Press release dated November 12, 2020

Daiichi Sankyo successfully defends itself against an early market entry of generic competitors

The Japanese pharmaceutical company Daiichi Sankyo successfully defended itself against the early market entry of generic competitive products for its successful pharmaceutical product Sevikar®.

The companies ratiopharm and TAD pharma (a company of the Slovenian KrKA group) had attempted to launch generic competitive products prior to the expiry of the effective terms of protection for Sevikar®. They used their own non-generic marketing authorizations for a pharmaceutical product as a basis, which, however, directly referred to documents and data that Daiichi Sankyo had submitted to the competent authorities in the context of the marketing authorizations for Sevikar®. Pursuant to Sec. 24b (1) German Medicinal Products Act, these documents and this data are protected against being used as reference for a limited time. Specifically, among other things, a pharmaceutical product, the marketing authorization of which refers to the documents of a reference pharmaceutical product, must not be put into circulation before a term of 10 years has expired since the first marketing authorization of the reference pharmaceutical was granted (market exclusivity). The authority in charge of examining the marketing authorizations of TAD Pharma and ratiopharm, the German Federal Institute for Drugs and Medical Devices (BfArM), had granted the non-generic marketing authorizations before the terms of protection expired. Daiichi Sankyo filed oppositions against the grant of the marketing authorization with the German Federal Institute for Drugs and Medical Devices. The German Federal Institute for Drugs and Medical Devices confirmed the suspensive effect related thereto on the concerned marketing authorizations of TAD Pharma and ratiopharm. The ineffectiveness of the marketing authorizations until the terms of protection of Sevika® expired was confirmed in subsequent preliminary proceedings for legal protection by both the Administrative Court of Cologne and the Higher Administrative Court of the German federal state of North Rhine-Westphalia. In response, the German Federal Institute for Drugs and Medical Devices withdrew the respective marketing authorizations of ratiopharm and TAD until the terms of protection of Sevikar® expires.

TAD Pharma sought a final clarification by way of a complaint for the continuation of the proceedings on the merit seeking a declaratory finding. Now, the Administrative Court of Cologne confirmed the lawfulness of the temporary withdrawal of the marketing authorizations. TAD Pharma may appeal the decision.

BARDEHLE PAGENBERG

Prinzregentenplatz 7
81675 Munich, Germany
T +49.(0)89.928 05-0
F +49.(0)89.928 05-444
info@bardehle.de
www.bardehle.com

BARDEHLE PAGENBERG
Partnerschaft mbB
Patentanwälte Rechtsanwälte
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Daiichi Sankyo has actively defended and enforced its intellectual property rights for Sevikar® against competitors over the past few years. This was initially achieved based on effective patent protection, after its expiry by way of corresponding supplementary certificate of protection, and, in parallel as well as after the expiry, by way of the protection of documents under pharmaceuticals law.

Representatives of Daiichi Sankyo: BARDEHLE PAGENBERG (Munich)
Johannes Heselberger (Attorney-at-Law & European Patent Attorney, Partner)
Dr. Axel Berger (Patent Attorney, European Patent Attorney, Partner)

Sträter Rechtsanwälte: Prof. Burkhard Sträter

Private expert: Dr. Ulrich Patzak

Daiichi Sankyo Co., Ltd., Inhouse:
Koki Ishibashi, Tomoki Echigo (IP department)

Daiichi Sankyo Europe GmbH, Inhouse:
Martin Fürle (General Counsel), Andrea Witt (Regulatory Affairs)

Representatives of TAD Pharma: Noerr
Dr. Ralph Nack, Dr. Armin Kühne

Representatives of Ratiopharm: Simmons & Simmons
Caroline von Nussbaum

Administrative Court of Cologne, 7th Chamber:
Andreas Fleischfresser (presiding judge)

BARDEHLE PAGENBERG combines the professional expertise of attorneys-at-law, patent attorneys, professional representatives before the European Patent Office, specialized trademark lawyers and qualified technical consultants. Our consulting services are tailored to our clients' individual needs and the specific circumstances of each case.

Follow us on Twitter: https://twitter.com/bardehleIP

Press contact:

Gabriela Tröger
Marketing & PR
Prinzregentenplatz 7
81675 Munich, Germany

T +49.(0)89.928 05-0
F +49.(0)89.928 05-444
gabriela.troeger@bardehle.de
www.bardehle.com