

No-challenge and pay-for-delay agreements in patent licence and settlement agreements under European competition law

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In a world that seems to grow increasingly litigious and complex, one can hardly deny the benefits of amicable settlements. At the very least, such settlements lessen the burden on infringement and validity courts. However, any kind of agreement relating to the validity and/or enforceability of a patent goes to the heart of the relationship between IP and competition law. In the European Union those agreements have to be reviewed carefully under Article 101 of the Treaty on the Functioning of the European Union (TFEU), to evaluate whether they are compatible with the internal market and do not in any way encumber research and development (R&D), by overextending the temporarily limited monopoly granted by a patent in exchange for the disclosure of an invention. Accordingly, any agreement limiting or prohibiting a party from challenging a patent or providing for a de facto extension of the 20-year monopoly right granted by a patent entails by nature a potential conflict with antitrust. Since patent and antitrust law coexist and both serve legitimate interests, the tension between them is intentional and finding the right balance serves the purpose of driving technological development and fostering technological progress.

Paragraph 1 of Article 101 TFEU enumerates the types of conduct on the part of ‘undertakings, associations of undertakings and concerted practices’ that are prohibited as being ‘incompatible with the internal market’. Paragraph 2 stipulates that any agreements or decisions prohibited by paragraph 1 shall be automatically void. The legal effect of Article 101(2) TFEU not only extends to ‘undertakings’ or ‘associations of undertakings’ but also binds public authorities and courts throughout the EU.¹ However, the European lawmaker is aware that such agreements may also contain clauses conducive to technical or economic progress and hence are beneficial to customers and consumers. This is why, under

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Abstract

- No-challenge clauses prohibit one party to an agreement from mounting a legal challenge against—in particular—patent rights that are the subject of the agreement. Similarly, pay-for-delay agreements oblige a party to acknowledge the patent owner’s rights and delay their market entry in return for a value transfer (pecuniary or not) from the patentee. Such IP agreements may limit or partition markets in contravention of Article 101(1) Treaty on the Functioning of the European Union (TFEU).
- The Commission’s Report on competition enforcement in the pharmaceutical sector has shown that around one-third of competition issues leading to intervention decisions concern horizontal agreements between competitors. However, they can also—and often do—promote technical or economic progress and are thus permissible under Article 101(3) TFEU.
- The article discusses the balance of interests in free competition, as well as the promotion of technological progress in the context of Article 101 TFEU, the Technology Transfer Block Exemption and recent European case law and attempts to provide guidelines regarding the admissibility of the said clauses under European law.

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¹ Karsten Schmidt in Immenga/Mestmäcker, *Wettbewerbsrecht* (6th edn, 2019), art 101(2) AEUV Marignal note (mn) 14.

certain circumstances, Article 101(1) TFEU could be ‘declared inapplicable’ according to Article 101(3). In the final analysis, Article 101 TFEU represents a balancing

of interests of the concerned markets, businesses and customers.

The importance of competition rules, particularly in the pharmaceutical industry, was noted during the Pharmaceutical Sector Inquiry conducted by the European Commission in 2008. In its summary, the Commission stressed that it would pursue any antitrust infringement in the sector, wherever ‘required to protect the Community interest,’² because the pharmaceutical sector ‘is essential for the health of Europe’s citizens, who need access to innovative, safe and affordable medicines.’³ This is backed up by recent figures in a Commission report on competition law enforcement in the pharmaceutical sector, published on 28 January 2019. Between 2009 and 2017, the Commission and national Competition Authorities investigated over 100 cases and handed down 29 antitrust decisions in this sector, imposing fines totalling more than one billion euros.⁴ Following the conclusion of the Pharmaceutical Sector Inquiry, it was considered important to continue monitoring patent settlements between originators and generic manufacturers.⁵ The main objectives of monitoring were to gain a better understanding of the use of this type of settlement agreements and to identify those settlements that delay generic market entry. In those reports, both pay-for-delay and no-challenge clauses were named as strategies to delay generic entry and therefore potential violations of EU competition laws.⁶ The intention to carry out stricter competition law analyses relates to the ‘Pharmaceutical Strategy for Europe’ adopted by the European Commission in 2020. In order to provide accessible and affordable treatments, the Commission will consider targeted policies that support greater generic and biosimilar competition, accompanied by a strengthened enforcement of the EU competition rules.⁷

No-challenge clauses prohibit one party to an agreement from mounting a legal challenge against—in particular—patent rights that are the subject of the agreement. No-challenge clauses can be incorporated into both licensing and settlement agreements. Similarly, pay-for-delay agreements oblige a party to acknowledge the patent

owner’s rights and delay its market entry in return for a value transfer (pecuniary or not) from the patentee. They can eg be concluded independently of any licence, patent nullity or infringement dispute or proceedings and could even take effect after patent expiry.

Such IP agreements may indeed limit or partition markets in contravention of Article 101(1) TFEU. The Commission’s Report on competition enforcement in the pharmaceutical sector has shown that around one-third of competition issues leading to intervention decisions concern horizontal agreements between competitors.⁸ However, they can also—and often do—promote technical or economic progress and are thus permissible under Article 101(3) TFEU.⁹ For example, licensing agreements by their very nature share technical innovations with competitors by granting them exclusive or non-exclusive rights and thus foster the spread and furtherance of innovation.

Formerly, the EU Commission was the only competent body empowered to carry out such balancing of interests and to declare the inapplicability of Article 101(1) TFEU by virtue of Article 101(3). However, after adoption of Council Regulation No 1/2003/EC,¹⁰ national public authorities and courts may now apply Article 101(3) autonomously.¹¹ This means that Articles 101(1) and (3) TFEU are in a rule–exception relationship directly applicable by the courts, even outside the scope of any preceding EU Commission declaration. However, it is not up to the discretion of the authorities or courts *whether* they wish to rely on Article 101(3) TFEU or not. Rather, they *shall* apply paragraph 3 if the relevant conditions are met.¹²

Although authorities and courts regularly adjudicate on individual cases, the EU Commission retains its competence. It can still make declarations under Article 101(3) TFEU for categories of agreements, decisions or concerted practices by way of regulation (Article 288 TFEU).¹³ Such declarations have the effect of a regulatory block exemption. An example that is highly relevant for IP agreements is Commission Regulation No 316/2014/EU on the application of Article 101(3) TFEU

2 European Commission, Executive Summary of the Pharmaceutical Sector Inquiry Report of 8 July 2009, 19.

3 *ibid.*, 1.

4 Report from the Commission to the Council and the European Parliament Competition Enforcement in the Pharmaceutical Sector (2009–2017) of 29 January 2019, 9.

5 European Commission, Executive Summary of the Pharmaceutical Sector Inquiry Report of 8 July 2009, 27.

6 Exemplary: European Commission, 8th Report on the Monitoring of Patent Settlements of 9 March 2018, 2ff.

7 European Commission, Pharmaceutical Strategy for Europe of 25 November 2020, 12.

8 See n 4, 10.

9 Klaus/Derra, NZKart 2020, 115, 121.

10 EU (4 January 2003), Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Article 81 and 82 of the Treaty, OJ L1, 1.

11 Reinhard Ellger in Immenga/Mestmäcker, *Wettbewerbsrecht* (6th edn, 2019), art 101(3) AEUV mn 13ff.

12 *ibid.*, mn 16 with further references.

13 *ibid.*, art 101 Abs 3 AEUV mn 334.

to categories of technology transfer agreements, the so-called Technology Transfer Block Exemption Regulation (TTBER).¹⁴

The TTBER constitutes a balancing of interests of both free competition and the promotion of technological progress and provides legal certainty for intellectual property rights (IPR) holders. It promotes the dissemination of new technologies through licensing and follow-on innovation.¹⁵ However, the TTBER has only partially achieved this goal, as it is often unclear and contains quite a few contradictory provisions. The Commission has published specific Guidelines on the application of Article 101 TFEU to technology transfer agreements,¹⁶ dealing not only with Article 101 TFEU but also with the TTBER (EU Commission Guidelines). However, these guidelines are not free of ambiguities and contradictions either.

As the TTBER is subject to interpretation (as is the text of Article 101 TFEU), this invariably requires the involvement of the courts. In particular, the Court of Justice of the European Union (CJEU) is competent to give preliminary rulings under Article 267 TFEU on the interpretation of Articles 101(1)–(3) TFEU as well as the TTBER.

In practice, this makes it quite hard to determine on a case-by-case basis whether (1) an agreement between undertakings, (2) decisions by associations of undertakings or (3) concerted practices between or by undertakings is void or prohibited under EU competition laws. For technology transfer agreements, the proper procedure would be, first, to evaluate whether Article 101(1) TFEU is violated at all; secondly, to check whether the respective paragraph is inapplicable under the TTBER and, thirdly, to assess whether it is inapplicable by directly applying Article 101(3).¹⁷ Providing answers to these questions requires careful scrutiny of the EU Commission Guidelines and the CJEU case law.

Furthermore, relevant for the interpretation of Article 101(3) TFEU in the field of pharmaceuticals is Commission Regulation No 1217/2010/EU. This Regulation exempts from the scope of Article 101(1) TFEU agreements that serve the purpose of R&D. The Regulation

requires that the market share of the parties involved does not exceed 25 per cent.

I. No-challenge clauses

Clauses that prohibit the other contractual party from challenging the IP right in question are frequently included in licensing agreements, especially cross-licences, as well as in judicial and extrajudicial settlements. It seems obvious that IPR holders do not want to have their IP rights challenged in the future by a party with whom they previously agreed on a licence or settled a legal dispute concerning the very same IP right. This is particularly relevant for patents. For that reason, an agreement may set out the legal consequences following a violation of such clauses. Common examples are penalty payments or automatically increased licence fees to the licensor, or even the extraordinary termination of the licensing agreement (termination-upon-challenge, see Section I.1), possibly combined with claims for damages.¹⁸ No-challenge clauses may even lead to a procedural objection in opposition or nullity proceedings calling for their inadmissibility and dismissal before the patent office or the patent court, respectively.¹⁹

An unintended effect may be that such clauses are anti-competitive and counterproductive, since they may prevent weak and possibly even invalid patents from being challenged and subsequently restricted or revoked. This can solidify unjustified monopoly positions, restrict the market in question and distort competition (Article 101(1)(b) TFEU). Hence, there must be a balancing of interests.

Patent holders/licensors frequently need to exchange information with the licensee of the patent. This might go beyond what is contained in the patent document, eg practical application of the invention or company-internal know-how. Perhaps even confidential information must be disclosed, whereby the licensee could acquire special insights into the patent that might make the patent vulnerable to attacks.²⁰ The licensor thus needs a mechanism to defend its patent against abuse of the contractual relationship, which will ensure that a licensee does not challenge the patent or exploit any information disclosed to him in order to circumvent royalty obligations.

14 EU (28 March 2014), Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements Text with EEA relevance, OJ L93, 17.

15 Recitals 3 and 4 TTBER.

16 EU (28 March 2014), Communication from the Commission — Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, OJ C89, 3.

17 Bechtold, NZKart 2020, 459, 460.

18 Böttger/Kreksen, EuZW 2014, 653, 656.

19 Thus, eg German Federal Court of Justice (FCJ) NJW 1953, 1260—Exceptio Pacti; GRUR 1958, 177, 178—Aluminiumflachfolien; German Federal Patent Court (FPC) judgment of 3 December 2009, case 10 Ni 8/08.

20 Ann, Patentrecht, 8th edn, s 42 mn, 18.

On the other hand, in terms of competition laws, the other party and the wider public, respectively, have no interest in establishing or maintaining unfair monopolies. Hence, it must remain possible to challenge weak or invalid patents. Indeed, the possibility of opposing patents is an elementary principle of patent law. Licensees might understandably want to avoid the risk of punitive actions such as termination of the licensing agreement and possibly infringement proceedings in the aftermath of the terminated licence, not to mention damages that might far exceed the royalties.²¹ Therefore, no-challenge clauses may prevent the other party, particularly a licensee, from challenging patents.

No-challenge clauses seem to contain the same inherent potential for conflict as patents themselves. On the one hand, patents incentivize R&D and thereby foster technical progress. Licences on the underlying technical invention during the lifetime of the patent share the innovation with market players even before patent expiry and thus facilitate an earlier distribution of new technologies. Patents and licences have in common that they are a *limitation* on free competition for a defined period. Licences have the additional feature that the licensor and the licensee *share the market* between them.

If a patent is invalid, it must be possible to file an opposition against it or request revocation. A licensing agreement must allow for such action on the part of the licensee. On the other hand, if the licensing agreement is weighted too much in favour of the licensee, deterring patent holders from licensing at all, or even from entering into technology cooperation agreements, this could in turn ultimately stifle R&D. In any case, no-challenge clauses have no bearing on the legitimate public interest in challenging patents that do not satisfy the novelty or inventive step requirements or inventions that are not capable of industrial application, as *the public as such* is not a contractual party to a licensing agreement, settlement or any agreement with the patent holder. Therefore, public interest alone in the revocation of wrongly granted patents cannot per se lead to the inadmissibility of a no-challenge agreement.²² Any future licensee is free to choose between agreeing to a no-challenge clause in a licensing agreement or risking infringement proceedings. In order to pre-empt (or react to the threat of) infringement proceedings, such licensee is free to file a nullity

action based on the presumed invalidity of the underlying patent.²³

In summary, invalid patents hinder R&D, especially when the party that is closely affected by such patents (eg licensee) is prevented from challenging them. However, an unfavourable legal licensing framework can have the same effect if the result is that technology transfer is stifled. This complex balancing of interests might be the reason why the courts and the European Commission have always viewed such clauses very critically both at the national and European levels.²⁴

The TTBER recognizes this and therefore establishes an exemption within the meaning of Article 101(3) TFEU for technology transfer agreements that do not infringe Article 101(1) TFEU. However, Article 5(1)(b) TTBER explicitly excludes no-challenge agreements from this exemption, which is why such no-challenge agreements are generally considered to be anti-competitive.²⁵ The justification given in the EU Commission Guidelines is that licensees are normally best placed to assess the validity of the IP right in question.²⁶

The European Commission and the CJEU were both critical of no-challenge agreements and classified them as unlawful restrictions of competition.²⁷ The decision in the case *Bayer and others v Süllhöfer* represented a shift in position.²⁸ The European Commission concluded that the no-challenge agreement in question did not constitute a violation of Article 101 TFEU. Since the agreement reached was a settlement, the public interest in ending legal disputes overrode competition concerns. The CJEU emphasized the need for a case-by-case assessment with regard to the respective legal and economic context. Nevertheless, the principle that no-challenge agreements are classified as being anti-competitive was upheld.

21 See EU Commission Guidelines, para 137.

22 Cf, eg Ann, *Patentrecht*, 8th edn, s 42 mn, 18, 19, who argues that the interest the licensee has in being able to relieve himself of the burden of royalties is instrumentalized in the general interest if one does not want to recognize a no-challenge clause per se.

23 Sophie Lawrance, 'The competition law treatment of no-challenge clauses in licence agreements: an unfortunate revolution?', *JIPLP* 9(10) (2014), 802, 806.

24 Cf Commission Decision of 9 June 1972, case IV/26.813—Raymond-Nagoya; CJEU *Windsurfing v Commission*, C-193/83, mn 89ff = GRUR Int 1986, 635, 640; *Bayer and others v Süllhöfer*, C-65/86, mn 17 = GRUR Int 1989, 56, 57; EU Commission Guidelines, mn 134; on the national level of Germany, increasingly only from the 1980s onwards, cf inter alia FPC GRUR Int 1997, 631, 633ff.

25 Even the case where the licensor of a non-exclusive licence is granted a right of termination-upon-challenge was also deliberately no longer exempted by the Commission in the 2014 Regulation, cf *Winzer*, *Der Lizenzvertrag*, pt 2. B mn 155, pt 6. C mn 268. See Section II.1.

26 EU Commission Guidelines, para 134.

27 Anne-Kathrin Lauer, *Die Nichtangriffsverpflichtung im deutschen und europäischen Kartellrecht* [The No-Challenge Obligation under German and European Antitrust Laws] (Heidelberger Schriften zum Wirtschaftsrecht und Europarecht) vol 98, 2021, 49ff.

28 CJEU, *Bayer and others v Süllhöfer*, C-65/86 = GRUR Int 1989, 56.

According to the Guidelines and the current case law of the CJEU, there are only three generally accepted exceptions to this principle:

- a *free licence grant*, since the licensee does not suffer any competitive disadvantages of having to pay a fee,²⁹
- paid licences if they relate to a *technically obsolete process* that the licensee has not used at all³⁰ or
- *exclusive licences* according to Article 5(1)(b) TTBER, with specific regard to *termination clauses* (see, later, licensor's right of termination).

If a no-challenge clause does not fall under one of these three exceptions, it is *likely*, but not certain, that the agreement infringes EU competition law.³¹ In this respect, the lack of exemption is not to be equated with an established infringement of competition law. Instead, a case-by-case assessment is necessary. The EU Commission Guidelines confirm this and require an individual assessment of the clauses not covered by the block exemption.³² The Guidelines also explain that the rest of a licensing agreement containing such a clause might still be applicable for a block exemption if the said clause is severable from the remainder.³³ As clarified by the CJEU in the *Windsurfing* decision³⁴ and now by the EU Commission Guidelines,³⁵ this assessment is defined as follows:

The public interest in strengthening the incentive of the licensor to license out, by not being forced to continue dealing with a licensee that challenges the very subject matter of the licensing agreement, must be balanced against the public interest in eliminating any obstacle to economic activity that may arise where an intellectual property right was mistakenly granted. In balancing those interests, it should be taken into account whether the licensee fulfils all the obligations under the agreement at the time of the challenge, in particular the obligation to pay the agreed royalties.³⁶

The EU Commission Guidelines name the *value* of the licensed technology as a specific criterion for classifying no-challenge clauses 'likely' to violate Article 101(1) that are not exempted under Article 101(3) TFEU.³⁷ Therefore, in terms of no-challenge clauses with regard to eg standard-essential patents, such balancing of interests appears to support a violation of Article 101 TFEU. As

the Guidelines provide no legal definition of 'valuable technology', the courts are free to interpret this broadly, making the balancing more likely in favour of the said violation.

However, regardless of whether the licensed technology is valuable or not, the outcome may differ in the case of *exclusive* licences, which grant the licensee the right to exploit and sublicense, and thereby block the licensor (i.e. the patent holder) from doing so.³⁸ In that case, such balancing appears to be in favour of a no-challenge agreement (including a contractual penalty and the procedural objection of an inadmissible exercise of rights). Here, the licensee essentially assumes, albeit for a licence fee, the position of the patent holder by exploiting the patent himself, monetizing the exploitation by others through granting sublicences and trying to prevent third parties (including the patentee) from suing for patent infringements. In such a strong position, it seems unlikely that the obligation not to challenge the patent would outweigh different interests, as the royalties might be the patentee's only source of income.³⁹

1. Termination-upon-challenge clauses

An alternative to no-challenge clauses is a provision according to which the patentee is granted a right of termination if the licensee challenges the licensed IPR. This right of termination-upon-challenge is also referred to as an indirect no-challenge obligation.⁴⁰ The licensee is thereby de facto deterred from challenging the patent, as an attack would expose them to the risk of a patent infringement claim after termination of the licence.⁴¹

This can be particularly problematic for the licensee in the case of a standard-essential patent. In such cases, the licensed patents are necessary in order to be able to implement the technology standard. Not using the subject matter of the patented invention could therefore ultimately make it impossible for the licensee to continue operating in the relevant market and could represent an insurmountable obstacle. This is true a fortiori if the patent holder enjoys a dominant market position, as excluding the licensee would result in a significant limitation of the market.⁴²

²⁹ *ibid*, mn 17 = GRUR Int 1989, 56, 57.

³⁰ *ibid*, mn 18 = GRUR Int 1989, 56, 57.

³¹ See also Ullmann/Deichfuß in Benkard, PatG, 11th edn, s 15, mn 142.

³² EU Commission Guidelines, para 128.

³³ *ibid*.

³⁴ CJEU *Windsurfing v Commission*, C-193/83, mn 92 = GRUR Int 1986, 635, 641.

³⁵ EU Commission Guidelines, para 136ff.

³⁶ *ibid*, para 138.

³⁷ *ibid*, para 134.

³⁸ Cf. the understanding of the term in art 1(1)(p) TTBER.

³⁹ This argument is addressed by the EU Commission Guidelines, para 139, specifically for termination clauses in exclusive licence agreements. However, it is obviously equally valid for no-challenge agreements in exclusive licences.

⁴⁰ Böttger/Kreksen, EuZW 2014, 653, 655; Marc Schweda in Loewenheim/Messen/Riesenkampff/Kersting/Meyer-Lindemann, Kartellrecht, 4th edn, TTBER art 5 Non-exempted Restrictions, mn 235.

⁴¹ Cf EU Commission Guidelines, para 136.

⁴² Cf Lauer (n 27) 132ff.

The legal classification of termination-upon-challenge clauses seems to be clear. The 2004⁴³ TTBER generally exempted such indirect no-challenge clauses.⁴⁴ The 2014 TTBER amended this exemption to the extent that it only applied to contractual termination rights in the case of *exclusive* licences.⁴⁵ The Commission justified this by citing the lower probability of anti-competitive effects in the case of exclusive licences. Thereby, it mentioned the existence of a special economic dependency in this case, also for the patent holder, as well as the possible negative impact on innovation and licensing as compelling reasons justifying the exemption.⁴⁶

In contrast, the non-exemption of the licensor's termination rights in the case of *non-exclusive* licensing agreements is justified by the need to resolve a conflict of interests.⁴⁷ The public interest in eliminating invalid property rights in order to promote innovation and research stands in direct contradiction to the licensor's interest in disengaging from the contract with the licensee in the event of an attack on the former's IP right.⁴⁸ The de facto effect of the termination right as a no-challenge clause is further strengthened where the licensee is dependent on the licensed IP right. This dependency may exist both in the form of a substantial financial risk and, as explained earlier, in particular in the case of standard essential patents.⁴⁹

The (sole) exemption of termination rights in the case of exclusive licences does not necessarily mean that the inclusion of termination clauses in non-exclusive licensing agreements automatically constitutes an antitrust infringement. As explained earlier, a decision regarding such licences can only be made after carrying out a case-by-case assessment and evaluation. In the pharmaceutical sector, the possibility of termination-upon-challenge clauses is likely to remain of significance, since relevant patents are usually licensed on an exclusive basis.⁵⁰

One argument in favour of a termination clause is illustrated by the fact that the EU Commission Guidelines

specifically address scenarios where the patented technology is valuable or where the licensor has a 'very significant' market position.⁵¹ Consequently, outside such scenarios, termination clauses in non-exclusive licences seem likely to be justifiable. The key criterion is whether the individual case provides a *significant disincentive* to challenge the IP right and therefore 'produces the same effect' as a no-challenge clause.⁵²

Another argument could be that termination-upon-challenge clauses merely balance the interests of patentee and licensee: if the licensee has an interest in challenging the subject matter of the licensing agreement, the patentee might have an equally justified interest in terminating that same agreement with the licensee. Moreover, even a contestable clause under antitrust laws may still lead to the licensee nonetheless observing it and refraining from challenging the licensed IP right.⁵³ The licensee is obliged to challenge neither the clause nor the IP right.

2. In the context of a settlement

In contrast to licensing agreements, it seems less problematic if no-challenge or termination-upon-challenge clauses are agreed in the context of dispute resolution proceedings. As commonly observed in these cases,⁵⁴ the patentee will have brought an infringement action against the alleged infringer, who in return will bring a nullity action against the patent. If they now agree to settle the dispute, the patentee will grant the (alleged) infringer a licence for the patent in dispute but will in turn insist on introducing a condition that the now licensee will not again challenge the patent in the future. The final withdrawal of revocation proceedings by the alleged infringer is, in the end, a precondition for the patentee entering into such a settlement. The admissibility (under antitrust laws) of a no-challenge clause (or termination-upon-challenge clause) in a settlement agreement is thus an essential motivating factor for the patentee.⁵⁵

In such cases, the EU Commission assumes that no-challenge clauses, *in principle*, do not infringe Article 101(1) TFEU, since in this context the precise purpose of the agreement is to resolve existing conflicts or avoid future ones.⁵⁶ However, the Commission does mention exceptions where one may presume an infringement of

43 Regulation (EC) No 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements (27 April 2004) OJ L123, 11.

44 See n 23, 802, 803.

45 Cf art 5(1)(c) TTBER; EU Commission Guidelines, para 136; critically Lauer (n 27) 139.

46 EU Commission Guidelines, para 139.

47 In the literature, however, there are voices in favour of exemption also in the case of simple licence agreements, eg Schweda (n 40), TTBER art 5 Non-exempted Restrictions, mn 243.

48 Böttger/Kreksen, EuZW 2014, 653, 655ff.

49 EU Commission Guidelines, para 136; Böttger/Kreksen EuZW 2014, 653, 656.

50 Heitz, PharmR 2022, 538, 544.

51 EU Commission Guidelines, para 136.

52 *ibid*, para 137.

53 Cf Schweda (n 40), TTBER art 5 Non-exempted Restrictions, mn 244; dissenting opinion Böttger/Kreksen EuZW 2014, 653, 657.

54 The sector inquiry came to the conclusion that the vast majority of settlements was reached in the context of litigation cases; cf Executive Summary of the Pharmaceutical Sector Inquiry Report of 8 July 2009, 12.

55 Lauer (n 27) 98; Böttger/Kreksen, EuZW 2014, 653, 654ff.

56 EU Commission Guidelines, para 242.

Article 101(1). Such an infringement may exist if the IP right was granted based on incorrect or misleading information.⁵⁷ No-challenge or termination-upon-challenge clauses are likely to be equally problematic if the settlement agreement is not based on a *serious and objectively justified* assumption that claims against the settling party could actually be enforced based on the patent in dispute (this would be the case, eg if the parties deliberately intend to protect patents that are obviously invalid, or they even use a settlement mala fide only as a cover-up where the actual intention is to divide the market among themselves).⁵⁸ In particular, it might be considered a violation of Article 101(1) TFEU to grant licences in the mere guise of settlement agreements.

A detailed case-by case-examination is therefore always called for, especially since the CJEU does not seem to differentiate between no-challenge clauses agreed in the context of a licensing agreement or a settlement agreement.⁵⁹ Nor does the CJEU seem inclined to treat court settlements differently from out-of-court settlements.⁶⁰ However, both differentiations would appear to be justified if the parties are acting in good faith. A typical example would be where settlements are agreed after a nullity action has been filed (ie the parties' arguments for and against invalidity have been exchanged). In such a case, this could be considered as an *informed decision* of the parties, which therefore should be binding based on the principle of the freedom of contract. This would be comparable to US antitrust laws that allow for no-challenge agreements in settlements only after 'discovery', ie a court-ordered exchange of information or evidence before trial.⁶¹

There are other instruments apart from direct or indirect (termination-upon-challenge) no-challenge clauses that may have the same effect of preventing the other party from challenging the patent and whose admissibility in terms of antitrust laws seems easier to justify because they allow the patent in question to be challenged:

- penalty payments, agreed damage claims or an increase of royalty payments upon challenge; such clauses provide a level of financial compensation, which lessens the financial risk of the patent being invalidated,
- substantial signing fee for the licensing or settlement agreement, which reduces the incentive for a challenge and
- royalty front-loading, ie initial payment of a lump sum for the full licence term, which has the advantage (for the patentee) that this payment cannot be recovered even in the event of an invalidation of the patent⁶²; such a clause also reduces the incentive for a challenge.

II. Pay-for-delay agreements

I. General

For the owner of a patent covering medicinal products, another way of resolving or avoiding disputes would be to contractually oblige manufacturers of generic drugs to acknowledge the patent owner's rights and delay their market entry in return for a value transfer from the patentee. The clause relating to the actual *point in time* of the envisaged market entry would then be a crucial element of such a contract. As IP protection for many 'blockbuster' pharmaceuticals, which have generated large profits and will soon be competing on price with generics, is gradually expiring,⁶³ such agreements will retain their relevance.

Such an agreement between the parties will usually prevent one party from placing its own products on the market and could therefore potentially violate Article 101(1) TFEU.⁶⁴ The agreement could also result in unlawful market sharing.⁶⁵ An assessment of these scenarios will likely largely depend on the time of the envisaged market entry (as mentioned earlier). There are two possible scenarios:

- Envisaged market entry *before or upon expiry* of the patent⁶⁶: Here, the parties are only interested in avoiding market entry during the patent term, which could potentially bear the risk of a legal challenge being

57 *ibid*, para 243.

58 FCJ GRUR 1952, 141—Tauchpumpe II; NJW 1955, 630—Rote Herzwandvase; GRUR 2005, 845—Abgasreinigungsvorrichtung. Subjective characteristics have lost importance compared to objective indications and are even considered dispensable in the literature, Lorenz PharmR 2006, 221, 226.

59 CJEU *Bayer and others v Süllhöfer*, C-65/86, mn 15 = GRUR Int 1989, 56, 57; in contrast, apparently more recently at lower instance, CJEU *Krka v Commission*, T-684/14 = GRUR-Prax 2019, 100.

60 CJEU *Nungesser and others v Commission*, C-258/78 [1982] ECR 2015, mn 89; *Bayer and others v Süllhöfer*, C-65/86, mn 15 = GRUR Int 1989, 56, 57.

61 Cheng, JIPEL 2016, 437 (454) with reference to *Rates Tech., Inc. v Speakeasy, Inc.*, 685 F3d 163 (2d Cir 2012).

62 See, eg CJEU *Genentech v Hoechst and Sanofi-Aventis Germany*, C-567/14 (headnote) = EuZW 2016, 743.

63 Picht/Chrobak, GRUR 2019, 475, 476.

64 Cf also Commission, Decision *Perindopril (Servier)* of 9 July 2014, Case AT.39612, mn 1118ff.—C(2014) 4955—final.

65 Schweda (n 40), introduction, mn 43.

66 The so-called authorized generics, where the original patent holder grants a licence to the generic manufacturer, are of concern under competition law due to the first-mover advantage that accrues to an early generic entry, cf Kyle Antitrust Law Journal 2016, 1, 9ff.

lodged against the patent before its expiry. This situation is comparable to no-challenge or termination-upon-challenge clauses, whereby there is no market entry but also no royalties being payable; rather a compensation payment is made by the patentee. This may be justifiable in some cases and could avoid a violation of Article 101(1) TFEU.

- Envisaged market entry *after expiry* of the patent: Here, the intention of the parties is to delay market entry beyond the (maximum) term of the patent. This could represent a strong indication of an *intended* restriction of competition, which would make it impossible to justify such a clause even in individual cases (in contrast to an *effected* restriction of competition, see Section II.2.b.).

An agreement on financial incentives in return for a waiver of market entry is therefore regarded in the CJEU's case law as irrefutable evidence of an intentional restriction of competition.⁶⁷ The CJEU recently had an opportunity to comment on such scenarios in the *Lundbeck* case. In March 2021, it dismissed the appeal lodged against a judgment of the General Court of the European Union (GC).⁶⁸

2. Lundbeck

In the *Lundbeck* case, the eponymous undertaking launched the antidepressant *citalopram* as the original manufacturer and obtained patent protection for the compound and the manufacturing process in almost all countries of the European Economic Area. *Citalopram* became a blockbuster drug, prompting Lundbeck to begin developing a strategy to delay generic market entry until consumers had switched to Lundbeck's successor product, *Escitalopram*. This strategy included, among other things, entering into agreements with several generic manufacturers regarding their market entry.⁶⁹

On 19 June 2013, the EU Commission found an infringement of Article 101(1) TFEU in four cases and imposed a fine on *Lundbeck* in the total amount of €93 766 000. *Lundbeck* appealed this decision to the GC and requested an annulment of the Commission's decision. The GC dismissed the case on 8 September 2016.

The subsequent appeal filed with the CJEU was also dismissed on 25 March 2021. These decisions now clarify to a certain extent the circumstances under which pay-for-delay agreements violate European antitrust laws. In particular, the CJEU looked at whether there is potential competition and whether this competition is restricted.

(a) Potential competition

This criterion under Article 101(1) TFEU concerns the intended market entry of the generic manufacturer. In general, the requirements for affirming this criterion are not high.⁷⁰ To confirm that there is potential competition, it is sufficient to establish that the generic manufacturer has *real and concrete possibilities* of joining the market and competing with the undertakings currently operating in the market.⁷¹ In the CJEU's view, it is relevant here whether the generic manufacturer has a *firm intention and an inherent ability* to enter the market on its own and is not prevented from doing so by *insurmountable barriers* to entry.⁷² The generics manufacturer's intention to enter the market must be reflected in preparatory measures required for market entry, in particular the application for marketing authorization.⁷³ In particular, a process patent for the production of an active ingredient that is in itself in the public domain is not necessarily an insurmountable barrier to entering the active ingredient market.⁷⁴ This would implicate that a patent for an active ingredient would rule out the criterion of 'potential competition'.⁷⁵ The fact that there is uncertainty as to the validity of the patent is of no relevance to the question of insurmountable barriers.⁷⁶ Finally, the assessment depends on the subjective perception of the originator.⁷⁷ The fact that the originator makes a value transfer to the generic manufacturer indicates that the originator perceives the generic manufacturer as potential competition.⁷⁸

⁷⁰ Langguth, NZKart 2021, 160, 161.

⁷¹ See CJEU *Generics and Others v Competition and Markets Authority*, C-307/18, mn 36 = NZKart 2020, 131, 131ff and the case law cited therein.

⁷² CJEU *Lundbeck v Commission*, C-591/16 P, mn 54ff = EuZW 2021, 726, 727; called a two-pronged test by Kellerbauer, EuZW 2020, 706, 708.

⁷³ CJEU *Lundbeck v Commission*, C-591/16 P, mn 86 = EuZW 2021, 726, 730; Oechsler/Dörrhöfer, NZKart 2021, 432, 433; Gschwindt, GRUR Int 2021, 250, 252; Hull/Clancy, JECLAP 2021, 143, 146.

⁷⁴ CJEU *Lundbeck v Commission*, C-591/16 P, mn 62 = EuZW 2021, 726, 728.

⁷⁵ Langguth, NZKart 2021, 160, 161; Oechsler/Dörrhöfer, NZKart 2021, 432, 433.

⁷⁶ CJEU *Lundbeck v Commission*, C-591/16 P, mn 60 = EuZW 2021, 726, 728; Oechsler/Dörrhöfer, NZKart 2021, 432, 433. According to Subiotto, DAF/COMP/WD(2014) 79, there are several factors in the European system that incentivize originator companies to make reverse payments to generics even if their patent position is strong.

⁷⁷ CJEU *Lundbeck v Commission*, C-591/16 P, mn 75ff = EuZW 2021, 726, 729.

⁷⁸ CJEU *Lundbeck v Commission*, C-591/16 P, mn 88 = EuZW 2021, 726, 730; Oechsler/Dörrhöfer, NZKart 2021, 432, 433.

⁶⁷ GC *Lundbeck v Commission*, T-472/13; *Biogaran (perindopril)*, T-677/14, mn 116.

⁶⁸ CJEU *Lundbeck v Commission*, C-591/16 P = EuZW 2021, 726; the appeal was brought against GC *Lundbeck v Commission*, T-472/13.

⁶⁹ Cf Summary of Commission Decision of 19 June 2013 relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA Agreement (Case AT.39226—*Lundbeck*).

(b) Restriction of competition

A further criterion for an infringement of Article 101(1) TFEU is the existence of a restriction of competition. What is decisive is whether such restriction is the *object* or (only) the *effect* of an agreement. Restrictions of competition by effect additionally require a detailed examination of the actual effects on the actual market, whereas intentional restrictions of competition (ie by object) are *always* considered as being anti-competitive.⁷⁹

The GC had already held in the contested decision that the concept of ‘restriction by object’ must be narrowly interpreted.⁸⁰ It only covers those agreements between undertakings which, when taken in isolation, by reason of their content, the aims pursued and the economic and legal context in which they are carried out, affect competition to such an extent that it is unnecessary to consider any further effects.⁸¹ In interpreting such agreements, the specific features of the pharmaceutical sector must be taken into account.⁸² In its assessment, the CJEU grants the parties some leeway as to how they come to an agreement.⁸³ Still, certain forms of agreement between undertakings may, by their very nature, be regarded as harmful to the proper functioning of normal competition.⁸⁴

According to the CJEU, this is especially the case where an examination of the competition restrictions shows that the agreed transfers of value can be explained *solely by the commercial interest in avoiding competition on the merits*, which both the patentee and the undertaking accused of infringing the patent have. Accordingly, in such cases, competitors deliberately opt for practical cooperation rather than engage in risky competition.⁸⁵ Thus, it must be determined on a case-by-case basis whether the net positive balance of the values transferred from the originator to the generic manufacturer is actually high enough to induce the generic manufacturer to refrain from entering the market and competing on the merits with the originator.⁸⁶ This positive balance does not necessarily have to be higher than the profits that the generic manufacturer would have obtained if it had prevailed in patent

litigation.⁸⁷ According to the CJEU, if this is the case, no further examination is required; the existence of a restriction of competition by the object can then be assumed as a matter of course.⁸⁸ Yet, on the other hand, the CJEU provides the opportunity to show and prove that the transferred values cannot be *solely* explained by the interest in avoiding competition.⁸⁹ In a previous decision, the CJEU provided guidance as to the sort of transfers of value from the originator to the generic manufacturer that may be justified if they are appropriate and strictly necessary having regard to the legitimate objectives of the parties to the agreement.⁹⁰ In this case, the effects of the said transfer must be assessed in further detail.

(c) Duty of diligence obligations of generic companies

Another point highlighted by the CJEU in the context of the above-mentioned case concerns the duty of diligence of the undertakings concerned to *retain relevant documents*. More specifically, it concerned two companies, *Xellia Pharmaceuticals* and *Alpharma*, which argued in their appeal against a *Lundbeck*-related GC decision that the EU Commission had infringed their rights of defence by not informing them of the proceedings until 8 and 9 years, respectively, after the initiation of such proceedings against the undertakings. It is true that in this case the CJEU found an error of law on the part of the GC, which had relied on case law concerning the retention of documents in the event of an excessively long duration of proceedings and thus after the opening of administrative proceedings. However, the present case concerned documents that had already been lost or destroyed before the opening of proceedings.

The CJEU did not overturn the decision as it considered the operative part of the GC’s judgment to be correct for other reasons: it stated that the duty of diligence of the respective undertakings regarding retention of relevant documents already arose from a sector inquiry initiated by the EU Commission. In 2008, the Commission had launched an investigation into the pharmaceutical sector with the aim of ascertaining whether agreements on the amicable settlement of disputes violated Articles 101 and 102 TFEU. Companies that engaged in the conduct that was the subject of the sector inquiry would therefore have to expect that the Commission might subsequently open

79 Cf also CJEU *Groupeement des cartes bancaires v Commission*, C-67/13 P, mn 48ff = EuZW 2014, 901, 903.

80 GC *Lundbeck v Commission*, T-472/13, mn 343.

81 CJEU *Lundbeck v Commission*, C-591/16 P, mn 131, 141 = EuZW 2021, 726, 732ff; recently confirmed for vertical agreements in CJEU *Visma v Konkurences padome*, C-306/20, mn 62 = NZKart 2021, 679, 681; Nagy, NZKart 2022, 238, 244.

82 *Oechsler/Dörrhöfer*, NZKart 2021, 432, 434.

83 *ibid.*

84 CJEU *Generics and others v Competition and Markets Authority*, C-307/18, mn 67 = NZKart 2020, 131, 132.

85 CJEU *Lundbeck v Commission*, C-591/16 P, mn 98, 114 = EuZW 2021, 726, 730ff.

86 Cf EU Commission Guidelines, para 239: ‘significant value transfer’.

87 CJEU *Lundbeck v Commission*, C-591/16 P, mn 99 = EuZW 2021, 726, 730.

88 Cf CJEU *Lundbeck v Commission*, C-591/16 P, mn 116ff = EuZW 2021, 726, 731.

89 Cf *Oechsler/Dörrhöfer*, NZKart 2021, 432, 434ff.

90 CJEU *Generics and Others v Competition and Markets Authority*, C-307/18, mn 85 = NZKart 2020, 131, 133.

individual proceedings against them.⁹¹ The CJEU emphasized that this was true a fortiori in the present case, as Recital 8 of the decision of 15 January 2008 to initiate the sector inquiry expressly states that:

... to the extent that the inquiry into the pharmaceutical sector reveals the possible existence of anticompetitive agreements or practices or abuses of a dominant position, the Commission ... could envisage [initiating] investigations against individual entities possibly resulting in decisions based on Article [101 and/or 102 TFEU].⁹²

(d) Consequences

The CJEU's case law presented earlier demonstrates how undertakings, especially pharmaceutical companies, must exercise caution in concluding agreements with other pharmaceutical companies. As regards pay-for-delay agreements, they should pay great care and attention to whether the necessary criteria are met in order to avoid a violation of Article 101(1) TFEU. For example, they should avoid delays after patent expiry to prevent the finding of intended restrictions of competition. The circumstances of each individual case must be carefully analysed.⁹³ Under US law, a pay-for-delay agreement may also amount to a restriction of competition. The Supreme Court had ruled that a case-by-case analysis is always necessary.⁹⁴

Further guidance on pay-for-delay agreements might be given by the pending referrals *Servier and Others v Commission*.⁹⁵ The CJEU has yet to issue guidance on how pro-competitive effects stemming from a settlement can be taken into consideration when assessing a restriction by object.⁹⁶

Secondly, as soon as a sector inquiry is initiated by the EU Commission in the sector that concerns them, companies should carefully archive relevant records and documents in order to be able to defend themselves as effectively as possible in the event of proceedings being brought against them.

III. Conclusion

EU antitrust laws pursue a somewhat hard-line approach as regards no-challenge clauses, termination-upon-challenge clauses and pay-for-delay agreements. In practical terms, the only clear and legitimate route is the granting of an *exclusive* licence, providing the licensor a right of termination-upon-challenge of the underlying patent by the exclusive licensee (scenario 1). Such cases are block-exempted by the TTBER.

As regards no-challenge clauses agreed in *exclusive* licences (scenario 2) or termination-upon-challenge clauses agreed in *non-exclusive* licences (scenario 3), the TTBER does not exempt either of these scenarios. While this must not be misunderstood as meaning that they would be regarded as anti-competitive per se and therefore invalid, they must undergo a case-by-case assessment. Such an assessment must balance the interests of the patentee, the licensee and the public. No-challenge clauses in *non-exclusive* licences (scenario 4) are rather difficult to justify.

It should be borne in mind that, if the invalidity of no-challenge clauses is opted for, the licensee will not have to fear any contractual penalties if he challenges the underlying patent and will also not run the risk of an infringement suit by the patentee because of the contractually granted right to use the patent. If the validity challenge should prove successful, the licensee can rid himself of (at least) future royalty payment obligations. If the attack should prove unsuccessful, the licensee can simply continue to use its licence. Hence, the absence of a no-challenge clause puts the licensee in a rather favourable position. In addition, the licensee may have garnered information from the licensor in the course of the cooperation pursuant to the licensing agreement, which would provide ammunition for a validity attack.

This may arguably result in a disparity, which may deter patentees from granting licences or agreeing on a contractual cooperation. Moreover, even as a matter of principle, such a disparity cannot be in the interests of competition law, which in such contractual situations strives for *equality of arms*. The above considerations argue in favour of allowing for a licensor's right of termination also in non-exclusive licensing agreements in order to attain a 'level playing field'. In such a case, the licensee may still challenge the licensed rights. However, the licensee may not do so without running the risk that the licensor will terminate the licensing agreement and sue them for patent infringement. While such a risk may indeed be regarded as a considerable deterrent for the licensee, the possibility nevertheless exists. Moreover, the public's interest in having erroneously granted monopoly

91 CJEU *Xellia Pharmaceuticals and Alpharma v Commission*, C-611/16 P, mn 154.

92 *ibid.*

93 The German FCJ implemented the CJEU's criteria for determining whether an agreement represents an intended restraint of competition (wording, objective and economic/legal context) in GRUR 2021, 1328, mn 33—Porsche-Tuning II.

94 *FTC v Actavis, Inc.*, 570 US 136 (2013).

95 Cases C-176/19 P and C-201/19 P: in her non-binding opinion, the Advocate General endorses the criteria developed in Lundbeck to establish a restriction of competition by object, Conclusions de l'Avocate Générale, C-176/19 P, mn 142.

96 Tayar/Ortoli, JECLAP 2022, 32, 34.

rights invalidated is still protected. This is because third parties (including future and ex-licensees) can always take action against the patent because no-challenge and termination-upon-challenge clauses only bind the contractual parties.

In this respect, sincere settlement agreements deserve special consideration. In such cases, no-challenge and termination-upon-challenge clauses are in principle permissible, as settlement agreements are intended to resolve or avoid an actual legal dispute. This situation changes if there are objective doubts as to the earnestness/sincerity of the legal dispute to be settled, ie if the parties apparently deliberately create the basis for the settlement in order to actually divide the market between themselves under the guise of an (out-of-court) settlement of the dispute. The same goes for licences in the guise of settlements.

Although the CJEU probably does not acknowledge such differentiation between a licensing agreement and a settlement, it considers free licences with a no-challenge obligation to be permissible under competition law. In particular, in the case of settlements, however, a deal is often made in such a way that infringement and nullity actions conducted in parallel are withdrawn by the respective parties and the patentee grants a *free* licence in exchange for a (future) no-challenge clause. This begs the question of whether the same principle should also apply to *very low* or *front-loaded royalties*.

Apart from this consideration, substantial signing fees and royalty front-loading are the best examples of how to avoid the risks of no-challenge or termination-upon-challenge clauses, which *de facto* have the same effect of preventing the other party from challenging the patent. This is because these measures do not provide for a specific consequence upon the filing of a challenge against the patent but rather reduce the incentive

to launch a challenge. Then again, the legal permissibility of such measures under European competition law has not yet been confirmed. It also requires that, at an early stage of negotiations, the licensee has sufficient financial resources to satisfy such demands by a licensor. This effectively works to the advantage of larger companies.

On the other hand, under current European law, pay-for-delay agreements increasingly threaten to restrict competition. According to CJEU case law, this depends above all on whether there is potential competition (competitor determined to enter the market without insurmountable barriers to market entry), which is or is intended to be restricted by the agreement. It is particularly relevant whether and for how long before or after expiry of the patent term market entry is to be delayed (length of delay) and what is the proportional value of the transfers made in return for this (amount of payment/compensation). Significant financial transfers that can only be explained by an intention to substitute competition by practical cooperation would in any case be considered an anti-competitive act if there is no possibility of an individual assessment because a restriction of competition is *intended* and not only effected by the agreement. The same might apply to delays beyond expiry of the patent.

The European Commission has recently stressed the necessity of companies assessing for themselves whether their practices comply with antitrust rules.⁹⁷ In any event, the parties to licensing or settlement agreements are well advised to observe the criteria laid down by the CJEU and, in the absence of a case specifically exempted by the TTBER, draft the relevant clauses in such a way that their admissibility under competition law can be justified by the circumstances of the individual case.

97 See n 4, 8.