

**Question for written answer E-001827/2014
to the Commission**

Rule 117

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Subject: EU-Canada Comprehensive Economic and Trade Agreement: levelling the playing field for the life sciences industry

An agreement in principle on the key elements of the Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada was reached on 18 October 2013. This agreement is the first that the EU will be signing with a G8 nation and marks a precedent for other free trade agreements that the EU is negotiating.

One of the objectives of the negotiations on the EU side was to level the playing field between the EU and Canada on intellectual property rights (IPRs) in the life sciences sector, including enforcement of patent rights. The lack of an effective right of appeal for innovators in Canadian patent invalidity proceedings means that they do not have the same level of recourse as generic companies. This amounts to a significant inequality between the legal rights applicable to innovators and generics in Canada.

In its 'Technical Summary of Final Negotiated Outcomes' on the CETA released on 29 October 2013, the Canadian Government publicly indicated that it had agreed to restore fairness to this procedure by granting innovative manufacturers an effective right of appeal within the Canadian regulatory framework. However, it further stated that this would provide 'scope for Canada to end the practice of dual litigation'.

The EU's objective in seeking an effective right of appeal for innovators was to rebalance the existing discrimination within the Canadian system. It had nothing to do with ending 'dual litigation', which could mean compounding the present imbalance in rights by removing or diminishing the existing legal rights of patent holders. Canada's actions in relation to 'dual litigation' could in fact nullify or weaken the concession made to the EU related to the right of appeal.

1. Has the Commission enquired about the plans of the Government of Canada regarding its publicly stated ambition to end the practice of 'dual litigation', and, if so, how has Canada responded?
2. Even if Canada may claim that ending 'dual litigation' is a matter of domestic law and policy, does the Commission not think that it affects the outcome on right of appeal, and thus the broader 'level playing field' negotiated by the Commission in CETA?
3. Is the Commission seeking assurances from Canada that an effective right of appeal for innovators will be implemented without removing or diminishing any other existing rights of innovators regarding the enforcement of their patents?