Amendment 1

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Report

Dolors Montserrat
A pharmaceutical strategy for Europe
(2021/2013(INI)

Motion for a resolution
Paragraph 163

163. Notes that patent protection is a key incentive for companies to invest in innovation and produce new medicines; notes, at the same time, that the exclusionary effect of patents may lead to limited market supply and reduced access to medicines and pharmaceutical products; stresses that a balance should be struck between encouraging innovation through the exclusionary effect of patents and ensuring access to medicines and protecting public health; recalls that a company that markets a medicine can enjoy data exclusivity for a period of eight years as of the first marketing authorisation pursuant to Article 14(11) of Regulation (EC) No 726/2004; calls on the Commission to propose a revision of that regulation to provide for the possibility of

Amendment

163. Notes that patent protection should be a key incentive for companies to invest in innovation and produce new medicines; notes, at the same time, that the exclusionary effect of patents may lead to limited market supply and reduced access to medicines and pharmaceutical products; stresses that a balance should be struck between encouraging innovation through the exclusionary effect of patents and ensuring access to medicines and protecting public health; recalls that a company that markets a medicine can enjoy data exclusivity for a period of eight years as of the first marketing authorisation pursuant to Article 14(11) of Regulation (EC) No 726/2004; calls on the Commission to propose a revision of that regulation to facilitate the granting of
temporarily authorising the granting of compulsory licences in the event of a health crisis in order to allow for the production of generic versions of life-saving medicines; recalls that this is one of the public health flexibilities in the field of patent protection already included in the WTO’s TRIPS Agreement, as further reaffirmed by the 2001 Doha Declaration; calls on the Commission to ensure that the implementation of EU free trade agreements (FTAs) does not interfere with the possibility of invoking flexibilities provided by the TRIPS Agreement and to provide guidance to Member States in order to encourage voluntary licensing over immediate compulsory licensing; stresses that FTAs should not focus exclusively on enforcing intellectual property standards in third countries, but should take into account the impact on generic and biosimilar medicines in the EU and in third countries, as well as ensure coordination of regulatory standards; compulsory licences and allow for the production of generic versions of life-saving medicines; recalls that this is one of the public health flexibilities in the field of patent protection already included in the WTO’s TRIPS Agreement, as reinforced by the 2001 Doha Declaration; calls on the Commission to ensure that the implementation of EU free trade agreements (FTAs) does not interfere with the possibility of invoking flexibilities provided by the TRIPS Agreement and to provide guidance to Member States in order to encourage compulsory and voluntary licensing; stresses that FTAs should not focus exclusively on enforcing intellectual property standards in third countries, but should take into account the impact on generic and biosimilar medicines in the EU and in third countries, as well as ensure coordination of regulatory standards;