

Brazil's Federal Court Reviews Medicines Mailbox Patents

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This week the media [reported](#) that the Brazilian federal court removed the patent protection for eculizumab, sold under the brand name Soliris by Alexion Pharmaceuticals Inc. Eculizumab is used in the treatment of [paroxysmal nocturnal hemoglobinuria \(PNH\)](#), a rare and life-threatening blood disease. The product was [approved by the US FDA](#) for this indication in 2016. Brazil's health care system spent \$184.2 million to treat 442 patients with Soliris, an average of over \$416,000 per patient. The ruling of the federal court may affect more pharmaceutical mailbox patents. This blog explains why this is.

When the World Trade Organization (WTO) was created, and the TRIPS Agreement went into force on 1 January 1995, Brazil did not grant patents for pharmaceuticals. Therefore Brazil could make use of a transitional flexibility in the TRIPS Agreement that allowed developing countries not yet granting medicines patents to delay the granting of patents until 1 January 2005. TRIPS (Article 70.8), however, did require countries that made use of this transition flexibility to provide a mailbox in which would-be patent holders could file their patent applications from 1 January 1995 onwards. Brazil had such a mailbox, which was maintained until May 1997 when Brazil's new TRIPS-compliant patent law went into force and the National Institute of Industrial Property (INPI), the Brazilian patent office, started to grant pharmaceutical patents. Brazilian patent law (Article 40) prescribes that the patent term shall be 20 years for inventions. The patent term was set to be 20 years from filing and not less than 10 years from the date of grant. This minimum 10-year protection is not required by TRIPS and was included to cover instances where the INPI would take more than 10 years to examine and grant a patent. The 10-year minimum did not extend to mailbox patents; however, INPI has been granting mailbox patents with a ten-year duration since 1997 even though this was not required. Hence, patent PI 9507594 claiming eculizumab granted on 10 August 2010 was due to expire 10 years later.

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In 2013, the head of INPI published a brief confirming that the term of the mailbox patent should be 20 years from the date of filing and that there was no minimum term. A court decision of June 2015 then established that the patent on eculizumab had expired on 1 May 2015, 20 year from the filing date. Although companies had been seeking 10 year patent terms from grant of the patent, the Brazilian courts have now confirmed that this minimum term is not available for mailbox patent applications made before the entering into force of the Brazil patent law. The mailbox patent term clock starts to tick from date of filing not from date of grant. INPI then moved to seek correction of mailbox patent terms or revocation of mailbox patents at the Brazil court. The Brazil patent office expects that more corrections to patent term mailbox patents may follow.

The court's decision was reported erroneously by some media as a compulsory license. That it is not, but the decision to correct the term of protection is expected to open the door for biogenerics (biosimilars) of the product. Just like a compulsory licence would have done.