



Dr med Kokularajah Paheenthararajah

Senior Associate

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Kokularajah Paheenthararajah advises clients on complex cross-border patent disputes (infringement litigation as well as in nullity proceedings) with a particular focus on Life Sciences (biotechnology, pharmaceuticals and medical devices). He also regularly advises on regulatory and product liability defense in the Life Sciences Sector.

Kokularajah is admitted as a lawyer as well as a physician in Germany.

LANGUAGES SPOKEN

- English
- German

EXPERIENCE

- Advising and representing a global pharmaceutical company in enforcing its "Second Medical Use" patent for its neuropathic pain blockbuster
- Advising a global pharmaceutical company on the experimental use privilege (Roche-Bolar exemption) in connection with Phase-III clinical trials on a novel bi-specific monoclonal antibody for the treatment of a hematologic disease
- Advising and representing a global pharmaceutical company on a PD-1 inhibitor (monoclonal antibody) for the immunotherapy of cancers
- Advising a leading scientist on licensing issues related to a recombinant pharmaceutical for the treatment of a hematologic disease
- Advising and representing a global medical devices company in enforcing its patent on DNA amplification and sequencing
- Advising and representing a global diagnostics company on an immunologic test for early detection of pre-eclampsia/HELLP-syndrome (gestosis)
- Ongoing advice of a global pharmaceutical company on compliance, anti-corruption, cooperation with hospitals and physicians, clinical trials and professional codes of physicians

RELATED SERVICES

- Patent Litigation
- Patent Prosecution and Strategic Patent Counseling

RELATED SECTORS

- Life Sciences
- Technology

LANGUAGES SPOKEN

English German

CREDENTIALS

Prior Experience

Prior to joining the Cologne office of DLA Piper in October 2017, Kokularajah worked as a lawyer at a leading international patent litigation and life sciences practice of a Magic Circle law firm in Munich (2014-2017). Before that, he worked as a legal assistant at the litigation and life sciences practice of another Magic Circle law firm (2006-2014).

Education

- University of Cologne, Ph. D. (Medicine), 2014
- Higher Regional Court of Cologne, Second State Examination (Law), 2014
- University Hospital Cologne / University of Cologne, Second State Examination (Medicine), 2012
- University of Cologne, First State Examination (Medicine), 2008
- University of Cologne, First State Examination (Law), 2006

Life Sciences Know-how

Kokularajah received additional medical training for physicians, inter alia, at the University Hospital Cologne, King's College London and St. John's Medical College Bangalore. For his medical doctoral thesis Kokularajah received the Doctoral Dissertation Award of the Medical Faculty of the University of Cologne.

Kokularajah is registered as a physician (Arzt) with the Bezirksregierung Cologne.

INSIGHTS

Publications

Germany's push towards Healthcare 4.0 – A guide to the new fast-track pathway to reimbursement for digital health apps

6 January 2020

The Internet of Medical Things (IoMT) continues to be one of the hottest topics in the global life sciences and healthcare industry. The new German Digital Healthcare Act (*DHA – Digitale-Versorgung-Gesetz/DVG*) entered into force on December 19, 2019. This legislation massively pushes Germany towards Healthcare 4.0 and may usher in an era of great opportunities: not only for traditional players in the life sciences and healthcare market, but also for newcomers to this sector, including tech giants, tech startups and data-driven enterprises.

Biomarker-based cancer diagnostics: German pricing regulator sets high validation and reimbursement standards for novel diagnostic methods

10 July 2019

On 20 June 2019, for the first time, the German Federal Joint Committee (FJC – Gemeinsamer Bundesausschuss / G-BA), the highest decision-making body of the joint self-government of physicians, dentists, hospitals and statutory health insurance funds (SHI – gesetzliche Krankenversicherung / GKV) in Germany, made the resolution that a specific biomarker-based test to support the treatment decision for or against adjuvant chemotherapy, i. e. after primary surgery, in certain breast cancer patients may be reimbursed by the SHIs.

Medical cannabis: An analysis of the landmark decision of the Düsseldorf Higher Regional Court stopping the

import and sales of cannabis extracts for medical purposes without marketing authorization

15 MAY 2019

In a landmark preliminary injunction of 2 August 2018 (docket no. 15 U 21/18), the Düsseldorf Higher Regional Court ruled that, under the circumstances of the individual case, a medical cannabis product may, due to the way it is objectively presented, trigger the marketing authorization requirement for so-called "*finished medicinal products*" ("*Fertigarzneimittel*"). This may particularly be the case if the product, in its specific form, can objectively be used as a *finished medicinal product*, even though it is only intended as a component for the manufacture of *magistral medicinal preparations* ("*Rezepturarzneimittel*") in pharmacies. As a consequence, the placing of such a cannabis product on the German market may be prohibited as an unfair competition practice in case there is no marketing authorization for the specific product in place.

The infringement of second-medical-use patents

15 MAY 2018

In its two recent decisions, the Düsseldorf Higher Regional Court redefined the requirements for the infringement of second-medical-use patents. Besides the cases of "'purposeful preparation'" of a medicament for the protected use, now, a direct infringement also "'in some other way'" may be considered if the medicament is objectively suitable for the patented use and the supplier takes advantage of external circumstances, which ensure that the offered medicament is used for the patented purpose. Thus, the recent case law increases liability risks for the infringement of secondmedical- use patents.

- Cegl/Paheenthararajah, "The enforcement of second-medical-use patents after the "estrogen blocker" [Östrogenblocker] decision of the Higher Regional Court Düsseldorf", GRUR-Prax 2018, 225-227
- Paheenthararajah/Karenberg/Hick/Rothschild, "Medical sales representatives in the operating theatre: legal risks and medical-ethical conflicts," *MedR*, 2014, Volume 32, Issue 1, pp 7-17
- Paheenthararajah/Karenberg/Hick, "Medical sales representatives in the operating theatre: patients' informed consent required," *Dtsch Arztebl*, 2013; 110(46): A-2190 / B-1927 / C-1872
- Bellinghausen/Paheenthararajah, "Counter attack: Action for damages versus US plaintiffs' attorneys for taking obviously abusive US class actions versus German companies," *ZIP*, 2008, 492-497