PHARMACEUTICAL ANTITRUST

Germany

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Getting The Deal Through

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Pharmaceutical Antitrust

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Quick reference guide enabling side-by-side comparison of local insights into pharmaceutical regulatory law (framework, authorities, pricing, distribution and intersection with competition law); competition legislation and regulation (legislation and enforcement authorities, public and private enforcement and remedies, sector inquiries, health authority and NGO involvement); review of mergers; anticompetitive agreements; anticompetitive unilateral conduct; and recent trends.

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PHARMACEUTICAL REGULATORY LAW

Regulatory framework

What is the applicable regulatory framework for the authorisation, pricing and marketing of pharmaceutical products, including generic drugs?

The Medicinal Products Act (AMG) covers the general requirements for pharmaceutical products, including their development, marketing authorisation and distribution. Further provisions relate to the import of drugs and the monitoring of drug risks (pharmacovigilance).

The Ordinance on the Manufacturing of Medicinal Products and Active Ingredients (AMWHV) governs the manufacturing and testing of pharmaceutical products. Drug prices are regulated in the Ordinance on the Pricing of Medicinal Products (AMPreisV) with supplementary provisions in Book V of the German Social Code (SGB V), regarding ia rebates for statutory health insurers, rules regarding the physicians' prescription practice and the pharmacists' dispensation decision. There is also a special law on the marketing of pharmaceuticals, the Health Services and Products Advertising Act (HWG).

The legal framework for veterinary medicinal products has recently been reformed. The main provisions can now be found in the new Veterinary Medicinal Products Act (TAMG).

Finally, EU legislation plays an important role in German pharmaceutical law. The AMG is largely based on Directive 2001/83/EC. Regulation (EC) No 726/2004 contains provisions on the European Medicines Agency (EMA) and the centralised market authorisation procedure. Regulation (EU) 2019/6 directly applies to veterinary medicinal products.

Law stated - 01 May 2022

Regulatory authorities

Which authorities are entrusted with enforcing these rules?

In principle, the local authorities of the 16 German states have power to enforce.

However, significant areas of pharmaceutical law enforcement are delegated to three federal agencies. The Federal Institute for Drugs and Medical Devices (BfArM) is responsible, in particular, for the marketing authorisation of medicinal products and for pharmacovigilance. With regard to veterinary drugs, these tasks are performed by the Federal Office of Consumer Protection and Food Safety (BVL). The Paul Ehrlich Institute (PEI) is responsible for certain categories of medicinal products, including vaccines (both for human and veterinary use), allergens and antibodies.

Other tasks related to the marketing authorisation of medicinal products are assigned to the EMA.

Moreover, the implementation of the rules on healthcare supply is carried out by collective agreements (under public law) on the national level between the National Association of Statutory Health Insurance Funds and the healthcare suppliers, ie pharma companies, medical appliances, hospitals, associations of physicians and other healthcare suppliers, as well as on the regional level in every state.

Law stated - 01 May 2022

Pricing

Are drug prices subject to regulatory control?

With regard to the regulation of drug prices, German pharmaceutical law distinguishes between prescription (Rx) drugs

and over-the-counter (OTC) drugs. While prices for Rx drugs are strictly regulated, prices for OTC drugs are in principle not subject to regulation.

The base prices for Rx drugs are affected heavily by law. In principle, pharmaceutical companies may set their Rx drug prices freely. De facto, however, the price for an Rx drug is linked to the amount that will be reimbursed by statutory health insurance. This amount is agreed upon between the National Association of Statutory Health Insurance Funds and the manufacturer of a pharmaceutical product, based on the procedure laid down in section 130b SGB V. Setting a price above the reimbursement amount is not prohibited by law. However, in this case, the patients would need to pay excess amounts themselves, which in practice forces the pharmaceutical companies to align their drug prices with the agreed reimbursement amount.

In addition, several types of mandatory rebates are prescribed for the benefit of statutory health insurance. These apply to both pharmaceutical companies and pharmacies (sections 130 and 130a SGB V). Besides, individual rebate agreements may be agreed in addition. As regards mandatory rebates, the Federal Court of Justice (FCJ) held in 2015 that private health insurers are equally entitled to receive certain manufacturer rebates (I ZR 127/14).

The regulation of Rx drug prices within the distribution chain is based on section 78 AMG and the AMPreisV. By fixing the price margins between manufacturers and wholesalers as well as between wholesalers and pharmacies, the legislator guarantees a uniform pharmacy retail price for Rx drugs. The underlying objective is to protect patients.

In the case Deutsche Parkinson Vereinigung (C-148/15 of 2016), the European Court of Justice (ECJ) ruled that price fixing for pharmaceutical products in pharmacies violates the principle of free movement of goods. As a result, mail-order pharmacies based in other EU member states were exempt from the price regulation, until the Act on Strengthening Local Pharmacies (VOASG) came into force in 2021. The VOASG effectively circumvents the ECJ ruling, by requiring pharmacies to enter into a framework contract with the statutory health insurance funds that binds them to the AMG price regulation.

Finally, prices for OTC drugs are generally not subject to regulatory control. However, there are certain exemptions, in particular with regard to OTC drugs exceptionally prescribed by a doctor.

Law stated - 01 May 2022

Distribution

Is the distribution of pharmaceutical products subject to a specific framework or legislation? Do the rules differ depending on the distribution channel?

The AMG contains the general legal framework for the distribution of pharmaceutical products. In addition, special legislation applies depending on the distribution channel, for example, the Ordinance on the Wholesale of Medicinal Products (AM-HandelsV) or the Pharmacies Act (ApoG). Finally, the SGB V may also affect the distribution of pharmaceutical products. For example, section 129 SGB V requires pharmacies to dispense generic instead of originator drugs if not expressly excluded by the prescribing doctor.

In Germany, the retail sale of pharmaceutical products is exclusively delegated to pharmacies (section 43 AMG). This pharmacy monopoly was confirmed by the Federal Constitutional Court (1 BvR 100/57 of 1959).

However, there are a number of exceptions to the pharmacy monopoly. Depending on their specific risk classification, some OTC drugs are approved for sale outside of pharmacies (eg, in drugstores or supermarkets). The details are set out in the Ordinance on pharmacy-only medicinal products (AMVerkRV). Section 47 AMG lists further exceptions, including direct supplies of certain categories of pharmaceutical products to hospitals or doctors, and the supply of samples. Whereas the pharmacy monopoly in principle also applies to veterinary drugs, veterinarians can operate an in-house dispensary in their own veterinary practice (section 44 TAMG).

Until 2003, the sale of pharmaceutical products by mail order was strictly prohibited. According to the ECJ, this violated European law (DocMorris , C-322/01 of 2003). German law now allows for the operation of mail-order pharmacies (including those based in other EU member states).

Law stated - 01 May 2022

Intersection with competition law

Which aspects of the regulatory framework are most directly relevant to the application of competition law to the pharmaceutical sector?

The regulatory framework for pharmaceutical products does not supersede competition law rules, as stated exemplarily in paragraph 4 of section 52b AMG. Section 69 paragraph 2 SGB V clarifies the extent to which competition law is applicable to statutory health insurance funds. However, the comprehensive social healthcare regulation certainly affects the scope of application which remains for competition law in the pharmaceutical sector, namely areas outside the applicable rules and frameworks:

- regulation of the development and marketing authorisation of pharmaceutical products;
- regulation of the manufacturing and the import of pharmaceutical products;
- pricing regulation (with regard to Rx drugs); and
- regulation of the distribution of pharmaceutical products.

Typical antitrust issues that arise in this context include anticompetitive agreements between originator and generic companies ('pay-for-delay' agreements) and other lifecycle management strategies seeking to extend patent protection, restrictions of parallel trade in distribution agreements, excessive prices by market-dominant healthcare suppliers, collusion on the demand side (where not regulated), and mergers.

Law stated - 01 May 2022

COMPETITION LEGISLATION AND REGULATION

Legislation and enforcement authorities

What are the main competition law provisions and which authorities are responsible for enforcing them?

The Act against Restraints of Competition (GWB) is the main competition legislation in Germany. It governs anticompetitive agreements, abusive practices, merger control and procedural matters. In addition, the GWB explicitly refers to EU competition rules, including the relevant block exemption regulations. Supplementary provisions for administrative proceedings and fines can be found in the Administrative Procedures Act (VwVfG) and the Administrative Offences Act (OWiG), respectively. Finally, bid rigging behaviour is sanctioned by the Criminal Code (StGB).

In general, the Federal Cartel Office (FCO) is the federal authority responsible for competition law enforcement, including articles 101 and 102 TFEU. Its decisions can be appealed before the Düsseldorf Higher Regional Court, and further appealed to the FCJ. The Federal Ministry for Economic Affairs and Climate Action can clear mergers for public policy reasons. Criminal offences such as bid rigging are prosecuted by the Public Prosecutors.

Law stated - 01 May 2022

Public enforcement and remedies

What actions can competition authorities take to tackle anticompetitive conduct or agreements in the pharmaceutical sector and what remedies can they impose?

There are no special provisions applicable to the pharmaceutical sector. Accordingly, the general rules apply.

In the course of formal proceedings, the FCO may conduct investigations and collect any evidence required. This includes requests for information, seizure of documents and materials, inspection of business records and dawn raids. Undertakings and their employees are obliged to cooperate with the FCO during investigations, and failure to comply with this obligation may result in substantial fines.

If, after concluding an investigation, the FCO finds that an infringement has occurred, it may impose fines on the undertakings and their representatives involved. With regard to undertakings and associations of undertakings, the maximum fine amounts to up to 10 per cent of the worldwide annual group turnover (section 81c GWB). The FCO may grant immunity from or reduce fines for undertakings who contribute to uncovering or proving a cartel by cooperating with the FCO (leniency programme, sections 81h-81n GWB).

In addition, the FCO can take measures to end anticompetitive behaviour. This includes the right to impose behavioural or even structural remedies (divestiture) to the extent that they are necessary and proportionate. The undertakings concerned can also offer commitments, which, if accepted by the FCO, will be legally binding. Finally, the FCO may order interim measures pursuant to section 32a GWB. The applicable legal requirements have only recently been lowered. Such measures are now permissible if the existence of a competition law infringement is more likely than not, and if such measures are required to protect competition or because of an imminent threat of serious harm to another undertaking.

Law stated - 01 May 2022

Private enforcement and remedies

Can remedies be sought through private enforcement by a party that claims to have suffered harm from anticompetitive conduct or agreements implemented by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Competitors or other market participants affected by competition law infringements can seek remedies in the form of an injunction and damages (sections 33 and 33a GWB). Such claims must be brought before the ordinary courts.

Injunctive relief can also be sought by way of an application for interim measures if urgency can be demonstrated. The applicable legal standard is set out in the Civil Procedure Code (ZPO).

Claims for damages are limited to the damage actually incurred by the claimant –there are no punitive damages under German law. With regard to follow-on actions, the facts included in decisions of the competent competition authorities, including the European Commission and competition authorities in other EU member states, are res iudicata (ie, binding on the court). The passing-on defence is permissible though to date has not been applied by the courts. Finally, leniency applicants are not exempt from liability for damages. In recent years, the number of cartel damage litigation cases has increased significantly and the FCJ's recent claimant-friendly decisions may further accelerate this trend.

Law stated - 01 May 2022

Sector inquiries

Can the antitrust authority conduct sector-wide inquiries? If so, have such inquiries ever been conducted into the pharmaceutical sector and, if so, what was the main outcome?

The FCO can conduct sector inquiries to analyse the structure and competitive conditions in certain economic sectors. Section 32a GWB awards extensive investigative powers to do so.

To date, the FCO has initiated 17 sector inquiries, most recently into the areas of 'scoring' in online retail, household waste, hospitals and public charging infrastructure for electric vehicles. There has not yet been an inquiry into the pharmaceutical sector.

Law stated - 01 May 2022

Health authority involvement

To what extent do health authorities or regulatory bodies play a role in the application of competition law to the pharmaceutical sector? How do these authorities interact with the relevant competition authority?

Health authorities and regulatory bodies do not play an important role in the application of competition law in the pharmaceutical sector. They may, however, interact with the FCO in an informal manner, (eg by providing information regarding the regulatory framework or by reporting anticompetitive conduct).

Law stated - 01 May 2022

NGO involvement

To what extent do non-government groups play a role in the application of competition law to the pharmaceutical sector?

NGOs, trade associations and consumer groups do not play an important role in the application of competition law to the pharmaceutical sector.

In theory, certain trade and consumer associations have the right to file class actions seeking injunctive relief (but not damages). They can also demand that profits generated by way of anticompetitive behaviour be disgorged for the benefit of the federal budget. However, the relevant provisions have so far been of no practical relevance.

In addition, the FCO can consult them with regard to the competitive landscape in the pharmaceutical sector. Like other parties, these stakeholders can also file complaints regarding alleged competition law infringements. However, the FCO is not obliged to initiate proceedings following complaints.

Law stated - 01 May 2022

REVIEW OF MERGERS

Thresholds and triggers

What are the relevant thresholds for the review of mergers in the pharmaceutical sector?

German merger control does not provide any sector-specific thresholds. In accordance with section 35 of the Act

against Restraints of Competition (GWB) a concentration is subject to merger control if in the last business year preceding the concentration:

- the combined aggregate worldwide turnover of all the undertakings concerned was more than €500 million, the domestic turnover of at least one undertaking concerned was more than €50 million and that of another undertaking concerned was more than €17.5 million; or
- the combined aggregate worldwide turnover of all the undertakings concerned was more than €500 million, the domestic turnover of one undertaking concerned was more than €50 million and neither the target undertaking nor any other undertaking concerned achieved a domestic turnover of more than €17.5 million, but the consideration for the acquisition exceeded €400 million and the target has substantial operations in Germany (transaction value threshold).

The transaction value threshold was introduced to enable the control of mergers where the target's lack of turnover does not adequately reflect its market potential. The German legislator attributed this risk particularly to the area of private R&D and mentioned the pharmaceutical sector as an example because the turnover potential of undertakings which develop technologies or products (eg, active pharmaceutical ingredients prior to drug approval) is often realised only after their sale. Together with the Austrian competition authority, the FCO has published a joint Guidance on Transaction Value Thresholds for Mandatory Pre-merger Notification.

The German merger control does not apply to transactions that fall within the scope of the EUMR.

Law stated - 01 May 2022

Is the acquisition of one or more patents or licences subject to merger notification? If so, when would that be the case?

The transfer of a patent or an already existing licence may constitute an acquisition of assets under section 37 No. 1 of the Act against Restraints of Competition (GWB) as the term includes intangible assets. A prerequisite is, however, that the patent is a substantial part of the seller's assets – either measured quantitatively in relation to total assets, or qualitatively, meaning that it represents the substance of the seller's market position which would transfer to the acquirer upon acquisition.

By contrast, the granting of a licence can only meet the criteria of acquisition of control under section 37 No. 2 GWB, since the acquisition of assets requires full rights. Even though the wording of section 37 No. 2 GWB does not expressly state that the licence must concern a substantial part of the seller's assets, the Federal Court of Justice has considered this an unwritten condition.

Law stated - 01 May 2022

Market definition

How are the product and geographic markets typically defined in the pharmaceutical sector?

Owing to the size of most pharmaceutical firms, the majority of mergers in this sector are examined by the European Commission. Therefore, the number of precedents from the FCO and German courts in this sector is limited. Any future German merger control practice will likely be guided by the European Commission's practice, which is briefly summarised below.

The relevant product market comprises all products which are substitutable from a demand-side view, with regard to

their characteristics, price and intended use.

Regarding finished dose pharmaceuticals (FDPs), the European Commission distinguishes between OTC drugs, typically purchased and paid for by patients themselves, and prescription drugs, which are reimbursed by statutory health insurers. For prescription medicines, substitutability depends on the prescribing physicians' perspective. The focus is on the therapeutic effect of medicines. Criteria determining therapeutic use and substitutability constitute relevant factors alongside price-based indicators.

Against this background, the European Commission defines the product market based on the Anatomical Therapeutic Chemical Classification System (ATC), as developed by the European Pharmaceutical Marketing Research Association (EphMRA). Level three (ATC3) is typically the starting point, while further analysis may lead to a deeper segmentation (ATC4 or molecule level) or a combination of different ATC3 levels. The European Commission considers a market definition based on the molecule level especially when generics have entered the market, since it assumes that originator and generic drugs are usually the closest substitutes. On the other hand a wider market definition is possible if specific circumstances indicate that an ATC3 market would not reflect market reality.

The FCO follows this approach. In Novartis/Roche (B3-11/03 of 2003) it applied ATC3 level to identify product market overlaps. The Kammergericht Berlin confirmed that the ATC classification could serve as a starting point for the product market definition of pharmaceutical products (Kart 18/93 of 1995).

In addition to products on the market, the European Commission also looks at pipeline products. It defines the relevant product market for pipeline products based on future indication, mode of action, and, where relevant, line of treatment. In this context the European Commission assumes that the market definition can be less clearly defined than for marketed products due to the intrinsic uncertainty in analysing products that do not exist yet (M.9461 of 2020 – AbbVie/Allergan). In respect of potential competition it examines programmes in Phase II and III clinical trials (M.9461 of 2020 – AbbVie/Allergan). However, according to the European Commission pipeline programmes at earlier stages may have an impact on innovation competition (M.9461 of 2020 – AbbVie/Allergan).

Further, the European Commission examines overlaps in upstream markets. It principally assumes that each active pharmaceutical ingredient (API) belongs to a separate product market but substitutability between APIs, either in general or for certain applications, must also be considered (M.10247 of 2021 – CVC/Cooper).

The relevant geographic market of a product encompasses the competitive space where competition is sufficiently homogeneous and where conditions clearly differ from neighbouring spaces. According to the European Commission, geographic markets for FDPs are national, since prescription conditions and reimbursement rules for pharmaceuticals differ greatly between the member states in view of different health insurance systems and resulting variations in pricing and reimbursement, regulatory conditions, medical guidelines, product offerings and patient or doctor preferences (M.9461 of 2020 – AbbVie/Allergan). The Kammergericht Berlin confirmed this view (Kart 18/93 of 1995). For APIs and pipeline products, the European Commission considers the geographic scope of the market to be at least EEA-wide (M.7645 of 2015 – Mylan/Perrigo and M.9461 of 2020 – AbbVie/Allergan).

Law stated - 01 May 2022

Sector-specific considerations

Are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?

There is no sector-specific guidance for the pharmaceutical industry, the general principles apply.

The FCO will likely follow the European Commission's practice. In the pharmaceutical sector, the European Commission adapts the market definition depending on the respective market stage concerned. Thus, it assumes that the relevant product market may narrow to the molecular level after the introduction of generics because it considers originator and

generic drugs to be usually closest substitutes. It also takes into account the specific regulatory framework in respect of supply, marketing, pricing, procurement and reimbursement of pharmaceuticals. Similarly, the Kammergericht Berlin took the different regulations into account when defining the market (Kart 18/93 of 1995).

Law stated - 01 May 2022

Addressing competition concerns

Can merging parties put forward arguments based on the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

According to section 36(1) No. 1 of the Act against Restraints of Competition (GWB) the FCO does not prohibit a concentration even if it impedes competition when the merging parties can show that the concentration will also lead to improvements of competitive conditions which will outweigh the impediment to competition. However, this clause only relates to markets other than the one in which the restraint of competition occurs. The burden of proof lies with the undertakings, and the FCO construes this provision quite strictly.

Furthermore, a boost to R&D activities can represent an efficiency gain. The FCO takes efficiencies into account as a balancing factor (B3–135/13 of 2014). However, it is very restrictive in acknowledging an efficiency defence and assumes that the undertakings bear the burden of proving the conditions of the efficiency defence (the efficiencies must benefit consumers, be merger-specific, and be verifiable).

Pursuant to section 42(1) GWB, the Federal Minister for Economic Affairs and Energy will, upon application, authorise a concentration prohibited by the FCO if, in the individual case, the restraint of competition is outweighed by advantages to the economy as a whole, or if the concentration is justified by an overriding public interest. The protection and improvement of research infrastructures may constitute this public interest. However, this political clearance provision is applied in a restrictive manner.

Law stated - 01 May 2022

Horizontal mergers

Under which circumstances will a horizontal merger of companies currently active in the same product and geographical markets be considered problematic?

Regardless of the sector, according to section 36(1) of the Act against Restraints of Competition (GWB), the FCO prohibits a concentration which would significantly impede effective competition, especially via the creation or strengthening of a dominant position.

In order to evaluate horizontal mergers, the FCO will generally use the combined market shares of the parties as a starting point. Pursuant to section 18(4) GWB, an undertaking is considered dominant if it has a market share of at least 40 per cent. However, a merged entity can also be found to hold a dominant position below this threshold, or the presumption can be rebutted. Other relevant factors for the assessment are competitors' market shares, potential competition and barriers to entry, as well as countervailing buyer power. These criteria are further detailed in the Guidance on Substantive Merger Control published in March 2012 by the FCO. As at the European level, a prohibition may also be considered if effective competition is significantly impeded by the elimination of a maverick or by a merger between close competitors – this SIEC test has been given an autonomous interpretation by the Federal Court of Justice (KVR 34/20 of 2021 – CTS Eventim/Four Artists).

Law stated - 01 May 2022

Product overlap

When is an overlap with respect to products that are being developed likely to be problematic? How is potential competition assessed?

The few published merger control decisions of the FCO in the pharmaceutical sector did not involve overlapping pipeline products. However, it is likely that it would follow the European Commission's approach. In terms of potential competition the European Commission examines overlaps between the parties' pipeline products at advanced stages of development (M.9461 of 2020 – AbbVie/Allergan). For pharmaceutical products, this would be programmes in Phase II and III clinical trials (M.9461 of 2020 – AbbVie/Allergan). The Commission also inspects the impact of the concentration on innovation competition. In this regard, it examines the risk of a significant loss of innovation competition resulting from the discontinuation, delay or realignment of the overlapping pipelines, including early-stage pipeline programmes (M.9461 of 2020 – AbbVie/Allergan).

According to German decision practice, a merger with a potential competitor may justify a prohibition because it may increase the acquirer's market power, as the target can no longer have a disciplinary effect. However, if other companies also pursue product pipelines which could compete with future products of the merging parties, this potential competition may act as a disciplining force and prevent the creation or strengthening of a dominant position. The anticipated market entry must be likely, timely and sufficient (FCO, Guidance on Substantive Merger Control). Barriers to entry influence the probability of market entry (FCO, Guidance on Substantive Merger Control). In the pharmaceutical sector, these can result, in particular, from EMA approval or a lack of freedom to operate.

Law stated - 01 May 2022

Remedies

Which remedies will typically be required to resolve any issues that have been identified?

From the few mergers in the pharmaceutical sector examined at the national level, it is not possible to determine which remedies will typically be required to resolve issues in the pharmaceutical sector. However, the FCO has published guidelines which explain the requirements that need to be met to clear an otherwise inadmissible concentration subject to remedies (FCO, Guidance on Remedies in Merger Control).

According to these guidelines, the FCO in general only accepts structural remedies. Pursuant to section 40(3) sentence 2 of the Act against Restraints of Competition (GWB), remedies offered must not seek to implement an ongoing supervision of market behaviour. Therefore, behavioural remedies are accepted only under narrow conditions and in the rarest of cases. Furthermore, the FCO will typically require that the divestiture take the form of an up-front buyer divestiture.

Law stated - 01 May 2022

ANTICOMPETITIVE AGREEMENTS

Assessment framework

What is the general framework for assessing whether an agreement or concerted practice can be considered anticompetitive?

The prohibition of anticompetitive agreements and concerted practices is set out in Section 1 of the Act against Restraints of Competition (GWB). The provision is virtually the same as article 101(1) of the Treaty on the Functioning

of the European Union(TFEU). Furthermore, the Federal Cartel Office (FCO) as well as German courts will directly apply article 101 TFEU next to section 1 GWB in cases that may affect trade in the whole of Germany or between EU member states.

Certain pro-competitive agreements and concerted practices are exempt from the prohibition pursuant to section 1 GWB. The conditions for an exemption are set out in section 2 GWB, with the provision applying the same conditions as under article 101(3) TFEU. Section 2 GWB also includes a dynamic referral to the different block exemptions at European level, of which the following are of particular relevance to the pharmaceutical sector:

- Regulation (EU) No. 1217/2010 on research and develop agreements;
- Regulation (EU) No. 1218/2010 on specialisation agreements;
- Regulation (EU) No. 330/2010 on vertical agreements and concerted practices; and
- Regulation (EU) No. 316/2014 on technology transfer agreements.

Law stated - 01 May 2022

Technology licensing agreements

To what extent are technology licensing agreements considered anticompetitive?

Technology licensing agreements can relate to patents and supplementary protection certificates (SPC) for medicines or other pharmaceutical products and are therefore of particular significance in the pharmaceutical industry.

Technology licensing agreements are considered pro-competitive within the meaning of section 1 of the GWB. Even when technology licensing agreements are found to restrict competition, they are regularly block-exempted (Regulation (EU) No. 316/2014). Section 2 GWB refers to the block exemptions on the European level. The market share thresholds for an exemption differ:

- if the parties are competitors, their combined market share cannot exceed 20 per cent; and
- if the parties are not competitors, the share on their respective markets cannot exceed 30 per cent.

In addition, the exemption falls away if the agreement contains hard-core restrictions (eg, price limitations, customer or market allocation, restrictions on the licensee to exploit its own technology, etc), listed in article 4.

Certain technology licensing agreements may instead be within the safe harbour of the block exemptions for research and development agreements (Regulation No. 1217/2010) or specialisation agreements (Regulation No. 1218/2010). Both regulations are due for revision as of 1 January 2023.

Law stated - 01 May 2022

Co-promotion and co-marketing agreements

To what extent are co-promotion and co-marketing agreements considered anticompetitive?

Co-promotion and co-marketing agreements are categorised as commercialisation agreements. The principles under EU law also apply in German law, in particular the guidance provided in the European Commission's horizontal guidelines. Hereunder, they may only be considered anticompetitive if the parties have a certain market power. The European Commission's horizontal guidelines provide a safe harbour for a combined market share of up to 15 per cent (paragraph 240). If this is exceeded, the market effects must be assessed. Particular care should be taken as to which information the parties share with each other, as the exchange of commercially sensitive information may

be found to artificially increase transparency in the market facilitating collusion.

In 2007, the FCO fined nine state pharmacist associations, the Federal Association of Pharmaceutical Manufacturers and five pharmaceutical companies approximately €0.5 million for entering into a co-promotion agreement and hosting lecture events encouraging pharmacists to continue to observe manufacturer recommended price levels countering the liberalisation of OTC drug prices in early 2004 (B 3-6/05 of 2007).

Law stated - 01 May 2022

Other agreements

What other forms of agreement with a competitor are likely to be an issue? How can these issues be resolved?

Virtually any form of agreement between competitors can result in restrictions to competition, depending on the specific terms of the agreement.

The illicit exchange of strategic information between competitors, as well as outright agreements on prices and rebates, will be considered anticompetitive and investigated as a cartel.

Given the costly and time-consuming efforts to develop new medicines and medical devices, agreements on R&D cooperation are common in the healthcare industry. R&D cooperation in the field of basic research and between non-competitors is not of concern from an antitrust perspective. Moreover, an R&D cooperation may be exempted based on the R&D block exemption regulation (Regulation (EU) No. 1217/2010 of 14 December 2010) provided the combined market share threshold of 25 per cent is not exceeded by the parties. Beyond this threshold, the individual agreement's effects on competition must be assessed. Typical pro-competitive effects include faster development of product and process innovation, avoidance of duplicate R&D and overall increase of efficiency. Typical anticompetitive effects would be the slowing down of innovation, the reduction of innovation or quality of products entering the market and more generally of R&D competition between the parties. As a general rule, pure R&D cooperations without a joint exploitation of results rarely give rise to restrictive effects on competition, whereas this can be different for a more comprehensive cooperation involving, in a second step following the R&D phase, joint licensing, joint production or marketing, or both.

In any event, the agreement must not be used as a platform for an anticompetitive exchange of information and there must be no spillover effects outside the relevant R&D cooperation, which would align the market behaviour of the parties.

Law stated - 01 May 2022

Issues with vertical agreements

Which aspects of vertical agreements are most likely to raise antitrust concerns?

The assessment of anticompetitive elements in vertical agreements is addressed comprehensively by the European Commission's vertical block exemption regulation (Regulation (EU) No. 330/2010 of 20 April 2010 on the application of article 101(3) TFEU to categories of vertical agreements and concerted practices; VBER). The current VBER expires on 31 May 2022 and a new VBER will enter into force on 1 June 2022. The main changes focus on dual distribution, parity obligations, where the scope of the safe harbour has been narrowed whereas the scope has been widened on certain restrictions of a buyer's ability to actively approach individual customers and certain practices relating to online sales.

In vertical relationships within the pharmaceutical sector, resale price maintenance, agreements on price fixing or price recommendation may raise antitrust concerns. While restricting a buyer's ability to set its sales prices is considered a

hardcore restriction and cannot be subject to exemption under the VBER, article 4 lit a VBER allows for setting maximum sales prices and non-binding price recommendations as long as these measures do not actually have the effect of fixed or minimum sales prices. The FCO will test vertical agreements against the VBER and has already fined undertakings for such practice in the past. In 2008, the FCO imposed a fine totaling €10.34 million against a pharmaceutical company for promising special discounts for pharmacies that observed non-binding price recommendations.

Another example that has particular relevance for the pharmaceutical sector is the pharmacy-only distribution channel (Apothekenbindung). This special type of selective distribution system allows to ensure that medical products are only distributed in pharmacies by trained personnel. The conditions for an exemption are set out in article 4 lit c Nr i VBER and require that the selective distribution system is based on standardised criteria, without hardcore restrictions, such as the imposition of fixed or minimum resale prices or certain territorial or customer sales restrictions and the market share threshold of 30 per cent on both levels (supplier and distributing pharmacy) is not exceeded.

Law stated - 01 May 2022

Patent dispute settlements

To what extent can the settlement of a patent dispute expose the parties concerned to liability for an antitrust violation?

The exposure to antitrust risks in the context of settlement discussions is highly case specific. In general, parties to a patent dispute settlement risk infringing competition law if the settlement conditions reach beyond the scope (eg, the scope of protection, territorial scope or the duration) of the dispute in question. This could for example be the case if a patentee demands royalty payments for patent free countries; the German Supreme Court (BGH) in its decision of 5 July 2005 has declared such a clause void (X ZR 14/03).

Moreover, parties to a patent dispute settlement between an originator and a generic manufacturer risk an antitrust violation where settlements involve payments or other value transfers from the originator to the generic manufacturer in return for a delayed market entry. The European Commission has emphasised (eg, in its Communication of 25 November 2020 on the 'Pharmaceutical strategy for Europe') that strategies to impede the entry of generics continue to require competition law scrutiny and, accordingly, pay-for-delay (or reverse payment) settlement clauses have been struck down under article 101(1) TFEU in several European Commission cases confirmed by the EU courts.

In its first decision on pay-for-delay agreements in 2013, the European Commission imposed a €146 million fine on Lundbeck and five generic manufacturers. The generic manufacturers committed in a settlement agreement not to enter the market for Lundbeck's antidepressant medicine citalopram for a certain period and in return received cash payments. On appeal, the ECJ (C-591/16 P of 2021) first confirmed its preliminary ruling in GSK (Paroxetine) or Generics (C-307/18 of 2020) that the mere existence of a patent does not prevent a finding of potential competition if the generic company has a firm intention and the ability to enter the market. Second, the ECJ found the settlement agreements to restrict competition 'by object', namely, to be anticompetitive by their very nature, but, however, established a strict standard: It must be evident from the settlement agreement that the intended value transfers cannot have any other explanation than to allow the patentee to stave off upcoming competition.

In its second decision the European Commission fined the manufacturer Servier and several generic companies in July 2014 for having entered into agreements that delayed market entry of generic versions of Servier's perindopril after the molecule patent for the drug had expired. Currently, the decision of the General Court in Servier (T-691/14 of 2018) is under appeal before the ECJ (C-176/19 P and C-201/19 P), with a decision expected later this year or in early 2023.

Moreover, the decision of the General Court in the appeal by Teva and Cephalon (T-74/21) against the European Commission's decision to fine them for delaying the market entry of a cheaper generic version of Cephalon's drug for

sleep disorders, modafinil, by entering into a number of commercial side-agreements to their patent settlement agreement is still pending. According to the European Commission decision, Teva committed to stay out of the modafinil markets not because it was convinced of the strength of Cephalon's patents, but because of the substantial value transferred to it through small cash payments and other benefits such as increased purchase prices. The case involves the particularity that Teva had already entered the market in the UK and was in the process of receiving approval for other markets as well.

Law stated - 01 May 2022

Joint communications and lobbying

To what extent can joint communications or lobbying actions be anticompetitive?

When engaging in joint communications and lobbying, pharmaceutical companies must ensure, as is advisable with any competitor contact, that such contacts are not misused as a vehicle for anticompetitive behaviour, such as the exchange of strategic information, for example, on price, or unjustified calls for boycott.

The principles that are relevant under EU law also apply in a German context. Article 101 TFEU and section 1 GWB not only prohibit the direct exchange of strategic data between competitors but also the indirect exchange through a common agency (for example a trade association). However, such indirect exchange of information must lead to a 'concerted practice' and thus requires some direct access to current competitor information, in non-aggregated form, in order to constitute an infringement of article 101 TFEU.

Law stated - 01 May 2022

Public communications

To what extent may public communications constitute an infringement?

In general, exchanges of public information are unlikely to constitute an infringement of article 101 TFEU. According to the horizontal guidelines of the European Commission, exchanges of 'genuinely public' information may decrease the likelihood of achieving a collusive outcome on the market to the extent that non-participating competitors, as well as customers, may be able to shield against potential anticompetitive effects. 'Genuinely public' information is such information that is accessible to all competitors and customers.

However, depending on the facts underlying the case at hand, public exchanges of information may also facilitate a collusive outcome in the market. For instance where a public announcement of a price increase by one competitor is made sufficiently in advance to see how competitors react and is then followed by public announcements of other competitors each interacting strategically with this information (for example by readjusting an earlier announcement to an announcement made by competitors), this strategy could be used to collude on prices.

In the Container Shipping case (AT.39850 of 2016), the European Commission considered public announcements of future prices to be an anticompetitive information exchange. For several years, the shipping companies had regularly announced publicly (eg, on their websites or in the press) the amount of the intended price increase (as a percentage, including implementation date), the geographic area concerned and, if necessary, adjusted their price increases to competitors' announcements even before these were implemented. The European Commission did not impose a fine on the shipping companies but accepted as commitments essentially that the companies remove their obligation to announce price increases early and in the future only announce prices that are binding for customers.

Law stated - 01 May 2022

Exchange of information

Are anticompetitive exchanges of information more likely to occur in the pharmaceutical sector given the increased transparency imposed by measures such as disclosure of relationships with HCPs, clinical trials, etc?

Even if no concrete agreement is reached, the exchange of certain competitively sensitive information between competitors will be covered by the prohibition of cartels in article 101 TFEU or section 1 GWB as a 'concerted practice' and will raise serious antitrust risks if it reduces strategic uncertainty in the market thereby facilitating collusion. The European Commission and the FCO have applied increasingly strict standards with regard to the exchange of information between competitors.

When assessing an information exchange under antitrust law, the market structure must be taken into account, as well as the content of the information exchanged. As regards the content of the information exchanged, sharing of market-related or 'strategic' data is problematic. According to the European Commission's horizontal guidelines, the most strategic information is related to prices (eg, actual prices, discounts, increases, reductions or rebates) and quantities (sales volumes, capacities), followed by information about costs and demand (production costs, customer lists, qualities, marketing plans, risks and investments). The strategic usefulness of data also depends on its aggregation and age because the exchange of historic data as well as of genuinely aggregated data is unlikely to be indicative of the competitors' future conduct or to provide a common understanding on the market.

At first glance, the transparency requirements in the pharmaceutical sector, which have increased in recent years, entail an increased risk of collusion and anticompetitive information exchange. However, these transparency rules contain exceptions for commercially sensitive information. One example is Regulation No. 536/2014 (of 16 April 2014 on clinical trials on medicinal products for human use): it provides for the establishment of an EU-wide database as a single entry point for the submission of data and information relating to clinical trials. This EU database is publicly accessible unless confidentiality is justified inter alia for protecting commercially confidential information (see article 81(4) lit b)). Through a careful use of these exemptions for sensitive information, pharmaceutical companies may minimise the effects of disclosures on market transparency.

Law stated - 01 May 2022

ANTICOMPETITIVE UNILATERAL CONDUCT

Abuse of dominance

In what circumstances is conduct considered to be anticompetitive if carried out by a firm with monopoly or market power?

The framework for assessing unilateral anticompetitive conduct is primarily set out in section 19 of the Act against Restraints of Competition (GWB). The addressee of this provision is any undertaking found to hold a 'dominant position' by applying a set of criteria included in section 18 GWB. The German prohibition of unilateral anticompetitive conduct is further extended by section 20 GWB, which stipulates certain behavioural rules for undertakings with 'relative market power' in regard to the other side of the market or their competitors. In January 2021, the German legislator introduced section 19a GWB, which prohibits abusiveconduct of undertakings of paramount significance for competition across markets. So far, only Big Tech companies have become subject to an assessment under these new rules.

Section 19(1) GWB provides a catch-all clause by merely stating that the abuse of a dominant position is prohibited. This allows for a certain degree of flexibility for the enforcement agency. Section 19(2) GWB offers more precise rules,

listing five (non-exhaustive) examples for what may constitute abusive behaviour. This includes a prohibition of first and second line foreclosure, exploitation and discrimination of competitors and customers and, under specific circumstances, of a refusal to provide access to essential facilities.

Law stated - 26 May 2022

De minimis thresholds

Is there any de minimis threshold for a conduct to be found abusive?

There is no de minimis threshold for a conduct to be found abusive under German law. Rather, there is an element of 'sliding scales': the more pronounced dominance is, the less it takes to find an abuse.

Law stated - 26 May 2022

Market definition

Do antitrust authorities approach market definition in the context of unilateral conduct in the same way as in mergers? If not, what are the main differences and what justifies them?

The Federal Cartel Office (FCO) will approach market definition in the context of unilateral behaviour in the same way as in mergers, as both regimes rely on the same framework for assessing the existence of market dominance (section 18 of the Act against Restraints of Competition).

Law stated - 26 May 2022

Establishing dominance

When is a party likely to be considered dominant or jointly dominant? Can a patent owner be dominant simply on account of the patent that it owns?

The assessment of market dominance relies on a framework laid down in section 18 of the Act against Restraints of Competition (GWB). According to this provision's paragraph 1, a single undertaking is to be found dominant if it:

- has no competitors;
- is not exposed to any substantial competition; or
- has a paramount market position in relation to its competitors.

According to section 18(4) GWB, an undertaking is considered to be dominant if it has a market share of at least 40 per cent – which is, however, only an indication that the authority should investigate; the threshold may be undercut or exceeded.

Pursuant to section 18(5) GWB, two or more undertakings may be considered to be jointly dominant if:

- no substantial competition exists between them with respect to a certain type of goods or commercial services; and
- they fulfil in their entirety the requirements of section 18(1) GWB (outlined above).

Three or fewer undertakings are presumed to be dominant if they reach a combined market share of 50 per cent, five or

fewer undertakings that reach a combined market share of two thirds (section 18(6) GWB).

The mere fact of holding a patent does not constitute a dominant position for the patent owner. Only if the relevant patent represents a dominant position, because, for example, a pharma company owns the sole patent to treat a particular indication, could the dominance rules come into play. We note that patents approaching loss of exclusivity tend to be considered as offering a monopoly until generic entry, since in the European Commission's practice the market at that time narrows down to the molecule (a position that is under attack in the Servier case currently before the ECJ).

Law stated - 26 May 2022

IP rights

To what extent can an application for the grant or enforcement of a patent or any other IP right (SPC, etc) expose the patent owner to liability for an antitrust violation?

Generally, the application for the grant or enforcement of a patent or any other IP right does not expose the patent owner to liability for an antitrust violation under German law, even if the applicant or the patent owner would (come to) hold a dominant position.

However, as regards standard essential patents (SEP), the patent holder may be required to offer a licence under fair, reasonable and non-discriminatory (FRAND) terms. Furthermore, the Federal Court of Justice has held in 2020 (KZR 36/17) that a SEP holder's claim for injunctive relief can also be considered abusive if the infringer has not (yet) declared its willingness to conclude a licence agreement under FRAND conditions in a legally binding manner, where it is the patent holder who is to be blamed for not having made sufficient efforts to conclude a licence agreement with an infringer who is in principle willing to conclude such agreement under FRAND terms.

Finally, the abuse of patent rights or a regulatory position, for example, with a view to impeding generic entry, may be considered abusive (ECJ, Astra Zeneca , C-457/10 P of 2012). This line of cases is slowly forming, in EU and member states enforcement practice, and its exact limits are still unclear. The latest case opened is the Commission's current Teva investigation of 4 March 2021 into patent filing practices and communication measures.

Law stated - 26 May 2022

When would life-cycle management strategies expose a patent owner to antitrust liability?

Life-cycle management strategies have not been subject to scrutiny by either the FCO or German courts so far. However, it seems likely that they would follow the EU institutions' lead in case such a scenario comes to their attention in the future. The assessment would largely depend on the individual strategy. If such strategy would, for example, be comparable to the strategy applied by AstraZeneca, which was assessed by the ECJ in 2012 (C-457/10 P of 2012), the German courts would likely consider this decision a de facto precedent for abuse of the patent or regulatory system.

A German law specific question in this regard is the admissibility of individual rebate contracts between pharma companies and statutory health insurance providers, which seek to bridge across loss of exclusivity into generic competition and make use of the privilege that rebated drugs receive under German social security law as regards their dispensation in pharmacies. These contracts may be subject to antitrust liability, or at least very close scrutiny, in case the FCO would opt to investigate.

Law stated - 26 May 2022

Communications

Can communications or recommendations aimed at the public, HCPs or health authorities trigger antitrust liability?

The FCO has not yet published a case where it would have assessed if communications or recommendations aimed at the public, HCPs or health authorities triggers antitrust liability. However, it appears likely that the FCO would follow the EU authorities' lead on this, namely, considering misleading statements and disparagement strategies as abusive (see ECJ in Hoffmann-LaRoche/Novartis , C-179/16 of 2018).

Law stated - 26 May 2022

Authorised generics

Can a patent owner market or license its drug as an authorised generic, or allow a third party to do so, before the expiry of the patent protection on the drug concerned, to gain a head start on the competition?

This scenario is yet to be assessed by the FCO or German courts. However, generally there are no apparent reasons why such a strategy would be in violation of German antitrust law. As far as the statutory health insurers are concerned, at least as long as no individual rebate agreements have been concluded, pharmacists must make their dispensation decision based on the available generics' pricing. Therefore, any first-mover could be challenged effectively by way of price competition.

Law stated - 26 May 2022

Restrictions on off-label use

Can actions taken by a patent owner to limit off-label use trigger antitrust liability?

Yes, actions taken by a patent owner who holds a dominant position to limit off-label use could trigger antitrust liability. However, the assessment needs to be made on a case-by-case basis, focusing on the individual conduct. This scenario is yet to be assessed by the FCO or German courts. In its decision F Hoffmann-La Roche , the ECJ scrutinised practices aiming at limiting the off-label use of a product, in particular by communicating allegedly misleading information to healthcare professionals and health authorities (C-179/16 of 2018).

Law stated - 26 May 2022

Pricing

When does pricing conduct raise antitrust risks? Can high prices be abusive?

Similar to EU law, pricing may be considered abusive and thus raise antitrust risks primarily in two scenarios:

- excessively low pricing, including via rebate schemes, may be considered as predatory, impeding competitors.
- excessively high pricing may be considered as exploitative with regard to customers.

German authorities are reluctant to consider predatory pricing as an abuse, mainly because price competition is

generally the desired outcome. Even below-cost selling will not necessarily constitute illicit predatory pricing. The FCJ requires an overall assessment of all relevant circumstances, which relies on specific evidence as well as on a synopsis of subjective and objective criteria.

Excessive pricing is primarily covered by a dedicated example stipulated in section 19(2) No. 2 of the German Act against Restraints of Competition (GWB). Whether a price is excessive will be assessed by comparing it to the price which would be expected under effective competition, and any deviation must be significant. However, excessive pricing may also fall under the general prohibition of section 19(1) GWB. Here, the FCO would focus on a comparison between costs and earnings, similar to the test regularly applied by the European Commission.

Cases, which have been decided on an EU level in the context of illicit pricing strategies, will be a good indication of the potential views of the FCO or German courts on a specific issue.

Law stated - 26 May 2022

Sector-specific issues

To what extent can the specific features of the pharmaceutical sector provide an objective justification for conduct that would otherwise infringe antitrust rules?

So far, there have been no cases where the FCO or a court would have accepted the specific features of the pharmaceutical sector as an objective justification. However, it is generally possible that the FCO will take such aspects into consideration when conducting a balancing of interest test, which is often required as a condition before concluding that certain conduct violates antitrust rules. In particular, the FCO and the German courts may be willing to take certain legislative objectives of the German social security system into consideration, for example, the preferential treatment of rebated drugs as regards the pharmacist's dispensation decision. In its 1995 Importarzneimittel decision (KVR 10/94), the Federal Court of Justice found that the privileged treatment of imported drugs (due to lower prices), must be included in the overall assessment. In that case a restriction of – legally privileged – imports was all the more abusive since it subverted the legislator's goal to grant preferential treatment to imported drugs under section 129 SGB V.

Law stated - 26 May 2022

UPDATES AND TRENDS

Recent developments

Are there in your jurisdiction any emerging trends or hot topics regarding antitrust regulation and enforcement in the pharmaceutical sector?

There have not been recent fundamental updates or emerging trends regarding the antitrust regulation and enforcement in the pharmaceutical sector.

The Federal Cartel Office (FCO) launched a sector inquiry into hospitals in Germany in 2006. On 9 September 2021 it presented its final report. The sector inquiry analysed the prevailing competition conditions of hospitals in Germany and was supposed to deliver information that refines the methods of merger control cases. Where it did identify ongoing concentration tendencies in the hospital sector, most mergers were considered to not raise competition concerns. Nevertheless, the sector inquiry stresses the importance of merger control to safeguard operator diversity between hospitals.

Accordingly, the FCO has continued to frequently review hospital mergers, but has cleared the large majority of filings: between 2003 and 2020 out of 325 notified mergers, only seven were prohibited and eight filings were withdrawn. The

FCO bases its assessment primarily on patient flow data on a case-by-case basis to determine whether the merger project is likely to cause changes in the catchment area around hospitals. In geographic terms, more than 80 per cent of all patients treated at a hospital stem from within a radius of 35 kilometres around the hospital. Prohibitions were issued where the competitive strength of the merging parties would have significantly impeded effective competition within this radius (see, eg, Klinikum Esslingen/Kreiskliniken Esslingen , B3 – 135/13 of 2013).

Apart from that, the FCO has dealt with several cooperation agreements related to the covid-19 pandemic. One of the cooperation agreements concerned the pharmaceutical sector and sought to build an emergency B2B platform between pharma wholesalers (VCI Emergency Platform for Vaccination Equipment) to secure a sufficient supply of vaccination equipment, such as syringes, cannulas and NaCl-solution. The platform allowed federal states and the wholesalers to exchange information on their current supply situation and capability to deliver. This transparency was intended to improve coordination along the supply chain and avoid shortages or misallocation of vaccine materials. The FCO has given its green light, namely, informed the parties involved that it would not initiate a proceeding against the platform since it did not provide information on supply prices and volumes and was limited to the covid-19 emergency situation.

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Law stated - 01 May 2022

Jurisdictions

China	Lifang & Partners
Czech Republic	dubanska & co
European Union	Herbert Smith Freehills LLP
France	Intuity
Germany	Allen & Overy LLP
India	AZB & Partners
Japan	Anderson Mōri & Tomotsune
Norway	Advokatfirmaet Thommessen AS
South Africa	Herbert Smith Freehills LLP
Turkey	Zesa Attorney Partnership
USA	Clifford Chance