THE PHARMACEUTICAL INTELLECTUAL PROPERTY AND COMPETITION LAW REVIEW

FOURTH EDITION

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PREFACE

Despite the industry's critically important response to the covid-19 pandemic, which saved millions of lives around the world, the attacks on industry – and science – continue. The pharmaceutical business is under unprecedented pressure – pricing is a constant focus of new legislation, patenting and business strategies are under continual scrutiny, and regulatory and compliance burdens are growing. Combine that complexity with the fact that pharmaceuticals are truly one of the most global industries, with many companies operating in dozens of countries with differing legal regimes and healthcare systems, and you have a 'perfect storm' for industry lawyers.

While there has been significant harmonisation in certain areas, the nuances of these local frameworks require careful attention from both a strategic planning and operational perspective in order to achieve business objectives across jurisdictions. Maximising the value of intellectual property can make the difference in deciding whether to pursue the development of an important new treatment, and in maintaining success in the marketplace. Similarly, a failure to carefully manage risks in dealings with competitors, such as generic and biosimilar companies, can result in huge civil and criminal liabilities. As companies are all too familiar, this is an area of significant enforcement activity around the world, with large fines being imposed and transactions thwarted if applicable legal constraints are not heeded. Moreover, the links between intellectual property, such as exclusivities, and drug pricing and affordability are a constant source of political scrutiny, as well as patient and physician concern.

Our objective in structuring this updated volume is to give practitioners in the field a one-volume introduction to these critical issues in an array of jurisdictions. It is hoped this book will reduce some of the burdens associated with bringing new treatments and cures to patients while achieving global business success. I would like to thank the authors for their renewed contributions to this edition of *The Pharmaceutical Intellectual Property and Competition Law Review*; they have produced what we believe is a very useful tool for managing global risks in this area.

Daniel A Kracov
Arnold & Porter
Washington, DC
August 2023

Chapter 5

GERMANY

Christopher Weber and Benjamin Pesch[1]

I OVERVIEW

In this chapter, we aim to provide an overview of the general principles and recent developments in the area of intellectual property and competition law in Germany in relation to the pharmaceutical sector. Although Germany is home to some of the oldest and best-known pharmaceutical companies in the world, a lot of manufacturing has moved abroad, and the market is highly regulated because of, what is essentially, compulsory universal health insurance.

The covid-19 pandemic, general price increases, lack of competition between health insurance companies and rising costs of healthcare are prone to put pressure on the new federal government, which has been in office since the end of 2021, to rein in costs sooner or later; however, the focus of the government is to combat supply bottlenecks of innovative medicines and vaccines and to bring the production of medicines, including the production of active ingredients and excipients, back to Germany or the European Union.

To this end, bureaucracy for production facilities will be reduced and – one could say in typical continental European fashion – subsidies for those production facilities will be granted.

In the area of patent law, there are several striking developments: on the one hand, the Patent Act has been reformed in 2022, adding more ideas on proportionality to what has been called the 'automatic injunction'; on the other hand, the Unified Patent Court (UPC) successfully launched on 1 June 2023. For patents that have not been 'opted-out' of this new system, this increases the risk for both patentees and potential infringer, and all that under a fairly speedy system, too – a rare opportunity to shape a new system.

Concerning legislation in the area of competition law, the national legislator has initiated a legislative procedure concerning a general (11th) amendment of the Act against Restraints of Competition dealing with (1) measures after a sector inquiry; (2) the disgorgement of benefits by the competent competition authority; and (3) the enforcement of the Digital Markets Act in Germany, which may also be applied in the pharmaceutical sector. With respect to the enforcement of competition law in the pharmaceutical sector, the FCO still deals with mergers on a regular basis; in addition, the FCO is further engaged with anticompetitive behaviour.

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II LEGISLATIVE AND REGULATORY FRAMEWORK

i General framework of pharmaceutical law

As can be gathered from the parallel chapters on other EU Member States, German law is highly harmonised with EU law in this area. The core of German pharmaceutical law is the Medicinal Products Act of 1976 (MPA), as published on 12 December 2005 and last updated on 20 December 2022.

The MPA requires a marketing authorisation procedure (Section 21 et seq. MPA) to be followed to prove the quality, efficacy and safety of the medicinal product. Special strict liability in the event of damage to medicinal products is also included in the law.

Homoeopathic remedies, provided they do not specify an area of application, are exempt from the proof of efficacy; however, as the new federal health secretary is a friend of evidence-based medicine, this might change soon.

In the broader sense, the Pharmacy Act and the Narcotics Act are relevant, as is the Therapeutic Products Advertising Act governing the advertising of medicinal products and products that are advertised as having effects on health.

In addition to those laws, there are a number of ordinances and administrative regulations, such as the Ordinance for the Manufacture of Medicinal Products and Active Pharmaceutical Ingredients. Authorisation requirements are specified in the Medicines Evaluation Guidelines, which transpose Annex I of Directive 2001/83/EC into German law. For the dispensing of medicinal products, the Medicinal Products Prescription Ordinance is to be consulted, and for narcotics that can be prescribed, the Narcotics Prescription Ordinance. Details on clinical trials are set out in the Good Clinical Practice Ordinance, which makes good clinical practice mandatory.

ii Patents, their duration and their extension

Patent law is governed by a handful of laws, mainly the Patent Act, the European Patent Convention, the Agreement on a Unified Patent Court and the respective treaties. Patents, irrespective of whether they are granted by the European Patent Office or the German Patent and Trademark Office, have a duration of 20 years from their filing date, if the annual fees are paid and they are not retroactively nullified.

Additionally, as in other European jurisdictions, supplementary protection certificates (SPCs) may be granted in accordance with Regulation (EC) No. 469/2009.

iii Pricing and public purchasing

Germany spends more than €30 billion per year on medicinal products, and there is a plethora of measures that try to keep prices in check. Generally, manufacturers are free to set the prices as they wish. Further, all drugs must be sold through pharmacies, which apply an additional surcharge to the one already applied by wholesalers.

Prescription drugs are paid for by health insurance companies, while patients only need to pay a nominal fee of a few euros. Health insurance companies generally negotiate rebate agreements with drug manufacturers, using their bigger purchasing power to negotiate.

After patent expiry, prices can be fixed to a maximum amount. If the price in the pharmacy is higher than the fixed amount, patients must pay the difference, providing a strong incentive for patients to choose cheaper products (often generics) to save money. The fixed prices are reviewed at least once per year and are often decreased. Since 2004, it is also possible to set fixed prices for patent protected products under quite limited circumstances.

The respective rules are stipulated in Sections 35 to 36 of the Fifth Book of the Social Code. It can be expected that owing to cost pressure, the number of products with fixed (maximum) prices will increase.

iv Encouraging innovation

As legislation is harmonised in the European Union, and as competition law at the European level provides for a uniform approach, innovation is encouraged mostly at the EU level (e.g., the Pharmaceutical Strategy for Europe[2] from 2020).

The German Federal Ministry for Education and Research has multiple programmes for direct subsidies to help innovation in specific areas, such as target drug delivery and computational life sciences.[3]

III NEW DRUGS AND BIOLOGICS – APPROVAL, INCENTIVES AND RIGHTS

i Drugs

The EU centralised procedure (CP),[4] through the European Medicines Agency (EMA) in Amsterdam, the Netherlands, is the most important procedure for new drug applications in Germany. The mutual recognition procedure (MRP) and the decentralised procedure (DCP) are the applicable methods for obtaining approval of new drug applications:

a In the MRP, the application is made to the medicines agency of one country in a coordinated fashion with the agencies of other countries. Once approval is granted, it is recognised by all those countries.

b In the DCP, identical applications are made to several local agencies, and one country's agency is chosen as the leading one.

Countries may still decline applications under these regimes on grounds of danger to public health, which can lead first to discussions in a coordination group and later to arbitration before the EMA. All these rules apply to veterinary products *mutatis mutandis*.

National applications are possible in Germany through the Federal Institute for Drugs and Medical Devices for drugs and the Paul Ehrlich Institute for vaccines.

During the covid-19 pandemic, it became publicly known that there is also a way to expedite approval through the EMA's rolling review. In this procedure, the data is submitted to and reviewed by the EMA as it becomes available.

Additionally, there are specific expedited procedures for seasonal influenza vaccines, as well as an accelerated assessment within 150 days instead of the usual 210 days if the drug is effective against an illness that could not be treated previously.

Market authorisations for orphan drugs that treat diseases afflicting fewer than five out of 10,000 persons in the European Union are only granted through the CP. Status as an orphan drug may then be granted by the European Commission upon recommendation by the EMA's Committee for Orphan Medicinal Products. Incentives include lower fees

2 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Pharmaceutical Strategy for Europe, COM/2020/761 final.

3 Federal Ministry of Education and Research, 'Förderung und Projekte'.

4 Regulation (EC) No. 726/2004 of 31 March 2004.

for the application and prolonged market exclusivity. Regulatory protection is provided in Article 14(11) of Regulation (EC) No. 726/2004. Newly authorised products benefit from eight years of protection of the approval data (regulatory data protection) and a 10-year period of market protection, which may be extended to 11 years if during the first eight years at least one new therapeutic indication is obtained that brings significant clinical benefit over existing therapies.

Parallel to that, patent protection for 20 years from the date of filing the application is available, followed by five years of protection under an SPC if the requirements for that are met.

ii Generic and follow-on pharmaceuticals

Simplified conditions for authorisation apply to generic versions of medicinal products with market authorisation. To successfully apply for a generic market authorisation, the manufacturing and pharmaceutical qualities must be documented, and the bioavailability and bioequivalence to the original medicinal product must be proven. For the remaining non-clinical and clinical data, the applicant can refer to the data on the reference medicinal product.

Regarding regulatory protection, generic market authorisations can be applied for after eight years have passed since the initial original market authorisation. The launch can then take place after a further two or three years.

iii Biologics and biosimilars

Where a biological medicinal product that is similar to a reference biological medicinal product does not meet the requirements of a generic medicinal product, in particular because the starting materials or the manufacturing process of the biological medicinal product differ from those of the reference biological medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to those differences must be provided.

The type and number of additional documents must be submitted in accordance with the relevant criteria, according to the state of scientific knowledge; however, the results of other tests from the marketing authorisation dossier of the reference medicinal product shall not be submitted.

iv Recent Constitutional Court case

Recently, the German Constitutional Court had to decide a case in which the decentralised procedure and regulatory protection were the key points.[5]

A generic company had marketing authorisations for the veterinary medicinal product Enroxil, which is essentially identical in content to Baytril, in the Czech Republic, Hungary and Poland. With reference to the UK marketing authorisation for Baytril, the authority competent for marketing authorisation of medicinal products in the United Kingdom (the UK authority) granted a national marketing authorisation for Enroxil as a generic product in September 2005.

In 2006, a company commissioned by the generic company for this purpose applied for a national marketing authorisation for Enroxil before the German Federal Office in the MRP of the UK reference marketing authorisation. After the Federal Office objected to the lack of

5 Federal Constitutional Court, decision of 27 April 2021 – 2 BvR 206/14.

documents on environmental compatibility during the formal preliminary examination of the application for authorisation, the UK authority sent the assessment report prepared in 2004 on the extension of the British authorisation for Baytril, which was based on the data from the Ecotoxicology Database (ECOTOX) prepared by the legal predecessor of the first defendant. The Federal Office then granted the authorisation.

The licensee of the original manufacturer sued the German Federal Office for a national marketing authorisation on the grounds that the authorisation by the UK authority should not have been accepted unchecked and that the ECOTOX data was used unlawfully.

In the end, all courts up to the Federal Constitutional Court dismissed the action, finding that the German Federal Office only needs to assess whether there is any danger to public health or the environment. The questions of whether formally a generic application or a mutual recognition was the right pathway and whether the UK authority had a right to send the ECOTOX data to Germany are irrelevant to the German Federal Office; thus, the marketing authorisation was rightfully granted.

The decisions clearly show the focus of the authorisation procedures for quick and unbureaucratic grants of authorisations.

v The Regional Court Munich issues anti-anti-suit injunction in life science patent litigation

Anti-anti-suit injunctions are rare in life sciences patent litigation. However, in a patent infringement proceeding before the Regional Court Munich, 10x Genomics recently requested an anti-anti-suit injunction against the US company NanoString and its German subsidiary. The Regional Court Munich issued the anti-anti-suit injunction.[6]

The background to this anti-anti-suit decision was that the Regional Court Munich ruled against NanoString for indirect infringement of the German part of EP 2 794 928 B1. As a consequence, NanoString requested an anti-suit injunction and an anti-enforcement injunction at the US District Court Delaware. The anti-anti-suit decision of the Regional Court Munich therefore was the answer to NanoString's requests before the US District Court Delaware. Anti-anti-suit injunctions have become widely known in German patent litigation, particularly in the field of standard-essential patents. However, patent infringers are now less likely to request anti-suit-injunctions because they can no longer successfully assert their FRAND objection in German SEP disputes.[7] It therefore will be exciting to see whether anti-suit injunctions and anti-anti-suit injunctions make a comeback in the life sciences sector. Overall, the global trend of different national courts interfering with each other by way of anti-suit injunctions and anti-anti-suit injunctions, and so on, does not bode well for the supposed global rules based order.

vi The objection of disproportionality in German patent law

In 2022, the German legislator codified the disproportionality objection in the German Patent Act (PatG). This is a substantial change. Previously, Section 139 PatG stated that a patent infringer may be sued by the infringed person for injunction if there is a risk of repetition. The new version of Section 139 PatG now adds that the claim is excluded if it

6 Regional Court Munich, decisions of 17 May 2023 – 7 O 2693/22 and 7 O 5812/22.

7 cf. Kiefer/Walesch, Mitt. 2022, 97 et seq.

would lead to disproportionate hardship for the infringer or third parties not justified by the exclusive right due to the special circumstances of the individual case and the requirements of good faith.

According to the reasoning of the law, the objection of disproportionality and the compulsory licence under patent law are different legal instruments.[8] However, the Regional Court Düsseldorf did not follow this reasoning. The Court ruled on 7 July 2022 (*Sofosbuvir*),[9] that the objection of disproportionality is subsidiary to the compulsory licence action. It was decisive for the Court that the principles of the compulsory licence should not be evaded by the objection of disproportionality.

This decision has been partially criticised in literature. Subsidiarity of the objection of disproportionality would make it more difficult to consider and safeguard third party interests.[10] This, however, had been precisely one of the reasons for the introduction of the disproportionality objection.

IV PATENT LINKAGE

European patents can be challenged within nine months of their grant in an opposition procedure before the European Patent Office and after lapse of the opposition period before the competent national courts. European patents can be challenged before the Unified Patent Court while an objection procedure is pending. German patents can be challenged within the same period at the German Patent and Trademark office (DPMA).

After the end of either opposition period, the Federal Patent Court (FPC) is competent for nullity actions. While an opposition is pending, nullity proceedings are inadmissible. Decisions of the FPC can be appealed before the Federal Court of Justice (FCJ), Germany's highest civil court.

There is no link between opposition procedures or nullity actions on the one hand, and marketing authorisation procedures on the other. Neither is dependent nor formally linked to the other one.

Patents can be challenged based on lack of novelty, lack of inventive step, lack of disclosure, inadmissible extension and other, less relevant grounds. Anyone wanting to clear the way for market introduction would need to challenge the validity of the patent in one of those ways.

If the patent's validity is weak (e.g., if a novelty attack seems to have a high likelihood of success), the product may still be launched. If an infringement action is then started, a request may be made to stay the infringement action pending the outcome of the opposition or nullity action. The reason for this is the bifurcated German patent system, where specialised courts handle infringement matters, while the equally specialised FPC handles nullity matters; thus, the infringement courts cannot declare a patent void, but may stay a pending infringement action and wait for the FPC's decision.

Negative declaratory actions (e.g., with the goal of finding a patent not infringed by a specific product) are available in principle but require a legal interest, which under these circumstances mostly requires that the patentee has threatened the new market entrant with a

8 BT-DS 19/25821 P. 55.

9 Regional Court Düsseldorf, decision of 7 July 2023 – 4c O 18/21.

10 See also at Stief, PharmR 2023, 61, 64.

patent infringement action by way of a warning letter seeking a cease-and-desist declaration. Other reasons, such as failure of the patentee to answer whether they consider their patent to be infringed by a specified product, unfortunately do not give rise to such legal interest.

'Clearing the way' strategies, therefore, lack sure paths in Germany, while the case law on patent infringement is, in turn, highly developed, with the highest case load in Europe.

After many years of delays, the UPC launched on 1 June 2023. For the first time in history, it is possible to file for injunctive relief with effect across all 17 Member States party to the Agreement on a Unified Patent Court (UPCA) and to file a revocation action against a patent with the same effect. The risk was therefore raised for both patentees and potential infringer; however, legal certainty can be reached more quickly, with positive effects for the pharmaceutical market.

Something that still must be discussed is the role of supplementary protection certificates (SPCs) with the UPC. As of right now, there are close to no rules regarding SPCs and the UPC. Article 32 UPCA claims that the jurisdiction of the UPC extends to SPCs, however, further rules regarding SPCs can not be found in the provisions.

On 27 April 2023, the European Commission published several proposals for solutions regarding the treatment of SPCs before the UPC. Two of the four proposals refer to medicinal products.

The first proposal is based on the fact that the current purely national procedures lead to significant legal uncertainty.[11] The European Commission identifies a clear need to complement the unitary patent by a unitary SPC and proposes to grant the patentee the 'possibility of filing a "combined" centralised SPC application in which he/she would request the grant of both a unitary SPC (for those Member States in which the basic patent has unitary effect) and national SPCs (for other Member States).'[12]

The second proposal aims to simplify the EU's SPC system, as well as to improve its transparency and efficiency.[13] The goal is supposed to be met by introducing a centralised procedure for granting SPCs for medicinal products.[14] The European Commission states that, 'This would allow applicants to obtain SPCs in the respective designated Member States subject to marketing authorisations having been granted in/for each of them, by filing a single "centralised SPC application" that would undergo a single centralized examination procedure . . .'[15]

V COMPETITION ENFORCERS

The major legal source in Germany concerning competition is the Act against Restraints of Competition (ARC). Under the ARC, there are several institutions when it comes to the protection of competition; however, the Federal Cartel Office (FCO) is the most relevant national institution with respect to the pharmaceutical sector.

The FCO is a higher federal authority within the scope of business of the Federal Ministry for Economic Affairs and Climate Action (FMEA). It is exclusively responsible for:

a merger control (only under specific conditions, the FMEA may overrule the FCO);

11 COM(2023)222, Proposal of the European Commission, 27 April 2023 p. 1.

12 COM(2023)222, Proposal of the European Commission, 27 April 2023 p. 2.

13 COM(2023)231, Proposal of the European Commission, 27 April 2023 p. 2.

14 ibid.

15 ibid.

b antitrust consumer protection;
c the maintenance of the competition register in which certain economic offences by companies relevant for award procedures are listed; and
d the enforcement of the prohibition on cartels.

In addition, it is responsible on the federal level for:
a the enforcement of the prohibition on abusive practices by companies with a dominant or strong market position;
b merger control; and
c the review of the awarding of public contracts by contracting authorities.

Besides the FCO, there are state cartel offices (SCOs). They are competent if the anticompetitive behaviour exclusively affects the specific federal state, which is, however, rarely the case.

Appeals against decisions of the FCO are exclusively handled by the Higher Regional Court of Düsseldorf. The Federal Court of Justice is competent for revisions.

VI MERGER CONTROL

There are no specific provisions for merger control in the pharmaceutical sector. Accordingly, the general provisions apply.

The prerequisites for the FCO to consider merger control are that (1) the thresholds in Section 35 ARC are fulfilled (turnover or transaction threshold);[16] (2) a merger as defined in Section 37 ARC shall take place; and (3) the merger does not have 'community dimension' as defined in Article 21 of the European Commission Merger Regulation (ECMR).

Merger control may be carried out over two phases (Section 40 ARC): (1) a preliminary investigation procedure; and (2) a main investigation procedure if further examination of the merger is required. Except in exceptional cases, the whole procedure takes five months from the filing of the notification of the planned merger (since 2021).

The FCO may grant (1) clearance; (2) clearance under further conditions and obligations for the undertakings; or (3) prohibit the merger (Section 40 ARC). A merger will be prohibited if it significantly impedes effective competition, in particular if it is expected to create or strengthen a dominant position and no exception according to Section 36 ARC applies.

The definition of the relevant market follows the 'demand-side-oriented market concept' (*Bedarfsmarktkonzept*). The decisive question is whether the products are functionally exchangeable from the point of view of the customer or person disposing of the product in question (*Verbrauchsdisponenten*).[17] In the past, national courts and the FCO have defined the respective relevant markets in the pharmaceutical sector based on the following aspects:

16 The thresholds were amended with the 10th Amendment of the ARC, see FCO, 'Amendment of the German Act against Restraints of Competition' (19 January 2021).

17 KG, decision of 18 October 1995 – Kart 18/93 – *Fresenius/Schiwa*; FCO, decision of 13 August 2003, B3-11/03 – *Novartis/Roche*; for anticompetitive behaviour, see FCJ, decision of 3 July 1976 – KVR 4/75 – *Vitamin B12*; FCJ, decision of 16 December 1976 – KVR 2/96 – *Valium*; FCJ, decision of 12 February 1980 – KVR 3/79 – *Valium II*.

a The functional exchangeability of products depends in particular on the therapeutical effect and the intended use of the product in question.[18] In this regard, the national courts and the FCO have referred to the Anatomical Therapeutic Chemical (ATC) classification of the European Pharmaceutical Marketing Research Association in the past, which categorises pharmaceuticals, inter alia, based on their therapeutical indication (ATC class 3) and their active substance (ATC class 4).[19]

b Further criteria have been, for example, the manufacturing process,[20] prices and medical application[21] as well as side effects, toxicity and tolerance.[22]

c With respect to prescription drugs, the physicians' point of view and their prescription habits have been identified to be decisive for the question of functional exchangeability of products.[23] This is because consumers are limited in their choice by the prescribing habits of physicians.

d Prescription drugs and OTC drugs have been found to form different markets due to differences in receipt (prescribed by physician as opposed to autonomous purchase), in pricing (determination of pharmacy prices for prescription drugs by the state) and in payment (coverage of costs by insurance company for prescription drugs).[24]

e The hospital market and the wholesale have been found to form different markets because only hospital pharmacies are able to buy bulk packages for prices significantly below the prices the wholesalers must pay, are technically more competent than wholesalers, very price sensitive and regularly conduct annual contracts.[25]

f The sales of prescription drugs by local pharmacies and mail-order pharmacies have been found to form one market due to the offer of a comparable assortment on similar terms and comparable competitive conditions.[26]

Geographically, the markets are also defined based on the 'demand-side-oriented market concept'[27] and have been found to be national in the pharmaceutical sector.[28] This is because the markets still deviate in view of regulation, market authorisation and social law, IP law and

18 KG, decision of 18 October 1995 – Kart 18/93 – *Fresenius/Schiwa*; FCO, decision of 30 November 2000, B-24410-U-91/00; FCO, Activity Report 1981/82, p. 59 – *Grindsted Products/BASF*.

19 KG, decision of 18 October 1995 – Kart 18/93 – *Fresenius/Schiwa*; FCO, decision of 13 August 2003, B3-11/03 – *Novartis/Roche*.

20 FCO, Activity Report 1981/82, p. 59 – *Grindsted Products/BASF*.

21 KG, decision of 18 October 1995 – Kart 18/93 – *Fresenius/Schiwa*.

22 For anticompetitive behaviour, see FCJ, decision of 16 December 1976 – KVR 2/96 – *Valium*; FCJ, decision of 12 February 1980 – KVR 3/79 – *Valium II*.

23 KG, decision of 18 October 1995 – Kart 18/93 – *Fresenius/Schiwa*; for anticompetitive behaviour, see FCJ, decision of 16 December 1976 – KVR 2/96 – *Valium*.

24 FCO, decision of 30 July 2010 – B3 59/10 – *Medco Health Solutions/Celesio*.

25 For anticompetitive behaviour, see FCJ, decision of 12 February 1980 – KVR 3/79 – *Valium II*.

26 FCO, decision of 30 July 2010 – B3 59/10 – *Medco Health Solutions/Celesio*; FCO, decision of 2 July 2018, B3-89/18 – *apo-rot/DocMorris*.

27 KG, decision of 18 October 1995 – Kart 18/93 – *Fresenius/Schiwa*; for anticompetitive behaviour, see FCJ, decision of 13 July 2004 – KVR 2/03 – *Sanacorp/ANZAG*.

28 KG, decision of 18 October 1995 – Kart 18/93 – *Fresenius/Schiwa*; FCO, decision of 5 June 2009, B3-64/09 – *GlaxoSmithKline/Pfizer*.

the price level of the drugs.[29] The respective legal frameworks thus lead to different competitive conditions in the respective countries. In contrast, the market for active substances has been found to be at least EU-wide.[30]

In the past year, a few merger control cases were published with the FCO, for example:

a On 14 May 2023, the FCO granted the acquisition by GlaxoSmithKline of all shares and control from Bellus Health Inc dealing with the pipeline product Camlipixant.[31]

b On 12 May 2023, the FCO registered the planned acquisition by Cheplapharm Arzneimittel GmbH of authorisations, trademarks and domains from Eli Lilly concerning Seroquel (active substance: Quetiapine) and Zyprexa (active substance: Olanzapine).[32]

c On 3 April 2023, the FCO cleared the acquisition by BioNTech SE of all shares and control from InstaDeep Ltd concerning the development of immunotherapy and research on active substances.[33]

d On 10 August 2022, the FCO cleared the joint venture between the NOWEDA Apothekengenossenschaft eG and the Burda Verlag GmbH concerning the digital platform 'IhreApotheken.de'.[34]

If a merger has 'community dimension', the ECMR applies. This is the case if the thresholds in Article 1 ECMR are fulfilled, and a merger as defined in Article 3 ECMR is at issue. Article 21(2) ECMR rules that the European Commission is exclusively competent for the application of the ECMR.

Under certain conditions, the European Commission may refer a merger to a Member State to have it controlled under national law. Member States can also request the Commission to examine a merger that does not have a community dimension but affects trade between Member States (Article 22 ECMR). In 2021, the Commission published guidance on the application of this referral mechanism and in December 2022 further practical information in the form of a Q&A to motivate Member States to make more use of this mechanism. This is because a number of cross-border transactions, including in the pharmaceutical sector, that

29 KG, decision of 18 October 1995 – Kart 18/93 – Fresenius/Schiwa.

30 FCO, decision of 30 November 2000, B-24410-U-91/00.

31 FCO, B3-60/23.31.

32 FCO, B3-61/23.

33 FCO, B3-42/23.

34 FCO, 'Bundeskartellamt clears Burda's participation in NOWEDA's digital platform "IhreApotheken.de"' (10 August 2022).

could have an impact on the EU market escaped review by both the Commission and the Member States in the past.[35] Member States have already made use of this referral mechanism in the pharmaceutical context.[36]

VII ANTICOMPETITIVE BEHAVIOUR

As with merger control, there are no specific provisions under German law for anticompetitive behaviour in the pharmaceutical sector. Therefore, the FCO applies Section 1, 2 and 18 et seq. ARC if the anticompetitive behaviour exclusively concerns the German market. If EU trade is affected, the FCO must also apply Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU).[37] The Commission will generally investigate anticompetitive behaviour in the sense of Articles 101 and 102 TFEU if more than three Member States are substantially affected.[38]

Because of the harmonisation of the ARC with EU law, Sections 1 and 2 ARC concerning anticompetitive agreements substantially correspond to Article 101 TFEU. The provisions cover horizontal as well as vertical agreements. Section 2 ARC clarifies that the EU block exemption regulations apply. The most relevant regulations in the IP and pharmaceutical context are the Technology Transfer Block Exemption,[39] the Research and Development Block Exemption[40] and the Vertical Block Exemption[41] to which the Commission has also published guidelines.[42]

35 Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases, (2021/C 113/01), Introduction, No. 10; see also European Commission, 'Practical information on implementation of the "Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases – Frequently Asked Questions and Answers (Q&A)'.

36 European Commission, 'Mergers: Commission starts investigation for possible breach of the standstill obligation in Illumina / GRAIL transaction' (20 August 2021). Since Illumina violated its standstill obligation, the Commission ordered interim measures for the first time in EU merger history, see 'Mergers: Commission adopts interim measures to prevent harm to competition following Illumina's early acquisition of GRAIL' (29 October 2021). On 6 September 2022, the Commission prohibited the acquisition, see 'Commission prohibits acquisition of GRAIL by Illumina'.

37 Article 3(1) of Council Regulation (EC) No. 1/2003 of 16 December 2002. The European Commission has started an initiative to evaluate the procedures following changes to the economic landscape, e.g., digitalisation, see https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13431-EU-antitrust-procedural-rules-evaluation_en.

38 Commission Notice on cooperation within the Network of Competition Authorities (2004/C 101/03), No. 14.

39 Commission Regulation (EU) No. 316/2014 of 21 March 2014. On 17 April 2023, the European Commission initiated a public consultation to get an impression of the functioning of the block exemption and the respective guidelines, see https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13636-EU-competition-rules-on-technology-transfer-agreements-evaluation_en.

40 Commission Regulation (EU) No. 2023/1066 of 1 June 2023. Transitory regime from 1 July 2023 to 30 June 2025 for agreements in force on 30 June 2023 which do not satisfy the conditions for exemption established by this Regulation but which satisfy the conditions for exemption established by Regulation (EU) No. 1217/2010.

41 Commission Regulation (EU) No. 2022/720 of 10 May 2022.

42 A new version of the Horizontal Guidelines is announced to enter into force once they are published in the Official Journal of the EU, see https://ec.europa.eu/commission/presscorner/detail/en/ip_23_2990.

Also, with respect to the abuse of a dominant position, the harmonisation of the ARC with EU law has led to Section 19 ARC substantially corresponding to Article 102 TFEU. The requirement of market dominance is defined in Section 18 ARC.

The definition of the relevant market follows the principles set out with respect to merger control. However, the national courts and the FCO do not seem to explicitly refer to the ATC classification in the context of anticompetitve behaviour.[43]

If the FCO institutes proceedings, it may:

a conduct sector inquiries;[44]

b gather evidence by inspection and hearing witnesses and experts;

c seize objects;

d request information and documents;

e inspect and examine business documents at the undertaking's premises during normal business hours; and

f conduct dawn raids concerning business premises, homes, land and objects.

If the FCO concludes that there has been anticompetitive behaviour, it may:

a request the (group of) companies to cease and desist from the anticompetitive behaviour;

b impose fines on (groups of) companies of up to 10 per cent of the worldwide turnover in the preceeding fiscal year;

c impose fines on persons like directors or board members responsible for the anticompetitive behaviour of up to €1 million; or

d disgorge the benefits achieved by the anticompetitive behaviour.

Competitors and other aggrieved market players may claim an injunction and rectification as well as damages (only the actual damages but no punitive damages).

Anticompetitive clauses in agreements are automatically invalid, and under certain circumstances the whole agreement may be invalidated.

In the past, the FCO has dealt, inter alia, with the following constellations:

a agreements on prices between drug manufacturers;[45]

b agreements on prices and co-promotion for OTC drugs between pharmacies;[46]

c suggestions at speech events to refrain from price competition and to follow the recommended retail price;[47]

d target agreements between drug manufacturers and pharmacies providing rebates for placing drugs as premium drugs for the recommended retail price;[48]

43 See, for example, FCJ, decision of 16 December 1976 – KVR 2/96 – *Valium*; FCJ, decision of 12 February 1980 – KVR 3/79 – *Valium II*.

44 To date, the FCO has not conducted a sector inquiry into the pharmaceutical sector but only into hospitals, see FCO 'Final report on the sector inquiry into hospitals: Merger control guarantees competition and quality' (2 September 2021).

45 FCO, B 3-144/08, 'Retraction of Price Agreement for Colistin Antibiotics'.

46 FCO, 'Bundeskartellamt imposes fines against pharmacists on account of price agreements for non-prescription medicines' (8 January 2008).

47 FCO, decision of 21 December 2007, B3-6/05.

48 FCO, 'Bundeskartellamt imposes fine against Bayer Vital' (28 May 2008).

e agreements on the return of clients of pharmacies and, therefore, profits and market shares from one to other pharmaceutical wholesalers;[49]

f distribution agreements between a drug manufacturer and a distributor that oblige (1) the manufacturer to exclusively distribute its products with the distributor and (2) the distributor not to sell any other competitive products;[50]

g stagger of rebates in the sense that distributors are only supplied if they achieve a certain profit with the products;[51] and

h agreements between an association representing the interests of pharmacies and health insurance companies that the health insurance companies will not influence physicians and patients to purchase products from other providers but will indicate the possibility of purchasing the products in the pharmacies represented by the association.[52]

Currently, the FCO is dealing with coordinated price increases by a working group of associations of medical aid providers (referred to as ARGE) to the detriment of health insurance companies. The FCO sent its preliminary investigation results to ARGE for comments on 25 January 2023.[53]

Finally, it is worth mentioning that the national legislator has initiated a legislative procedure concerning a general (11th) amendment of the ACR, which is currently pending at the Federal Parliament. The bill focuses three aspects.[54]

First, it amends the provisions on sector inquiries. Sector inquiries shall be accelerated to be conducted in 18 months. In addition, measures are introduced that the FCO may apply within 18 months after publishing the report on the sector inquiry to stop disruption of the competition. Currently, the FCO can only prepare a report on its findings and initiate individual procedures against undertakings due to anticompetitive behaviour. In contrast, the FCO will soon be able to order, for example, that companies conduct their business relations with each other in a certain way, that they implement transparent, non-discriminatory and open norms and standards, that they draft agreements including clauses on disclosure of information in a certain way, or even that business units have to be separated. Under certain conditions, the FCO may even order market-dominant undertakings or those with paramount market-overarching importance to demerge. The measures are available irrespective of an actual anticompetitive behaviour. However, they shall be subsidiary to the existing measures of the FCO.

Second, the FCO's measure of disgorging benefits achieved by anticompetitive behaviour shall be strengthened. The bill provides for a statutory presumption that the benefit amounts to at least 1 per cent of the national turnover achieved by the anticompetitive behaviour. The amount of the benefit may be estimated by the FCO. However, the disgorging is limited to 10 per cent of the turnover of the (group of) undertakings in the preceding fiscal year. The statutory presumption is disprovable by showing that neither the (group of) undertakings

49 FCO, decision of 28 August 2006, B3-129/03 – *FCO v. Andrae Noris Zahn/Sanacorp Pharmahandel, Phoenix Pharmahandel/Gehe Pharma Handel*.

50 FCO, decision of 14 July 2009, B3-64/05 – *FCO v. Merck/VWR*.

51 FCO, decision of 19 May 2011, B3-139/10 – *FCO v. Merck/VWR*.

52 FCO, decision of 29 September 2014, B3-123/11 – *FCO v. Apothekerverband Westfalen-Lippe eV*.

53 FCO, 'Statement of objections issued against associations of medical aids providers' (25 January 2023).

54 https://dserver.bundestag.de/btd/20/068/2006824.pdf (16 May 2023).

nor the involved persons have achieved a benefit in the respective amount in the relevant time. In addition, the presumption does not apply if the achievement of benefits is excluded due to the specific nature of the anticompetitive behaviour.

Finally, the bill considers the new Digital Markets Act (DMA) rendered on the EU level. Although the European Commission is competent for the enforcement of the DMA, the FCO shall be able to conduct investigations in cases of potential violation of the DMA and then submit a report to the Commission.

VIII OUTLOOK AND CONCLUSIONS

As in 2021, the pharmaceutical sector does not seem to have played a major role in German competition law. This is not surprising since mergers on the one hand and anticompetitive behaviour on the other hand increasingly have a community dimension. Accordingly, projects and decisions concerning the pharmaceutical sector will continue to mainly take place at the EU level.

The regulatory provisions stem from those at the European level, and the case law seems to be set in stone. No changes seem to be imminent.

Regarding patent infringement, the case law will continue to develop. The UPC may change everything or nothing at all, but it will certainly raise the stakes in any case. In each case, almost the whole European Union will be covered. In a year, we will see more clearly in this regard as the first round of case law will have developed.