



KINGDOM OF BELGIUM
Federal Public Service
**Foreign Affairs,
Foreign Trade and
Development Cooperation**

Ref: B(2016)2894204692/06/2016
Direction générale des Affaires européennes

Your contact person:
Attaché
Tel: [Art.4(1)(b)] Fax:
E-mail: [Art.4(1)(b)] @diplobel.fed.be

Ms. Cecilia MALMSTRÖM
Commissioner for Trade
European Commission
Rue de la Loi 200
1049 BRUSSELS

your communication of your reference

our reference

DGE-E5/[Art.4(1)(b)]/EUR 0504

To be quoted in all correspondence

date

17 JUNI 2016

Subject: Protection of Intellectual Property Rights (IPR) for pharmaceuticals in CETA.

Madam Commissioner,
Dear Cecilia,

As one of the key achievements of the EU-Canada Comprehensive Economic and Trade Agreement (CETA), the Commission created a unique opportunity to improve the protection of Intellectual Property Rights (IPR), a crucial offensive interest for the EU. During the negotiations, European fabricants of brand pharmaceutical products asked for the right to appeal in patent linkage proceedings, a right already granted by the Canadian authorities to generic drug manufacturers.

Given the important economic contribution of the pharmaceutical sector in Belgium, I have welcomed the European Commission's efforts to address this asymmetrical treatment of EU innovators during the CETA negotiations, resulting in a higher IPR protection by giving all litigants (generic drug manufacturers as well as patent holders) an equivalent and effective right to appeal (I refer particularly to the "article 20.8 of the Intellectual Property" chapter, covering patent linkage mechanisms relating to pharmaceutical products).

The previous Federal Government of Canada stated that the CETA provisions gave scope to end the current practice of "dual litigation". This practice refers to a situation that can arise when a generic drug producer in Canada wins a proceeding under Canada's patent linkage regime, and the innovator then subsequently sues the generic producer for monetary damages in a separate infringement action. Canadian generic producers argue indeed that they should not have to address infringement actions in the event that they win the patent invalidity proceeding.

The purpose of having a right to appeal for innovators was however to rebalance the existing discrimination and has nothing to do with ending the practice of "dual litigation", which could remove the right of innovators to enforce their patents using patent infringement proceedings. This could possibly undermine the concession related to the right of appeal negotiated by the European Commission. Under the current Canadian system, generic drug manufacturers can appeal their linkage cases but can also impeach innovator patents under the Patent Acts, and therefore also engage in "dual litigation". Adding a right to appeal for innovators would redress the existing imbalance in rights, but forcing innovators to choose between a linkage appeal and patent infringement would paradoxically result in ending an old discrimination only to create a new one.

I note that so far the new Canadian Federal Government has yet to clarify its intentions on this issue and that this ambiguity is already the source of preoccupations in the pharmaceutical sector.

To prevent in due time any initiative undermining the achievement of CETA in rebalancing IPR-protection for the European innovators, I would therefore plead to you for a high-level initiative of the European Commission with the Canadian authorities to clarify our understanding of CETA progress in terms of IPR and safeguard the interests of our pharmaceutical innovators. Time being of the essence, this clarification should take place before the signature of the agreement.

Yours sincerely,

[Art.4(1)(b)]

Didier REYNDERS

