfilled promise, the patent will be construed in favour of the patentee if it can reasonably be read to exclude the promise. We await further guidance on these important issues from the Supreme Court following the hearing regarding esomeprazole (AstraZeneca's NEXIUM®) on November 8. We also await the ruling in the Eli Lilly NAFTA matter, following the hearing regarding several Eli Lilly products that was held May 30 – June 8.

New guidance document for biosimilars. Health Canada released a revised guidance document on the approval pathway for biosimilar biologic drugs in December, which includes new guidelines for selecting reference biologics, satisfying the scientific review requirements of the Biologics and Genetic Therapies Directorate, labelling, and post-market considerations. Health Canada also released a revised fact sheet with a section on drug and patient access.

PMPRB litigation. The role and powers of the Patented Medicine Prices Review Board were at issue in a number of proceedings in 2016, including the PMPRB's jurisdiction over generic products, the constitutionality of the excessive pricing provisions of the *Patent Act*, and the PMPRB's excessive pricing guidelines.

Generics permitted to rely on cross-referenced submission. The FCA held that generic manufacturers could rely on cross-referenced submissions without addressing relevant patents on the Patent Register. Following the release of the FCA's decision, Health Canada provided notice that the decision will affect the application of section 5 of the *Regulations* with respect to administrative drug submissions. Janssen has filed for leave to appeal the FCA decision with the Supreme Court of Canada.

Apotex sues Canada for $500 million. Following two successful challenges to the Minister of Health's import ban on certain Apotex drug products, Apotex sued the federal government for $500 million in general, special, aggravated and punitive damages.

Double patenting. The FCA issued two decisions on double-patenting in 2016 relating to tadalafil (Eli Lilly's CIALIS®). In the first, the FCA offered some welcome guidance on the issue, including the distinction between obviousness and obviousness-type double patenting, and a consideration of the relevant date. In the second, the FCA raised new questions regarding the relevant date.

Meaningful costs in patent cases. Over the last year, the Federal Court has granted costs awards that are more reflective of the actual cost and complexity of patent cases in at least six decisions. The court also introduced new guidelines for the case management of applications under the *Regulations* that emphasize early scheduling, strict time management, narrowing of issues, and limiting the amount of material to be reviewed by hearing judges.

Section 8 damages. The FCA issued two important decisions regarding section 8 of the *Regulations* in 2016. In June, the FCA set aside a section 8 decision regarding venlafaxine hydrochloride (Pfizer's EFFEXOR XR®) over hearsay evidence relating to Teva's ability to manufacture and sell its generic venlafaxine hydrochloride product in the hypothetical world. In July, in an appeal relating to omeprazole (AstraZeneca's LOSEC®), the FCA considered the impact of a successful infringement judgement on a prior order for section 8 damages, and affirmed that it is for the judge hearing the infringement action to ensure a party is not under- or overcompensated.

Regulation of self-care products. Health Canada is proposing to change the way that it regulates non-prescription drugs, natural health products and cosmetics, which will now be referred to collectively as "self-care products." Health Canada published a consultation paper that seeks to combine the separate regulatory frameworks for each of these products into one regulatory framework.

FCA harmonizes standard of review. In September the FCA released an important decision after sitting in a panel of five for the first time in 23 years. The court unanimously confirmed that there is a single standard of review for all appeals from discretionary orders of prothonotaries and motion judges, including on further appeal to the Court of Appeal. Factual determinations are reviewable for palpable and overriding errors, while questions of law are reviewable for correctness.

For more information, please contact your IP/Life sciences or healthcare practice professional at Norton Rose Fulbright Canada LLP.

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