

Biosimilars Around the World

Last month's Supreme Court ruling in *Sandoz v. Amgen* brought greater certainty to both biosimilar applicants and originators in the United States. The July 2017 issue of Sterne Kessler's Global Patent Prosecution Newsletter includes information on worldwide biosimilar approvals and their global uptake, with a focus on the US, Europe, and Japan.

Sterne Kessler's Global Patent Prosecution Newsletter is designed to help meet the needs of biotech/pharmaceutical companies regarding global patent prosecution strategies. For more information, please contact [Paul Calvo](#) or [John Covert](#). If you wish to unsubscribe from this and other newsletters, please click on the unsubscribe link below.

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You Can Dance If You Want To

By: [Paul A. Calvo, Ph.D.](#), [Timothy J. Shea](#), and [Paul A. Ainsworth](#)

In borrowing a page from the '80s band "Men Without Hats," on June 12, 2017, the U.S. Supreme Court brought greater certainty for both biosimilar applicants and originator companies.

In *Sandoz Inc. v. Amgen Inc.*, the Supreme Court ruled on two key issues relating to the "patent dance" under the Biologics Price Competition and Innovation Act (BPCIA).

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Biosimilars in Europe

By: [Paul A. Calvo, Ph.D.](#)

Europe has led the way globally with respect to biosimilar medicines since 2005. In that year, the European Medicines Agency (EMA) issued regulatory guidelines for the development and assessment of biosimilars.

Their initial overarching biosimilar guidelines were recently updated in 2014.[1] Large portions of these EMA guidelines have been adopted by countries around the world, including: Australia, New Zealand, Canada, Japan, Korea, Singapore, South Africa and Switzerland.

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Biosimilar Uptake and Patent Litigation in Japan

By: [Paul A. Calvo, Ph.D.](#)

Biosimilar uptake in Japan has been a bit mixed, but according to experts the volume shares of biosimilars suggests it could be a key market in years to come.[1]

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Approved Biosimilar Products Around The World

Product name	Active substance	Therapeutic area	Authorization date	Manufacturer/ Company name
Abasaglar (previously Abasria)	insulin glargine	Diabetes	9 Sep 2014	Eli Lilly/Boehringer Ingelheim
Abseamed	epoetin alfa	Anaemia Cancer Chronic kidney failure	28 Aug 2007	Medice Arzneimittel Pütter

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