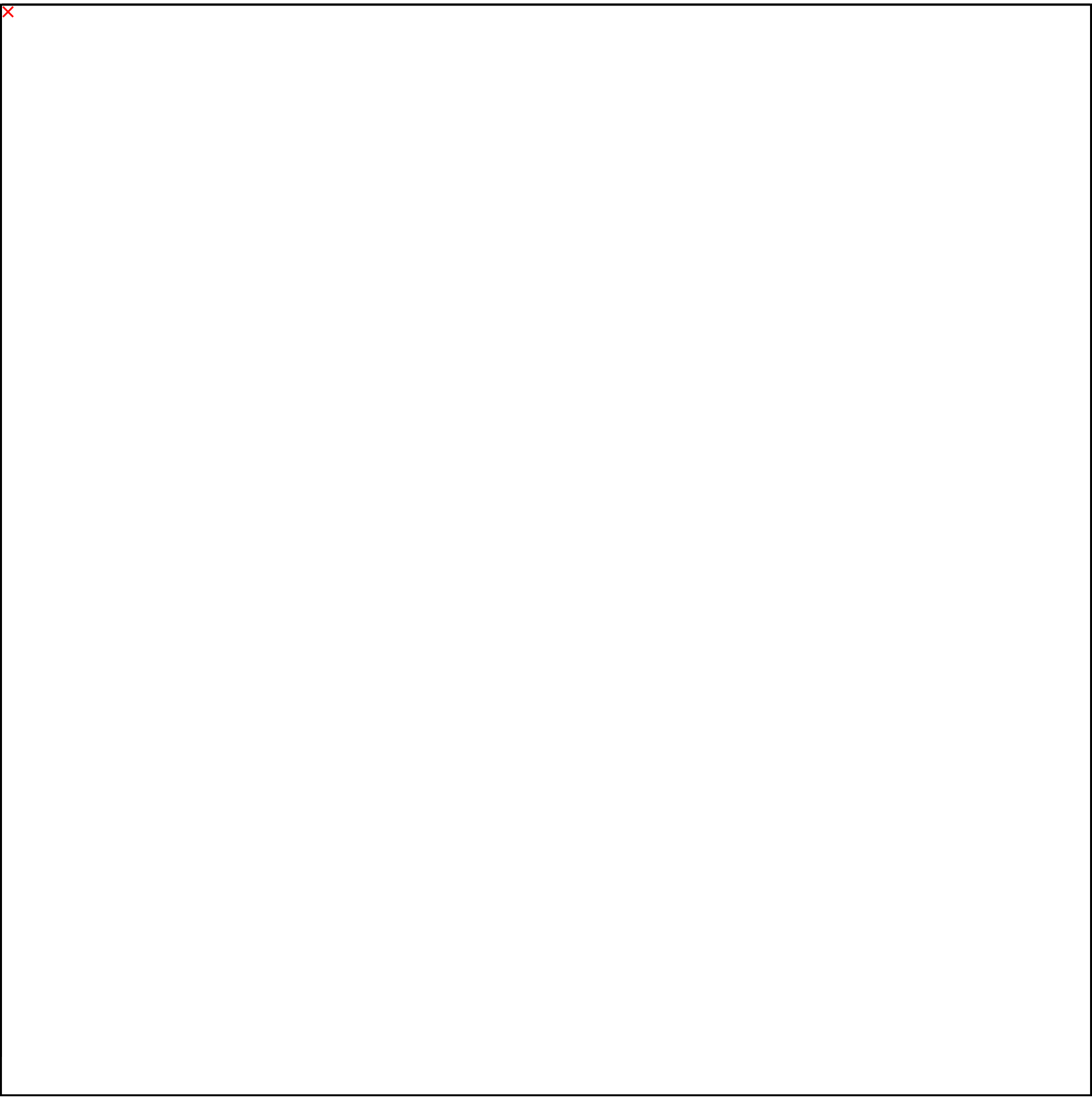

We Promise that it is Still Worthwhile to File Pharma Patents in Canada

Nov 10, 2016

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The "promise doctrine" is getting a lot of press in the pharma industry. We know that some big pharma companies are ticked off, for example, from Eli Lilly launching a NAFTA claim against the Canadian government over invalidated patents for atomoxetine and olanzapine. A recent survey sponsored by the brand name pharma association says that the weakening patent environment in Canada is hitting Canadian R&D in the pocketbook.

Is it really that bad? Let's take a high level look at the patent landscape in the Great White North.

Granted, the reemergence of the promise doctrine has Canadian patent attorneys scratching their heads as to the applicability and scope of the doctrine. It has provided a field day for generic companies challenging patents – but they have won some cases and lost others – it is not open season on pharma patents in Canada. Examples of cases where brand-name drug company patents were found valid in spite of generic challenges based on promise doctrine include cases for clopidogrel sulfate[1] (the blockbuster drug Plavix) and celcoxib[2] (the blockbuster drug Celebrex).

The promise doctrine issue was just on the table at the Supreme Court of Canada[3] in an oral hearing held November 8, 2016 as part of an appeal to our highest court. There should be a judgment next year providing clarity on fundamental issues such as whether there should even be a promise doctrine, and, if so, what would be the scope.

CIPO has also been making life difficult for certain diagnostics inventions, by following the US lead and making objections to certain types of diagnostic inventions as not being patentable subject matter. Many pharmaceutical products have companion diagnostics, so patenting diagnostic invention is important for pharmaceutical companies. CIPO's position is not properly based on case law, so it remains to be seen if CIPO's position will hold up to a future appeal to a court.

In the meantime, the patent environment for innovative companies in Canada still has many benefits, such as "linkage regulations." The US has linkage regulations (Orange Book, ANDA proceedings etc), but the EU does not have such regulations. So Canada is ahead of Europe on that important issue of proactive patent enforcement. One can easily judge the up-side of these linkage regulations to brand name pharma merely by how they have made the Canadian generic industry association apoplectic for over two decades.

The Canadian government also just introduced a new Bill that provides for patent term extension. So, even though a brand-name industry funded survey indicates that morale and research dollars are down, companies keeping their eye on the ball know that it's still a pretty darn good environment in Canada to file patents AND do R&D.

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1 *Sanofi-Aventis* v. *Apotex Inc.,* 2013 FCA 186

2 *Apotex Inc. v. Pfizer Canada Inc* , 2014 FCA 250

3 *AstraZeneca Canada Inc. v. Apotex Inc*., 2015 FCA 158.