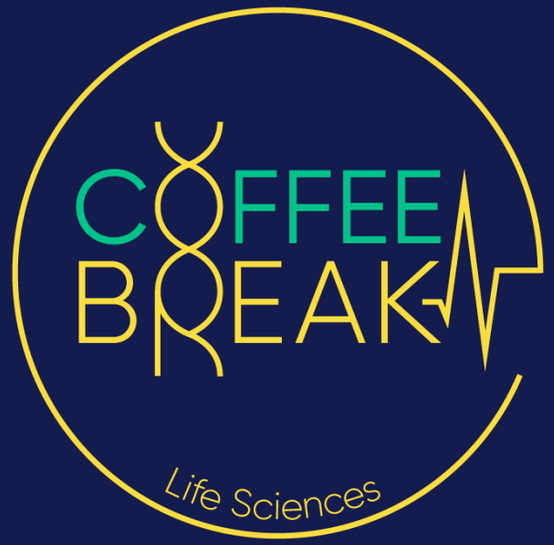

TaylorWessing

Session #4

Webinar

16.04.2025

COFFEE BREAK Life Sciences

TaylorWessing

Unfair competition law consequences of inaccurate risk classification of medical devices

16 April 2025 | Dr. Daniel Tietjen

Agenda

1 Overview: Conformity assessment & risk classification of a medical device

Conformity assessment & risk classification of a medical device

Conformity assessment as a requirement for placing on the market according to Art. 5 MDR

- The **conformity assessment** is based on the risk classification, Art. 52 MDR
- The **risk classification** is based on the intended purpose of the product, Art. 52 para. 1 MDR
- The **'intended purpose'** means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation, Art. 12 No. 12 MDR

Risk classification according to the MDR:

Class I	Low risk potential →	Manufacturer can declare conformity himself
Class IIa	Medium risk potential	Conformity assessment requires the involvement of a notified body
Class IIb	Increased risk potential	
Class III	High risk potential	

2 | OLG Hamburg, judgement of 20 June 2024, ref. 3 U 3/24 – *Risk classification of a health app*

OLG Hamburg, judgement of 20 June 2024,
ref. 3 U 3/24 – *Risk classification of a health app* [I]

Decision of the court:

The app in question, which is intended for the

"asynchronous examination of skin changes by means of recording, storing, displaying and transmitting digital images of the affected skin areas, as well as answering an anamnesis questionnaire and communicating (via chat) with medical specialists"

must not be made available on the market unless it is certified as a **class IIa, IIb or III** medical device in accordance with **classification rule 11, annex VIII MDR**.

Background:

- Competition law proceedings between two companies that offer health apps on the market (Dermanostic and Onlinedoctor)
- Respondent in the action has classified her health app as a class I medical device according to the MDR and therefore CE certified it herself without involving a notified body

OLG Hamburg, judgement of 20 June 2024,
ref. 3 U 3/24 – *Risk classification of a health app* [II]

Functionality of the app in question:

- Patients with skin conditions send dermatologists:
  - ✓ photographs of the affected skin and
  - ✓ an anamnesis questionnaire to be completed by the patient
- The anamnesis questionnaire varies according to the respective skin problem, which the patient specifies from a selection provide by the app
- Based on the information provided, the patient receives a medical diagnosis – not synchronised – along with treatment suggestions and prescription if necessary

OLG Hamburg, judgement of 20 June 2024,
ref. 3 U 3/24 – *Risk classification of a health app* [III]

Risk classification of software – classification rule 11, annex VIII MDR:

*Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as **class IIa**, except if such decisions have an impact that may cause:*

- *death or an irreversible deterioration of a person's state of health, in which case it is in **class III**; or*
- *a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as **class IIb**.*

*Software intended to monitor physiological processes is classified as **class IIa**, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as **class IIb**.*

*All other software is classified as **class I**.*

OLG Hamburg, judgement of 20 June 2024,
ref. 3 U 3/24 – *Risk classification of a health app* [IV]

Interpretation of the term "provide" by the OLG Hamburg:

- The software itself must not create diagnoses or generate, produce, create or manufacture information by, for example, undertaking its own evaluation/analysis or assessment of the communicated, measured or photographed data and images

- Software also provides the result of a structured collection of medical data if, after its programming, the patient's own diagnostic decision – in form of his answers – influences the questions asked in the context of anamnesis and thus the information given to the doctor

- Sufficient, if the software intervenes and influences the diagnostic process

- A restrictive interpretation of the wording is not appropriate in view of the high level of protection of the health for patients and users that the MDR is intended to achieve

OLG Hamburg, judgement of 20 June 2024,
ref. 3 U 3/24 – *Risk classification of a health app* [V]

Key takeaway:

- Asynchronous telemedicine software must also be certified as a **class IIa** medical device if it does not collect its own data to make a medical diagnosis, but instead transmits patient data in a structured manner

- Medical devices that have undergone the wrong conformity assessment procedure as a result of inaccurate classification:
  - ✓ do not meet the requirements of the MDR and
  - ✓ are subject to the prohibition of placing on the market and putting into service of **Art. 5 MDR**

- **Classification rule 11** leads to a higher classification of many software medical devices: They are usually classified at least in **class IIa**, which requires the **involvement of a notified body**

Update: OLG Hamburg, judgement of 20 June 2024,
ref. 3 U 3/24 – *Risk classification of a health app* [VI]

Recent decision of the OLG Hamburg of 23 January 2025:

- Rejection of the application for the court to impose a means of enforcing compliance
- No violation of the previous court-ordered ban by the current version of the app since the app versions differ significantly

Background:

- In response to the judgement of the OLG Hamburg of 20 June 2024, the respondent in the action had withdrawn her original app and launched a new version of the app with:
  - ✓ a revised purpose and
  - ✓ a static patient questionnaire, that replaced the original dynamic one

Note:

- The court did not have to address the question whether the marketing of the new app version constitutes a new violation of the unfair competition law
- Now: Dermanostic has received a class IIa CE certificate for the app.

3 Consequences of distributing a medical device without an adequate conformity assessment

Unfair competition law consequences

Legal consequences under unfair competition law of a breach of Sec. 3, 3a UWG:

- Cease and desist claims for elimination and injunctive relief, regardless of fault – Sec. 8 UWG
- Claims for compensation for damages, based on fault – Sec. 9 UWG

Enforcement of competition claims by means of:

- Cease and desist letter containing request to sign a cease and desist declaration
- Application for a preliminary injunction at the civil courts in case of urgency (!!!)
- Lawsuit on the merits at the civil courts

Administrative law & Criminal law consequences

Administrative law consequences:

- Administrative offence proceedings and fines
- Intervention by the regulatory authorities

Criminal law consequences:

- Criminal proceedings
- Investigation proceedings by the public prosecutor

Key take aways

1. Strongly recommended to perform a careful risk classification, particularly if you wish to distribute a medical device as class I product without notified body.

2. In case of an inaccurate risk classification competitors can apply for a preliminary injunction under unfair competition law. If a preliminary injunction is issued by a court it is required to immediately stop the distribution of the medical device and distributors must be notified. If the device is the key product of a company (like in the Dermanostic case) this can lead to significant economic issues.

3. But it is also possible to take legal action against competitors who are distributing their medical devices without proper conformity assessment procedure to ensure a fair competition.

Questions

Speaker

Dr. Daniel Tietjen

Partner

Dr Daniel Tietjen –
Your Contact for Life Sciences matters

Daniel Tietjen specialises in advising and representing national and international clients in the life sciences sector. His focus is, among others, on all areas of pharmaceutical law, medical device law, pharmaceutical-advertising law, unfair competition law, and trademark law.

For more than 10 years, he has been coordinating and supervising disputes concerning competition law and trademark law for his clients and has, besides his specific focus on litigation, also longstanding experience in advising clients on regulatory and compliance matters, particularly, in the aforementioned areas of law, which is advantageous for conducting transactions.

In context with managing litigation and advising his clients, Daniel is characterised by a strong client focus and his ability to find appropriate and efficient solutions to legal problems.

"

"Daniel Tietjen: Years of working in the life sciences industry have led to a great deal of experience and industry knowledge, which ensures not only legally competent but also strategically helpful support for our projects.' , Client, The Legal 500 2025

Recommended lawyer: Healthcare and life sciences, The Legal 500 2025

"Daniel Tietjen always reacts quickly, works very conscientiously and is always very solution-oriented.", Client, The Legal 500 2024

"Daniel Tietjen has excellent knowledge of competition law, in particular the law on the advertising of medicinal products, and regularly supports us in this area. I very much appreciate his practical and creative approach to finding solutions.", Client, The Legal 500 2024

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Key areas of expertise

- Patents Technology & Life Sciences
- Life Sciences & Healthcare
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