

Congress of the United States
Washington, DC 20515

April 10, 2014

The Honorable Michael Froman
United States Trade Representative
600 17th Street NW
Washington, DC 20508

Dear Ambassador Froman,

We are writing to express our strong concerns about the lack of adequate and effective intellectual property (IP) rights in Canada. We are particularly troubled by Canada's application of internationally inconsistent patent standards, which appears to violate their international obligations and are having real economic consequences for innovative American companies. While we appreciate that USTR expressed serious concern about these practices in last year's Special 301 report, given Canada's continued failure to bring its patent standards in line with international obligations and best practices, we urge you to elevate Canada to the Special 301 Priority Watch List in 2014.

IP is one of the main engines of the United States' innovative economy. Approximately one third of U.S. jobs and 60 percent of our exports rely on IP. With more than 95 percent of the world's population living outside of the United States, strong IP protections are therefore essential to U.S. growth and competitiveness.

Unfortunately, we believe that Canadian courts have significantly weakened patent standards through a unique misinterpretation of the internationally accepted utility standard, directly harming the competitiveness and economic growth of U.S. innovators. This patent utility standard is inconsistent with Canada's international trade obligations, including the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), of which both Canada and the United States are parties. Under these obligations, an invention has "utility" if it is "useful" or "capable of industrial application." However, in order to establish utility, Canadian courts are sometimes requiring evidence more appropriately considered in the regulatory approval phase of drug development. Further, they will not consider evidence developed and submitted after the filing date of the patent application to determine utility.

This new and unique interpretation has so far resulted in 18 revoked patents for innovative medicines on the basis that they are not "useful." This has occurred after these drugs had been approved by the Canadian health regulatory agency as safe and effective and are in wide use by patients in Canada. No other country has denied or revoked patents on any of these 18 medicines on these grounds, and, perhaps most egregiously, we understand that the companies in Canada that have sought to have these patents revoked on the basis that they are not "useful" are now marketing the very same supposedly not useful medicines to patients themselves. Innovative American companies undertake substantial financial risks on clinical drug development, and Canada's patent utility standard discourages the investment of the

significant resources necessary to develop new medicines, negatively affecting the patients and families who rely upon innovative cures and treatments.

Canada's actions are in violation of their international obligations and are undermining the intellectual property environment upon which innovation rests. We urge you to use all tools available to address these concerns with Canada, including by elevating Canada to the Priority Watch List in the 2014 Special 301 report. Thank you for your service and for your time and consideration of this matter.

Sincerely,


Todd Young
Member of Congress


Bill Pascrell
Member of Congress


Pat Tiberi
Member of Congress


Richard Neal
Member of Congress

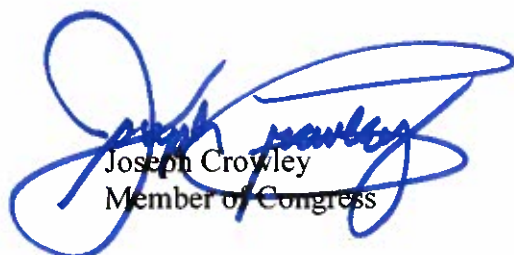

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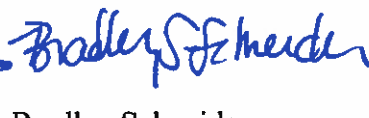
Derek Kilmer
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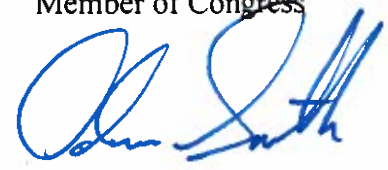
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