JUDGMENT OF THE COURT (Fourth Chamber)

30 January 2020 (*)

(Reference for a preliminary ruling — Competition — Pharmaceutical products — Barriers to the entry on the market of generic medicines arising from settlement agreements (relating to disputes concerning process patents) concluded by a manufacturer of originator medicines who is the holder of those patents and manufacturers of generic products — Article 101 TFEU — Potential competition — Restriction by object — Characterisation — Restriction by effect — Assessment of effects — Article 102 TFEU — Relevant market — Inclusion of generic medicines in the relevant market — Abuse of dominant position — Characterisation — Justification)

In Case C-307/18,

REQUEST for a preliminary ruling under Article 267 TFEU from the Competition Appeal Tribunal (United Kingdom), made by decision of 27 March 2018, received at the Court on 7 May 2018, in the proceedings

Generics (UK) Ltd,

GlaxoSmithKline plc,

Xellia Pharmaceuticals ApS,

Alpharma LLC, formerly Zoetis Products LLC,

Actavis UK Ltd,

Merck KGaA

v

Competition and Markets Authority,

THE COURT (Fourth Chamber),

composed of M. Vilaras, President of the Chamber, S. Rodin, D. Šváby (Rapporteur), K. Jürimäe and N. Piçarra, Judges,

Advocate General: J. Kokott,

Registrar: C. Strömholm, administratror,

having regard to the written procedure and further to the hearing on 19 September 2019,

after considering the observations submitted on behalf of:

– Generics (UK) Ltd, by C. Humpe and S. Kon, Solicitors,

– GlaxoSmithKline plc, by B. Sher, R. Hoare, J. Kontogeorges and R. Bickler, Solicitors, D. Scannell and C. Thomas, Barristers, and J.E. Flynn QC,

– Xellia Pharmaceuticals ApS and Alpharma LLC, by L. Tolaini and B. Jasper, Solicitors, and R. O'Donoghue QC,

– Actavis UK Ltd, by C. Firth, Solicitor, and S. Ford QC,

– Merck KGaA, by S. Smith, A. White and B. Bär-Bouyssière, Solicitors, and R. Kreisberger QC,

– the Competition and Markets Authority, by C. Brannigan, R. Browne, V. Pye and N. Rouse, Solicitors, D. Bailey, Barrister, and J. Turner QC and M. Demetriou QC,

– the European Commission, by F. Castilla Contreras, T. Vecchi, B. Mongin and C. Vollrath, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 22 January 2020,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Articles 101 and 102 TFEU.

2 The request has been made in proceedings where the opposing parties are Generics (UK) Ltd ('GUK'), GlaxoSmithKline plc ('GSK'), Xellia Pharmaceuticals ApS, Alpharma LLC, formerly Zoetis Products LLC, Actavis UK Ltd and Merck KGaA, on the one hand, and the Competition and Markets Authority (United Kingdom) ('the CMA'), on the other, concerning the latter's decision of 12 February 2016 that those companies had taken part in unlawful agreements and concerted practices, that GSK had abused a dominant position and that financial penalties should be imposed on them ('the CMA decision').

Legal context

EU law

3 Paragraphs 17, 20 and 24 of the Commission Notice on the definition of relevant market for the purposes of Community competition law (OJ 1997 C 372, p. 5; 'the notice on market definition'), state:

'17. The question to be answered is whether the parties' customers would switch to readily available substitutes or to suppliers located elsewhere in response to a hypothetical small (in the range 5% to 10%) but permanent relative price increase in the products and areas being considered. If substitution were enough to make the price increase unprofitable because of the resulting loss of sales, additional substitutes and areas are included in the relevant market. This would be done until the set of products and geographical areas is such that small, permanent increases in relative prices would be profitable. The equivalent analysis is applicable in cases concerning the concentration of buying power, where the starting point would then be the supplier and the price test serves to identify the alternative distribution channels or outlets for the supplier's products. In the application of these principles, careful account should be taken of certain particular situations as described within paragraphs 56 and 58.

…

20. Supply-side substitutability may also be taken into account when defining markets in those situations in which its effects are equivalent to those of demand substitution in terms of effectiveness and immediacy. This means that suppliers are able to switch production to the relevant products and market them in the short term [that is, such a period that does not entail a significant adjustment of existing tangible and intangible assets (see paragraph 23)] without incurring significant additional costs or risks in response to small and permanent changes in relative prices. When these conditions are met, the additional production that is put on the market will have a disciplinary effect on the competitive behaviour of the companies involved. Such an impact in terms of effectiveness and immediacy is equivalent to the demand substitution effect.

…

24. The third source of competitive constraint, potential competition, is not taken into account when defining markets, since the conditions under which potential competition will actually represent an effective competitive constraint depend on the analysis of specific factors and circumstances related to the conditions of entry. If required, this analysis is only carried out at a subsequent stage, in general once the position of the companies involved in the relevant market has already been ascertained, and when such position gives rise to concerns from a competition point of view.'

United Kingdom law

4 Part I of the Competition Act 1998 includes Chapters I to V of that act. Within Chapter I, section 2 of that chapter provides:

'Agreements … preventing, restricting or distorting competition

(1) …, agreements between undertakings, decisions by associations of undertakings or concerted practices which:

(a) may affect trade within the United Kingdom, and

(b) have as their object or effect the prevention, restriction or distortion of competition within the United Kingdom,

are prohibited unless they are exempt in accordance with the provisions of this part.

(2) Subsection 1 applies, in particular, to agreements, decisions or practices which:

…

(b) limit or control production, markets, technical development or investment;

(c) share markets or sources of supply …'

5 Section 18 of the Competition Act 1998, in Chapter II of Part I of that act, provides:

'Abuse of dominant position

(1) …, any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the United Kingdom.

(2) Conduct may, in particular, constitute such an abuse if it consists in:

…

(b) limiting production, markets or technical development to the prejudice of consumers;

…

…'

6 Section 60 of that act, which is in Chapter V of Part I thereof, states:

'Principles to be applied in determining questions

(1) The purpose of this section is to ensure that so far as is possible (having regard to any relevant differences between the provisions concerned), questions arising under this Part in relation to competition within the United Kingdom are dealt with in a manner which is consistent with the

treatment of corresponding questions arising in EU law in relation to competition within the European Union.

(2) At any time when the court determines a question arising under this Part, it must act (so far as is compatible with the provisions of this Part and whether or not it would otherwise be required to do so) with a view to securing that there is no inconsistency between:

(a) the principles applied, and decision reached, by the court in determining that question; and

(b) the principles laid down by the Treaty and the European Court, and any relevant decision of that Court, as applicable at that time in determining any corresponding question arising in EU law.

(3) The court must, in addition, have regard to any relevant decision or statement of the Commission.

…'

The dispute in the main proceedings and the questions referred for a preliminary ruling

7 Paroxetine is a prescription-only anti-depressant medicine, belonging to the group of medicines known as selective serotonin re-uptake inhibitors ('SSRIs'). It was marketed in the United Kingdom by GSK, the manufacturer of the originator medicine ('the originator company' or 'the originator'), under the brand name 'Seroxat'.

8 Following the expiry, in January 1999, of the patent obtained by GSK for the active ingredient of that originator medicine and, in December 2000, of the period of 'data exclusivity' in relation to that active ingredient, GSK was faced with the possibility that manufacturers of generic medicines ('generic companies' or 'generics') would seek a marketing authorisation ('an MA') in the United Kingdom, using an abridged procedure, for their own version of that medicine.

9 In that period, GSK obtained a number of 'secondary' patents, including patent GB 2 297 550 ('the Anhydrate patent') covering four polymorphs of the active ingredient in question and the process to produce them. The Anhydrate patent, issued in 1997, was declared partially invalid by the Patents Court (United Kingdom) and, to the extent that it remained valid, expired in 2016.

10 Further, by mid-2000, GSK was informed that several manufacturers of generic medicines, including IVAX Pharmaceuticals UK ('IVAX'), GUK and Alpharma, were contemplating entering the United Kingdom market offering for sale a generic version of paroxetine. IVAX had submitted an MA application in Ireland and had obtained from BASF AG the active ingredient of paroxetine on the basis of which that application had been submitted. GUK had obtained an MA for paroxetine in Denmark in April 2001. Last, Alpharma had submitted an MA application in the United Kingdom on 30 May 2001.

11 Against that background, GSK entered into three agreements with the manufacturers of generic medicines concerned.

12 The first agreement ('the GSK/IVAX agreement') entered into with IVAX on 3 October 2001 and expiring on 29 June 2004, appointed IVAX as the 'sole distributor' in the United Kingdom, of 20 mg paroxetine hydrochloride, to a maximum volume of 770 000 packs of 30 tablets, to be sold as an authorised generic medicine, in return for an annual 'promotional allowance' of 3.2 million pounds sterling (GBP) paid by GSK.

13 The second agreement ('the GSK/GUK agreement') was entered into with GUK on 13 March 2002 and expired on 1 July 2004. That agreement followed various court proceedings, including the Anhydrate patent revocation proceedings brought on 27 July 2001 by BASF, the infringement proceedings brought against GUK on 18 September 2001 by GSK in relation to the same patent and the granting by the Patents Court on 23 October 2001 of an interim injunction prohibiting GUK from entering the market, at which time GSK gave an undertaking to compensate GUK for any loss or harm

that it might sustain if the interim injunction was granted at the initial hearing, but that injunction was ultimately held to be inappropriate ('the cross-undertaking in damages'). On 13 March 2002, namely the day before the proceedings brought by BASF and GSK were down for trial, GSK and GUK reached a settlement agreement which involved the discharge of the injunction and the cross-undertaking in damages given by GSK, the waiver of all claims to damages and the staying of proceedings. Under that agreement, GSK undertook to purchase all GUK's stock of generic paroxetine intended for sale in the United Kingdom for a sum of 12.5 million United States dollars (USD), to pay 50% of GUK's legal costs up to a maximum of GBP 0.5 million and to pay GUK an annual marketing allowance of GBP 1.65 million. For its part, GUK undertook to enter into a sub-distribution agreement with IVAX for 750 000 20 mg packs of paroxetine at an indexed price, and undertook, in common with all the companies in the Merck group, not to make, import or supply paroxetine hydrochloride in the United Kingdom during the currency of the supply agreement between IVAX and GUK.

14 The third agreement ('the GSK/Alpharma agreement') was entered into with Alpharma on 12 November 2002 and expired on 13 February 2004. That agreement followed the infringement proceedings brought by GSK against Alpharma and GSK's claim for interim relief. When the court seised indicated to the parties that such relief was likely to be granted, Alpharma gave an undertaking to that court on 1 August 2002 not to sell paroxetine in the United Kingdom prior to delivery of the final judgment, while GSK gave a cross-undertaking in damages. On 12 November 2002 a settlement was agreed by those two manufacturers under which the parties agreed to discharge their reciprocal undertakings and to abandon their claims. It was further provided that Alpharma would enter into a sub-distribution agreement with IVAX for the supply of 500 000 20 mg paroxetine packs (increased to 2 020 000 packs then reduced to 620 000 packs), that GSK would pay to Alpharma GBP 0.5 million towards its legal costs in the proceedings, GBP 3 million 'in respect of the production and preparation cost for launch in the UK market by Alpharma of [paroxetine]' and GBP 100 000 per month for a term of 12 months, as a 'marketing allowance', and that GSK would give Alpharma an option to purchase some products that GSK might sell in other therapeutic areas. In return for those benefits, Alpharma undertook not to make, import or supply in the United Kingdom any paroxetine hydrochloride other than what it would purchase from IVAX or what would be manufactured by GSK. That agreement also provided that Alpharma had the right to terminate the agreement on one month's notice in the event of the formation of a 'generic market' or on the demise 'whether by invalidation, surrender, abandonment, or otherwise' of the process claim in the Anhydrate patent. Alpharma exercised that right following delivery of the judgment on 5 December 2003 in a parallel case that permitted manufacturers of generic medicines to enter the market, and Alpharma then entered the paroxetine market in February 2004.

15 Against that background, the CMA adopted on 12 February 2016 the decision in which it found that:

– GSK held a dominant position in the market for paroxetine and had abused that position, contrary to the prohibition in Chapter II of Part I of the Competition Act 1998 by entering into the GSK/IVAX, GSK/GUK and GSK/Alpharma agreements;

– GSK and GUK (and Merck) had infringed the prohibition in Chapter I of Part I of the Competition Act 1998 and, after 1 May 2004, Article 101 TFEU, by entering into the GSK/GUK agreement; and

– GSK and the companies in the Alpharma group (Actavis UK, Xellia Pharmaceuticals — formerly Alpharma UK Limited — and Alpharma) had infringed the prohibition in Chapter I of Part I of the Competition Act 1998 by entering into the GSK/Alpharma agreement.

16 Consequently, the CMA imposed on those companies financial penalties to a total of GBP 44.99 million.

17 As regards, however, the GSK/IVAX agreement, the CMA imposed no penalty, in accordance with the Competition Act 1998 (Land and Vertical Agreements Exclusion) Order 2000 (SI 2000/310)

which, until its repeal on 30 April 2005, excluded vertical agreements from the prohibition laid down in Chapter I of the Competition Act 1998.

18 The companies on which penalties had been imposed brought an appeal against that decision before the Competition Appeal Tribunal (United Kingdom).

19 The Competition Appeal Tribunal considers that, in order to give a ruling on that appeal, it must determine, in accordance with EU law, whether the manufacturers of medicines concerned, namely GSK, GUK, Alpharma and IVAX were potential competitors with respect to the supply of paroxetine in the United Kingdom in the period concerned and whether the three agreements entered into by GSK with the manufacturers concerned of generic medicines constituted a restriction of competition 'by object' ('restriction by object') or by effect' ('restriction by effect'). That court considers that it must also define the product market on which GSK supplied paroxetine in order to ascertain whether that manufacturer of medicines held a dominant position in that market and whether it abused that position.

20 The Competition Appeal Tribunal holds, first, that, in order to assess the lawfulness of the CMA decision, in so far as it concerns restrictions of competition, it is necessary to interpret Article 101 TFEU. That court also states that the General Court of the European Union has given rulings in cases where the opposing parties include the same manufacturers of medicines as those involved in the main proceedings, on issues that are comparable to those arising this case, though all the applicants in the main proceedings dispute the relevance of those rulings to this case. Further, the Competition Appeal Tribunal considers that the rules governing the assessment of a restriction by effect, the subject of Question 6 that is referred for a preliminary ruling, remain uncertain. That court considers, second, that it is required to rule on novel issues of law in relation to the interpretation of Article 102 TFEU which concern both the definition of the relevant market and the definition of abuse of a dominant position and possible justification of the latter.

21 In those circumstances, the Competition Appeal Tribunal decided to stay the proceedings and to refer to the Court the following questions for a preliminary ruling:

'(1) Potential competition

For the purpose of Article 101(1) [TFEU], are the holder of a patent for a pharmaceutical drug and a generic company seeking to enter the market with a generic version of the drug to be regarded as potential competitors when the parties are in bona fide dispute as to whether the patent is valid and/or the generic product infringes the patent?

(2) Does the answer to Question 1 differ if:

(a) there are pending court proceedings between the parties involving this dispute; and/or

(b) the patent-holder has obtained an interim injunction preventing the generic company from launching its generic product on the market until determination of those proceedings; and/or

(c) the patent holder regards the generic company as a potential competitor?

(3) Restriction by object

When there are pending court proceedings concerning the validity of a patent for a pharmaceutical drug and whether a generic product infringes that patent, and it is not possible to determine the likelihood of either party succeeding in those proceedings, is there a restriction of competition "by object" for the purpose of Article 101(1) [TFEU] when the parties make an agreement to settle that litigation whereby:

(a) the generic company agrees not to enter the market with its generic product and not to continue its challenge to the patent for the duration of the agreement (which is no longer than the unexpired period of the patent), and

(b) the patent holder agrees to make a transfer of value to the generic company in an amount substantially greater than the avoided litigation costs (including management time and disruption) and which does not constitute payment for any goods or services supplied to the patent holder?

(4) Does the answer to Question 3 differ if:

(a) the scope of the restriction on the generic company does not go beyond the scope of the patent in dispute; and/or

(b) the amount of the value transfer to the generic company may be less than the profit it would have made if it had instead succeeded in the patent litigation and entered the market with an independent generic product?

(5) Do the answers to Questions 3 and 4 differ if the agreement provides for the supply by the patent holder to the generic company of significant but limited volumes of authorised generic product and that agreement:

(a) does not give rise to any meaningful competitive constraint on the prices charged by the patent holder; but

(b) brings some benefits to consumers which would not have occurred if the patent holder had succeeded in the litigation, but which are significantly less than the full competitive benefits resulting from independent generic entry which would have occurred if the generic company had succeeded in the litigation, or is this relevant only to assessment under Article 101(3) [TFEU]?

(6) Restriction by effect

In the circumstances set out in Questions 3-5, is there a restriction of competition "by effect" for the purpose of Article 101(1) [TFEU] or does that depend upon the court finding that in the absence of that settlement:

(a) the generic company would probably have succeeded in the patent proceedings (i.e. that the chance that the patent was valid and infringed was below 50%); alternatively

(b) the parties would probably have entered into a less restrictive settlement (i.e. that the chance of a less restrictive settlement was above 50%)?

(7) Market definition

Where a patented pharmaceutical drug is therapeutically substitutable with a number of other drugs in a class, and the alleged abuse for the purpose of Article 102 [TFEU] is conduct by the patent holder that effectively excludes generic versions of that drug from the market, are those generic products to be taken into account for the purpose of defining the relevant product market, although they could not lawfully enter the market before expiry of the patent if (which is uncertain) the patent is valid and infringed by those generic products?

(8) Abuse

In the circumstances set out in Questions 3-5 above, if the patent holder is in a dominant position, does its conduct in entering into such an agreement constitute an abuse within the meaning of Article 102 [TFEU]?

(9) Does the answer to Question 8 differ if the patent holder makes an agreement of that kind not in settlement of actual litigation but to avoid litigation being commenced?

(10) Does the answer to Question 8 or 9 differ if:

(a) the patent holder pursues a strategy of entering into several such agreements to preclude the risk of unrestricted generic entry; and

(b) the consequence of the first such agreement is that by reason of the structure of the national arrangements for reimbursement by the public health authorities to pharmacies of their costs of purchasing pharmaceutical drugs, the reimbursement level for the pharmaceutical drug in question is reduced, resulting in a substantial saving to the public health authorities (albeit a saving which is significantly less than that which would arise upon independent generic entry following a successful outcome for the generic company in patent litigation); and

(c) that saving was no part of the intention of the parties when entering into any of the agreements?'

Preliminary observations

22 It is apparent from the CMA decision, summarised in paragraph 15 of the present judgment, that the CMA imposed penalties with respect to the practices of GSK, GUK and Alpharma on different grounds and on different legal bases.

23 Penalties were imposed with respect to the GSK/GUK agreement under competition law on the basis of Chapter I of Part I of the Competition Act 1998 for its entire duration and on the basis of Article 101 TFEU for the period subsequent to 1 May 2004. With respect to the GSK/Alpharma agreement, however, which came to an end before that date, penalties were imposed solely on the basis of Chapter I of Part I of the Competition Act 1998.

24 Again, a penalty was imposed on GSK for an abuse of a dominant position solely on the basis of Chapter II of Part I of that act and not of Article 102 TFEU.

25 In that regard, it is true that, under the procedure laid down in Article 267 TFEU, the Court has no jurisdiction to interpret national law, that being exclusively for the national court (judgments of 7 September 2006, *Marrosu and Sardino*, C-53/04, EU:C:2006:517, paragraph 54, and of 18 November 2010, *Georgiev*, C-250/09 and C-268/09, EU:C:2010:699, paragraph 75).

26 The Court does, however, have jurisdiction to give a ruling on a request for a preliminary ruling concerning the provisions of EU law in situations where, although the facts in the main proceedings do not fall directly within the scope of that law, the provisions of that law have been made applicable under national law by means of a reference made in national law to their content (see, to that effect, judgments of 21 December 2011, *Cicala*, C-482/10, EU:C:2011:868, paragraph 17; of 18 October 2012, *Nolan*, C-583/10, EU:C:2012:638, paragraph 45; and of 15 November 2016, *Ullens de Schooten*, C-268/15, EU:C:2016:874, paragraph 53).

27 Where, in regulating purely internal situations, national legislation adopts the same solutions as those adopted in EU law in order, for example, to avoid any distortion of competition, or to ensure that a single procedure is applied in comparable situations, it is clearly in the interest of the European Union that, in order to forestall future differences of interpretation, provisions or concepts taken from EU law should be interpreted uniformly, irrespective of the circumstances in which they are to be applied (see, to that effect, judgments of 18 October 1990, *Dzodzi*, C-297/88 and C-197/89, EU:C:1990:360, paragraph 37; of 17 July 1997, *Leur-Bloem*, C-28/95, EU:C:1997:369, paragraph 32; and of 18 October 2012, *Nolan*, C-583/10, EU:C:2012:638, paragraph 46).

28 In this case, as is apparent both from the information sent by the referring court to the Court and the replies of the parties to a question put by the Court at the hearing, section 2 of the Competition Act 1998, in Chapter I of Part I of that act, and section 18 of that act, in Chapter II of Part I, must be applied

in a way that is compatible with the corresponding provisions of EU law, as is required in essence by section 60 of that act.

29 Consequently, a reply should be given to this request for a preliminary ruling.

Consideration of the questions referred for a preliminary ruling

Questions 1 to 6 (Article 101 TFEU)

Questions 1 and 2 (potential competition)

30 As a preliminary point, it must be recalled that Article 101(1) TFEU states that all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market are incompatible with the internal market and are prohibited.

31 Accordingly, if the conduct of undertakings is to be subject to the prohibition in principle laid down in Article 101(1) TFEU, that conduct must not only reveal the existence of coordination between them — in other words, an agreement between undertakings, a decision by an association of undertakings or a concerted practice –, but that coordination must also have a negative and appreciable effect on competition within the internal market (see, to that effect, judgment of 13 December 2012, *Expedia*, C-226/11, EU:C:2012:795, paragraphs 16 and 17).

32 The latter requirement means, with respect to horizontal cooperation agreements entered into by undertakings that operate at the same level of the production or distribution chain, that the coordination involves undertakings who are in competition with each other, if not in reality, then at least potentially.

33 That is the background to the sending by the referring court of Questions 1 and 2, which can be examined together.

34 By those questions, the referring court seeks, in essence to ascertain whether Article 101(1) TFEU must be interpreted as meaning that a manufacturer of an originator medicine who is the holder of a manufacturing process patent for an active ingredient which is in the public domain, on the one hand, and manufacturers of generic medicines who are taking steps to enter the market of the medicine containing that active ingredient, on the other, where those parties are in dispute as to whether that patent is valid or whether the generic medicines concerned infringe that patent, are in potential competition with each other. The referring court also seeks to ascertain whether the existence of court proceedings relating to the validity of the patent concerned, which are still pending and which have given rise to an application for interim relief and the granting of interim measures, and the fact that the patent holder may perceive the manufacturers of generic medicines to be potential competitors, constitute factors that may influence the response to that question.

35 In this case, it is only the concept of ‘potential competition’ that is at issue, given that the manufacturers of generic medicines who concluded the agreements at issue with GSK had not entered the market for paroxetine at the time when those agreements were concluded.

36 In order to assess whether an undertaking that is not present in a market is a potential competitor of one or more other undertakings that are already present in that market, it must be determined whether there are real and concrete possibilities of the former joining that market and competing with one or more of the latter (see, to that effect, judgment of 28 February 1991, *Delimitis*, C-234/89, EU:C:1991:91, paragraph 21).

37 Accordingly, when the agreement at issue is one which has the effect of temporarily keeping an undertaking outside a market, it must be determined whether there would have existed, in the absence

of that agreement, real and concrete possibilities for that undertaking to enter that market and compete with the undertakings established in that market.

38 Such a criterion means that there can be no finding of a potential competitive relationship as an inference merely from the purely hypothetical possibility of such entry or even from the mere wish or desire of the manufacturer of generic medicines to enter the market. Conversely, there is no requirement that it must be demonstrated with certainty that that manufacturer will in fact enter the market concerned and, a fortiori, that it will be capable, thereafter, of retaining its place there.

39 The assessment of whether there is potential competition must be carried out having regard to the structure of the market and the economic and legal context within which it operates.

40 In that respect, first, as regards, as in the main proceedings, the pharmaceutical sector, the specific features of which with respect to the implementation of EU competition law have previously been noted by the Court (see, to that effect, judgment of 23 January 2018, *F. Hoffmann-La Roche and Others*, C-179/16, EU:C:2018:25, paragraphs 65 and 80), and more particularly the opening of a market, of a medicine containing an active ingredient that has recently entered the public domain, to the manufacturers of generic medicines, the effects of which on prices have been emphasised by the referring court, due account must be taken of the regulatory constraints that are characteristic of the medicine sector. One of those constraints is Article 6 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicines for human use (OJ 2001 L 311, p. 67), as amended by Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 (OJ 2007 L 324, p. 121, and corrigendum OJ 2009 L 87, p. 174), which provides that no medicine may be placed on the market of a Member State unless an MA has been issued by the competent authorities of that Member State or an authorisation has been granted in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicines for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1), as amended by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 (OJ 2009 L 87, p. 109) (judgment of 23 January 2018, *F. Hoffmann-La Roche and Others*, C-179/16, EU:C:2018:25, paragraph 53).

41 Second, full account must be taken of the intellectual property rights and, in particular, the patents held by the manufacturers of originator medicines relating to one or more processes of manufacturing an active ingredient that is in the public domain, rights which enjoy a high level of protection in the internal market under Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ 2004 L 157, p. 45, and corrigendum OJ 2004 L 195, p. 16) and Article 17(2) of the Charter of Fundamental Rights of the European Union (see, to that effect, judgment of 16 July 2015, *Huawei Technologies*, C-170/13, EU:C:2015:477, paragraph 57).

42 Further, as the Advocate General stated in point 60 of her Opinion, the perception of the established operator is a factor that is relevant to the assessment of the existence of a competitive relationship between that party and an undertaking outside the market since, if the latter is perceived as a potential entrant to the market, it may, by reason merely that it exists, give rise to competitive pressure on the operator that is established in that market.

43 In the light of the foregoing, in order to assess whether, on the one hand, a manufacturer of originator medicines who is the holder of a process patent for an active ingredient that is in the public domain and, on the other, a manufacturer of generic medicines preparing to enter the market of the medicine containing that active ingredient who have entered into an agreement such as those at issue in the main proceedings are potential competitors of each other, it is necessary to determine, first, whether, at the time when that agreement was concluded, the manufacturer concerned of generic medicines had

taken sufficient preparatory steps to enable it to enter the market concerned within such a period of time as would impose competitive pressure on the manufacturer of originator medicines.

44 Those steps may include the measures taken by the particular manufacturer of generic medicines to put itself in a position to have, within that period, the required administrative authorisations for the marketing of a generic version of the medicine concerned and an adequate stock of that generic medicine either through its own production or through supply contracts concluded with third parties. Of equal relevance in that regard are all the legal steps actually undertaken by that manufacturer with a view to challenging, either as a principal issue or as an incidental question, the process patents held by a manufacturer of originator medicines, or, again, the range of marketing initiatives adopted by the manufacturer of generic medicines in order to market its medicine. Such steps permit the conclusion that a manufacturer of generic medicines has a firm intention and an inherent ability to enter the market of a medicine containing an active ingredient that is in the public domain, even when there are process patents held by the manufacturer of originator medicines.

45 Second, the referring court must determine that the market entry of such a manufacturer of generic medicines does not meet barriers to entry that are insurmountable.

46 In that regard, the existence of a patent which protects the manufacturing process of an active ingredient that is in the public domain cannot, as such, be regarded as an insurmountable barrier, and does not mean that a manufacturer of generic medicines who has in fact a firm intention and an inherent ability to enter the market, and who, by the steps taken, shows a readiness to challenge the validity of that patent and to take the risk, upon entering the market, of being subject to infringement proceedings brought by the patent holder, cannot be characterised as a ‘potential competitor’ of the manufacturer of originator medicines concerned.

47 The arguments of the companies on whom the CMA imposed penalties in relation to (i) the presumption of validity attached to a process patent held by the manufacturer of originator medicines, (ii) the uncertain outcome of the dispute as to the validity of that patent, and (iii) the existence of injunctions granted by a national court, whereby the manufacturers of generic medicines are on an interim basis prohibited from selling the generic version of the originator medicine at issue, cannot undermine that finding.

48 As regards, in the first place, the argument that the validity of the patent concerned should be presumed, it is common ground that such a presumption is the automatic consequence of the registration of a patent and its subsequent issue to its holder. That factor therefore sheds no light, for the purposes of applying Articles 101 and 102 TFEU, on the outcome of any dispute in relation to the validity of that patent, something which, moreover, cannot ever be known as a result of the very conclusion of the agreement between the holder of the process patent and the manufacturer concerned of generic medicines.

49 If it were to be accepted that the presumption of validity of a process patent relating to an active ingredient that is in the public domain precludes the holder of that patent from being in a relationship of potential competition with any party that is allegedly infringing that patent on the market of the medicine containing that active ingredient, that would have the consequence, as regards agreements such as those at issue in the main proceedings, that Article 101 TFEU would be deprived of all meaning and that would be liable, thereby, to frustrate EU competition law (see, by analogy, judgment of 13 July 1966, *Consten and Grundig* v *Commission*, 56/64 and 58/64, EU:C:1966:41, p. 346).

50 Admittedly, as stated by the Advocate General in point 83 of her Opinion, that does not mean that the competition authority concerned must disregard any question relating to patent law that might influence the finding of the existence of such a competitive relationship. Any patents protecting an originator medicine or one of its manufacturing processes are indisputably part of the economic and legal context characterising the relationships of competition between the holders of those patents and the manufacturers of generic medicines. However, the assessment of the rights conferred by a patent, to be carried out by the competition authority, must not consist of a review of the strength of the patent or

of the probability of a dispute between the patent holder and a manufacturer of generic medicines being brought to an end with a finding that the patent is valid and has been infringed. That assessment must rather concern the question whether, notwithstanding the existence of that patent, the manufacturer of generic medicines has real and concrete possibilities of entering the market at the relevant time.

51 To that effect, account must be taken of, inter alia, the following: that the uncertainty as to the validity of patents covering medicines is a fundamental characteristic of the pharmaceutical sector; that the presumption of validity of a patent for an originator medicine does not amount to a presumption that a generic version of that medicine properly placed on the market is illegal; that a patent does not guarantee protection against actions seeking to contest its validity; that such actions, and, in particular, the 'at risk' launch of a generic medicine, and the consequent court proceedings, commonly take place in the period before or immediately after the market entry of such a generic medicine; that, to obtain an MA for a generic medicine, there is no requirement to prove that that marketing does not infringe any originator medicine patent rights; and that, in the pharmaceutical sector, potential competition may be exerted before the expiry of a compound patent protecting an originator medicine, since the manufacturers of generic medicines want to be ready to enter the market as soon as that patent expires.

52 As regards, next, the argument that there is a genuine dispute, the outcome of which is uncertain, between the manufacturer of the originator medicine and a manufacturer of the generic version of that medicine who seeks to obtain access to the market for that medicine, the genuineness of their dispute, particularly when it is the subject of court proceedings, far from precluding the existence of any competition between them, rather constitutes evidence of the existence of a potential competitive relationship between them.

53 As regards, last, the argument concerning interim injunctions granted by a national court prohibiting a manufacturer of generic medicines from entering the market of a medicine containing an active ingredient that is in the public domain, it must be observed that interim measures in no way prejudge the merits of an infringement action brought by the patent holder, a fortiori when, as in the main proceedings, such an injunction is granted in return for a cross-undertaking in damages, given by that patent holder.

54 Third, the finding that a manufacturer of generic medicines has a firm intention and an inherent ability to enter the market of an active ingredient that is in the public domain, if not called into question by the existence of insurmountable barriers to such market entry, can be confirmed by additional factors.

55 In that regard, the Court has previously had occasion to acknowledge that the conclusion of an agreement between a number of undertakings, operating at the same level in the production chain, some of which had no presence in the market concerned, constitutes a strong indication that a competitive relationship existed between those undertakings (see, by analogy, judgment of 20 January 2016, *Toshiba Corporation* v *Commission*, C-373/14 P, EU:C:2016:26, paragraphs 33 and 34).

56 A further such indication is the intention, made known by a manufacturer of originator medicines and acted upon, to make transfers of value to a manufacturer of generic medicines in exchange for the postponement of the latter's market entry, even though the former claims that the latter is infringing one or more of its process patents. The greater the transfer of value, the stronger the indication.

57 That intention discloses the perception of the manufacturer of originator medicines of the risk that the manufacturer concerned of generic medicines presents to its commercial interests, that perception being relevant to the assessment of the existence of potential competition, as stated in paragraph 42 of the present judgment, where that perception affects the conduct on the market of the manufacturer of originator medicines.

58 In the light of the foregoing, the answer to Questions 1 and 2 is that Article 101(1) TFEU must be interpreted as meaning that a manufacturer of originator medicines who is the holder of a manufacturing

process patent for an active ingredient that is in the public domain, on the one hand, and the manufacturers of generic medicines who are preparing to enter the market of the medicine containing that active ingredient, on the other, who are in dispute as to whether that patent is valid or whether the generic medicines concerned infringe that patent, are potential competitors, where it is established that the manufacturer of generic medicines has in fact a firm intention and an inherent ability to enter the market, and that market entry does not meet barriers to entry that are insurmountable, which it is for the referring court to assess.

Questions 3 to 5 (characterisation of a 'restriction by object')

59 Taking into consideration the answer given to Questions 1 and 2, Questions 3 to 5 must be examined only with regard to an agreement between, on the one hand, a manufacturer of originator medicines who is the holder of a manufacturing process patent for an active ingredient that is in the public domain and, on the other, a manufacturer of generic medicines who is preparing to enter the market of the medicine containing that active ingredient, who are potential competitors.

60 By Questions 3 to 5, which can be examined together, the referring court seeks, in essence to ascertain whether Article 101(1) TFEU must be interpreted as meaning that a settlement agreement — with respect to pending court proceedings between a manufacturer of originator medicines and a manufacturer of generic medicines, who are potential competitors, concerning the validity of a patent, held by the former, for the process of manufacturing the active ingredient of an originator medicine that is in the public domain and whether a generic version of that product infringes that patent — whereby the manufacturer of generic medicines undertakes not to enter the market of the medicine containing that active ingredient and not to pursue its action seeking the revocation of that patent for the term of the agreement, in consideration for transfers of value to it by the manufacturer of originator medicines, constitutes an agreement that has as its object the prevention, restriction or distortion of competition.

61 The referring court also seeks to ascertain whether one or more of the following factors influence the response to be given that question:

– it is impossible to determine which party is likely to succeed in those proceedings;

– the extent of the restriction on competition imposed on the manufacturer of generic medicines does not exceed that of the patent at issue;

– the sums transferred are significantly higher than the legal costs that were avoided and do not constitute payment for goods or services to be supplied to the manufacturer of originator medicines by the manufacturer of generic medicines, but are nonetheless lower than the profits that the former would have achieved if it had been successful in the patent proceedings and if it had entered the market with an independent generic medicine;

– the settlement agreement provides for the supply by the manufacturer of originator medicines, who is the holder of the patent, to the manufacturer of generic medicines of considerable, but limited, quantities of an authorised generic medicine which does not give rise to a significant competitive restriction on the prices charged by the holder of the patent, but does obtain for consumers benefits that they would not have had if the holder of the patent had been successful in the patent proceedings, though those benefits are significantly lower than the competitive benefits that would have resulted for them from bringing onto the market the independent generic medicine if the manufacturer of generic medicines had been successful in the patent proceedings.

62 In addition to the factors mentioned in paragraphs 30 and 31 of the present judgment, it must be recalled that, if a concerted practice is to be subject to the prohibition in principle laid down in Article 101(1) TFEU, a concerted practice must have as its 'object or effect' the prevention, restriction or distortion to an appreciable extent of competition within the internal market.

63 It follows that that provision, as interpreted by the Court, makes a clear distinction between the concept of restriction by object and the concept of restriction by effect, evidence with regard to each of those concepts being subject to different rules.

64 Accordingly, as regards practices characterised as 'restrictions by object', there is no need to investigate their effects nor a fortiori to demonstrate their effects on competition in order to classify them as 'restrictions of competition', within the meaning of Article 101(1) TFEU, in so far as experience shows that such behaviour leads to falls in production and price increases, resulting in poor allocation of resources to the detriment, in particular, of consumers (judgment of 19 March 2015, *Dole Food and Dole Fresh Fruit Europe* v *Commission*, C-286/13 P, EU:C:2015:184, paragraph 115 and the case-law cited).

65 Concerning such practices, all that is required is the demonstration that they can in fact be classified as 'restrictions by object', though mere unsubstantiated allegations are not however sufficient.

66 On the other hand, where the anticompetitive object of an agreement, a decision by an association of undertakings or a concerted practice is not established, it is necessary to examine its effects in order to prove that competition has in fact been prevented or restricted or distorted to an appreciable extent (see, to that effect, judgment of 26 November 2015, *Maxima Latvija*, C-345/14, EU:C:2015:784, paragraph 17).

67 It is clear from the Court's case-law that the concept of restriction of competition 'by object' must be interpreted strictly and can be applied only to some concerted practices between undertakings which reveal, in themselves and having regard to the content of their provisions, their objectives, and the economic and legal context of which they form part, a sufficient degree of harm to competition for the view to be taken that it is not necessary to assess their effects, since some forms of coordination between undertakings can be regarded, by their very nature, as being harmful to the proper functioning of normal competition (judgments of 26 November 2015, *Maxima Latvija*, C-345/14, EU:C:2015:784, paragraph 20, and of 23 January 2018, *F. Hoffmann-La Roche and Others*, C-179/16, EU:C:2018:25, paragraphs 78 and 79).

68 When determining that context, it is necessary to take into consideration the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market or markets in question (judgment of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraph 53 and the case-law cited).

69 In this case, the medicines sector not only has strong barriers to entry linked to the conditions attached to the placing of medicines on the market, those conditions being described in paragraphs 40 and 47 of the present judgment, but is also marked, as observed by the referring court with respect to the United Kingdom, by a pricing mechanism that is strictly controlled by legislation and strongly influenced by the market entry of generic medicines. Such entry leads, in the short term, to a very appreciable fall in the sale price of medicines containing an active ingredient that are henceforth sold not only by the manufacturer of the originator medicine, but also by manufacturers of generic medicines.

70 It follows from all the foregoing, of which the manufacturers of originator medicines and the manufacturers of generic medicines cannot be unaware, that the medicines sector is particularly sensitive to a delay in the market entry of the generic version of an originator medicine. Such a delay leads to the maintenance on the market of the medicine concerned of a monopoly price, which is very appreciably higher than the price at which generic versions of that medicine would be sold following their market entry and which has considerable financial consequences, if not for the final consumer, at least for social security authorities.

71 It must therefore be determined whether an agreement, such as those entered into by GSK with Alpharma or GUK, displays, in itself, a sufficient degree of harm to competition, so that an examination of its effects is not required for the purposes of applying Article 101(1) TFEU.

72 It is apparent from the documents available to the Court and from paragraphs 13 and 14 of the present judgment that, in essence, the agreements entered into between GSK and GUK and Alpharma, respectively, constitute two sets of complex agreements which display considerable similarities.

73 Both took the form of settlement agreements with respect to a dispute relating to a patent for the process of manufacturing an active ingredient that is in the public domain, paroxetine.

74 Those settlement agreements followed the bringing, by GSK, of infringement proceedings against GUK and Alpharma, which led, on the one hand, to the latter parties challenging, directly or indirectly, the validity of the patent concerned and, on the other, to a national court granting, in exchange for a 'cross-undertaking in damages' given by GSK, an interim injunction prohibiting GUK and Alpharma from entering the market.

75 Those agreements led (i) to the undertakings by GUK and Alpharma, while those agreements remained valid, not to enter the market, and not to manufacture and/or import the generic medicines manufactured under the patent at issue, and, further, not to persist in their challenges to that patent; (ii) to the conclusion of a distribution agreement enabling them to enter the market with a limited quantity of generic paroxetine manufactured by GSK; and (iii) to the payment by GSK to them of sums of money in various forms the amount of which, according to the referring court, is significantly higher than the costs of litigation that were avoided and which do not constitute payment for goods or services supplied by GUK or Alpharma to GSK.

76 It must be observed that, according to the very wording of the questions referred, the background to those agreements is a genuine dispute relating to a process patent, that dispute being the subject of proceedings before a national court. Accordingly, those agreements cannot be regarded as agreements bringing to an end entirely fictitious disputes, or as designed with the sole aim of disguising a market-sharing agreement or a market-exclusion agreement. When agreements are of that nature, they are as harmful to competition as market-sharing agreements or market-exclusion agreements, and such agreements have to be characterised as 'restrictions by object'.

77 Consequently, it is necessary to assess, as requested by the referring court, whether those agreements may, nonetheless, be treated as equivalent to such market-sharing or market-exclusion agreements.

78 In accordance with settled case-law, each economic operator must determine independently the policy which he intends to adopt on the internal market (judgment of 19 March 2015, *Dole Food and Dole Fresh Fruit Europe* v *Commission*, C-286/13 P, EU:C:2015:184, paragraph 119).

79 In that regard, and concerning more particularly the conduct of undertakings linked to intellectual property rights, the Court has held, inter alia, that an industrial or commercial property right, as a legal entity, does not possess those elements of contract or concerted practice referred to in Article 101(1) TFEU, but the exercise of that right might fall within the ambit of the prohibitions contained in the Treaty if it were to manifest itself as the subject, the means or the consequence of an agreement or concerted practice (judgment of 8 June 1982, *Nungesser and Eisele* v *Commission*, 258/78, EU:C:1982:211, paragraph 28 and the case-law cited), notwithstanding the fact that it may constitute the legitimate expression of the intellectual property right attached to the patent which empowers the holder of that patent, inter alia, to oppose any infringement (see, to that effect, judgment of 31 October 1974, *Centrafarm and de Peijper*, 15/74, EU:C:1974:114, paragraph 9) or also the fact, raised by the Commission, that settlement agreements are encouraged by the public authorities in that they make possible savings in terms of resources and are thus beneficial for the public at large.

80 It follows that, in prohibiting certain ‘agreements’ between undertakings, Article 101(1) TFEU makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind (judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke*, 65/86, EU:C:1988:448, paragraph 15).

81 Accordingly, settlement agreements whereby a manufacturer of generic medicines that is seeking to enter a market recognises, at least temporarily, the validity of a patent held by a manufacturer of originator medicines and gives an undertaking, as a result, no longer to challenge that patent and not to enter that market are liable to have effects that restrict competition (see, by analogy, judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke*, 65/86, EU:C:1988:448, paragraph 16), since challenges to the validity and scope of a patent are part of normal competition in the sectors where there exist exclusive rights in relation to technology.

82 Likewise, a clause in an agreement providing that a patent will not be challenged may, in the light of its legal and economic context, restrict competition within the meaning of Article 101(1) TFEU (judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke*, 65/86, EU:C:1988:448, paragraph 16).

83 Further, the Court has also held that agreements whereby competitors deliberately substitute practical cooperation between them for the risks of competition can be characterised as ‘restrictions by object’ (see, to that effect, judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 34).

84 That said, it is indeed possible that a manufacturer of generic medicines finding itself in the situation envisaged by the referring court in Questions 3 to 5, after assessing its chances of success in the court proceedings between it and the manufacturer of the originator medicine concerned, may decide to abandon entry to the market concerned and, in that context, may conclude with the manufacturer of the originator medicine an agreement in settlement of those proceedings. Such an agreement cannot, however, be considered, in all cases, to be a ‘restriction by object’, within the meaning of Article 101(1) TFEU.

85 The fact that such an agreement involves transfers of value, either pecuniary or non-pecuniary, made by the manufacturer of the originator medicine to the manufacturer of generic medicines is not sufficient ground to classify it as a ‘restriction by object’, since those transfers of value may prove to be justified, that is, appropriate and strictly necessary having regard to the legitimate objectives of the parties to the agreement.

86 That may, in particular, be the case where the manufacturer of generic medicines receives from the manufacturer of the originator medicine sums that correspond in fact to compensation for the costs of or disruption caused by the litigation between them, or that correspond to remuneration for the actual supply, immediate or subsequent, of goods or services to the manufacturer of the originator medicines. That may also be the case when the manufacturer of the generic medicines discharges undertakings, particularly financial, given by the patent holder to him, such as a cross-undertaking in damages.

87 However, such a characterisation as a ‘restriction by object’ must be adopted when it is plain from the analysis of the settlement agreement concerned that the transfers of value provided for by it cannot have any explanation other than the commercial interest of both the holder of the patent and the party allegedly infringing the patent not to engage in competition on the merits.

88 As stated by the Advocate General in point 114 of her Opinion, the conclusion of an agreement under which a competitor of the patent holder undertakes not to enter the market and to cease its challenge to the patent in exchange for payment of a substantial sum, the sole consideration for which is that undertaking, amounts precisely to ensuring protection for that patent holder against actions seeking the revocation of its patent and to establishing a presumption that the products which may be put on the market by its competitor are unlawful. Therefore, it cannot be maintained that entering into such an

agreement falls within the exercise, by the patent holder, of its prerogatives stemming from the object of the patent. That is all the more the case when it is for public authorities and not private undertakings to ensure compliance with statutory requirements.

89 Accordingly, it cannot be asserted that the conclusion of such an agreement represents, on the part of the manufacturers of generic medicines, no more than their recognition of patent rights, presumed to be valid, of the holder of that patent. If the patent holder makes, in their favour, a significant transfer of value, the sole consideration for which is their undertaking not to enter the market and no longer to challenge the patent, that indicates, in the absence of any other plausible explanation, that it is not their perception of the patent's strength, but the prospect of that transfer of value which has induced them to refrain from entering the market and challenging the patent.

90 In order to assess whether transfers of value contained in a settlement agreement, such as those at issue in the main proceedings, can have no explanation other than the commercial interest of the parties to that agreement not to engage in competition on the merits, it is important, first, as stated by the Advocate General in point 120 of her Opinion, to take into consideration all the transfers of value made between the parties, whether those were pecuniary or non-pecuniary.

91 As envisaged by the referring court and by the Advocate General in points 120 and 170 to 172 of her Opinion, that may involve taking account of indirect transfers resulting, for example, from profits to be obtained by the manufacturer of generic medicines from a distribution contract concluded with the manufacturer of originator medicines enabling the former manufacturer to sell a possibly defined quota of generic medicines manufactured by the manufacturer of originator medicines.

92 Further, it is necessary to assess whether the net gain arising from the transfers of value by the manufacturer of originator medicines in favour of the manufacturer of generic medicines may be justified, as envisaged in paragraph 86 of the present judgment, by the existence of any quid pro quo or waivers by the manufacturer of generic medicines that are proven and legitimate.

93 Last, if that is not the case, it has to be determined whether that net gain is sufficiently large actually to act as an incentive to the manufacturer concerned of generic medicines to refrain from entering the market concerned.

94 In that regard, taking into account the uncertainty as to the outcome of those proceedings, there is no requirement that the transfers of value should necessarily be greater than the profits which the manufacturer of generic medicines would have made if it had been successful in the patent proceedings. All that matters is that those transfers of value are shown to be sufficiently beneficial to encourage the manufacturer of generic medicines to refrain from entering the market concerned and not to compete on the merits with the manufacturer of originator medicines concerned.

95 If such is the case, the agreement concerned must, in principle, be characterised as a 'restriction by object', within the meaning of Article 101(1) TFEU.

96 Such a conclusion cannot be rebutted, first, on the ground that the undertakings that have entered into such agreements argue either that settlement agreements such as those at issue in the main proceedings do not exceed the scope and the remaining period of validity of the patent to which they relate and, therefore, are not anticompetitive, or that restrictions stemming from such agreements are merely ancillary within the meaning of the judgment of 11 July 1985, *Remia and Others* v *Commission* (42/84, EU:C:1985:327).

97 While the conclusion by the holder of a patent with a party allegedly infringing that patent of a settlement agreement that does not exceed the scope and duration of remaining validity of the patent does constitute an expression of the intellectual property right of its holder, which permits that holder, inter alia, to oppose any infringement (see, to that effect, judgment of 31 October 1974, *Centrafarm and de Peijper*, 15/74, EU:C:1974:114, paragraph 9), the fact remains that, as also observed by the

Advocate General in point 114 of her Opinion and as stated in paragraph 79 of the present judgment, that patent does not permit its holder to enter into contracts that are contrary to Article 101 TFEU.

98 Second, the fact that there is uncertainty as to the validity of the patent, whether that is due to the existence of a genuine dispute between the holder of that patent and the particular manufacturer of generic medicines, the existence of court proceedings prior to the conclusion of the settlement agreement at issue or, last, the granting of an interim injunction by a national court prohibiting the party allegedly infringing the patent from entering the market, in exchange for the holder of the patent concerned giving a cross-undertaking in damages, is again of no relevance to the question of whether characterisation as a 'restriction by object' can be ruled out.

99 If it were accepted that such factors made it possible to exclude from characterisation as a 'restriction by object' a practice capable of displaying, in itself, a sufficient degree of harm to competition, that would be liable excessively to circumscribe the scope of that concept, even if it is to be interpreted strictly, as recalled in paragraph 67 of the present judgment.

100 It is precisely the uncertainty as to the outcome of the court proceedings in relation to whether the patent held by the manufacturer of the originator medicine is valid and whether the generic version of that medicine infringes that patent which contributes, for as long as it lasts, to the existence of a situation of at least potential competition between the two parties to those proceedings.

101 Moreover, as follows from paragraphs 48 and 49 of the present judgment, uncertainty as to the outcome of those proceedings cannot be sufficient ground to exclude from characterisation as a 'restriction by object' a settlement agreement which may conceivably attain the degree of harm to competition mentioned in paragraph 67 of the present judgment.

102 As stated above in paragraph 48 of the present judgment, the presumption of validity attached to a patent, no more than the existence of court proceedings prior to the conclusion of a settlement agreement and the granting of an interim injunction by a national court, sheds no light, for the purpose of application of Articles 101 and 102 TFEU, on the outcome of any dispute in relation to the validity of that patent, something which, moreover, cannot ever be known as a result of the very conclusion of the agreement between the holder of the process patent and the manufacturer concerned of generic medicines.

103 Last, and in response to Question 5, it must be observed that, where the parties to that agreement rely on its pro-competitive effects, those effects must, as elements of the context of that agreement, be duly taken into account for the purpose of its characterisation as a 'restriction by object', as recalled in paragraph 67 of the present judgment and in point 158 of the Opinion of the Advocate General, in so far as they are capable of calling into question the overall assessment of whether the concerted practice concerned revealed a sufficient degree of harm to competition and, consequently, of whether it should be characterised as a 'restriction by object'.

104 Since taking account of those pro-competitive effects is intended not to undermine characterisation as a 'restriction of competition' within the meaning of Article 101(1) TFEU, but merely to appreciate the objective seriousness of the practice concerned and, consequently, to determine the means of proving it, that is in no way in conflict with the Court's settled case-law that EU competition law does not recognise a 'rule of reason', by virtue of which there should be undertaken a weighing of the pro- and anticompetitive effects of an agreement when it is to be characterised as a 'restriction of competition' under Article 101(1) TFEU (see, to that effect, judgment of 13 July 1966, *Consten and Grundig* v *Commission*, 56/64 and 58/64, EU:C:1966:41, page 343).

105 However, taking into consideration such matters presupposes that the pro-competitive effects are not only demonstrated and relevant, but also specifically related to the agreement concerned, as mentioned, concerning the agreements at issue in the main proceedings, by the Advocate General in point 144 of her Opinion.

106 Further, as again observed by the Advocate General in point 166 of her Opinion, the mere existence of such pro-competitive effects cannot as such preclude characterisation as a ‘restriction by object’.

107 If such effects are demonstrated, relevant and specifically related to the agreement concerned, those pro-competitive effects must be sufficiently significant, so that they justify a reasonable doubt as to whether the settlement agreement concerned caused a sufficient degree of harm to competition, and, therefore, as to its anticompetitive object.

108 In that regard, the factual situation raised by the referring court in Question 5(a) and (b), read in the light of the order for reference and mentioned by the Advocate General in points 168 to 172, 175 and 179 of her Opinion, suggest that the settlement agreements at issue in the main proceedings essentially gave rise to pro-competitive effects that were not only minimal but probably uncertain.

109 While the referring court finds that those agreements did in fact give rise to a slight reduction in the price of paroxetine, that court observes at the same time that, as is clear in particular from Question 5(a), the supply of paroxetine by GSK to the manufacturers of generic medicines provided for by those agreements did not give rise to meaningful competitive pressure on GSK. The referring court states on that point that, because of the limited volumes supplied, there being no technical reason for the capping of those volumes, the manufacturers of generic medicines had no interest in competing on prices. Further, in Question 5(b), the referring court alludes to the fact that the agreements concerned brought to consumers some benefits which they would not have had if the holder of the patent had been successful in the proceedings relating to that patent, while observing that those benefits were significantly less than the competitive benefits that would have followed the placing on the market of an independent generic product if the manufacturers concerned of generic medicines had been successful in those proceedings. Last, the referring court states that, first, the change in the structure of the market induced by the agreements at issue was due not to the introduction of competition, but to a controlled reorganisation of the market for paroxetine engineered by GSK, and, second, that the supply of paroxetine and the transfer of market share by GSK to the manufacturers of generic medicines should be understood as non-pecuniary transfers of value.

110 Such pro-competitive effects, not only minimal but probably uncertain, cannot be sufficient justification for holding a reasonable doubt, even if those effects are identified by the referring court, that a settlement agreement such as those at issue in the main proceedings revealed sufficient harm to competition, which is in any event exclusively for the referring court to determine.

111 In the light of the foregoing, the answer to Questions 3 to 5 is that Article 101(1) TFEU must be interpreted as meaning that a settlement agreement, with respect to pending court proceedings between a manufacturer of originator medicines and a manufacturer of generic medicines, who are potential competitors, concerning whether the process patent (for the manufacture of an active ingredient of an originator medicine that is in the public domain) held by that manufacturer of originator medicines is valid and whether a generic version of that medicine infringes that patent, whereby that manufacturer of generic medicines undertakes not to enter the market of the medicine containing that active ingredient and not to pursue its action challenging the validity of that patent for the duration of that agreement, in return for transfers of value in its favour by the manufacturer of originator medicines, constitutes an agreement that has as its object the prevention, restriction or distortion of competition:

– if it is clear from all the information available that the net gain from the transfers of value by the manufacturer of originator medicines in favour of the manufacturer of generic medicines can have no other explanation than the commercial interest of the parties to the agreement not to engage in competition on the merits;

– unless the settlement agreement concerned is accompanied by proven pro-competitive effects capable of giving rise to a reasonable doubt that it causes a sufficient degree of harm to competition.

Question 6 (characterisation as a 'restriction by effect')

112 First, it must be observed that, according to the request for a preliminary ruling, the referring court considered that if the settlement agreements at issue had not existed, there would have been a real possibility that the manufacturers concerned of generic medicines would have been successful against GSK in the proceedings relating to the process patent concerned, or alternatively, that the parties to those agreements would have entered into a less restrictive form of settlement agreement.

113 However, the referring court adds that, if, before the existence of a 'restriction by effect' can be concluded, it is necessary to find that there was a more than 50% probability that the manufacturer of generic medicines would have succeeded in proving that it was entitled to enter the market or, alternatively, that the parties would have concluded a less restrictive form of settlement agreement, such a finding cannot be made on the information available to it.

114 Accordingly, Question 6 must be understood as seeking, in essence, to ascertain whether Article 101(1) TFEU must be interpreted as meaning that if the existence of the appreciable potential or real effects on competition of a settlement agreement such as those at issue in the main proceedings is to be proved, and, if, therefore, that agreement is to be characterised as a 'restriction by effect', that presupposes a finding that, in the absence of that agreement, either the manufacturer of generic medicines who is a party to that agreement would probably have succeeded in the proceedings relating to the process patent concerned, or that the parties to that agreement would probably have concluded a less restrictive settlement agreement.

115 As stated in paragraph 66 of the present judgment, in the event that analysis of the concerted practice concerned does not reveal a sufficient degree of harm to competition, it is then necessary to examine the effects of that practice and, in order to classify that practice as a 'restriction of competition' within the meaning of Article 101(1) TFEU, to identify the factors which establish that competition was, in fact, prevented, or restricted, to an appreciable extent.

116 To that effect, it is necessary to take into consideration the actual context in which that practice occurs, in particular the economic and legal context in which the undertakings concerned operate, the nature of the goods or services affected, as well as the real conditions of the functioning and the structure of the market or markets in question (judgment of 11 September 2014, *MasterCard and Others* v *Commission*, C-382/12 P, EU:C:2014:2201, paragraph 165 and the case-law cited).

117 In accordance with settled case-law, the restrictive effects on competition may be both real and potential, but they must, in any event, be sufficiently appreciable (see, to that effect, judgments of 9 July 1969, *Völk*, 5/69, EU:C:1969:35, paragraph 7, and of 23 November 2006, *Asnef-Equifax and Administración del Estado*, C-238/05, EU:C:2006:734, paragraph 50).

118 In order to assess the effects of a concerted practice with regard to Article 101 TFEU, competition should be assessed within the actual context in which it would occur in the absence of the agreement in dispute (judgment of 11 September 2014, *MasterCard and Others* v *Commission*, C-382/12 P, EU:C:2014:2201, paragraph 161).

119 It follows that, in a situation such as that at issue in the main proceedings, the establishment of the counter-factual does not involve, on the part of the referring court, any definitive finding in relation to the chances of success of the manufacturer of generic medicines in the patent proceedings or to the probability of the conclusion of a less restrictive agreement.

120 The sole purpose of the counter-factual is to establish the realistic possibilities with respect to that manufacturer's conduct in the absence of the agreement at issue. Accordingly, while that counter-factual cannot be unaffected by the chances of success of the manufacturer of generic medicines in the patent proceedings or again in relation to the probability of conclusion of a less restrictive agreement, those factors constitute, however, only some factors among many to be taken into consideration in order to

determine how the market will probably operate and be structured if the agreement concerned is not concluded.

121 Consequently, in order to establish the existence of appreciable potential or real effects on competition of settlement agreements such as those at issue in the main proceedings, the referring court does not have to find either that the manufacturer of generic medicines who is a party to that agreement would probably have been successful in the patent proceedings, or that the parties to that agreement would probably have concluded a less restrictive settlement agreement.

122 In the light of the foregoing, the answer to Question 6 is that Article 101(1) TFEU must be interpreted as meaning that if a settlement agreement, such as those at issue in the main proceedings, is to be demonstrated to have appreciable potential or real effects on competition, and, therefore, is to be characterised as a 'restriction by effect', that does not presuppose a finding that, in the absence of that agreement, either the manufacturer of generic medicines who is a party to that agreement would probably have been successful in the proceedings relating to the process patent at issue, or the parties to that agreement would probably have concluded a less restrictive settlement agreement.

Questions 7 to 10 (Article 102 TFEU)

Question 7 (definition of the relevant market)

123 By Question 7, the referring court seeks to ascertain whether, where a patented medicine is therapeutically substitutable with a number of other medicines of a therapeutic class and where the alleged abuse within the meaning of Article 102 TFEU consists in the patent holder effectively excluding from the market generic versions of that medicine, those generic medicines should be taken into consideration for the purposes of definition of the product market concerned, although they could not lawfully enter the market before the expiry of the patent if (as is uncertain) that patent is valid and if that patent is infringed by those generic medicines.

124 As a preliminary point, it must be observed that that question must be placed in the context of the debate pursued before the referring court as to the extent of the product market for the purposes of determining whether GSK held a dominant position. GSK argued, in particular, that, given the centrality of therapeutic substitutability, the SSRIs other than paroxetine ought also to be included in the product market.

125 However, as is clear from the reply of the referring court to the Court's request for information, the issue of whether SSRIs other than paroxetine are also to be included in the product market concerned is not the subject of this question, the referring court having found as a fact that the other SSRIs exercised little pressure on the prices of Seroxat set by GSK.

126 Consequently, Question 7 concerns solely the issue whether Article 102 TFEU must be interpreted as meaning that, in a situation where a manufacturer of originator medicines containing an active ingredient which is in the public domain, but the process of manufacturing which is covered by a process patent, the validity of which is uncertain, impedes, on that basis, the market entry of generic versions of that medicine, there should be taken into consideration for the definition of the product market concerned not only the originator version of that medicine but also its generic versions, although the latter would not be able legally to enter the market before the expiry of that process patent.

127 In that regard, it must be recalled that the definition of the relevant market, in the application of Article 102 TFEU, is, as a general rule, a prerequisite of any assessment of whether the undertaking concerned holds a dominant position (see, to that effect, judgment of 21 February 1973, *Europemballage and Continental Can* v *Commission*, 6/72, EU:C:1973:22, paragraph 32), the objective being to define the boundaries within which it must be assessed whether that undertaking is able to behave, to an appreciable extent, independently of its competitors, customers and consumers (see, to that effect, judgment of 9 November 1983, *Nederlandsche Banden-Industrie-Michelin* v *Commission*, 322/81, EU:C:1983:313, paragraph 37).

128 The definition of that relevant market involves defining, first, the product market and then, secondly, the geographical market (see, to that effect, judgment of 14 February 1978, *United Brands and United Brands Continentaal* v *Commission*, 27/76, EU:C:1978:22, paragraphs 10 and 11).

129 As regards the product market, which is the only point at issue in this question, it is clear from settled case-law that the concept of the relevant market implies that there can be effective competition between the products or services which form part of it, and this presupposes that there is a sufficient degree of interchangeability between all the products or services forming part of the same market in so far as a specific use of such products or services is concerned. That interchangeability or substitutability is not assessed solely in relation to the objective characteristics of the products and services at issue. There must also be taken into consideration the conditions of competition and the structure of supply and demand on the market (judgment of 23 January 2018, *F. Hoffmann-La Roche and Others*, C-179/16, EU:C:2018:25, paragraph 51 and the case-law cited).

130 In that context, and as the Advocate General stated, in essence, in point 222 of her Opinion, the interchangeability or substitutability of products are naturally dynamic, in that a new supply of products may alter the conception of the products considered to be interchangeable with a product already present on the market or as substitutable for that product and, in that way, justify a new definition of the parameters of the relevant market.

131 As regards, in particular, the definition of the product market to which, for the possible application of Article 102 TFEU, an originator medicine belongs such as, in the main proceedings, the paroxetine marketed as ‘Seroxat’, which can be therapeutically substituted with other SSRIs, it is clear from the point made in the preceding paragraph of the present judgment that a supply of generic medicines containing the same active ingredient, in this case paroxetine, could lead to a situation where the originator medicine is considered, in the professional circles concerned, to be interchangeable only with those generic medicines and, consequently, to belong to a specific market, limited exclusively to medicines which contain that active ingredient.

132 Such a finding presupposes, however, in accordance with the principles set out in paragraph 129 of the present judgment, that there is a sufficient degree of interchangeability between the originator medicine and the generic medicines concerned.

133 Such is the case if the manufacturers concerned of generic medicines are in a position to present themselves within a short period on the market concerned with sufficient strength to constitute a serious counterbalance to the manufacturer of the originator medicine already on the market (see, to that effect, judgment of 21 February 1973, *Europemballage and Continental Can* v *Commission*, 6/72, EU:C:1973:22, paragraph 34).

134 That is accordingly true where, on the expiry of the patent relating to the active ingredient concerned, or of the data exclusivity period of that active ingredient, those manufacturers of generic medicines are in a position to enter the market immediately or within a short period, particularly where those parties have formed a prior effective strategy for market entry, have taken the steps necessary to achieve it, such as, for example, the lodging of an MA application or the obtaining of such an MA, or have concluded supply contracts with third-party distributors.

135 In that regard, as stated by the Advocate General in point 239 of her Opinion, evidence of the perception, by the manufacturer of originator medicines, of the immediacy of the threat of market entry by the manufacturers of generic medicines might also be taken into account in order to assess the significance of the competitive constraints imposed by the latter.

136 The fact that the manufacturer of originator medicines relies on an intellectual property right over the process of manufacturing the active ingredient concerned as capable of possibly impeding the market entry of generic versions of the originator medicine containing that active ingredient cannot be sufficient ground for any other finding.

137 While, admittedly, and as recalled in paragraph 41 of the present judgment, Directive 2004/48 and Article 17(2) of the Charter of Fundamental Rights ensure a high level of protection of intellectual property in the internal market, the fact remains that the process patent on which a manufacturer of originator medicines is likely to rely in order to impede the placing on the market of a generic version of a medicine containing an active ingredient that is in the public domain does not offer any certainty to the manufacturer of the originator medicine concerned that the generic medicine containing that active ingredient may not lawfully be placed on the market or that that patent is safe from any challenge, as was moreover the case in the main proceedings, as is clear from paragraph 14 of the present judgment.

138 Consequently, and provided that the conditions set out in paragraphs 133 and 134 of the present judgment are satisfied, the generic versions of an originator medicine containing an active ingredient which is in the public domain, but the process of manufacturing which is protected by a patent, the validity of which remains uncertain, must be taken into account for the purposes of definition of the relevant market, if due regard is to be given to the case-law cited in paragraph 129 of the present judgment, which requires the taking into consideration of the conditions of competition and the structure of supply and demand in the market concerned.

139 That conclusion does not contradict the Court's case-law that if pharmaceutical products are manufactured or sold illegally, that prevents such products, in principle, from being regarded as substitutable or interchangeable (judgment of 23 January 2018, *F. Hoffmann-La Roche and Others*, C-179/16, EU:C:2018:25, paragraph 52). That case-law concerns not the entry into the market of generic versions of an originator medicine of which the active ingredient is in the public domain which are alleged to infringe a process patent, but the placing on the market of a medicine in the absence of an MA issued by the competent authority of a Member State in accordance with Directive 2001/83 or an authorisation issued in accordance with the provisions of Regulation No 726/2004, the objective of that legislation being the protection of the health of patients and public health (judgment of 23 January 2018, *F. Hoffmann-La Roche and Others*, C-179/16, EU:C:2018:25, paragraphs 81 and 82).

140 In the light of the foregoing, the answer to Question 7 is that Article 102 TFEU must be interpreted as meaning that, in a situation where a manufacturer of originator medicines containing an active ingredient which is in the public domain, but the process of manufacturing which is covered by a process patent, the validity of which is disputed, impedes, on the basis of that process patent, the market entry of generic versions of that medicine, there must be taken into consideration, for the purposes of definition of the product market concerned, not only the originator version of that medicine but also its generic versions, even if the latter would not be able to enter legally the market before the expiry of that process patent, if the manufacturers concerned of generic medicines are in a position to present themselves within a short period on the market concerned with sufficient strength to constitute a serious counterbalance to the manufacturer of originator medicines already on that market, which it is for the referring court to determine.

Questions 8 to 10

141 As a preliminary point, it must be observed that, by Question 8, the referring court seeks to ascertain whether, in the circumstances such as those of the main proceedings and on the assumption that the holder of process patent at issue, in this case GSK, holds a dominant position, the fact that it concluded a settlement agreement such as those at issue in the main proceedings constitutes an abuse of that dominant position within the meaning of Article 102 TFEU.

142 It is however clear from the documents available to the Court that a penalty was imposed on GSK not because it had committed a number of abuses of a dominant position by concluding each of the agreements at issue with IVAX, GUK and Alpharma respectively, but for having committed a single abuse of a dominant position because of its overall strategy of concluding those agreements with those manufacturers of generic medicines.

143 Consequently, the Court must answer from that perspective alone, as alluded to by the referring court in Question 10(a).

144 It must also be observed, as is apparent from Question 9 and Question 10(b), read in the light of the reply of the referring court to the Court's request for information, that a penalty was imposed on GSK for having committed an abuse of a dominant position not only because of the agreements concluded with GUK and Alpharma, with respect to which penalties were also imposed under United Kingdom and EU competition law, but also because of a third agreement concluded with IVAX which (i) was entered into not to bring to an end ongoing court proceedings but in order to avoid such proceedings; (ii) was exempted from the scope of United Kingdom competition law due to a specific provision of domestic law; and (iii) gave rise to favourable effects, namely a reduction in the level of reimbursement for the medicine concerned because of the structure of the national system for the reimbursement of pharmacies by the public health authorities, securing substantial savings for those authorities.

145 Consequently, Questions 8 to 10, taken together, must be understood as seeking to ascertain whether Article 102 TFEU must be interpreted as meaning that the strategy of a dominant undertaking that is the holder of a process patent, for the production of an active ingredient that is in the public domain, which leads it to conclude, either as a precaution or following the bringing of court proceedings challenging the validity of that patent, a number of settlement agreements, the effect of which is, at least, to keep temporarily outside the market potential competitors who manufacture generic medicines using that active ingredient, constitutes an abuse of a dominant position, within the meaning of Article 102 TFEU, even though one of the agreements concerned was exempted from the scope of national competition law.

146 In accordance with settled case-law, the same practice may give rise to an infringement of both Article 101 TFEU and Article 102 TFEU, even if the two provisions pursue distinct objectives (see, to that effect, judgments of 13 February 1979, *Hoffmann-La Roche* v *Commission*, 85/76, EU:C:1979:36, paragraph 116, and of 16 March 2000*, Compagnie maritime belge transports and Others* v *Commission*, C-395/96 P and C-396/96 P, EU:C:2000:132, paragraph 33).

147 Accordingly, a contract-oriented strategy of a manufacturer of originator medicines holding a dominant position in a market may be penalised not only under Article 101 TFEU by reason of each agreement taken individually but also under Article 102 TFEU for the possible additional damage that strategy may cause to the competitive structure of a market in which, because of the dominance in that market of that manufacturer of originator medicines, the degree of competition is already weakened (see, to that effect, judgment of 13 February 1979, *Hoffmann-La Roche* v *Commissio*n, 85/76, EU:C:1979:36, paragraph 120).

148 In that regard, it must be recalled that the concept of 'abuse of a dominant position' within the meaning of Article 102 TFEU is an objective concept relating to the conduct of a dominant undertaking which, on a market where the degree of competition is already weakened precisely because of the presence of the undertaking concerned, through recourse to methods different from those governing normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition (judgments of 13 February 1979, *Hoffmann-La Roche* v *Commission*, 85/76, EU:C:1979:36, paragraph 91, and of 19 April 2012, *Tomra Systems and Others* v *Commission*, C-549/10 P, EU:C:2012:221, paragraph 17).

149 However, the fact that an undertaking is in a dominant position does not disqualify it from protecting its own commercial interests if they are attacked, and it must be conceded the right to take such reasonable steps as it deems appropriate to protect its commercial interests (judgment of 14 February 1978, *United Brands and United Brands Continentaal* v *Commission*, 27/76, EU:C:1978:22, paragraph 189).

150 More particularly, the exercise of an exclusive right linked to an intellectual property right, such as the conclusion of settlement agreements between the holder of a patent and parties allegedly infringing that patent in order to bring to an end litigation relating to that patent, is one of the rights of the holder of an intellectual property right, and consequently the exercise of such a right, even when done by a dominant undertaking, cannot in itself constitute an abuse of the dominant position (see, to that effect, judgment of 16 July 2015, *Huawei Technologies*, C-170/13, EU:C:2015:477, paragraph 46 and the case-law cited).

151 However, such conduct cannot be accepted when its purpose is precisely to strengthen the dominant position of the party engaging in it and to abuse that position (see, to that effect, judgment of 14 February 1978, *United Brands and United Brands Continentaal* v *Commission*, 27/76, EU:C:1978:22, paragraph 189), as when such conduct is intended to deprive parties demonstrated to be potential competitors of effective access to a market, such as that of a medicine containing an active ingredient that is in the public domain.

152 Accordingly, when the intention of a manufacturer of originator medicines holding a dominant position is to protect its own commercial interests, in particular by defending its patents, and to guard itself against the competition of generic medicines, that alone does not justify resorting to practices that fall outside the scope of competition on the merits (see, by analogy, judgment of 16 July 2015, *Huawei Technologies*, C-170/13, EU:C:2015:477, paragraph 47 and the case-law cited).

153 A dominant undertaking has a special responsibility not to allow its behaviour to impair genuine, undistorted competition in the internal market (judgment of 6 September 2017, *Intel* v *Commission*, C-413/14 P, EU:C:2017:632, paragraph 135 and the case-law cited).

154 From that perspective, it must, further, be observed that if such conduct is to be characterised as abusive, that presupposes that that conduct was capable of restricting competition and, in particular, producing the alleged exclusionary effects (see, to that effect, judgments of 17 February 2011, *TeliaSonera Sverige*, C-52/09, EU:C:2011:83, paragraphs 64 and 66, and of 6 September 2017, *Intel* v *Commission*, C-413/14 P, EU:C:2017:632, paragraph 138), and that assessment must be undertaken having regard to all the relevant facts surrounding that conduct (see, to that effect, judgment of 17 February 2011, *TeliaSonera Sverige*, C-52/09, EU:C:2011:83, paragraph 68).

155 In this case, the information contained in the documents available to the Court indicate that the CMA and the referring court considered that the set of settlement agreements concluded on the initiative of GSK were part of an overall strategy on the part of that manufacturer of originator medicines and had, if not as their object, at least the effect of delaying the market entry of generic medicines containing the active ingredient ‘paroxetine’ that had earlier entered the public domain and, therefore, of preventing a significant fall in the prices of the originator medicines containing that active ingredient and produced by GSK; the direct consequence of that entry would have been an appreciable reduction in GSK’s market share and an equally appreciable reduction in the sale price of its originator medicine.

156 However, such a contract-oriented strategy, the actual nature of which it is for the referring court to determine having regard to the evidence available to it, constitutes, in principle, a practice that impedes, while adversely affecting at least the national health systems if not the final consumer, the growth of competition in the market of a medicine containing an active ingredient that is in the public domain.

157 The anticompetitive effects of such a contract-oriented strategy are liable to exceed the anticompetitive effects inherent in the conclusion of each of the agreements that are part of it. That strategy has a significant foreclosure effect on the market of the originator medicine containing the active ingredient at issue, depriving the consumer of the benefits of entry into that market of potential

competitors manufacturing their own medicine and, therefore, reserving that market directly or indirectly to the manufacturer of the originator medicine concerned.

158 In that regard, the fact, alluded to in the context of Question 9, that one of the settlement agreements at issue, namely the GSK/IVAX agreement, was entered into not to settle existing court proceedings but to avoid the bringing of such proceedings is immaterial.

159 Likewise, the fact that one of the settlement agreements concluded by that manufacturer of originator medicines, in this case the GSK/IVAX agreement, could not have been penalised under national competition law or that it might have led to substantial savings for the national health system cannot in itself call into question the finding that such a strategy existed and that it constituted an abuse.

160 Irrespective of whether the provision of United Kingdom law under which that agreement could not be penalised is in accordance with the principle of primacy attached to Article 101 TFEU, the mere fact that that agreement was not penalised does not mean that it did not have anticompetitive effects.

161 Consequently, and recalling that it is not the place of a dominant undertaking to dictate how many viable competitors are to be allowed to compete with it (see, to that effect, judgment of 19 April 2012, *Tomra Systems and Others* v *Commission*, C-549/10 P, EU:C:2012:221, paragraph 42), it cannot be ruled out that the GSK/IVAX agreement might have generated, taken together with the GSK/Alpharma and GSK/GUK agreements, cumulative effects from parallel restrictive agreements that were liable to strengthen GSK's dominant position, and, therefore, that the strategy of that manufacturer of originator medicines may prove to be abusive within the meaning of Article 102 TFEU, which, however, it is solely for the referring court to determine.

162 To that effect, it must also be recalled that, while, for the purposes of application of Article 102 TFEU, there is no requirement to establish that the dominant undertaking has an anticompetitive intent, evidence of such an intent, while it cannot be sufficient in itself, constitutes a fact that may be taken into account in order to determine that a dominant position has been abused (see, to that effect, judgment of 19 April 2012, *Tomra Systems and Others* v *Commission*, C-549/10 P, EU:C:2012:221, paragraphs 20, 21 and 24).

163 In this case, the CMA and the referring court consider that the conclusion by GSK of the agreements at issue was part of an overall strategy pursued by GSK to maintain as long as possible its monopoly position in the United Kingdom paroxetine market.

164 Consequently, if those matters are established, any anticompetitive intent on the part of GSK must be taken into consideration by the referring court in order to assess whether the conduct of GSK must be characterised as 'abuse of a dominant position' within the meaning of Article 102 TFEU.

165 That said, it must be recalled, in response to Question 10(b) and (c), that, in accordance with settled case-law, it is open to a dominant undertaking to provide justification for behaviour that is liable to be caught by the prohibition under Article 102 TFEU, in particular by establishing that the exclusionary effect produced by its conduct may be counterbalanced, or outweighed, by advantages in terms of efficiency that also benefit consumers (see, to that effect, judgment of 27 March 2012, *Post Danmark*, C-209/10, EU:C:2012:172, paragraphs 40 and 41 and the case-law cited).

166 To that effect, it is for the dominant undertaking to show that the efficiency gains likely to result from the conduct under consideration offset any likely negative effects on competition and the interests of consumers in the affected markets; that those gains have been, or are likely to be, brought about as a result of that conduct; that such conduct is necessary for the achievement of those efficiency gains, and that it does not eliminate effective competition, by removing all or most existing sources of actual or potential competition (judgment of 27 March 2012, *Post Danmark*, C-209/10, EU:C:2012:172,

paragraph 42), and consequently that undertaking has to do more than put forward vague, general and theoretical arguments on that point or rely exclusively on its own commercial interests.

167 It follows that the assessment of whether a practice that may be subject to the prohibition laid down in Article 102 TFEU is justified requires, inter alia, a weighing of the favourable and unfavourable effects on competition of the practice concerned (judgment of 6 September 2017, *Intel* v *Commission*, C-413/14 P, EU:C:2017:632, paragraph 140), which requires objective analysis of its effects on the market.

168 Accordingly, the taking into consideration of, inter alia, the efficiency gains of the practices concerned cannot depend on the objectives that may have been pursued by the party engaged in those practices and, therefore, on whether those practices result from deliberate intention or, on the contrary, are only fortuitous or accidental.

169 Such a conclusion is moreover confirmed by the Court's settled case-law that the concept of abuse of a dominant position is an objective one (see, inter alia, judgments of 13 February 1979, *Hoffmann-La Roche* v *Commission*, 85/76, EU:C:1979:36, paragraph 91, and of 16 July 2015, *Huawei Technologies*, C-170/13, EU:C:2015:477), which implies that any justifications of such a practice should themselves be assessed objectively.

170 Consequently, the fact that the financial implications of the GSK/IVAX agreement that are favourable to the national health system, referred to in Question 10(b), may have been accidental cannot have the result that, for that reason alone, such financial implications are excluded from the weighing of favourable and unfavourable effects on competition of the practice concerned, and those financial implications must therefore be duly taken into account in order to assess whether they do constitute efficiency gains that may arise from the conduct under examination and, if so, whether they offset the adverse effects that that conduct is capable of having on competition and the interests of consumers in the market affected.

171 In that regard, it must be stated that that weighing of effects should be carried out taking due account of the specific characteristics of the practice concerned and more particularly, with respect to a unilateral practice such as that at issue in the main proceedings, of the fact mentioned by the referring court in Question 10(b), namely the fact that the demonstrated favourable effects resulting from the GSK/IVAX agreement are significantly less than those which would have arisen upon the independent market entry of a generic version of Seroxat following a successful outcome for IVAX in the patent proceedings.

172 In the light of the foregoing, the answer to Questions 8 to 10, taken together, is that Article 102 TFEU must be interpreted as meaning that the strategy of a dominant undertaking, the holder of a process patent for the production of an active ingredient that is in the public domain, which leads it to conclude, either as a precautionary measure, or following the bringing of court proceedings challenging the validity of that patent, a set of settlement agreements which have, at the least, the effect of keeping temporarily outside the market potential competitors who manufacture generic medicines using that active ingredient, constitutes an abuse of a dominant position within the meaning of Article 102 TFEU, provided that that strategy has the capacity to restrict competition and, in particular, to have exclusionary effects, going beyond the specific anticompetitive effects of each of the settlement agreements that are part of that strategy, which it is for the referring court to determine.

Costs

173 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Fourth Chamber) hereby rules:

1. **Article 101(1) TFEU must be interpreted as meaning that a manufacturer of originator medicines who is the holder of a manufacturing process patent for an active ingredient that is in the public domain, on the one hand, and the manufacturers of generic medicines who are preparing to enter the market of the medicine containing that active ingredient, on the other, who are in dispute as to whether that patent is valid or whether the generic medicines concerned infringe that patent, are potential competitors, where it is established that the manufacturer of generic medicines has in fact a firm intention and an inherent ability to enter the market, and that its market entry does not meet barriers that are insurmountable, which it is for the referring court to assess.**

2. **Article 101(1) TFEU must be interpreted as meaning that a settlement agreement with respect to pending court proceedings between a manufacturer of originator medicines and a manufacturer of generic medicines, who are potential competitors, concerning whether a process patent (for the manufacture of an active ingredient of an originator medicine that is in the public domain) held by the manufacturer of originator medicines is valid and whether a generic version of that medicine infringes the patent, whereby that manufacturer of generic medicines undertakes not to enter the market of the medicine containing that active ingredient and not to pursue its action for the revocation of that patent for the duration of that agreement, in return for transfers of value in its favour by the manufacturer of originator medicines, constitutes an agreement which has as its object the prevention, restriction or distortion of competition:**

– **if it is clear from all the information available that the net gain from the transfers of value by the manufacturer of originator medicines in favour of the manufacturer of generic medicines can have no explanation other than the commercial interest of the parties to the agreement not to engage in competition on the merits;**

– **unless the settlement agreement concerned is accompanied by proven pro-competitive effects capable of giving rise to a reasonable doubt that it causes a sufficient degree of harm to competition.**

3. **Article 101(1) TFEU must be interpreted as meaning that if a settlement agreement, such as those at issue in the main proceedings, is to be demonstrated to have appreciable potential or real effects on competition, and, therefore, is to be characterised as a 'restriction by effect', that does not presuppose a finding that, in the absence of that agreement, either the manufacturer of generic medicines who is a party to that agreement would probably have been successful in the proceedings relating to the process patent at issue, or the parties to that agreement would probably have concluded a less restrictive settlement agreement.**

4. **Article 102 TFEU must be interpreted as meaning that, in a situation where a manufacturer of originator medicines containing an active ingredient which is in the public domain, but the process of manufacturing which is covered by a process patent, the validity of which is disputed, impedes, on the basis of that process patent, the market entry of generic versions of that medicine, there must be taken into consideration, for the purposes of definition of the product market concerned, not only the originator version of that medicine but also its generic versions, even if the latter would not be able to enter the market legally before the expiry of that process patent, if the manufacturers concerned of generic medicines are in a position to present themselves within a short period on the market concerned with sufficient strength to constitute a serious counterbalance to the manufacturer of originator medicines already on that market, which it is for the referring court to determine.**

5. **Article 102 TFEU must be interpreted as meaning that the strategy of a dominant undertaking, the holder of a process patent for the production of an active ingredient that is in the public domain, which leads it to conclude, either as a precautionary measure or following the bringing of court proceedings challenging the validity of that patent, a set of settlement**

agreements which have, at the least, the effect of keeping temporarily outside the market potential competitors who manufacture generic medicines using that active ingredient, constitutes an abuse of a dominant position within the meaning of Article 102 TFEU, provided that that strategy has the capacity to restrict competition and, in particular, to have exclusionary effects, going beyond the specific anticompetitive effects of each of the settlement agreements that are part of that strategy, which it is for the referring court to determine.

Vilaras	Rodin	Šváby
Jürimäe		Piçarra

Delivered in open court in Luxembourg on 30 January 2020.

A. Calot Escobar	M. Vilaras
Registrar	President of the Fourth Chamber

---

* Language of the case: English.