Court of Justice EU, 30 January 2020, Generics v Competition and Markets Authority

COMPETITION LAW

Article 101 TFEU

To assess whether a manufacturer of generic medicines that is not present in the market is a potential competitor of a manufacturer of originator medicines when the agreement at issue has the effect of temporarily keeping an undertaking outside a market

- **first it must be determined whether the manufacturer 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**
- **secondly it must be determined that the market entry of such a manufacturer of generic medicines does not meet barriers to entry that are insurmountable**
- **existence of a patent as such cannot be regarded as an insurmountable barrier, because validity can be challenged**

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.

Third the finding that a manufacturer of generic medicines has a firm intention and an inherent ability to enter the market without there being insurmountable barriers can be confirmed by additional factors:

- **an agreement between undertakings operating at same level in production chain, some of which had no presence in the market concerned, constitutes a strong indication that a competitive relationship existed between them**
- **intention by manufacturer of originator medicines and acted upon to make transfers of value to manufacturer of generic medicines in exchange of postponement of latter's market entry, even though the former claims the latter is infringing one or more of its process patents**
- **the greater the transfer of value, the stronger the indication**

A settlement agreement, with regard 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 held by that manufacturer of originator medicines is valid and whether a generic version of that medicine infringes that patent has as its object the prevention, restriction or distortion of competition:

- **when it is clear 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 parties not to engage in competition on the merits**

94 […] 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.

- **such transfers of value may involve indirect transfers resulting from profits to be obtained from a distribution contract concluded with the manufacturer of originator medicines enabling the generic manufacturer to sell a possibly defined quota of generic medicines manufactured by the manufacturer of originator medicines**

A *"restriction by object"* cannot be rebutted by:

- **the fact that the agreement does not exceed the period of validity of the patent**
- **the fact that there is uncertainty about the validity of the patent**

There is no *"restriction by object"* when 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

- **– 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.**

If a settlement agreement is to be demonstrated to have appreciable potential or real effects on competition and therefore has to be characterized 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**

Article 102 TFEU:

To define the product market in a situation where a manufacturer of originator medicines 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

- **not only the originator version of that medicine need to be taken into account, 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**

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.

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 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**

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Court of Justice EU, 30 January 2020

(M. Vilaras, S. Rodin, D. Šváby (Rapporteur), K. Jürimäe and N. Piçarra)

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 Commission, 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.

OPINION OF ADVOCATE GENERAL KOKOTT

delivered on 22 January 2020 (1)

Case C-307/18

Generics (UK) Ltd and Others

v

Competition and Markets Authority

(Request for a preliminary ruling from the Competition Appeal Tribunal (United Kingdom))

(Reference for a preliminary ruling — Competition — Agreements, decisions and concerted practices — Dominant position — Abuse — Pharmaceutical products — Agreements in settlement of patent disputes entered into by a patent-holding originator company and generic medicinal products manufacturers)

Table of contents

I. Introduction

1. May an agreement to settle a medicinal products patent dispute constitute a restriction of competition by object or by effect and may the conclusion of that agreement, possibly combined with entry into other agreements, constitute an abuse of a dominant position?

2. This, in a nutshell, is the essence of the 10 questions put by the Competition Appeal Tribunal (United Kingdom) ('*the CAT*') to the Court in this reference for a preliminary ruling. Those questions were raised in proceedings before the CAT between, on the one hand, Generics (UK) Ltd ('*GUK*') and other medicinal products manufacturers (2) and, on the other, the Competition and Markets Authority, United Kingdom ('*the CMA*') concerning three agreements entered into by GlaxoSmithKline plc ('*GSK*') with the generic manufacturers IVAX Pharmaceuticals UK ('*IVAX*'), GUK and Alpharma.

3. The agreements in question were entered into as agreements in settlement of patent disputes which had, in the case of GUK and Alpharma, already given rise to patent litigation. Under the GUK and Alpharma Agreements, the generic manufacturers concerned undertook, inter alia, not to enter the market with their products for an agreed period, while GSK undertook to make significant transfers of value in their favour.

4. According to the CMA, the purpose of those agreements was to induce those generic manufacturers to abandon their efforts to enter the market independently during the agreed period and those agreements were therefore akin to market exclusion agreements prohibited by Article 101 TFEU, while their conclusion by GSK constituted an abuse of a dominant position within the meaning of Article 102 TFEU. GSK and the generic manufacturers maintain, on the contrary, that the agreements in question cannot be seen as constituting infringements of EU competition law.

5. The present case takes place within the context of Lundbeck (3) and Servier, (4) currently pending before the Court, in which the European Commission found that agreements in settlement of patent disputes constituted infringements of Article 101 and, with regard to Servier, Article 102 TFEU. The Court's findings in

the present proceedings will also be instructive in those cases.

II. Legal framework

6. Section 2 of Chapter 1 of the UK Competition Act 1998 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;

...'

7. Section 18 of Chapter 2 of the UK Competition Act 1998 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;

...'

8. Section 60 of the UK Competition Act 1998 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.

...'

III. Background to the dispute

9. Paroxetine is a prescription-only antidepressant medicine which belongs to the group of selective serotonin re-uptake inhibitors ('*SSRIs*'). Paroxetine was marketed in the United Kingdom by the originator company GSK under the brand name '*Seroxat*'. Over the relevant period, GSK produced Seroxat in doses of 20 mg and 30 mg, but the 20mg dose was the more significant and more frequently prescribed.

10. Compound patent protection for paroxetine hydrochloride, the active pharmaceutical ingredient ('*API*') of that originator medicinal product expired in January 1999. Furthermore, GSK's right to data exclusivity relating to that API expired in December 2000, thus allowing generic manufacturers to seek a marketing authorisation ('*MA*') under the abridged procedure. (5)

11. By that time, GSK had obtained a series of secondary patents, including the GB 2 297 550 patent which covered four polymorphs of paroxetine hydrochloride anhydrate and the process to produce them ('*the Anhydrate Patent*'). That patent was granted in 1997, and was subsequently declared invalid in part by the High Court of Justice (England & Wales), Chancery Division (patents court) (United Kingdom) and, to the extent that it remained valid, it expired in 2013.

12. By mid-2000 GSK was aware that a number of generic manufacturers were considering entry into the UK market with generic paroxetine. Accordingly, IVAX had submitted an application for an MA in Ireland and obtained from BASF AG the paroxetine API on the basis of which that application was submitted, GUK had obtained an MA for paroxetine in Denmark in April 2001 and Alpharma had submitted an application for an MA in the United Kingdom on 30 May 2001.

13. Against that background, GSK entered into three agreements with the companies concerned.

A. Agreements entered into by GSK

1. The IVAX Agreement

14. The first agreement, entered into by GSK with IVAX on 3 October 2001 and terminated on 29 June 2004 ('*the IVAX Agreement*'), appointed IVAX as '*sole distributor*' in the United Kingdom, with a limit of 770 000 boxes per year, of 20 mg paroxetine hydrochloride in 30 tablet packs to be sold as an authorised generic, in exchange for an annual promotional allowance of 3.2 million pound sterling (GBP). The supply price at which GSK was to supply the product to IVAX, which was subsequently amended, was initially GBP 8.45 per pack and it was provided, inter alia, that IVAX had the immediate right to terminate the agreement if a generic product containing paroxetine hydrochloride as its active substance became available for GBP 8.45 or below for three consecutive days.

2. The GUK Agreement

15. The second agreement was entered into by GSK with GUK on 13 March 2002 ('*the GUK Agreement*'). It was initially planned to have a three-year term, but ended on 1 July 2004. It followed several events: first of all, revocation proceedings commenced on 27 July 2001 by BASF against GSK in respect of GSK's Anhydrate

Patent; subsequently, the commencement by GSK, on 18 September 2001, of infringement proceedings in respect of the same patent against GUK, in which GUK challenged the validity of that patent; and finally, the grant by the High Court of Justice (England & Wales), Chancery Division (patents court), on 23 October 2001, of an interim injunction prohibiting GUK from entering the market, at which time GSK gave a '*cross-undertaking in damages*'. (6)

16. On 4 December 2001 the High Court of Justice (England & Wales), Chancery Division (patents court) directed that the BASF and GUK cases, which both concerned the Anhydrate Patent, should be heard together the following March. On 13 March 2002, the day before that hearing, GSK and GUK reached the agreement at issue; the injunction and cross-undertaking in damages were discharged, all claims to damages were waived and the proceedings were stayed. Furthermore, under that agreement, GSK was to purchase all GUK's stock of generic paroxetine intended for sale in the United Kingdom for the sum of 12.5 million United States dollars (USD), pay 50% of GUK's costs in the litigation up to GBP 0.5 million, enter into a sub-distribution agreement with IVAX in favour of GUK ('*the IVAX-GUK Supply Agreement*') and pay GUK an annual marketing allowance of GBP 1.65 million; in return, GUK and all the companies in the Merck group undertook not to make, import or supply paroxetine hydrochloride in the United Kingdom during the currency of the IVAX-GUK Supply Agreement.

17. That IVAX-GUK Supply Agreement, which came into force on 14 March 2002 and was concluded for a term of three years, stated that IVAX would supply GUK with 750 000 packs of 20 mg paroxetine per annum at a price of GBP 8.45 and included a profit guarantee in that if GUK's average net selling price in any contract year fell below GBP 12.25 per pack, IVAX would pay it such sum as necessary to ensure that its profit did not fall below a margin of GBP 3.80 per pack. Moreover, it was agreed that the agreement could be terminated before the term initially laid down if the market price per pack of paroxetine fell below GBP 8.45 for at least three consecutive months in the third contract year or any time thereafter. At the same time as the IVAX-GUK Supply Agreement was entered into, GSK and IVAX amended the IVAX Agreement in order to adjust it accordingly.

3. The Alpharma Agreement

18. The third agreement, entered into by GSK with Alpharma on 12 November 2002 and terminated on 13 February 2004 ('*the Alpharma Agreement*') that was initially concluded for a term of one year and extended for an additional year subsequently, followed (i) the acquisition, by Alpharma, of an MA for paroxetine in the United Kingdom, (ii) infringement proceedings brought by GSK against Alpharma, (iii) a legal undertaking given by Alpharma not to sell paroxetine in the United Kingdom until judgment was given in those proceedings in relation to which a hearing was listed to take place in December 2002, and (iv) a cross-undertaking in damages given by GSK.

19. Under the Alpharma Agreement, Alpharma was to be discharged from its undertaking and GSK from its cross-undertaking in damages, and GSK's claim would be dismissed. The agreement also provided for a sub-distribution agreement to be entered into between IVAX and Alpharma for the supply to Alpharma of 500 000 packs (subsequently increased to 620 000 packs) of 20 mg paroxetine ('*the IVAX-Alpharma Supply Agreement*') and for several transfers of value by GSK to Alpharma, namely: payment of GBP 0.5 million towards the legal costs in the proceedings, a one-off payment of GBP 3 million in respect of the production and preparation costs for the launch of paroxetine on the UK market, a marketing allowance of GBP 100 000 per month and an option to purchase certain GSK products in order to ensure the transfer to Alpharma of at least GBP 500 000. In return, Alpharma undertook not to make, import or supply paroxetine hydrochloride in the United Kingdom save as purchased from IVAX or manufactured by GSK.

20. On 20 November 2002, IVAX and Alpharma entered into the Supply Agreement provided for in the Alpharma Agreement. That supply agreement could be terminated 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. In that context, a Generic Market was considered to be formed when the monthly average price of paroxetine, not including that sold by GSK and Alpharma, fell below GBP 9.50 per pack or when a paroxetine 20 mg product was sold other than under GSK's marketing authorisation. Furthermore, it was stated that if, during the two months following service of such notice to terminate, the average price of paroxetine fell below GBP 8.45, IVAX would pay Alpharma the difference between GBP 8.45 and that average price up to GBP 200 000. At the same time as the IVAX-Alpharma Supply Agreement was entered into, GSK and IVAX amended the IVAX Agreement in order to adjust it accordingly.

B. Additional and subsequent developments concerning the Anhydrate Patent and formation of a Generic Market

21. Prior to the implementation of the IVAX, GUK and Alpharma Agreements, the UK paroxetine market was characterised by the presence of parallel imports of paroxetine from other Member States of the European Union. Those parallel imports are due to the fact that there are, particularly because of the different income levels and regulatory regimes, differences between the prices of medicinal products in the Member States. Therefore, as long as generic versions of a certain medicinal product are not available in a Member State, it can be profitable to import branded medicines from other Member States and to sell them at a price lower than that charged in the importing Member State. Thus, from September 2001, parallel imports represented approximately 30 to 40% of the paroxetine dispensed in the United Kingdom and were sold at a slightly lower price than GSK's Seroxat. However, those parallel

imports concerned only the 20 mg dose of paroxetine, not the 30 mg dose.

22. Under the IVAX, GUK and Alpharma Agreements, those generic companies were supplied with significant but limited quantities of generic paroxetine manufactured by GSK, which they could sell under their own brand names and which they invoiced at approximately the price charged for parallel imports. Subsequently, between November 2001 and November 2003, IVAX, GUK and Alpharma gained approximately 60 percentage points on the 20 mg paroxetine market, replacing almost all the parallel imports (some 30 percentage points) and a part of GSK's Seroxat (another almost 30 percentage points). That change in the structure of the market led to a reduction in the overall weighted average price of 20 mg paroxetine of up to 4%. In contrast, the Agreements had no effect on GSK's sales of 30 mg paroxetine.

23. Paroxetine was a medicinal product reimbursed by the UK National Health Service ('*the NHS*'). The NHS reimbursement scheme comprised various categories including categories C and A for medicinal products which were not readily available in generic form and for those which were readily available in generic form respectively. Following the supply of generic paroxetine under the IVAX Agreement, the 20 mg paroxetine, which was originally classified in Category C moved to Category A with effect from 1 June 2002. This resulted in an immediate fall in the NHS Drug Tariff reimbursement price of 12%, a subsequent fall of 3% between June and November 2002 and a corresponding reduction in the costs borne by the NHS.

24. The judgment in the revocation proceedings as regards the Anhydrate Patent brought by BASF (7) was delivered on 12 July 2002. It held that most of the product claims in that patent were invalid but that two of the process claims were valid.

25. On 30 July 2002 Apotex, another generic manufacturer, obtained an MA for paroxetine in the United Kingdom and, together with its distributors Neolab and Waymade, commenced further revocation proceedings as regards the Anhydrate Patent, and GSK commenced infringement proceedings against those three companies. On 5 December 2003, the High Court of Justice (England & Wales), Chancery Division (patents court) held that the patent claims which had not been invalidated by the BASF judgment were not infringed by the process used by Apotex; this was upheld on appeal. (8) Subsequently, Neolab and Waymade entered the market in late December 2003 as distributors for Apotex with the 20 mg paroxetine product, which opened up the generic paroxetine market.

26. Alpharma then terminated the IVAX-Alpharma Supply Agreement and thereby brought to an end the Alpharma Agreement with effect from 13 February 2004, and entered the market with its own 20 mg and 30 mg paroxetine from February 2004. GUK subsequently terminated the IVAX-GUK Supply Agreement on 25 June 2004, which also put an end to its prohibition on the sale of paroxetine under the GUK Agreement. Finally, on 29 June 2004, IVAX and GSK terminated the IVAX Agreement.

27. The independent entry of generic paroxetine onto the market from the end of 2003 had a significant impact on prices. Thus, the prices of 20 mg paroxetine fell by 34% in the first three months following that entry, and by 69% the following year, while the price of 30 mg paroxetine had fallen by about 66% by December 2005. Average prices of 20 mg and 30 mg paroxetine had fallen by around 74% by December 2005.

C. The CMA Decision and the proceedings before the CAT

28. On 12 February 2016, the CMA adopted the decision at issue in the main proceedings ('*the CMA decision*'), (9) in which it found that

(1) GSK held a dominant position in the market for paroxetine and that it had abused that position contrary to the prohibition laid down by Chapter 2 of the UK Competition Act 1998 by entering into the IVAX, GUK and Alpharma Agreements;

(2) GSK and GUK and the latter's parent company, Merck, had infringed the prohibition laid down in Chapter 1 of the UK Competition Act 1998 and, for the period following 1 May 2004, Article 101 TFEU by entering into the GUK Agreement; and

(3) GSK and the companies in the Alpharma group, namely Actavis, Xellia and Alpharma LLC, had infringed the prohibition laid down in Chapter 1 of the UK Competition Act 1998 by entering into the Alpharma Agreement;

(4) In addition, the CMA imposed financial penalties on those companies in a total amount of GBP 44.99 million in respect of the infringements established.

29. Furthermore, the CMA concluded that it was not appropriate to impose penalties with respect to the IVAX Agreement in respect of the prohibition on anticompetitive agreements, in particular because it was excluded from the scope of Chapter 1 of the UK Competition Act 1998 under national legislation on vertical restraints which was applicable at the relevant time but subsequently repealed. (10)

30. The companies on whom penalties were imposed brought an appeal against the CMA decision before the CAT. The CAT points out that, in those actions, it must give a ruling, inter alia, by referring to EU law, on whether GSK, on the one hand, and GUK, Alpharma and IVAX, on the other, were potential competitors for the supply of paroxetine in the United Kingdom at the relevant time; whether the agreements entered into by GSK and GUK and Alpharma, respectively, constituted a restriction of competition by object and by effect; which was the relevant product market on which GSK supplied paroxetine for the purpose of determining whether it held a dominant position; and whether GSK's conduct constituted an abuse of a dominant position.

31. As regards the issues related to Article 101 TFEU, particularly concerning the existence of potential competition and of a restriction of competition by object, the CAT notes that those issues have already given rise to several judgments of the General Court in Lundbeck and others, (11) currently under appeal, the relevance of

which to the present case is disputed by all the applicants. Moreover, the CAT considers that the detailed rules for assessing a restriction by effect, which is the subject of the sixth question referred and of the Commission's decision in Servier, (12) remain uncertain. As regards the questions relating to Section 18 of the UK Competition Act 1998, which corresponds to Article 102 TFEU, which is also the subject of the Commission's decision in Servier, the CAT points out that it is facing new points of law concerning both the definition of the relevant market and the finding of a possible abuse of dominant position and of any potential defences in that regard.

IV. The procedure before the Court and the questions referred for a preliminary ruling

32. In those circumstances, the CAT, by a judgment of 8 March 2018 ('*the CAT judgment*'), (13) which was received, together with the questions referred and a summary of the main proceedings and of the main facts of the case, at the Court on 7 May 2018, decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'*Potential competition*

(1) 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?

Restriction by object

(3) 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)?

Restriction by effect

(6) 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%)?

Market definition

(7) 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?

Abuse

(8) 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?'

33. On 20 November 2018 the Court sent a request for information to the CAT, to which it replied on 17 December 2018.

34. In the proceedings before the Court of Justice, GUK, GSK, Xellia, Actavis, Merck, the CMA and the Commission submitted observations. Those same parties participated in the hearing on 19 September 2019.

V. Assessment

35. Before considering the questions referred for a preliminary ruling by the CAT (part B), it is necessary to clarify a point concerning the Court's jurisdiction to reply to those questions (part A).

A. The Court's jurisdiction to reply to the questions from the CAT

36. As stated above, (14) penalties were imposed by the CMA with respect to only the GUK Agreement under Article 101 TFEU for the period subsequent to 1 May 2004, (15) whereas penalties were imposed with respect to the Alpharma Agreement, which came to an end before that date, (16) only under Chapter 1 of the UK Competition Act 1998. Similarly, penalties were imposed on GSK for abuse of a dominant position only under Chapter 2 of the UK Competition Act 1998, since the CMA considered that GSK had held a dominant position only until the end of November 2003. (17)

37. Nevertheless, the Court has jurisdiction to reply to the questions from the CAT concerning Article 102 TFEU and Article 101 TFEU in relation to aspects of the case other than the GUK Agreement between 1 May and its termination on 1 July 2004. (18) As the referring court states, Sections 2 and 18 of the UK Competition Act 1998 correspond to Articles 101 and 102 TFEU and must, under Section 60 of the UK Competition Act 1998, be interpreted in accordance with them. It is settled case-law that questions referred for a preliminary ruling relating to facts which are outside the direct scope of EU law are admissible where the provisions of EU law have been made applicable by national legislation, which, in dealing with situations confined in all respects within a single Member State, follows the same approach as that provided for by EU law. (19)

B. The questions referred

38. The background to the questions referred to the Court by the CAT in these proceedings consists of the three agreements described above between the originator company GSK and the generic manufacturers IVAX, GUK and Alpharma concerning the antidepressant medication paroxetine.

39. Those agreements provided, in essence, in addition to payments by GSK to the generic manufacturers, for entry by those manufacturers onto the market with a limited quantity of generic paroxetine manufactured by GSK instead of independent entry by those companies onto the market with their own generic paroxetine. (20) Consequently, they entailed a certain reduction in the price of paroxetine and in the costs borne by consumers, which did not, however, bear any relation to the fall in prices and resulting savings caused by the independent entry of generics onto the market which did indeed take place from December 2003. (21)

40. The agreements in question were entered into in a situation in which, following the expiry of the patent for the paroxetine API in 1999 and the corresponding right to data exclusivity in 2000, GSK continued to hold secondary patents relating to that medicinal product, including, in particular, patents protecting certain manufacturing processes for its API, such as the Anhydrate Patent at issue in the main proceedings. (22)

41. In such a situation, generic manufacturers are able, from the point of view of patent law, to enter the market lawfully with generic copies of the originator product in two ways: either with generic copies manufactured in accordance with the manufacturing processes which remain protected by patents where those patents are declared invalid, or with generic copies manufactured via different processes, in which case those copies do not constitute an infringement of the manufacturing processes of the originator product which remain patent protected.

42. In other words and conversely, in a situation where the patent of a medicinal product's API has expired and an originator company holds only process patents, entry of the generic versions of the medicinal product in question infringes solely the patent rights of that originator if it is established that the process patents at issue are both valid and infringed by each of the potential entrants.

43. In the present case, however, the referring court starts from the assumption that it is impossible to know whether market entry with generic paroxetine by IVAX, GUK and Alpharma would have infringed any rights which GSK held by virtue of its disputed Anhydrate Patent in the main proceedings, since it is uncertain whether that patent was valid and infringed by the generic products at issue. That is due, inter alia, to the fact that GSK entered into the agreement with IVAX even before legal proceedings were commenced and that it concluded the agreements with GUK and Alpharma in order to settle ongoing judicial proceedings with those companies. Therefore, it is not known whether the Anhydrate Patent would have been declared invalid in the course of those proceedings, and it has never been determined whether the generic products of IVAX, GUK and Alpharma infringed the processes protected by that patent. (23)

44. That uncertainty as to the possible unlawful market entry, under patent law, of generic paroxetine by IVAX,

GUK and Alpharma, constitutes the leitmotif both of the arguments of the applicant companies in the main proceedings and of the questions put to the Court by the referring court regarding the assessment of the agreements entered into between GSK and those generic manufacturers under competition law.

45. Thus, GSK and the generic manufacturers maintain, inter alia, that, since it is impossible to know whether those manufacturers would have been able to enter the market without infringing GSK's patent rights, it is equally impossible to determine whether there was potential competition between the operators which could be restricted by the agreements at issue. In those circumstances, they claim that it is impossible to take the view that those agreements constituted restrictions of competition by object and by effect and that their conclusion constituted abuse of a dominant position.

46. According to GSK and the generic manufacturers, that is even more the case as those agreements provided certain benefits for consumers while it would have been wholly uncertain whether the more significant profits generated by an independent entry of the generic manufacturers onto the market would have been likely to materialise, since it would precisely have been impossible to know whether such entry would have been lawful. In those circumstances, it is alleged that the agreements at issue are as likely to have increased competition as to have restricted it, thereby making it impossible to impose any penalty under the prohibition of restrictions of competition.

47. The CAT considers, however, that, in spite of the fact that each of the parties was uncertain as to the outcome of the ongoing litigation, the agreements entered into do not reflect the respective assessment of those parties of their chances of success, but only the view that the terms of the agreements were commercially more advantageous than the risks of continuing the disputes. The reason for that was, according to the CAT, that the agreements effectively shared between GSK and the generic manufacturers GSK's monopoly profits, which were preserved because there was no independent market entry by the generics, as ensured by the very terms of the agreements. In that context, the CAT analyses the supply of paroxetine by GSK at a preferential price to the generic manufacturers for distribution by them as a value transfer of a non-monetary nature.

48. The CAT therefore concludes that, by the agreements at issue, GSK ensured, for the agreed period, the protection of its patent position against the risk of entry by generic competitors, in exchange for substantial value transfers that far exceeded the costs of the avoided litigation. Although such a process may be entirely rational in economic and commercial terms for all the parties, the CAT doubts, however, whether it is permissible under competition law. For the purposes of such analysis, the CAT nevertheless raises the question of the weight to be accorded to the situation under patent law and whether, against that background, it is possible to equate the agreements at issue with simple agreements for the exclusion of potential competitors from the market or with market-sharing agreements. (24)

1. Article 101 TFEU

49. As stated above, owing, in particular, to national legislation on vertical restraints applicable at the relevant time, the CMA only imposed penalties with respect to the GUK and Alpharma Agreements, but not the IVAX Agreement, under the prohibition of anticompetitive agreements. However, the IVAX Agreement was taken into account by the CMA when it assessed GSK's conduct in the light of the prohibition on the abuse of a dominant position. (25)

50. Although the CAT therefore refers only to the GUK and Alpharma Agreements in its questions on restrictions of competition by object or by effect, it nevertheless states that, for the purposes of examining the questions relating to abuse of a dominant position, it must also determine whether IVAX was a potential competitor of GSK at the relevant time.

51. In that regard, it should be noted that, in the context of the procedure referred to in Article 267 TFEU, the role of the Court is limited to interpreting the provisions of EU law referred to it, whereas it is for the referring court to apply that interpretation to the case before it. (26) Therefore, in the present case, it will ultimately be for the CAT to determine specifically whether IVAX, GUK and Alpharma were potential competitors of GSK at the relevant time and whether the GUK and Alpharma Agreements were restrictions of competition by object or by effect.

52. The Court's task, in contrast, is limited to assessing whether, in the circumstances defined in abstract terms by the CAT in the questions it has referred, a patent holder and generic manufacturers may be regarded as potential competitors and agreements entered into between those operators may be regarded as restrictions of competition by object or by effect. In defining the circumstances set out in its questions, the CAT has already taken into account the relevant characteristics of the respective agreements (that is to say, the IVAX, GUK and Alpharma Agreements for Questions 1 and 2, and the GUK and Alpharma Agreements for Questions 3 to 6).

53. It should therefore be pointed out purely for the sake of clarification that, in the following arguments concerning potential competition, the facts in the main proceedings referred to include, in so far as relevant, the three IVAX, GUK and Alpharma Agreements, whereas the agreements at issue in the main proceedings to which the following arguments concerning restrictions of competition by object and by effect refer include only the GUK and Alpharma Agreements.

54. That said, it is necessary to deal first with Questions 1 and 2 referred for a preliminary ruling, relating to the concept of potential competition (part a), before turning to Questions 3 to 5 (part b), and 6 (part c), which relate, respectively, to the concepts of restriction of competition by object and by effect.

(a) The concept of potential competition (Questions 1 and 2)

55. By its first and second questions, which should be dealt with together, the CAT asks the Court whether the holder of a patent for a pharmaceutical product and a generic manufacturer wishing to enter the market with a generic version of that product are to be regarded as potential competitors when the parties are in bona fide dispute as to whether the patent is valid and/or whether the generic product infringes the patent.
56. In addition, the CAT wishes to know whether (i) the existence of pending court proceedings between the parties concerning that dispute, (ii) the patent holder's obtaining of an interim injunction prohibiting the generic manufacturer from launching its product until judgment in those proceedings has been given, or (iii) the fact that the patent holder regards the generic manufacturer as a potential competitor, are likely to have an impact on the answer to that question.
57. In order to answer those questions, it must be noted first of all that, as the General Court has correctly held on a number of occasions, it is apparent from the terms of Article 101(1) TFEU relating to the impact of an agreement on competition that that provision applies solely to sectors open to competition. (27) To qualify an agreement between undertakings as having the object or effect of restricting competition presupposes, therefore, that there is competition which may be restricted.
58. Thus, if the examination of the economic and legal context of an agreement were to reveal that the undertakings in question could not be categorised as competitors, such an agreement likewise could not be categorised as restricting competition by its object or by its effects. Yet the examination of the conditions of competition on a market is based not only on existing competition between undertakings already present on that market, but also on potential competition between those undertakings and undertakings which are not yet present on that market. (28)
59. In order to examine whether an undertaking which is party to an agreement is a potential competitor on a particular market, it must be ascertained whether that market has insurmountable barriers to entry (29) and whether, if the agreement at issue had not been implemented, there would have been real concrete possibilities for the undertaking in question to penetrate it and to compete with the undertakings already established. (30) In that context, the essential factor on which categorisation as a potential competitor must be based is whether an undertaking has the ability to enter a particular market, but its intention to enter it may also be of relevance. (31)
60. Moreover, it has already been recognised by the Court that the conclusion by undertakings of an agreement the purpose of which is to keep one of them out of a specific market is a strong indication that a competitive relationship exists between them. (32) In the same vein, the perception of the established operator is a relevant factor in that regard, since it has been recognised that, irrespective of the intention of an undertaking outside a market to enter that market in the near future, the mere fact of the existence of such an undertaking may give rise to competitive pressure on the undertakings operating on that market, a pressure represented by the likelihood that a new competitor will enter the market if the market becomes more attractive. (33)
61. As the CAT explains, in the present case, its first and second questions are based on the reasoning that, if GSK's claims in the proceedings between it and GUK and Alpharma had proved to be correct, that is to say if the remaining claims of the Anhydrate Patent had been declared valid and infringed by the GUK and Alpharma products, entry onto the market of those generic producers would have constituted an infringement of GSK's patent rights. However, since judgments were never given in those proceedings because the agreements between the parties were intended specifically to bring to an end the ongoing court proceedings in that regard, (34) it is impossible to know whether entry of the generics onto the market would have infringed GSK's patent rights or not.
62. In those circumstances, the applicants in the main proceedings and, in particular, GSK, maintain that it is impossible to find that there was potential competition between GSK and the generic manufacturers in the paroxetine market. They claim that the existence of valid and infringed patents constitutes an insurmountable barrier to entry onto the market of an originator medicinal product protected by those patents and, therefore, where such patents exist, generic manufacturers do not have real concrete possibilities to enter that market.
63. According to that line of argument, it follows that, in a situation such as that in the main proceedings where the patent for the medicinal product API has expired but where the medicinal product is still protected by manufacturing patents, (35) the question of whether a generic manufacturer is a potential competitor of the holder of that patent pertains to the likelihood of that generic manufacturer being able either to have those manufacturing patents declared invalid or to find a method for manufacturing the API of the medicinal product concerned which does not infringe them.
64. Yet, in the present case, the CAT specifically found that it was impossible to assess that likelihood and to know whether or not generic entry onto the market would have infringed GSK's patent rights. Consequently, according to the applicants in the main proceedings, it is also impossible to categorise GSK and the generic manufacturers as potential competitors, since it is quite simply impossible to know whether the latter had real concrete possibilities to enter the paroxetine market when the agreements in question were entered into.
65. The assumption on which those arguments are based, namely that there may be potential competition between a medicinal product patent holder and the manufacturer of a generic of that same medicinal product solely when it is certain or at least highly likely that the latter will be able to enter the market without infringing the former's patent rights, is, however, erroneous for a number of reasons, which are explained below.

(1) Uncertainty as to the validity of a medicinal product patent and whether generic versions of that product infringe that patent as a constituent of competitive relationships in the pharmaceutical sector

66. First of all, as the General Court held in Lundbeck v Commission, (36) unless there is to be no distinction drawn between actual and potential competition, it cannot be necessary, in order to establish the existence of potential competition, to demonstrate with certainty that the generic undertaking would have entered the market and that that entry would inevitably have been successful; on the contrary, it must be sufficient to demonstrate that that undertaking had real, concrete possibilities in that respect.

67. Yet the fact that there is uncertainty as to the validity of patents protecting an originator medicinal product and as to whether a generic of that medicinal product infringes that patent is not such as to demonstrate that the market for the originator medicinal product has insurmountable barriers or that a generic manufacturer does not have real concrete possibilities to enter that market. That uncertainty is, on the contrary, a fundamental characteristic of competitive relationships in the pharmaceutical sector as in all sectors in which there are exclusive rights over technologies. (37) That applies both before and, in certain cases, after the market entry of generics of an originator medicinal product protected by patents since, as the Commission points out, in order to obtain an MA for a generic product, the manufacturer of that product is not required to show that it does not infringe any patent rights which continue to be held by the originator undertaking.

68. Thus, it is indeed true that, when granted by a public authority, an intellectual property right is normally assumed to be valid and an undertaking's ownership of that right is assumed to be lawful, (38) so that patents are assumed to be valid until they are expressly revoked or invalidated by a competent authority or court. However, that presumption of validity, as the General Court correctly held in Lundbeck v Commission and Servier and Others v Commission, cannot be equated with a presumption of illegality of generic products validly placed on the market which the patent holder deems to be infringing the patent. (39)

69. As the Court has stated, the purpose of a patent is indeed to ensure that the holder, in order to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements. (40) However, the subject matter of a patent cannot be interpreted as also affording protection against actions brought in order to challenge that patent's validity, in view of the fact that it is in the public interest to eliminate obstacles to economic activity which may arise where a patent was granted in error. (41) Consequently, the existence of patents protecting a certain medicinal product does not amount to a legal barrier excluding all competition such as the exclusive rights recognised as constituting such barriers in earlier cases. (42)

70. On the contrary, it is an integral part of patent law that, despite the presumption that patents are valid, there can be certainty as to that validity and as to whether competing products infringe that patent only once those matters have been examined by the competent national authorities and courts.

(2) Disputes relating to the validity of a patent or whether a generic product infringes that patent as factors which may indicate the existence of potential competition

71. Accordingly, it is customary that actions seeking to challenge the validity of a patent or to bring about an examination of its validity are part of the preparations for market entry of the generic version of an originator medicinal product which continues to be covered by patent rights. Such actions may consist not only of a direct challenge to those rights through proceedings for a declaration of the patent's invalidity or proceedings for a declaration of non-infringement in respect of the generic product, but also of the so-called '*at risk*' launch or the preparation of the so-called '*at risk*' launch of a generic version of a medicinal product on the market, (43) which is capable of giving rise to an action for infringement by the holder of the patent rights. This is, furthermore, perfectly illustrated by the facts constituting the background to the dispute in the main proceedings. (44)

72. Moreover, entry onto the market of a generic manufacturer amid uncertainty regarding the validity of patents continuing to protect the originator product or whether the generic product infringes those patents is all the more envisageable in a context such as that of the main proceedings, in which the patents at issue are not compound patents protecting the API of the originator medicinal product, in this case paroxetine, but rather process patents protecting certain methods of manufacturing that API. Consequently, unlike a compound patent, those process patents, irrespective of whether or not they are valid, do not prevent generic manufacturers from entering the market with paroxetine manufactured under other processes. (45)

73. It follows that the Commission is correct when it maintains, in connection with the present proceedings, that not only does the existence of a dispute between the patent holder and a generic manufacturer concerning the validity of the patent or whether the generic product at issue infringes that patent not prevent it being recognised that potential competition exists between those two operators, but on the contrary, is a factor capable of demonstrating that such potential competition exists. That is true, as the Commission correctly points out, both for cases in which such a dispute has not yet given rise to legal proceedings and for cases in which legal proceedings between the parties relating to the dispute in question are already ongoing.

74. More specifically, the existence of legal proceedings concerning the validity of a patent or whether a generic product infringes that patent is even capable of indicating that a generic manufacturer is preparing to

enter the market, since that is what gives rise to the legal proceedings on its part or on the part of the patent holder. Furthermore, as the CAT points out in relation to interim injunctions, (46) it is misconceived to take the view that the existence of judicial proceedings may preclude the existence of potential competition. If it were sufficient for legal proceedings to be ongoing in relation to a patent dispute in order to preclude the existence of potential competition between the operators who are party to the litigation, those operators would be able, by means of their litigation strategies, to influence it being found that potential competition exists between them.

75. In that context, it is not possible to accept the argument of the applicants in the main proceedings, and particularly GSK, according to which the view cannot be taken that there is a relationship of potential competition between the holder of a medicinal product patent and a manufacturer wishing to enter the market with a generic version of that medicinal product while uncertainty remains regarding the validity of the patent concerned or whether the generic product infringes that patent. That position is indeed not only contrary to the Court's case-law, cited above, concerning the scope of exclusive rights conferred by a patent, (47) but furthermore if that position were adopted, it would amount to precluding any potential competition and thereby preclude competition law from being applied during the preparatory stage of the market entry of generic medicinal products.

76. However, as the Commission has correctly pointed out during the present reference for a preliminary ruling, potential competition precisely requires protection since, if it were permissible to halt or delay future entrants' preparations for market entry by means of exclusion agreements, that potential competition could never come into existence by those operators entering the market. That is particularly the case in the pharmaceutical sector where entry requires long and costly preparations. (48) Therefore, as the Court has held, potential competition between undertakings holding patents for originator medicinal products and generic manufacturers of those same medicinal products may occur long before the expiry of a compound patent protecting the originator medicinal product. (49)

77. The likelihood of the generic manufacturer being successful in a dispute with the holder of an originator medicinal product patent cannot therefore constitute the decisive criterion for examining the competitive relationship between those operators. That is confirmed by the fact, correctly pointed out by the CAT, that it is not for the competition authority or the court examining that relationship to conduct an intellectual property *'mini-trial'* to assess the strength of the patent at issue.

(3) Scope of the competition authority's assessment of the intellectual property rights at issue

78. In that regard, it is appropriate to recall the Court's reasoning in its recent judgment in F. Hoffmann-La Roche and Others, (50) which concerned the relevance, for the purposes of the application of Article 101 TFEU, of the lawfulness of the placing on the market of a particular medicinal product from the point of view of EU pharmaceutical legislation.

79. In that judgment, the Court held that it is not for the national competition authorities to review whether the conditions under which a medicinal product is prescribed and marketed comply with that pharmaceutical legislation; such review can be carried out comprehensively only by the authorities with jurisdiction to ensure compliance with the rules governing pharmaceutical matters or by the national courts. (51) However, if those authorities or courts have not yet given a decision in that regard, the state of uncertainty surrounding the lawfulness of the conditions for marketing and prescribing the medicinal product at issue do not preclude a competition authority, for the purposes of the application of Article 101 TFEU, from finding that that product belongs to a particular market and therefore competes with the other medicinal product or products present on that market. (52)

80. Similarly, in its judgment in Slovenská sporiteľňa, (53) referred to by Advocate General Saugmandsgaard Øe in his Opinion in Hoffmann-La Roche, cited above, (54) the Court stated, in essence, that the alleged illegality of the presence of certain products or services on a given market does not mean that there is no competitive relationship, which is capable of being restricted, between those goods and the other goods present on that market.

81. That reasoning can be transposed, mutatis mutandis, to the present issue of the relevance, for the purposes of the application of Article 101 TFEU, of the lawfulness of the placing on the market of a generic medicinal product under patent law.

82. Here too, reviewing compliance with patent law of the placing on the market of such a generic medicinal product is not a matter for the competition authorities, but can be carried out comprehensively only by the national authorities or courts having patent law jurisdiction. (55) Therefore, if such authorities or courts have not yet given a decision in that regard, the state of uncertainty surrounding the lawfulness of the placing on the market of a generic medicinal product for the purposes of patent law cannot preclude a competition authority, for the purposes of applying Article 101 TFEU, from finding that that medicinal product competes with the originator medicinal product protected by the patent which is alleged to have been infringed.

83. Admittedly, that does not mean that the competition authority concerned must disregard any question relating to patent law which is capable of influencing the finding that such a competitive relationship exists. (56) Any patent rights protecting an originator medicinal product undeniably form part of the economic and legal context of the competitive relationships between the holders of such rights and the manufacturers of generic medicinal products. However, the competition authority's assessment of such patent rights must not consist of an examination of the strength of the patent or of the likelihood that a dispute between its holder and a manufacturer of generics might be brought to an end by

the finding that the patent is valid and has been infringed. Rather, that assessment must have regard to the question of whether, despite the existence of the patent rights at issue, the generic manufacturer has real concrete possibilities to enter the market at the relevant time.

84. In that regard, account must be taken, inter alia, of the broad parameters specific to patent law and the pharmaceutical sector which have just been mentioned, that is to say, that uncertainty as to the validity of patents covering medicinal products is a fundamental characteristic of the pharmaceutical sector; that the presumption that a patent for a medicinal product is valid does not amount to a presumption that a generic version of that medicinal product validly placed on the market is unlawful; that a patent does not ensure protection against actions seeking to contest its validity; that such actions and, in particular, the *'at risk'* launch of a generic medicinal product, as well as legal proceedings in that regard, often take place during the stage before or just after the market entry of such a generic medicinal product; that, in order to obtain a marketing authorisation for a generic medicinal product, it is not necessary to demonstrate that that placing on the market does not infringe any patent rights regarding the originator medicinal product; and that, in the pharmaceutical sector, potential competition may occur well before the expiry of a compound patent protecting an originator medicinal product, since the generic manufacturers wish to be ready to enter the market at the point when that patent expires.

85. In addition to that broad context, account must be taken of the factors specific to each individual case, such as, in the present case, the fact, which has already been pointed out, (57) that the patents at issue are not compound patents but process patents protecting certain methods of manufacturing the paroxetine API. Accordingly, those process patents, irrespective of whether or not they are valid, do not prevent generic manufacturers from entering the market with paroxetine manufactured under other processes. (58)

86. Moreover, as the case-law has acknowledged, (59) the patent holder's perception of the competitive pressure from generic manufacturers, similarly to those manufacturers' perception of their possibilities to successfully enter the market and their intentions in that regard, are also relevant factors for the purposes of assessing whether there is potential competition between those operators.

87. Thus, account may be taken of the fact that the patent holder regards a generic manufacturer as a potential competitor, which can be shown, inter alia, by the readiness of the former to make a value transfer in favour of the latter if it is established, in fact, that the (sole) consideration for that value transfer consists in the generic manufacturer refraining from entering the market. (60)

88. Similarly, account may be taken, as did the CAT in its judgment (61) and in its request for a preliminary ruling, of the progress of the generic manufacturers in preparing their entry onto the market in terms, inter alia, of investment, the building up of stocks of the medicinal product at issue or marketing strategies. As the CMA correctly explained, inter alia, at the hearing in these proceedings, it is those factors rather than an intellectual property *'mini-trial'* which may inform the competition authority regarding the perception of the operators involved of the patent's strength or as to whether the generic products concerned infringe it.

(4) The existence of interim injunctions or interim legal undertakings

89. Finally, the existence of interim injunctions or legal undertakings, such as those in the present case, temporarily prohibiting the generic manufacturers from entering the market pending the outcome of legal proceedings regarding the patent's validity or whether the generic product infringed it, (62) cannot cast doubt on the existence of potential competition between the holder of a patent for a medicinal product and a generic manufacturer wishing to enter the market with a generic version of that medicinal product.

90. Thus, it is indeed true that, as the case-law has acknowledged, in order to find that potential competition exists, it is important that the potential entry by an operator from outside the market can occur with sufficient speed to form a constraint on market participants. (63) However, that does not mean that that entry must be capable of taking place immediately; it is sufficient if it can take place within a reasonable period. (64)

91. However, both the interim injunction and the legal undertaking not to enter the market at issue in the main proceedings were to last for only a few months until the outcome of the respective disputes. Therefore, even though GUK and Alpharma were temporarily prevented from entering the market with generic paroxetine while those measures were in force, that does not establish that there was no longer potential competition between those generic manufacturers and GSK.

92. That is even more the case since the existence of such interim measures, even though they were to reflect an initial assessment by the court with jurisdiction in relation to the patent's validity or whether the generic products infringed that patent, does not, at that point, prejudge the final outcome of the ongoing dispute in that regard. As has already been pointed out, (65) the very existence of legal proceedings relating to a patent's validity or whether a generic product infringes that patent forms part, in the pharmaceutical sector, of the preparations for the market entry of such a product and indicates that potential competition exists between the operators involved. Similarly, a *'cross-undertaking in damages'*, such as that provided by GSK to GUK and Alpharma, that is to say GSK's undertaking to compensate those operators if subsequently it is found that the injunctions wrongly prevented them from entering the market, assumes that a competitive relationship exists. Finally, as has already been noted, (66) whether legal proceedings and interim injunctions exist depends on choices made by the operators involved and cannot therefore be equated with the existence of objective, factual or legal barriers which restrict entry

onto a particular market irrespective of the wishes of the economic operators concerned. (67)

93. Last, as the CAT noted, in essence, in its judgment, (68) if it were established that the agreements which were entered into between GSK and the generic manufacturers were restrictive of competition, and therefore subject to confirmation of that very fact, entry into those agreements during the very period in which the interim measures at issue (69) were in force is a strong indication that those measures did not eliminate potential competition between those operators. (70)

(5) Conclusion

94. It follows from the foregoing that uncertainty concerning the validity of a patent for a medicinal product or whether a generic version of that medicinal product infringes that patent does not prevent the patent holder and the generic manufacturer from being regarded as potential competitors. The existence of a bona fide dispute as to whether the patent is valid or whether the generic product infringes the patent, irrespective of whether or not that dispute has already given rise to judicial proceedings and interim injunctions or interim legal undertakings, is, on the contrary, a factor which is capable of demonstrating that potential competition exists between the patent holder and the generic manufacturer. Similarly, the patent holder's perception and the fact that it regards the generic manufacturer as a potential competitor are factors which are capable of demonstrating that potential competition exists between those two operators.

(b) The concept of restriction of competition by object (Questions 3 to 5)

95. The CAT has referred three questions to the Court on the concept of restriction of competition by object. It is appropriate to begin with Questions 3 and 4, which concern the circumstances in which agreements such as those at issue in the present case may constitute restrictions of competition by object. Subsequently, it is appropriate to deal with Question 5, which concerns whether such an agreement may constitute such a restriction, despite the fact that it provides consumers with some limited advantages.

(1) Questions 3 and 4

96. By Questions 3 and 4, which may be dealt with together, the CAT questions the Court regarding the circumstances in which a settlement agreement, entered into in order to put an end to ongoing court proceedings concerning the validity of a patent for a medicinal product and whether a generic version of that medicinal product infringes that patent, is capable of constituting a restriction of competition by object within the meaning of Article 101 TFEU, in a situation where it is not possible to determine which party is likely to succeed in those proceedings.

97. The CAT asks, in particular, whether such an agreement constitutes a restriction of competition by object where the generic company agrees not to enter the market with its 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 where the patent holder undertakes to make a transfer of value to the generic manufacturer in an amount substantially greater than the avoided litigation costs and which does not constitute payment for any goods or services supplied.

98. In addition, the CAT wishes to know whether the answer to that question may differ if the scope of the restriction on the generic manufacturer does not go beyond the scope of the patent in dispute or if the amount of the value transfer to that manufacturer is less than the profit it could have expected to make if it had succeeded in the patent litigation and entered the market independently.

99. In order to answer those questions, it should be noted, first, that Article 101 TFEU prohibits all agreements between undertakings which have as their object or effect the prevention, restriction or distortion of competition within the internal market, and that the anticompetitive object and anticompetitive effect are not cumulative but alternative conditions for assessing whether an agreement is caught by the prohibition set out in that provision. (71)

100. In other words, regardless of their effects, agreements are prohibited if they pursue an anticompetitive purpose. (72) The reason for that is that certain types of coordination, such as horizontal price-fixing by cartels, can be regarded, by their very nature, as being harmful to the proper functioning of normal competition, and therefore as revealing a sufficient degree of harm to competition that it may be held that there is no need to examine their effects. (73)

101. In order to determine whether an agreement has such an anticompetitive object, regard must be had to the content of its provisions, the objectives it seeks to attain and the economic and legal context of which it forms part. When determining that context, it is also 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. In addition, although the parties' intention is not a necessary factor in determining whether an agreement between undertakings is restrictive, there is nothing prohibiting the competition authorities, the national courts or the Courts of the European Union from taking that factor into account. (74)

102. Since the concept of restriction of competition *'by object'* must nevertheless be interpreted restrictively, an agreement must, in order to be regarded as constituting such a restriction, clearly reveal a sufficient degree of harm to competition. (75)

103. Where the analysis of a type of coordination between undertakings does not reveal a sufficient degree of harm to competition, the effects of the coordination must, on the other hand, be considered and, in order to prohibit it, it is necessary to find that factors are present which show that competition has in fact been prevented, restricted or distorted to an appreciable extent. (76)

104. In the present case, the Commission and the CMA take the view that the GUK and Alpharma Agreements constitute, in the same way as those at issue in Beef Industry Development Society and Barry Brothers, (77) market exclusion agreements. Accordingly, under those

agreements, GSK made substantial payments in favour of the generic manufacturers, the sole consideration for which was those manufacturers' undertaking not to enter the market independently with their own generic paroxetine during the agreed period. The agreements concerned, according to the Commission and the CMA, therefore clearly had an anticompetitive object and consequently constituted restrictions of competition by object.

105. GSK and the generic manufacturers maintain, on the contrary, before the CAT and before the Court that the GUK and Alpharma agreements cannot in any way be regarded as clearly revealing, as required by the case-law, (78) a sufficient degree of harm to competition so as to constitute restrictions of competition by object within the meaning of Article 101 TFEU. Rather, those agreements were complex arrangements reflecting a compromise in the specific context of a patent settlement agreement, which did not constitute simple market exclusion agreements.

106. As has already been noted above, (79) according to the CAT, to which it falls, as has also already been stated, to assess the facts of the case in the framework of the present reference for a preliminary ruling, (80) the GUK and Alpharma agreements (81) sought to guarantee GSK, during the agreed periods, protection against the risk of those generic competitors entering the market, in exchange for substantial value transfers which far exceeded the avoided litigation costs. The CAT nevertheless wonders whether, against the relevant patent background in the present case, such characteristics allow those agreements to be categorised as restricting competition by object.

107. Therefore, it is necessary to examine below the arguments put forward by GSK and the generic manufacturers which prompted that question from the referring court, in order to establish whether those arguments are capable of establishing that the agreements at issue in the main proceedings do not reveal sufficiently clearly a sufficient degree of harm to competition to be categorised as restrictions of competition by object.

(i) The *'potential to restrict competition'* of an agreement imposing a restriction which does not go beyond the scope and unexpired period of a patent

108. By an initial set of arguments, GSK and the generic manufacturers maintain that, since the scope and duration of the restrictions imposed by the agreements did not go beyond the scope and unexpired period of the patent at issue, those agreements did not have a greater potential to restrict competition than the legal scope of that patent. Thus, the restrictions imposed by the agreements simply implemented the right of the holder of that patent, that is to say GSK, to prevent infringements of its patent rights, which are presumed to be valid, by deterring infringing products from entering the market. Similarly, GUK and Alpharma undertook, under those agreements, to do no more than respect GSK's patent rights, which were presumed to be valid.

109. However, it is incorrect to take the view that, if the restrictions imposed do not go beyond the scope and unexpired period of a patent, (82) the conclusion of an agreement by which the holder of that patent pays a competitor not to enter the market is equivalent to the implementation of the patent holder's right to oppose any infringement, and to an undertaking by its competitors to respect its patent rights, which are presumed to be valid. (83)

110. First, contrary to Alpharma's assertions, in particular, it is not apparent from the case-law on which it relies that the Court has generally rejected the idea that agreements in the field of intellectual property may restrict competition. (84)

111. On the contrary, it is apparent from the case-law that, although 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 TFEU, the exercise of that right might, however, fall within the ambit of the prohibitions contained in that provision if it manifests itself as the subject, the means or the result of an agreement. (85) In other words, as the General Court summarised in Servier and Others v Commission, it is a question of penalising not the lawful exercise of intellectual property rights but the abuse of those rights. (86)

112. That is, furthermore, in accordance with the objectives of international and EU intellectual property law, which seeks to reconcile the protection of intellectual property rights, on the one hand, and the preservation of legitimate trade against any unjustified obstacle, on the other. (87) Accordingly, Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (88) states inter alia that it should not affect the application of the rules of competition, and that the measures for which it provides should not be used to restrict unduly competition in a manner contrary to the Treaty. (89)

113. In that regard, although, according to the case-law already cited above, (90) the object of a patent is to enable the patent holder to oppose any infringement, that object cannot, however, be interpreted as also affording protection against actions seeking to challenge the validity of the patent. The contrary would be inconsistent with the public interest in the elimination of all obstacles to economic activity which could arise if the patent were granted erroneously. Similarly, as the General Court has correctly acknowledged, the presumption of validity of a patent cannot be equated with a presumption of illegality of generic products validly placed on the market which the patent holder considers to be infringing that patent. (91)

114. Yet 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 return for payment of a substantial sum, the sole consideration for which is that undertaking, amounts precisely to ensuring protection for the patent holder against actions seeking to contest the validity of its patent and to establish a presumption that the products which may be put on the market by his 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 since, as has been stated in the case-law, it is for public authorities and not private undertakings to ensure compliance with statutory requirements. (92)

115. Similarly, it cannot be claimed that, from the point of view of the generic manufacturers, entering into such an agreement is equivalent solely to them acknowledging the patent rights, which are presumed to be valid, of the patent holder. If the patent holder makes, in their favour, a significant value transfer 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 value transfer which has induced them to refrain from entering the market and challenging the patent. That is also confirmed by the facts in the main proceedings, pointed out by the CAT, which demonstrate that the agreements at issue were the outcome of negotiations during which GSK gradually increased the amount of its offers until reaching a sufficient level to persuade the generic manufacturers to sign. (93)

116. Therefore, it is incorrect to maintain that the potential of the GUK and Alpharma Agreements to restrict competition was not more significant than the legal scope of the patent at issue. Indeed, the potential to restrict competition arising from the legal scope of that patent was limited to the possibility of opposing any challenge to its validity and any alleged infringement by the legal means available under patent law, which is the normal process of competition in sectors in which there are exclusivity rights over technologies. (94) By contrast, the potential to restrict competition of an agreement under which a patent holder *'buys'* an undertaking from a competitor to refrain from entering the market and from challenging the patent amounts to the elimination of any risk of challenge which thereby eliminates competition in relation to its patented product.

117. Thus, in the area of implementation of pharmaceutical patents as elsewhere, the concept inherent in the TFEU provisions on competition requires that each economic operator determines independently the policy which it intends to adopt on the market (95) and prohibits those operators from knowingly substituting practical cooperation between them for the risks of competition. (96) Yet entering into an agreement under which a patent holder pays a generic manufacturer to refrain from entering the market and from challenging the patent means precisely that those operators no longer determine independently their conduct in relation to the implications of that patent, but, on the contrary, agree on a concerted position in that regard.

118. Similarly, entering into such an agreement amounts, for the parties involved, to substituting, knowingly, practical cooperation between them for the risks of competition. In the present case, by continuing the dispute concerning the validity of the patent or the question of whether the generic products infringed it, GSK continued to have both the opportunity to keep all its profits arising from the absence of paroxetine generics and the risks of losing those profits following market entry of such generics. Similarly, the generic manufacturers continued to have both the opportunity to make significant profits by entering the market independently and the risk of not making any gains at all if the patent at issue were found to be valid and their products to have infringed it.

119. If, in such a situation, competitors enter into agreements such as those at issue in the main proceedings, that means that they take the view that it is more advantageous to them to replace those opportunities for gains and risks of losses with the certainty of an assured return consisting of a share of the profit made by the patent holder as a result of the generic manufacturers' concerted action of refraining from market entry. (97) That such sharing of the patent holder's profits may continue to be advantageous for all the parties is explained, inter alia, by the significant difference in the prices of medicinal products before and after generic products enter the market. (98) That also explains why it may be advantageous for the holder of a patent for an originator medicinal product to defer the entry of generic versions of that medicinal product even if only for a few months.

120. In those circumstances, the fact that the amount transferred by the patent holder to the generic manufacturer is less than the profit which the generic manufacturer was likely to make in the event of independent entry onto the market, does not mean that an agreement under which the sole consideration for payment of that sum is an undertaking to refrain from entering the market does not constitute a restriction of competition by object. Indeed, if the amount remains, however, sufficient to be an incentive, (99) it may continue to be advantageous for the generic manufacturer to enter into an agreement even if it is paid less than the profit it could have expected if it entered the market independently. The reason for that is that, in so doing, it replaces the risks and hazards inevitably linked to such market entry, as well as the need to make the necessary economic and commercial efforts for that purpose, with the certainty of obtaining, without further effort, a significant part of the patent holder's monopoly revenues.

(ii) The relevant *'counterfactual scenario'*

121. It follows from the foregoing that nor can the second set of arguments raised by GSK and the generic manufacturers establish that agreements such as those at issue in the present case do not have potential for sufficient harm to constitute restrictions of competition by object.

122. By that second set of arguments, GSK and the generic manufacturers maintain that, since, in the present case, as the CAT itself acknowledges, the status of the patent was wholly uncertain and the outcome of the dispute in that regard impossible to predict, it is also impossible to conclude that the agreements were capable of restricting competition. Indeed, it is impossible to

determine whether the counterfactual scenario, which would have taken place in the absence of the agreements, would have been more *'competitive'* than the situation created by those agreements, because it is impossible to know whether that scenario would have resulted in a legal victory for the generic manufacturers and their independent entry onto the market. Similarly, according to that line of argument, it is wrong to consider a scenario in which the generic manufacturers entered the market in infringement of GSK's patent rights as being more competitive than the scenario established by the agreements, since the specific aim of the patent system is precisely to protect competition on the merits and to protect innovation.

123. Thus, in particular, Merck maintains that, since the assessment of the agreements indicates doubts as to whether they had any effect on competition, those doubts must be resolved by a comprehensive analysis of the effects of those agreements.

124. It is, however, incorrect to claim that, since the status of the patent and the question of whether the generic products infringed it are, in the case in the main proceedings, uncertain, it is impossible to determine whether the agreements at issue were capable of restricting competition.

125. Indeed, in order to determine whether that was the case, it is not necessary to seek to ascertain whether, in the absence of the agreements, the generic manufacturers would certainly or very probably have entered the market following success in the patent proceedings. As the General Court summarised, in essence, in Lundbeck v Commission, (100) to apply such a criterion would be to confuse actual and potential competition and to ignore the fact that Article 101 TFEU also precisely protects the latter.

126. In order to ascertain whether the agreements at issue were capable of restricting competition, it is therefore necessary, rather, to examine whether, by means of those agreements, the parties substituted practical cooperation between them for the risks of normal competition, in which each party determines independently its conduct on the market. If that is the case, the situation created by the agreements is characterised by the fact that it is not the result of such normal competition, but the result of a concerted practice by which the parties eliminated the risks of competition.

127. It follows that, without prejudice to the question of whether a competition authority must establish a *'counterfactual scenario'* in order to determine whether an agreement has an anticompetitive object, the situation with which it is necessary to compare the situation put in place by the agreements is not, in any event, the scenario of one or the other of the parties being successful in the patent proceedings or the generics entering the market or refraining from entering it. On the contrary, the scenario with which the situation created by the agreements is to be compared is quite simply a situation in which the parties continued to manage their patent litigation independently and on the basis of their own assessment of the risks and opportunities in entering or refraining from entering the market. What is important is not to depict the situation concerning the patent which would have occurred in the absence of the agreements, but rather the situation concerning competition.

128. That is, moreover, consistent with the fact that, as the parties correctly state, a situation in which GSK was successful at the end of the disputes and thus prevented the generic manufacturers from entering the market independently would not have been less favourable in terms of competition than a situation in which the generics entered independently, following their being successful. What is crucial is indeed not whether the generics enter or refrain from entering the market independently, but whether that refraining is a result of normal competition or an anticompetitive concerted practice.

129. Such a conclusion is, furthermore, in accordance with the principles, already set out above, of patent law and its interaction with competition law. First, patent law does not guarantee protection against challenges to patents; uncertainty as to the status of patents and actions seeking to challenge them are therefore part of normal competition in the sectors concerned. (101) Second, it is not for the competition authorities to evaluate the strength of patents and to make predictions concerning the outcome of disputes in that matter, but nor is that necessary to assess patent agreements under competition law. (102)

(iii) The nature of the agreements as settlements of actual litigation

130. Finally, the third set of arguments put forward by the applicants in the main proceedings also fails to establish that agreements under which a generic manufacturer undertakes not to enter the market and to abandon its challenge to a patent in return for a substantial payment from the patent holder, the sole consideration for which is that undertaking, cannot constitute restrictions of competition by object.

131. That third set of arguments consists of a claim that, as agreements to settle ongoing court proceedings, the GUK and Alpharma Agreements pursued a legitimate objective which is from the outset incompatible with the categorisation of an agreement as restricting competition by its object, since such settlement agreements have a public interest and are encouraged by the public authorities. According to that argument, it is therefore possible to categorise such a settlement agreement as a restriction of competition by object, at most, in cases in which the patent is clearly invalid or fraudulent, and in which the proven intention of the parties consists in bringing an end, anticompetitively, to a purely fictitious dispute over such a patent.

132. In contrast, according to the applicants in the main proceedings, in an actual dispute concerning a legal patent, the outcome of which is impossible to predict, payments concurred upon in the agreements represent merely a compromise between the parties in view of the risk of losses likely to be suffered by GSK in the event of unlawful market entry by the generic producers on the one hand and the losses likely to be suffered by the latter

if they refrain from entering the market for no good reason on the other. To categorise such an agreement as a restriction of competition by object would deprive pharmaceutical operators of any possibility of settling a patent dispute and leave them no choice, when faced with such a dispute, other than to concede or to pursue the legal proceedings already commenced to their conclusion.

133. Yet, first, as the Court has already stated, Article 101 TFEU draws no distinction between agreements whose purpose is to put an end to a dispute and those entered into with other aims in mind, so that a court settlement may be invalid for breach of EU competition law. (103) The objective of encouraging settlement agreements cannot indeed shield such agreements from the application of competition law, the rules of which are part of public policy. (104)

134. Furthermore, as the Commission correctly points out, even in the case of an actual dispute with an uncertain outcome concerning a lawful patent, in order to assess whether an agreement to settle such a dispute has an anticompetitive object, it must be ascertained whether that agreement has actually resolved the dispute in question and whether those terms reflect a compromise between the parties in that regard. In other words, the question is whether the agreement is a genuine compromise reached on the basis of an independent assessment by the parties of their situation regarding the patent, or whether the agreement consists, rather, in putting an end to the dispute by means of a payment made by one of the parties to the other, so that the latter no longer challenges the patent and no longer competes.

135. Yet contrary to the parties' claims in the present case, it is apparent from the CAT's factual findings that the agreements at issue in the main proceedings do not seem to have settled the parties' patent disputes, but only to have deferred resolution of the disagreement in that regard until after expiry of the agreements. Rather than having been settled, the disputes between the parties therefore seem only to have been put on hold during the term of those agreements.

136. According to the CAT's findings, (105) the GUK and Alpharma Agreements provided only for an undertaking by those generic manufacturers to withdraw their challenge to GSK's patent and to refrain from entering the market with their products during the agreed period. On the other hand, no provision was made that, after that period, those manufacturers could enter the market without facing further opposition from GSK.

137. Likewise, it is not apparent that the undertaking to withdraw the challenge to GSK's patent and not to enter the market on the one hand, and the amount of the payments on the other hand, were linked in any way whatsoever to the risks of losses which could be suffered either by GSK if the generics entered the market unlawfully, or by the generic manufacturers if they refrained from entering the market and that was subsequently found to be for no good reason, owing to the invalidity of the patent or to the fact that the generic products did not infringe it.

138. Yet it cannot be claimed, on the pretext that it is concluded as an agreement to settle an actual patent dispute, that an agreement may avoid being categorised as a restriction of competition by object if its purpose is not, in reality, to settle the ongoing patent dispute, but only to defer that dispute in time by means of a payment inducing the patent holder's competitor not to compete during the term of the agreement.

139. It follows that nor can the applicants in the main proceedings argue that prohibiting that type of agreement deprives the parties to the patent proceedings of any possibility of reaching a settlement. Such settlements continue to be possible if they are genuinely intended to settle the disputes at issue and reflect a compromise between the parties reached following an independent assessment of the competitive situation by them. That is confirmed, furthermore, by an empirical study from the US cited by the CAT, (106) which revealed that after proceedings were brought by the competition authorities against agreements such as those at issue in the present case, the number of agreements of that type dramatically declined, although the overall number of patent settlements did not decline.

140. Finally, it follows from all the foregoing that nor can Alpharma's argument succeed, according to which the restrictions imposed by the agreements at issue should be regarded as restrictions which are ancillary to the settlement of patent disputes. Thus, it is true that it is apparent from the case-law that the prohibition laid down by Article 101 TFEU does not apply to a restriction of competition necessary for the implementation of an operation which is not itself caught by that prohibition. (107) However, in the present case, it does not appear that there is a legitimate operation for the implementation of which the agreed restrictions were necessary, since those restrictions were precisely themselves the subject matter of the agreements at issue.

(iv) Conclusion

141. It follows from the foregoing that an agreement to settle court proceedings, the outcome of which is uncertain, relating to an actual dispute concerning the validity of a patent or the question of whether a generic product infringes that patent, under which the patent holder gives an undertaking in favour of a generic manufacturer to make a value transfer in a sufficient amount to induce that manufacturer to abandon its efforts to enter the market independently, constitutes a restriction of competition by object if it is found that the sole consideration for that value transfer is that the generic manufacturer refrains from entering the market with its product and from continuing to challenge the patent during the agreed period, which it is for the referring court to review. That also applies where the restrictions imposed by such an agreement do not go beyond the scope and unexpired period of the patent and where the amount transferred to the generic manufacturer is lower than the profit it could have expected if it had entered the market independently.

(2) Question 5

142. The fifth question referred for a preliminary ruling by the CAT concerns the assessment, in the light of

Article 101 TFEU, of the benefits afforded to consumers by the GUK and Alpharma Agreements.
143. In the present case, according to the CAT, those agreements have brought certain benefits to consumers owing to the fact that they provided for the supply by GSK of significant but limited volumes of authorised generic paroxetine to the generic manufacturers, which those manufacturers distributed at a lower price than that charged by GSK for Seroxat, which led to a slight reduction in the average price of paroxetine. (108)
144. Moreover, according to the CAT, the replacement of parallel imports of paroxetine by the authorised generic paroxetine of IVAX, GUK and Alpharma (109) afforded some limited benefits to consumers in terms of quality, since the parallel imports had been subject to foreign language over-stickering, which patients found unattractive. (110) On the other hand, as the CAT stated, the reclassification of paroxetine in the NHS Drug Tariff and the corresponding reduction in the costs incurred by the latter were due solely to the IVAX Agreement. (111)
145. Against that background, the CAT is asking the Court, by the fifth question referred by it for a preliminary ruling, whether there is a restriction of competition by object
– where an agreement having the characteristics described in Questions 3 and 4 also provides that the patent holder shall supply the generic manufacturer, in order that the latter may market them, of significant but limited volumes of an authorised generic product;
– and where that does not give rise to any meaningful competitive constraint on the prices charged by the patent holder but brings some benefits to consumers which would not have occurred if the generic manufacturers had not entered the market at all;
– and where those benefits were, however, significantly less than those likely to result from the independent entry of those manufacturers onto the market.
146. In addition, the CAT wishes to know whether that point is relevant for answering the question of whether an agreement constitutes a restriction of competition by object within the meaning of Article 101(1) TFEU, or whether, on the contrary, it can only be assessed under Article 101(3) TFEU.
147. With regard to that last point, it should be noted that it is true that, where it is established that an agreement is caught by the prohibition laid down in Article 101(1) TFEU, because it constitutes a restriction of competition within the meaning of that provision, any benefits of that agreement can be assessed solely under Article 101(3) TFEU. (112)
148. As the case-law has recognised, if it were otherwise, Article 101(3) TFEU would lose much of its effectiveness. Therefore, EU law does not recognise a *'rule of reason'* which involves weighing the pro- and anticompetitive aspects of an agreement for the purpose of applying Article 101(1) TFEU. (113)
149. However, when examining the issue of whether an agreement constitutes a restriction of competition prohibited by Article 101(1) TFEU, the assessment of benefits allegedly resulting from that agreement may be relevant, in particular, in two respects: first the existence of such benefits may, in exceptional circumstances, call into question the very finding that there is a restriction of competition prohibited by Article 101(1) TFEU. Second, the existence of such benefits may, in certain circumstances, call into question the finding that there is a restriction of competition by object, making it necessary to examine the effects of the agreement in question.
(i) The relevance of benefits resulting from an agreement to a finding that there is a restriction of competition under Article 101(1) TFEU
150. First, it follows from the case-law that the aspects of coordination between undertakings that are positive for competition can be taken into account when examining the applicability of Article 101(1) TFEU if those aspects are such as to call into question the very finding that there is a restriction of competition prohibited by that provision.
151. Accordingly, the Court has held, for example, that selective distribution systems, although they necessarily affect competition in the common market, may, in certain circumstances, not infringe Article 101(1) TFEU, since they pursue a legitimate aim. (114)
152. Similarly, the Court has accepted that it is possible for coordination which is liable to restrict competition in the internal market because it restricts the parties' freedom of action not to be caught by the prohibition laid down in Article 101(1) TFEU if, in the light of its overall context and its objectives, the restrictive effects on competition which arise from it are inherent to the pursuit of those objectives. In order for that to be the case, it is nevertheless necessary that the restrictions imposed by the coordination at issue are strictly limited to what is necessary to ensure the implementation of legitimate objectives. (115)
153. The Court has recognised, for example, that those conditions could be met in the case of a prohibition imposed on the members of a purchasing association in the agricultural sector from belonging to competing cooperatives, (116) in the case of the prohibition of multi-disciplinary partnerships between members of the Bar and accountants (117) or in the case of rules concerning doping control in sport. (118) Therefore, this applies in cases where cooperation between undertakings constitutes an indivisible whole (119) pursuing one or more legitimate objectives, which can be attained only by imposing certain restrictions of competition which are indispensable to their realisation.
154. On the basis of the findings of fact made by the referring court, it seems doubtful, however, that the conditions for the application of that case-law are satisfied in the circumstances at issue in the main proceedings.
155. Thus, in the main proceedings, it is not even alleged that the benefits to consumers afforded by the GUK and Alpharma Agreements, namely the fall in the average price of paroxetine and the improvement in the labelling of medicine packs, (120) constituted the main objective of the respective agreements. Similarly, no-one has claimed that the restrictions imposed on GUK and Alpharma by those agreements, namely the prohibition

on manufacturing, importing or supplying paroxetine not supplied by GSK through IVAX, (121) were indispensable to the realisation of those benefits.

156. Rather, the applicants in the main proceedings do no more than state that, owing to those benefits, the GUK and Alpharma Agreements were ambivalent with regard to competition, so that it is impossible to conclude that those agreements clearly revealed a sufficient degree of harm to competition to be regarded as restrictions of competition by object.

(ii) The relevance of benefits resulting from an agreement to a finding of a restriction of competition by object under Article 101(1) TFEU

157. In that last regard, the other part of the fifth question referred by the CAT relates specifically to the matter of whether an agreement which, like the GUK and Alpharma Agreements, leads to certain benefits for consumers, may constitute a restriction of competition by object within the meaning of Article 101(1) TFEU.

158. As is apparent from the case-law cited above concerning the manner of determining whether an agreement has an anticompetitive object, the examination to be conducted for that purpose necessarily involves an analysis of contextual elements of the agreement in question. (122) Indeed, as has repeatedly been stated, the object of an agreement must be assessed not in the abstract but in the circumstances of the individual case, having regard to all relevant factors. (123) However, any alleged positive benefits or effects of an agreement are undeniably contextual elements which must be assessed when examining whether the object of that agreement is the restriction of competition.

159. The consequence of categorising an agreement as restricting competition by its object is, from a procedural point of view, to exempt the competition authority concerned from conducting a full examination of its effects, which demands more resources. (124) The reason for that exemption lies in the fact that experience has shown that an agreement seeking by its object to restrict competition, for example, by price-fixing or market sharing between competitors, is likely to have negative effects on competition, so that it is not necessary to examine whether and to what extent such an effect actually occurs. (125)

160. Therefore, as Advocate General Bobek has recently noted, the examination of the context of an agreement also serves to confirm that the harmfulness of an agreement which, in the light of its content and objectives, is capable of constituting a restriction of competition by object, is not called into question by the relevant contextual factors. In other words, it is necessary, *'in the light of the [information] present in the case file, [to] check that there are no specific circumstances that may cast doubt on the presumed harmful nature of the agreement in question'*. (126)

161. Yet when does a situation become one in which doubts arise as to the presumed harmfulness and, therefore, the anticompetitive object of a particular agreement?

162. As the Court has stated, in order to have an anticompetitive object, coordination between undertakings must be capable of having a negative effect on competition, which means that it must be capable, having regard to the specific legal and economic context, of resulting in the prevention, restriction or distortion of competition within the common market. By contrast, the question of whether and to what extent such effects actually result is not decisive. (127) That means that the prohibition on *'infringement by object'* may on no account be interpreted as meaning that an anticompetitive object gives rise merely to some kind of presumption of unlawfulness which may be rebutted if, in the specific case, no negative consequences for the operation of the market can be demonstrated. (128)

163. Therefore, as also stated in the case-law, in order to find that an agreement has, in itself, a sufficient degree of harm to competition for it to be unnecessary to examine its effects in order to determine whether it is capable of restricting competition, the agreement and its context must reasonably clearly reveal the potential to harm competition. (129)

164. It follows that, in order to conclude that an agreement has an anticompetitive object, it must be possible to determine that it is capable of restricting competition without having to examine its effects. Therefore, an analysis of the anticompetitive object of an agreement must switch to an analysis of the anticompetitive effects of that agreement where it is established that it is impossible to determine, despite an analysis of all the relevant inherent contextual factors, that that agreement is capable of restricting competition. (130)

165. From this it is clear that an agreement which results in certain benefits for consumers can no longer be categorised as restrictive of competition by its object if the existence of those benefits means that it is no longer possible, without analysing its effects, to know whether it is, as a whole, capable of restricting competition. In other words, the question is whether, taking into account the benefits afforded by the agreement, it continues to be possible to conclude that it nevertheless has an anticompetitive object. If that is not the case because those benefits give rise to doubts as to the anticompetitive object of the agreement or because it is unclear whether an agreement providing such benefits may have an anticompetitive object, it is then no longer possible to conclude that there is a restriction of competition by object and it is necessary to move on to an analysis of the effects.

166. By contrast, and contrary to the assertions of Merck, in particular, in these proceedings, there is no automatic switch to the obligation to carry out an analysis of the effects of an agreement once it is established that that agreement has afforded certain benefits or positive effects which must be taken into account for the purposes of examining whether the agreement constitutes a restriction of competition by object. It is not the fact of assessing certain positive effects secondary to an agreement which causes the analysis of the object of an agreement to switch to the analysis of its effects, but solely the fact that, to the

extent that this applies in the case at hand its effects raise doubts as to the anticompetitive object of the agreement.
167. In the present case, it is apparent from the matters set out above that, subject to the referring court reviewing that the sole consideration for the value transfer made by GSK to GUK and Alpharma was those operators refraining from entering the market with their products and from continuing to challenge the patent during the agreed period, the object of the GUK and Alpharma Agreements was to eliminate the risk of an independent entry of generics onto the market. (131)
168. If that is the case, the benefits provided by the agreements at issue to consumers, namely the 4% reduction in the average price of paroxetine and the improvement in the labelling of medicine packs, (132) are not such as to call into question the fact that those agreements constituted restrictions of competition by reason of their object. Those positive effects, when set against the legal and economic background to those agreements, do not give rise to doubt as to whether those agreements clearly revealed a sufficient degree of harm to competition to be regarded as restrictions of competition by object.
169. Thus, it is true that the CAT states that the slight reduction in the price of paroxetine caused by the agreements was not wholly immaterial. However, according to the findings of the CAT, the supply of paroxetine by GSK to the generic manufacturers provided for by the agreements did not give rise to any meaningful competitive pressure on GSK since, owing to the limited volumes supplied, the capping of which was not due to any technical reason, the generic manufacturers had no interest in competing on price.
170. In those circumstances, the CAT was correct to conclude that the change in market structure caused by the agreements was not due to the introduction of competition but to a controlled reorganisation of the paroxetine market engineered by GSK, and that the supply of paroxetine and the transfer of market share by GSK to the generic manufacturers are to be regarded as value transfers of a non-monetary nature. (133)
171. The analysis of the terms of the agreements at issue, as conducted by the CAT, does not therefore reveal a complex arrangement with pro- and anticompetitive components, from which it would be impossible to determine whether, overall, it has an anticompetitive object. (134) Rather, it appears that the object of the agreements was clearly to eliminate, by means of a value transfer, the risk of the generic manufacturers concerned entering the market independently, and that the implementation of their controlled entry with authorised paroxetine supplied by GSK was part of the incentives offered to them for that purpose.
172. In that regard, the implementation of that controlled entry by means of the supply of paroxetine at preferential prices and with the possibility of earning a profit margin, which was guaranteed by the terms of the agreements, (135) appears to be not only a means of masking the value transferred but also as giving added value to the generic manufacturers by comparison with a simple monetary transfer. That added value consisted of the possibility of distributing the authorised paroxetine supplied by GSK under their own brand and thus to build up a customer base and distribution networks. It may also correspond to a concession which GSK was required to make, but which also provided it with benefits in terms of maintaining its own production. (136)
173. However, even if the parties had deliberately intended to provide certain benefits to consumers by implementing the controlled entry of GUK and Alpharma onto the market, that would not raise doubts as to the harmfulness of the agreements at issue in terms of competition.
174. Indeed, as stated in the case-law, Article 101 TFEU, like the other competition rules laid down in the Treaty, is designed to protect not uniquely the immediate interests of individual competitors or consumers, but also to protect the structure of the market and thereby competition as such. In order to find that coordination between undertakings has an anticompetitive object, there does not therefore need to be a direct link between that practice and consumer prices. (137)
175. That must mean, conversely, that providing consumers with certain minimal benefits by means of a slight reduction in prices cannot call into question the anticompetitive object of an agreement which is, otherwise, designed to eliminate competition in relation to a particular product or on a particular market. However, in the present case, it has been observed that that was precisely the objective of the agreements at issue since their purpose was to induce the generic manufacturers to abandon their efforts to enter the market independently. (138)
176. In that context, it has also been observed that the *'competitive'* scenario with which it is necessary to compare the concerted situation implemented by the agreements is not that of certain independent market entry by the generic manufacturers, but that of a continuance of their efforts to that end on the basis of their independent assessment of the corresponding risks and opportunities. (139)
177. Therefore, it is necessary to reject the arguments of GSK and the generic manufacturers that the agreements were beneficial because they enabled a controlled market entry of the generic manufacturers while it was uncertain, owing to the impossibility of predicting the outcome of the ongoing patent disputes, that those manufacturers could have entered the market independently in the absence of the agreements. The same applies to the argument that, at least as regards the period during which the interim injunction and the legal undertaking preventing GUK and Alpharma from entering the market were in force, (140) the agreements enabled those manufacturers to enter the market, which they certainly would not have been able to do without the agreements.
178. Indeed, as has been stated, (141) what matters is not the entry of the generics onto the market at any price, but the fact that that entry takes place or does not take place through free competition and not due to a concerted action by the parties in place of free competition.

179. Moreover, as the CAT points out, although the benefits to consumers resulting from the agreements were certain and not potential, they were, nevertheless, paltry compared to the benefits afforded by the subsequent independent entry of generics to the paroxetine market. (142) However, the agreements precisely eliminated the possibility that such entry would take place during the agreed period.

(iii) Conclusion

180. It follows from the foregoing that the assessment of the benefits afforded to consumers by an agreement between competitors is relevant for the purposes of Article 101(1) TFEU in order to examine whether the existence of those benefits is likely to give rise to doubts as to the existence of a restriction of competition in general and a restriction of competition by object in particular. The fact that an agreement to settle a dispute between the patent holder and a generic manufacturer provides for the controlled entry by that manufacturer to the market, which does not give rise to any meaningful competitive constraint on the patent holder but provides consumers with limited benefits which they would not have had if the patent holder had been successful in the proceedings, is not, however, such as to create such a doubt, if the agreement at issue has otherwise as its object to induce the generic manufacturer to abandon its efforts to enter the market independently by means of a value transfer the sole consideration for which is that abandonment, which it is for the referring court to review.

(c) The concept of restriction of competition by effect (Question 6)

181. The sixth question referred for a preliminary ruling by the CAT relates to the anticompetitive effects of the GUK and Alpharma Agreements.

182. Before answering this question, it is necessary to make the preliminary point that, as has already been noted above, the anticompetitive object and anticompetitive effect are not cumulative but alternative conditions for the application of the prohibition laid down in Article 101(1) TFEU. In other words, an agreement is prohibited, irrespective of its effects, if its object is anticompetitive. Therefore, no account need be taken of the effects of an agreement if it is established that the object of that agreement is to prevent, restrict or distort competition within the common market. (143)

183. Accordingly, in the present case, the CAT could, at the very least under EU law, not address the question of the anticompetitive effects of the GUK and Alpharma Agreements if it found, on the basis of the answers which will be given by the Court to its Questions 3 to 5, that those agreements constituted restrictions of competition by object. Since the CAT will still have to conduct that examination following the Court's judgment in the present proceedings, its question relating to the anticompetitive effects of the GUK and Alpharma Agreements however remains relevant.

184. Moreover and in any event, as Advocate General Bobek recently explained in his Opinion in Budapest Bank and Others, the fact that a competition authority or a competent court does not have to examine the effects of an agreement if it has been found that that agreement has an anticompetitive object, does not mean that that authority or court cannot at the same time examine whether an agreement has both an anticompetitive object and anticompetitive effects. Similarly, it may also examine only whether an agreement has anticompetitive effects, if it deems that to be necessary and appropriate in the circumstances of the case. However, as Advocate General Bobek also noted, it is for that authority or court to gather the necessary evidence and make the legal categorisation of that evidence for each type of infringement concerned. (144)

185. That said, by its sixth question, the CAT asks the Court whether, in circumstances such as those set out in Questions 3 to 5, there is a restriction of competition by effect within the meaning of Article 101(1) TFEU. More specifically, it wishes to know whether, in order to establish that there is such a restriction, it must determine that, in the absence of the agreement at issue, the generic manufacturer would probably (that is to say with more than 50% probability) have been successful in the legal proceedings relating to the patent or the parties would probably (that is to say with a more than 50% probability) have concluded a less restrictive settlement agreement.

186. In order to answer that question, it is necessary, first, to consider whether the criteria thus envisaged by the referring court are relevant for assessing the restrictive effects of the agreements concerned in the present case. It is then necessary to examine what is meant, in the present case, by the requirement that, for an agreement to be caught by the prohibition by reason of its effects, those effects on competition must be appreciable.

(1) Criteria for assessing the effects on competition of agreements to settle pharmaceutical patent disputes

187. According to the case-law, where the analysis of the content of an agreement does not reveal a sufficient degree of harm to competition to conclude that there is a restriction of competition by object, the effects of the agreement should then be considered and, for it to be caught by the prohibition, it is necessary to find that factors are present which show that competition has in fact been prevented, restricted or distorted to an appreciable extent. (145)

188. In order to determine whether an agreement is to be considered to be prohibited by reason of the distortion of competition which is its effect, the competition in question should be assessed within the actual context in which it would occur in the absence of the agreement in dispute. (146) Moreover, when appraising the effects of an agreement it is necessary to take into consideration the actual context in which it is situated, 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 structure of the market or markets in question. (147)

189. In accordance with that case-law, it is true that it is necessary, in the present case, in order to examine whether the GUK and Alpharma Agreements constituted restrictions of competition by effect, to take

into account the background to those agreements in terms of patent law, since that is part of the actual context in which they were situated.
190. However, that does not mean that, in order to examine competition as it would have taken place in the absence of those agreements, it is necessary to assess the respective likelihood of the parties being successful in the patent proceedings ongoing between them or of entering into a settlement agreement which would have been less restrictive in terms of competition.
191. Thus, it is indeed true that, according to the Court, the scenario envisaged on the basis of the hypothesis that the agreement in question did not exist must be realistic and, from that perspective, it is permissible, where appropriate, to take account of the likely developments that would occur on the market in the absence of that agreement. (148)
192. However, that element of likelihood does not mean, in a context such as that at issue in the main proceedings, that the competition authority concerned must assess the likelihood that the patent will be found to be invalid or that the generic product will be found to have infringed it in order to examine the anticompetitive effects of the agreements at issue.
193. As has been shown above, it is not for the competition authorities to determine whether the placing of a generic medicinal product on the market is in accordance with patent law. (149) Therefore, such an authority also cannot be required to make predictions regarding the likely outcome of patent litigation.
194. However, as has also been stated above, nor are such predictions concerning the likely outcome of ongoing patent proceedings necessary to enable the competition authorities to assess the impact of agreements such as those at issue in the main proceedings in terms of competition. (150)
195. As has been noted, the likelihood of a generic manufacturer being successful in a dispute with a medicinal product patent holder is not the decisive criterion for examining the competitive relationship between those operators. (151) On the contrary, as has been shown, in the context of patent law regarding pharmaceutical matters, uncertainty as to the validity of patents for originator medicinal products and whether generic products infringe them is precisely a component of competitive relationships, at least before and, where appropriate, just after market entry of generic products. (152) Disputes in that regard are therefore the expression of the existence of potential competition between patent holders and generic manufacturers. (153)
196. Therefore, in order to examine whether the holder of the patent for a medicinal product and the generic manufacturer of that same medicinal product, between whom there is an ongoing dispute, are in potential competition, the competition authority does not have to show that the generic manufacturer would certainly or very probably have been successful in those proceedings and would have entered the market with its medicinal product. (154) On the contrary, it is sufficient for that authority to establish that, despite the patent rights at issue, the generic manufacturer had real concrete possibilities to enter the market at the relevant time, on the basis of the factors set out above. (155)
197. If that is the case, the authority concerned must then, in order to demonstrate that an agreement such as those at issue has had restrictive effects on competition, examine whether that agreement has had the effect of eliminating competition between those two operators and, consequently, the real concrete possibilities for the generic manufacturer to enter the market. If that is the case, it is then possible for the authority to find that the agreement has had restrictive effects on competition, since it will have eliminated a potential competitor and, in so doing, the possibility that the latter might become an actual competitor by entering the market.
198. As the Court has stated, the assessment of the effects of an agreement is not limited to actual effects alone, but must also take account of potential effects. (156) Moreover, that is only logical since, as has already been pointed out, Article 101 TFEU protects not only actual competition, but also potential competition without which the entry of new entrants to the market could never take place. (157)
199. In the present case, it is apparent from the arguments already presented that, subject to review by the referring court that the sole consideration for the value transfer made by GSK to GUK and Alpharma was those operators refraining from entering the market with their products and from continuing to challenge the patent, the GUK and Alpharma Agreements induced those generic manufacturers to cease their efforts to enter the market with their products and to cease to continue their challenge to the patent during the agreed period. (158) It follows that those agreements had the effect of eliminating, for that period, competition between GSK and those operators.
200. As has also already been stated, in those circumstances, the counterfactual scenario to be envisaged on the basis of the hypothesis that the agreement at issue did not exist is not a situation in which GUK and Alpharma would certainly or very probably have entered the market with their products, but a situation in which, on the basis of an independent assessment of the chances of success, they would have continued their efforts to that end. Similarly, it is not necessary to envisage a situation in which a less restrictive agreement would certainly or very probably have been entered into, but it is sufficient to envisage a situation in which an agreement would have been entered into not on the basis of cooperation between the parties which replaces competition, but on the basis of the parties' independent assessments of their chances of success in the dispute between them. As has been stated, the situation which would arise in the absence of the agreements at issue must not be examined in terms of patent law, but in terms of competition law. (159)
201. Moreover, to require a competition authority to predict the likelihood of one or the other of the parties to an agreement being successful in a patent dispute would effectively be to fail to take account of the actual context of that agreement. It does not correspond to the reality of patent law in the pharmaceutical sector that a

competition authority could predict with certainty or a high degree of probability the outcome of disputes relating to the validity of patents and whether generic products infringed them. (160)

202. It follows that, subject to confirmation of the facts to be carried out by the referring court, by eliminating competition between GSK and GUK and Alpharma respectively, the agreements concluded by GSK with those operators had restrictive effects on competition.

(2) The requirement of appreciable effects on competition

203. According to the case-law cited above, in order for an agreement to be caught by the prohibition by reason of its effects, it is necessary to examine whether, as a result of that agreement, competition has in fact been prevented, restricted or distorted to an appreciable extent. (161) That requirement is explained by the fact that agreements fall outside the prohibition of Article 101(1) TFEU if they have only an insignificant effect on the market. (162)

204. In order to determine whether an agreement affects competition to an appreciable extent by reason of its effects, it is necessary, in the context of that agreement, to take account, inter alia, of the nature of the products to which it relates and the position and importance of the parties on the market of the products concerned, and of the actual conditions of the functioning and structure of the market or markets in question. (163) Moreover, account may be taken of the isolated nature of the agreement at issue or, on the contrary, of its place in a series of agreements. In that regard, the existence of similar agreements, although not necessarily decisive, is a circumstance which, together with others, is capable of constituting the economic and legal context within which the agreement must be judged. (164)

205. The need to take those factors into consideration in order to determine whether the effects of an agreement on competition are appreciable is felt particularly in the case of agreements such as those at issue in the present case, between an operator established on a certain market and a potential entrant, which induce the latter to cease its efforts to enter the market and the effects of which consist, therefore, in eliminating competition between the two.

206. Thus, if an established operator eliminated, by such an agreement, a single insignificant potential competitor, among others, the effects on competition might not be appreciable, since there would continue to be competition between the established operator and the other potential competitors. However, if the established operator eliminates, by one or more agreements of that type, its sole or its few significant potential competitors, those agreements would affect to a very appreciable extent competition on the market concerned, or even eliminate it, at least for some time before new potential competitors emerged.

207. The structure of the market on which those agreements are based, the position of the parties on that market and, where appropriate, whether several agreements of the same type exist, are therefore essential factors for assessing the appreciable extent of the effects of those agreements.

208. In that regard, the pharmaceutical sector is characterised, in terms of its structure, generally by the fact that, before expiry of the compound patent and the data exclusivity for the API of a certain medicinal product, the patent holder's product is in principle the only one on the market. By contrast, when those exclusivity rights have expired or are close to expiry, generic manufacturers seek to enter the market with generic copies of the originator medicinal product, which causes major falls in the price of that originator product. (165)

209. In such a situation, agreements entered into by the holder of the patent for the API of the originator medicinal product with one or more potential generic entrants are capable of having very appreciable effects on competition. Depending on the position and number of those generic competitors, it is possible for such agreements to have the effect of eliminating to a large extent or even entirely potential competition relating to the product concerned. Yet that is not only capable of delaying the opening of the market to generic products and therefore the corresponding reduction in prices, but is also capable of reducing the incentives of the established operator, which preserves its monopoly revenues, in terms of innovation for the development of new products.

210. In the present case, the paroxetine produced by GSK was visibly the sole paroxetine on the United Kingdom market until expiry of the compound patent and of the data exclusivity for that medicinal product's API, although, at that time, several generic manufacturers were considering entering the market with generic paroxetine. According to the CAT, those manufacturers were precisely and at least initially, only IVAX, GUK and Alpharma, the first two of which were leading suppliers of generic products in the United Kingdom. (166)

211. It is for the referring court to establish, on the basis of the criteria laid down by the case-law, whether, in those circumstances, the GUK and Alpharma Agreements not only had effects but also appreciable effects on competition. To that end, the CAT will be able to take account not only of each agreement separately, but also of their cumulative effects on the overall market situation. Similarly, the CAT will be able to take account of the IVAX Agreement which, although not the subject of fines as a restriction of competition by object or by effect, (167) is undeniably a relevant factor in the economic and legal context of the GUK and Alpharma Agreements.

(3) Conclusion

212. It follows from the foregoing considerations that an agreement to settle a dispute between the holder of a patent over a medicinal product and the manufacturer of a generic version of that product constitutes a restriction of competition by effect prohibited by Article 101(1) TFEU if the effect of that agreement is to eliminate competition between those operators and if that effect is appreciable on the basis of the context of the agreement

which includes, inter alia, the structure of the market, the position of the parties on it and, where appropriate, the existence of other agreements of the same type. By contrast, the conclusion that such an agreement has such restrictive effects on competition does not presuppose a finding that, in the absence of that agreement, the generic manufacturer would probably have been successful in the patent dispute or the parties would probably have entered into a less restrictive settlement agreement.

2. Article 102 TFEU

213. The questions from the CAT concerning Article 102 TFEU relate, first, to the matter of whether the generic versions of paroxetine could be taken into account for the purposes of defining the relevant market in which GSK operated and, second, to the question of whether it is possible to categorise GSK's entering into the IVAX, GUK and Alpharma Agreements as an abuse of a dominant position within the meaning of Article 102 TFEU.

(a) Definition of the relevant market (Question 7)

214. Before answering the CAT's question concerning the definition of the relevant market for the purposes of applying Article 102 TFEU, it is necessary to define more precisely the scope of that question.

(1) The scope of Question 7

215. By its seventh question, the CAT wishes to know whether, where a patented pharmaceutical product is therapeutically substitutable with a number of other medicinal products in a class and the alleged abuse for the purpose of Article 102 TFEU consists in the patent holder excluding generic versions of that product from the market, those generic products should be taken into account, for the purpose of defining the product market concerned, although it is not known whether they could enter the market before expiry of the patent at issue without infringing it.

216. In the main proceedings, the parties agree that the relevant geographical market for the purposes of the application of Article 102 TFEU was the United Kingdom. By contrast, they disagree as to whether the relevant product market comprised solely paroxetine, as the CMA maintains, (168) or whether, on the contrary, that market included all antidepressant medicines in the group of SSRIs to which paroxetine belongs, (169) as GSK claims. That question is crucial since GSK acknowledges that, if the relevant product market were defined as being solely paroxetine, it then had a dominant position at the time of the agreements, while the CMA acknowledges that, if that market were defined as encompassing all the SSRIs, then GSK did not hold such a position at that time.

217. In its judgment (170) and in its request for a preliminary ruling, the CAT stated that it favoured the CMA's approach, according to which the relevant product market was solely paroxetine and not all SSRIs. However, it notes that it would need an answer to the question, which was a matter of dispute between the parties, as to whether it is appropriate to include the generic versions of paroxetine for the purposes of defining the product market at the time of the agreements, although, at that time, those generic products were not yet on the market and it is not known, owing to the uncertainty regarding the outcome of the disputes between GSK and the generic manufacturers, if they could enter the market without infringing GSK's patent rights.

218. It is apparent from the reasoning set out in the CAT judgment (171) that the CAT regards the answer to that question as decisive because, in its view, the relevant product market in which paroxetine evolved has altered with the emergence of the threat of generics of that medicinal product entering the market. Thus, whereas, prior to the emergence of that threat, paroxetine could be regarded as included in the broader market of all SSRIs, with the emergence of the threat of market entry by generics of paroxetine, a product market specific solely to that single molecule has formed. That approach is relevant, according to the CAT, in particular, because the definition of the market at issue for the purposes of Article 102 TFEU is dynamic and must be determined taking account of the abusive conduct under scrutiny. In order to confirm such an approach, the CAT finds it necessary to know whether it may include generics of paroxetine, although they were not yet present on the market at the time of the agreements, in its analysis of the relevant market on which GSK's conduct took place.

219. It is important to note that the dominant position referred to in Article 102 TFEU relates to a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors and customers and ultimately of consumers. (172)

220. Therefore, in the context of the application of Article 102 TFEU, the relevant market is defined in order to identify the boundaries within which the question of whether an undertaking may behave, to an appreciable extent, independently of its competitors, its customers and consumers must be assessed. The concept of the relevant market thus implies that there can be effective competition between the product 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 (173) The possibilities of competition must therefore be judged in the context of the market comprising the totality of the products which, with respect to their characteristics, are particularly suitable for satisfying constant needs and are only to a limited extent interchangeable with other products. In that context, an examination limited to the objective characteristics only of the relevant products cannot be sufficient: the competitive conditions and the structure of supply and demand on the market must also be taken into consideration. (174)

221. As the Commission summarised in paragraph 2 of its Notice on the definition of the relevant market for the purposes of Community competition law, (175) that definition is therefore a tool to identify the boundaries of

competition between firms. Accordingly, its main purpose is to identify systematically the competitive constraints that the undertakings involved face and to establish whether there are actual competitors capable of constraining the behaviour of those undertakings or of preventing them from acting independently of effective competitive pressure. In other words, it is necessary, according to the Court, to examine whether there are competing products which exercise significant competitive constraints over the undertakings in question. (176)

222. Such an examination of the competitive constraints faced by a certain undertaking, based on the conditions of competition and the structure of supply and demand on a certain market, is naturally dynamic in character. It is therefore quite conceivable that the emergence of a new supply of products alters the structure of the relevant market in such a way as to exclude other products which previously formed part of it. It follows that, in the present case, it cannot be ruled out that the relevant market on which paroxetine evolved was, as the CAT appears to consider, composed of all SSRIs at the beginning of the life-cycle of that active substance, whereas that market altered in such a way as to comprise only paroxetine when the threat of market entry by the generic versions of that molecule emerged.

223. It should be noted, however, that in the context of the preliminary ruling procedure established by Article 267 TFEU, any assessment of the facts of the case falls within the competence of the referring court. (177) Consequently, in the present case, it is for the CAT to assess the competitive constraints on Seroxat and to define thereby the relevant market on which it evolved. It is therefore for the CAT alone to examine the competitive pressure exerted on Seroxat by the other SSRIs and, as the case may be, by the generics of paroxetine, and consequently to establish as a result whether and, if necessary, during what period those medicinal products formed part of the same relevant market or different relevant markets.

224. It follows that the Court's function is limited, in the context of the present question referred, to giving guidance to the CAT on the issue of whether, when assessing the competitive constraints exerted on Seroxat at the time of the agreements in question, it may take account of generic paroxetine although the latter had not yet entered the market at that time and it was uncertain whether it could enter the market without infringing GSK's patent rights.

(2) The inclusion of generic paroxetine for the purposes of determining the relevant market

225. It is apparent from the wording of the seventh question asked by the CAT that its question as to whether it may take account of generic paroxetine when defining the relevant product market at the time of the agreements derives, first of all, from the fact that it is uncertain whether paroxetine generics could enter the market before expiry of GSK's patent rights without infringing the latter.

226. However, in that regard, it is already clear from the arguments set out above that uncertainty as to the validity of a patent for a medicinal product and whether a generic product infringes it does not in any way preclude there being a competitive relationship between the operators concerned. As has been demonstrated, such uncertainty is, on the contrary, a component of relationships of potential competition between patent holders and manufacturers of generic medicinal products in the pharmaceutical sector. (178)

227. Similarly, it is not for the competition authorities to conduct examinations and make predictions concerning the lawfulness in terms of patent rights of the market entry of a generic of a patented medicinal product. (179) Therefore, the state of uncertainty surrounding the lawfulness of the placing on the market of a generic medicinal product under patent law cannot preclude a competition authority, for the purposes of applying competition law, from finding that that medicinal product is in a competitive relationship with the originator medicinal product protected by the patent alleged to have been infringed and consequently falls within the same product market as that originator. (180)

228. It follows that it is not the uncertainty as to whether the generic manufacturers could enter the market before expiry of GSK's patent rights without infringing those rights which could prevent the CAT from taking account of generic paroxetine for the purposes of defining the relevant product market in the present case.

229. However, it is apparent from the explanations given by the CAT that its doubts in that regard derive not only from the fact that it is not known whether generic paroxetine could enter the market without infringing GSK's patent rights at the relevant time, but also from the fact that, at that time, those generics were not yet on the market and therefore were not yet actual competitors of GSK.

230. In that regard, GSK maintains that any competitive pressure exerted on a product by products supplied by potential competitors is irrelevant for defining the relevant market for the purposes of applying Article 102 TFEU. According to that line of argument, the analysis of substitutability between products must, on the contrary, be carried out only by reference to products that are actually available on the market at the relevant time. GSK claims that that point of view is confirmed by paragraph 24 of the Commission Notice on the definition of the relevant market for the purposes of Community competition law, (181) which states that potential competition is not taken into account when defining markets.

231. However, it is apparent from the case-law that the criterion for assessing whether a product may be taken into consideration when defining the relevant product market in connection with the application of Article 102 TFEU is not necessarily whether the manufacturer of that product is a potential competitor but rather whether it is in a position to enter the market with sufficient speed and strength to exert a significant competitive constraint on the undertaking that is already present on the market concerned.

232. As has already been stated, in the context of the application of Article 102 TFEU the relevant market is

defined in order to identify the boundaries within which an assessment must be made of whether an undertaking is able to behave, to an appreciable extent, independently of its competitors, its customers and consumers and thereby to hinder the maintenance of effective competition. The definition of the relevant market therefore serves to identify the significant competitive constraints that competition exerts on the undertakings in question. (182)

233. When identifying such competitive constraints on a certain market, account can be taken not only of demand-side substitutability but also of supply-side substitutability where it has effects equivalent to those of demand-side substitutability in terms of immediacy and effectiveness. In that context, the criterion of supply-side substitutability means that manufacturers are in a position to enter the market by a simple adaptation with sufficient strength to create a serious counterweight to manufacturers already present on the market. (183)

234. Although, as the General Court has already analysed, it is true that the questions of potential competition and supply-side substitutability do overlap in part, the distinction between them lies nevertheless in whether the possible entry of the competitor concerned to the market is immediate or not. (184) The necessary substitutability for the purposes of the definition of the relevant market must thus materialise in the short term. (185)

235. In the present case, the question of whether the generic versions of paroxetine may be taken into consideration for the purposes of defining the product market on which GSK was operating at the time of the agreements is a matter of supply-side substitutability, since the question is whether the producers of those generic versions could enter the market with sufficient speed and strength to exercise significant competitive constraint on GSK even before they entered the market.

236. For the purposes of examining that question, the referring court will therefore have to analyse whether, despite the uncertainty as to the outcome of the patent disputes between GSK, on the one hand, and IVAX, (186) GUK and Alpharma, on the other, the latter exerted a significant competitive constraint on GSK at the time of the agreements, because they were able to enter the market with sufficient speed and strength to create a serious counterweight to GSK.

237. As has been stated, it is important, in that analysis, to take account of the conditions of competition and the structure of supply and demand on the relevant market. (187) Therefore, in the present case, the CAT may inter alia take account of the fact that, in the pharmaceutical sector, it is common, after expiry of patent rights on the API of an originator medicinal product, for generic manufacturers to exert strong competitive pressure on the originator company, despite the existence of possible process patents which, irrespective of whether or not they are valid, do not prevent generic manufacturers entering the market with the API at issue manufactured according to other processes. (188)

238. Similarly, the CAT will have to take into consideration the progress made by each of the generic manufacturers concerned in their preparations for entering the market in terms, inter alia, of investment, building up of stocks of the medicinal product in question or marketing strategies and applying for and obtaining MAs for their products.

239. Lastly, evidence of GSK's perception of the immediacy of the threat of market entry by IVAX, GUK and Alpharma may also be taken into account in order to assess whether the competitive constraints exerted by those manufacturers on GSK at the relevant time were significant. In that regard, it is particularly relevant that GSK was willing to make substantial value transfers to those manufacturers in order to induce them to abandon their efforts to enter the market independently, value transfers which would make no sense if there were no competitive pressure on GSK from the generic manufacturers.

(3) Conclusion

240. It follows from the foregoing that the generic versions of a patented medicinal product, which are not yet on the market at the relevant time, may be taken into consideration for the purposes of defining the relevant product market within the meaning of Article 102 TFEU if their manufacturers are able to enter the market with sufficient speed and strength to create a serious counterweight to the patented medicinal product and thus exert significant competitive pressure on the patent holder, which it is for the referring court to review. In that context, the fact that there is, at the relevant time, uncertainty as to whether those generic versions may enter the market before expiry of the holder's patent rights without infringing those rights does not mean that there is no competitive relationship between the patent holder and the generic manufacturers in question and therefore does not prevent the generic products concerned from being taken into account for the purposes of defining the relevant product market.

(b) Abuse of a dominant position (Questions 8 to 10)

241. The questions referred for a preliminary ruling by the CAT concerning the abuse of a dominant position focus on two key points. The first set of questions concerns whether entry into agreements such as the IVAX, GUK and Alpharma Agreements, taken in isolation or as a whole, by a patent holder who is in a dominant position, constitutes an abuse of a dominant position within the meaning of Article 102 TFEU. The second set of questions focuses on the assessment, in that regard, of the benefits provided by the agreements in question.

242. Thus, first, by Question 8, the CAT wishes to know, first of all, whether for a patent holder in a dominant position the fact of entering into an agreement in the circumstances described in Questions 3 to 5 constitutes an abuse of a dominant position within the meaning of Article 102 TFEU. Then, by Question 9, it asks whether the answer to that question differs where the agreement in question has not been concluded as settlement of ongoing legal proceedings, but in order to avoid such proceedings being commenced, as was the case for the IVAX Agreement. Finally, by Question 10(a), the CAT wishes to know whether the reply to those questions

differs where the patent holder pursues a strategy of entering into several agreements of that type in order to eliminate the risk of independent entry onto the market by a generic product.

243. Second, by Question 10(b) and (c), the CAT questions the Court regarding the assessment, under Article 102 TFEU, of the benefits afforded by the IVAX agreement. It is appropriate, when dealing with that question, to address also the benefits afforded by the GUK and Alpharma Agreements. Indeed, the CAT refers to those benefits in Question 8, by its reference to the circumstances described in Questions 3 to 5: As is apparent from the arguments set out above, the circumstances referred to in Questions 3 and 4 relate to the patent position and to the respective undertakings of the parties when the GUK and Alpharma Agreements were entered into, while the circumstances indicated in Question 5 concern the benefits afforded by those agreements. (189) It is therefore appropriate to deal with those latter circumstances together with the examination of the benefits afforded by the IVAX Agreement, with regard to Question 10(b) and (c).

(1) The categorisation of entry into one or more agreements in settlement of patent disputes as abuse of a dominant position (Questions 8, 9 and 10(a))

244. As has just been stated, by Questions 8, 9 and 10(a), the CAT is asking the Court whether entry into agreements such as the IVAX, GUK and Alpharma Agreements, taken in isolation or as a whole, by a patent holder in a dominant position constitutes an abuse of a dominant position within the meaning of Article 102 TFEU. Those questions therefore concern inter alia the link between the application of Article 101 TFEU and that of Article 102 TFEU.

(i) The link between the application of Article 101 TFEU and that of Article 102 TFEU

245. In that regard, the Court has already explained that it is clear from the very wording of Articles 101 and 102 TFEU that the same practice may give rise to an infringement of both provisions, which may therefore be applied concurrently. (190) In fact, since Article 102 TFEU is expressly aimed at situations which clearly originate in contractual relations, the competition authorities are entitled, taking into account the nature of the reciprocal undertakings entered into and the competitive position of the various contracting parties on the market or markets in which they operate, to proceed on the basis of Article 101 or Article 102 TFEU. (191)

246. Although they seek the same aim, namely the maintenance of effective competition within the internal market, Articles 101 and 102 TFEU differ, however, in that Article 101 TFEU concerns agreements between undertakings, decisions of associations of undertakings and concerted practices, while Article 102 TFEU concerns unilateral activity of one or more undertakings. (192)

247. Moreover, Article 101 TFEU applies to agreements, decisions and concerted practices which are capable of appreciably affecting trade between Member States, regardless of the position on the market of the undertakings concerned. Article 102 TFEU, on the other hand, relates to the conduct of one or more economic operators, consisting in the abuse of a position of economic strength which enables the operator concerned to hinder the maintenance of effective competition on the relevant market by allowing it to behave to an appreciable extent independently of its competitors, its customers and, ultimately, consumers. (193)

248. It is true that a finding that an undertaking has a dominant position is not in itself a recrimination against the undertaking concerned, (194) since it is by no means the purpose of Article 102 TFEU to prevent an undertaking from acquiring, on its own merits, the dominant position on a market. (195)

249. However, the finding that an undertaking has a dominant position on a certain market means that that undertaking, irrespective of the reasons for that position, has a special responsibility not to allow its behaviour to impair genuine, undistorted competition on the internal market. (196) The actual scope of that special responsibility imposed on a dominant undertaking must be assessed in the light of the specific circumstances of each case which show a weakened competitive situation. (197)

250. As regards the concept of abuse, this is an objective concept referring to the conduct of a dominant undertaking which is such as to influence the structure of a market where, as a result of the very presence of the undertaking concerned, the degree of competition is weakened, and which, 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. (198) It follows that Article 102 TFEU prohibits a dominant undertaking from eliminating a competitor and from strengthening its position by using methods other than those which come within the scope of competition on the merits. (199)

251. If entry into an agreement prohibited by Article 101 TFEU is a priori always capable of constituting a method other than those which come within the scope of competition on the merits, entry into such an agreement by an undertaking in a dominant position is, therefore, in particular, capable of being caught in addition by the prohibition laid down in Article 102 TFEU if it is capable of influencing the structure of the market concerned in such a way as to hinder or even eliminate the remaining competition on that market. (200)

(ii) Entry into the agreements concerned in the main proceedings as use by GSK of a method other than competition on the merits

252. In the present case, it is apparent from the explanations given by the CAT that it takes the view that the answer to its questions concerning Article 102 TFEU depends, to a large extent, on the answer to its questions concerning whether the agreements entered into by GSK were capable of constituting restrictions of competition by object within the meaning of Article 101 TFEU, so that entering into them might also be capable of

constituting a method other than competition on the merits used by GSK to strengthen its position on the market within the meaning of Article 102 TFEU. It is apparent from the arguments already set out above that, subject to the review which it is for the referring court to carry out, that is the case so far as concerns the GUK and Alpharma Agreements. (201)

253. Subject also to the factual review which it is for the CAT to carry out, there can be no other conclusion as regards the IVAX Agreement, which was not the subject of fines imposed by the CMA under the prohibition on anticompetitive agreements and which has not been specifically examined above in relation to the questions on Article 101 TFEU. (202) Thus, according to the information supplied by the CAT, the only significant difference between the IVAX Agreement and the GUK and Alpharma Agreements lay in the fact that there were no legal proceedings ongoing between the parties at the time of entry into the IVAX Agreement. However, according to the CAT, if that agreement had not been entered into, IVAX would have wanted to enter the market independently and GSK would have initiated patent infringement proceedings against IVAX. In addition, even though in the IVAX Agreement, unlike the GUK and Alpharma Agreements, there was no express contractual restriction on independent entry by IVAX onto the market, (203) according to the CAT that was nevertheless the parties' intention and that was how they understood the agreement.

254. It follows that, without prejudice to the question of whether the IVAX Agreement thus also constituted a restriction of competition by object within the meaning of Article 101 TFEU and whether its exemption from the prohibition laid down by that provision under English law was compatible with EU law, which it is not for the Court to resolve in the present proceedings, it must be stated that the above considerations concerning the GUK and Alpharma Agreements also apply in full to the IVAX Agreement. Thus, if, which it is for the referring court to review, it had no purpose other than to induce IVAX to refrain from entering the market independently by means of a value transfer from GSK, the sole consideration for which was to so refrain, the entry into such agreement is akin to the use by GSK, of a method other than competition on the merits and is therefore capable of constituting an abuse of a dominant position within the meaning of Article 102 TFEU. The fact that the IVAX Agreement was not entered into as a settlement of ongoing legal proceedings, but in order to avoid such proceedings being initiated, does not in fact alter that finding.

(iii) GSK's entry into the agreements at issue in the main proceedings as a method capable of influencing the structure of the market concerned such as to hinder or even eliminate the remaining competition on that market

255. As regards the assessment of the agreements at issue in the main proceedings in terms of Article 102 TFEU, it should be stated as a preliminary point that, as explained in the case-law, although the fact that an undertaking is in a dominant position cannot disentitle it from protecting its own commercial interests if they are attacked, such a defence cannot be accepted if it arises in conduct constituting an abuse of a dominant position. (204) Similarly, although the exercise of a right by the proprietor of an intellectual property right, even if it is the act of an undertaking holding a dominant position, cannot in itself constitute an abuse of a dominant position, the exercise of the exclusive right by the proprietor may, in exceptional circumstances, involve abusive conduct. (205)

256. Next, as has been stated above, the entry by an undertaking in a dominant position into an agreement prohibited by Article 101 TFEU, which constitutes the use of a method other than competition on the merits, is, inter alia, capable of being caught also by the prohibition in Article 102 TFEU if it is capable of influencing the structure of the market concerned in such a way as to hinder or even eliminate the remaining competition on that market. (206) The finding that entering into an agreement also constitutes conduct prohibited by Article 102 TFEU therefore depends, inter alia, on the structure of competition on the market concerned and the position of the parties to the agreement on that market. (207)

257. In the present case, if it is established that an agreement between the holder of a patent for a medicinal product, which is in a dominant position on the market concerned, and a manufacturer of a generic version of that medicinal product seeks to induce the latter to undertake to abandon its efforts to enter the market independently by means of a value transfer the sole consideration for which is that abandonment, the entry into such an agreement by the patent holder is capable of being caught by the prohibition in Article 102 TFEU if it has the effect of influencing the structure of competition on the market concerned in such a way as to hinder the development of that competition or even to eliminate it.

258. That consequence is all the more likely since, as has already been stated, owing to the inherent characteristics of the pharmaceutical sector, such an agreement entered into between a patent holder and a manufacturer of generics, may, depending on the point in time at which it is concluded and the position and number of potential generic competitors, have the effect of eliminating to a large extent or even entirely potential competition relating to the product concerned, (208) thereby strengthening the patent holder's position by use of a method other than competition on the merits.

259. However, it is apparent from the facts underlying the dispute in the main proceedings that GSK was not the subject of fines under the national provision equivalent to Article 102 TFEU for entering into a single anticompetitive agreement, but for entering into the IVAX, GUK and Alpharma Agreements as a whole. (209)

260. Therefore, the question which arises in this case is not whether entering into only one of those agreements is capable of constituting an abuse of a dominant position within the meaning of Article 102 TFEU on the part of GSK, but whether entry into those agreements as a whole may be classified as such.

261. In those circumstances, it will be for the referring court to examine whether the entry, by GSK, into the IVAX, GUK and Alpharma Agreements was such as to hinder or even eliminate competition on the market concerned and thereby to strengthen GSK's dominant position by methods other than competition on the merits. In that examination, the CAT will be able to take into account, inter alia, the respective positions and importance of the generic manufacturers concerned in terms of competitive pressure exerted on GSK, and the existence or absence of other sources of competitive constraints at the relevant time. (210) Similarly, the CAT will be able to take into consideration the existence of any anticompetitive intent and overall strategy on the part of GSK seeking to eliminate its competitors, which are factual elements that are capable of being taken into account for the purposes of determining whether there is an abuse of a dominant position. (211)

(iv) Conclusion

262. It is apparent from the foregoing reasoning that entering into a number of patent dispute settlement agreements, whether or not those disputes have already given rise to the initiation of legal proceedings, by a patent holder who has a dominant position on the market concerned, with several manufacturers of generics, constitutes an abuse of a dominant position if those agreements seek to induce those manufacturers to undertake to abandon their efforts to enter the market independently by means of a value transfer the sole consideration for which is that abandonment and if entering into them is capable of influencing the structure of the market concerned in such a way as to hinder or even to eliminate the remaining competition on that market, thereby strengthening the patent holder's dominant position by methods other than competition on the merits, which it is for the referring court to review.

(2) The benefits afforded by the agreements at issue in the main proceedings (Question 10(b) and (c))

263. By Question 10(b) and (c), read in conjunction with Question 8, the CAT is asking whether the answer to its previous questions on the abuse of a dominant position differs if the agreements concerned afforded certain benefits to the national health system and to consumers, which were nevertheless significantly less than the benefits which would have been afforded by independent generic entry onto the market. (212) The CAT also wishes to know what role was played in that regard by the fact that the parties did not intend to bring about those benefits when they entered into the agreements at issue.

264. From a factual point of view, the CAT refers here, first, as regards the GUK and Alpharma Agreements, to the limited benefits already considered above afforded by those agreements to consumers in terms of costs and quality. (213) Second, as regards the IVAX Agreement, the CAT refers to the fact that it involved a reduction in the reimbursement level for paroxetine by reason of the structure of the national system for reimbursement to pharmacies by the public health authorities, which resulted in a substantial saving to those authorities. (214)

(i) The requirement to take the alleged benefits into consideration

265. First of all, it is important to clarify that whether or not those benefits afforded to consumers and to the national health insurance fund were intended by the parties at the time of entry into the agreements is not decisive for the CAT to take those benefits into account when examining whether there was an abuse of a dominant position by GSK.

266. As has been stated above, the concept of abuse of a dominant position is an objective concept. (215) Moreover, if any anticompetitive intent or strategies on the part of the dominant undertaking are capable of being taken into consideration for the purposes of finding an abuse of a dominant position, the presence of such intent or strategies is by no means indispensable for the purpose of reaching such a conclusion. (216) However, that must mean, conversely, that any benefits afforded by conduct which may be caught by the prohibition in Article 102 TFEU will also have to be assessed objectively and without requiring that the parties intended such benefits.

267. Furthermore, as the Court held in its judgment in Intel v Commission, (217) the authorities and courts responsible for applying competition law are required to examine all the arguments and evidence produced by the undertaking concerned seeking to call into question the substance of the findings regarding the existence of an abuse of a dominant position on its part. In that connection, the authorities and courts concerned are required, inter alia, to examine evidence adduced by the undertaking which is capable of demonstrating that the disadvantageous effects on competition of a certain practice may be counterbalanced or even outweighed by advantages in terms of efficiency which also benefit the consumer.

(ii) The possibility of justifying acts which are capable of falling within the prohibition laid down in Article 102 TFEU

268. Next, as regards the impact on the finding of abuse of a dominant position of taking such factors into consideration, it should be noted that, according to the case-law, it is open to a dominant undertaking to provide justification for behaviour that is liable to be caught by the prohibition laid down in Article 102 TFEU. In particular, such an undertaking may demonstrate, for that purpose, either that its conduct is objectively necessary, or that the exclusionary effect produced may be counterbalanced or even outweighed by advantages in terms of efficiency that also benefit consumers. (218)

269. In that last regard, the Court has stated that it is for the undertaking occupying a dominant position to demonstrate that the efficiencies likely to result from the conduct under consideration counteract the likely negative effects on competition and consumer welfare on the affected markets, that those efficiencies have been, or are likely to be, brought about as a result of that conduct, that such conduct is indispensable for the realisation of those efficiencies and that it does not eliminate effective competition, by removing all or most existing sources of actual or potential competition. (219)

270. In the present case, subject to findings of fact which it is for the CAT to make, it does not appear, on the basis of the information provided by the CAT, that the benefits afforded by the IVAX, GUK and Alpharma Agreements are capable of fulfilling the conditions thus imposed by the Court for justifying conduct which is capable of falling under Article 102 TFEU and thus escaping the prohibition laid down in that provision.
271. Thus, as regards the benefits afforded to consumers by the GUK and Alpharma Agreements, it has already been observed above that the supply of limited volumes of paroxetine by GSK to those generic manufacturers did not give rise to any significant competitive pressure on GSK but merely amounted to a controlled reorganisation of the paroxetine market by GSK and to the implementation of value transfers of a non-monetary nature. (220) There is no indication that it would have been otherwise as concerns the supply of limited volumes of paroxetine by GSK to IVAX. The fact that that agreement also had the effect of bringing about a reduction in the national health system's reimbursement prices, thereby resulting in a saving for that system, does not fundamentally alter the situation.
272. Article 102 TFEU covers not only those practices that directly cause harm to consumers but also practices that cause consumers harm through their impact on competition. (221) Therefore, limited benefits afforded to consumers cannot counterbalance harm caused by the elimination of all competition on the relevant market.
273. However, as is also apparent from the arguments already set out, the IVAX, GUK and Alpharma Agreements had precisely the effect of eliminating effective competition with regard to paroxetine by removing all existing sources of potential competition at the point in time when they were entered into, since they induced those generic manufacturers to abandon their efforts to achieve independent market entry for the agreed period in exchange for a value transfer. Therefore, the limited benefits afforded by those agreements were in no way capable of neutralising or even merely counterbalancing the negative effects of the latter on competition.
274. That is all the more true because, as has also been stated, even if it is not known whether the generic manufacturers could have entered the market independently in the absence of the agreements since the outcome of the patent proceedings between GSK and the generic manufacturers is uncertain, what counts is not the entry of the generic manufacturers to the market at any price but the fact that that entry does or does not take place due to free competition and not due to abusive conduct by GSK seeking, furthermore, to eliminate all competition on the relevant market. (222) Indeed, it is not for the undertaking in a dominant position to dictate the manner in which its competitors are permitted to enter the market and thereby to replace free competition with a reorganisation of the market carried out under its control. (223)

(iii) Conclusion

275. It follows from those considerations that when examining whether there is an abuse of a dominant position, a competition authority or competent court must take account of any benefits deriving from the conduct concerned, whether or not the operators involved intended them. However, such benefits may justify actions which are capable of being caught by the prohibition laid down in Article 102 TFEU only if the undertaking occupying the dominant position demonstrates that they neutralise the harmful effects of the conduct on competition on the affected markets. The fact that a number of settlement agreements concluded by a patent holder with manufacturers of generics provide for controlled entry by those manufacturers to the market which affords limited benefits to consumers is not, however, capable of satisfying those conditions, if those agreements otherwise have the effect of eliminating effective competition by removing all or most existing sources of potential competition, which it is for the referring court to review.

VI. Conclusion

276. In the light of the foregoing considerations, I propose that the Court reply as follows to the questions referred for a preliminary ruling from the Competition Appeal Tribunal (United Kingdom):
(1) Uncertainty concerning the validity of a patent for a medicinal product or whether a generic version of that medicinal product infringes that patent does not prevent the patent holder and the generic manufacturer from being regarded as potential competitors. The existence of a bona fide dispute as to whether the patent is valid or whether the generic product infringes the patent, irrespective of whether or not that dispute has already given rise to judicial proceedings and interim injunctions or interim legal undertakings, is, on the contrary, a factor which is capable of demonstrating that potential competition exists between the patent holder and the generic manufacturer. Similarly, the patent holder's perception and the fact that it regards the generic manufacturer as a potential competitor are factors which are capable of demonstrating that potential competition exists between those two operators.
(2) An agreement to settle court proceedings, the outcome of which is uncertain, relating to an actual dispute concerning the validity of a patent or the question of whether a generic product infringes that patent, under which the patent holder gives an undertaking in favour of a generic manufacturer to make a value transfer in a sufficient amount to induce that manufacturer to abandon its efforts to enter the market independently, constitutes a restriction of competition by object if it is found that the sole consideration for that value transfer is that the generic manufacturer refrains from entering the market with its product and from continuing to challenge the patent during the agreed period, which it is for the referring court to review. That also applies where the restrictions imposed by such an agreement do not go beyond the scope and unexpired period of the patent and where the amount transferred to the generic manufacturer is lower than the profit it could have expected if it had entered the market independently.

(3) The assessment of the benefits afforded to consumers by an agreement between competitors is relevant for the purposes of Article 101(1) TFEU in order to examine whether the existence of those benefits is likely to give rise to doubts as to the existence of a restriction of competition in general and a restriction of competition by object in particular. The fact that an agreement to settle a dispute between the patent holder and a generic manufacturer provides for the controlled entry by that manufacturer to the market, which does not give rise to any meaningful competitive constraint on the patent holder but provides consumers with limited benefits which they would not have had if the patent holder had been successful in the proceedings, is not, however, such as to create such a doubt, if the agreement at issue has otherwise as its object to induce the generic manufacturer to abandon its efforts to enter the market independently by means of a value transfer the sole consideration for which is that abandonment, which it is for the referring court to review.

(4) An agreement to settle a dispute between the holder of a patent over a medicinal product and the manufacturer of a generic version of that product constitutes a restriction of competition by effect prohibited by Article 101(1) TFEU if the effect of that agreement is to eliminate competition between those operators and if that effect is appreciable on the basis of the context of the agreement which includes, inter alia, the structure of the market, the position of the parties on it and, where appropriate, the existence of other agreements of the same type. By contrast, the conclusion that such an agreement has such restrictive effects on competition does not presuppose a finding that, in the absence of that agreement, the generic manufacturer would probably have been successful in the patent dispute or the parties would probably have entered into a less restrictive settlement agreement.

(5) The generic versions of a patented medicinal product, which are not yet on the market at the relevant time, may be taken into consideration for the purposes of defining the relevant product market within the meaning of Article 102 TFEU if their manufacturers are able to enter the market with sufficient speed and strength to create a serious counterweight to the patented medicinal product and thus exert significant competitive pressure on the patent holder, which it is for the referring court to review. In that context, the fact that there is, at the relevant time, uncertainty as to whether those generic versions may enter the market before expiry of the holder's patent rights without infringing those rights does not mean that there is no competitive relationship between the patent holder and the generic manufacturers in question and therefore does not prevent the generic products concerned from being taken into account for the purposes of defining the relevant product market.

(6) Entering into a number of patent dispute settlement agreements, whether or not those disputes have already given rise to the initiation of legal proceedings, by a patent holder who has a dominant position on the market concerned, with several manufacturers of generics, constitutes an abuse of a dominant position if those agreements seek to induce those manufacturers to undertake to abandon their efforts to enter the market independently by means of a value transfer the sole consideration for which is that abandonment and if entering into them is capable of influencing the structure of the market concerned in such a way as to hinder or even to eliminate the remaining competition on that market, thereby strengthening the patent holder's dominant position by methods other than competition on the merits, which it is for the referring court to review.

(7) When examining whether there is an abuse of a dominant position, a competition authority or competent court must take account of any benefits deriving from the conduct concerned, whether or not the operators involved intended them. However, such benefits may justify actions which are capable of being caught by the prohibition laid down in Article 102 TFEU only if the undertaking occupying the dominant position demonstrates that they neutralise the harmful effects of the conduct on competition on the affected markets. The fact that a number of settlement agreements concluded by the patent holder with manufacturers of generics provide for controlled entry by those manufacturers to the market which affords limited benefits to consumers is not, however, capable of satisfying those conditions, if those agreements otherwise have the effect of eliminating effective competition by removing all or most existing sources of potential competition, which it is for the referring court to review.

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1 Original language: French.

2 Namely, GlaxoSmithKline plc, Xellia Pharmaceuticals ApS, Alpharma, LLC, Actavis UK Ltd and Merck KGaA.

3 See Commission Decision C(2013) 3803 final of 19 June 2013 relating to a proceeding under Article 101 TFEU and Article 53 of the EEA Agreement (Case AT.39226 — Lundbeck); that decision was the subject of the judgments of the General Court of 8 September 2016, currently under appeal, in Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission (T-460/13, not published, EU:T:2016:453; Case C-586/16 P pending); Arrow Group and Arrow Generics v Commission (T-467/13, not published, EU:T:2016:450; Case C-601/16 P pending); Generics (UK) v Commission (T-469/13, not published, EU:T:2016:454; Case C-588/16 P pending); Merck v Commission (T-470/13, not published, EU:T:2016:452; Case C-614/16 P pending); Xellia Pharmaceuticals and Alpharma v Commission (T-471/13, not published, EU:T:2016:460; Case C-611/16 P pending); and Lundbeck v Commission (T-472/13, EU:T:2016:449; Case C-591/16 P pending).

4 See Commission Decision C(2014) 4955 final of 9 July 2014 relating to a proceeding under Article 101 and Article 102 TFEU (Case AT.39612 — Perindopril (Servier)); that decision was the subject of the judgments of the General Court of 12 December 2018, currently under appeal, in Biogaran v Commission (T-677/14, EU:T:2018:910; Case C-207/19 P pending); Teva UK

and Others v Commission (T-679/14, not published, EU:T:2018:919; Case C-198/19 P pending); Lupin v Commission (T-680/14, not published, EU:T:2018:908; Case C-144/19 P pending); Mylan Laboratories and Mylan v Commission (T-682/14, not published, EU:T:2018:907; Case C-197/19 P pending); Krka v Commission (T-684/14, not published, EU:T:2018:918; Case C-151/19 P pending); Servier and Others v Commission (T-691/14, EU:T:2018:922; Cases C-176/19 P and C-201/19 P pending); Niche Generics v Commission (T-701/14, not published, EU:T:2018:921; Case C-164/19 P pending); and Unichem Laboratories v Commission (T-705/14, not published, EU:T:2018:915; Case C-166/19 P pending).

5 See, concerning the legal framework in that regard, judgment of 28 June 2017, Novartis Europharm v Commission (C-629/15 P and C-630/15 P, EU:C:2017:498, paragraph 2 et seq.).

6 That is, the undertaking to comply with any order made by the High Court of Justice (England & Wales), Chancery Division (patents court) in the event that the court subsequently found that the injunction caused loss to GUK for which GUK should be compensated.

7 See above, points 15 and 16 of the present Opinion.

8 Moreover, the validity of the process claims for the Anhydrate Patent held to be valid in the BASF proceedings (point 24 of the present Opinion) was again upheld on appeal (but not at first instance) in the Apotex proceedings (see paragraphs 47 to 49 and footnote 14 of the CAT judgment, and paragraphs 3.135 and 3.136 of the CMA decision).

9 Reference: CE-9531/11.

10 The Competition Act 1998 (Land and Vertical Agreements Exclusion) Order 2000, SI 2000/310.

11 See above, footnote 3 of the present Opinion.

12 See above, footnote 4 of the present Opinion.

13 Reference: [2018] CAT 4, Case Nos: 1251-1255/1/12/16.

14 See above, point 28 of the present Opinion.

15 As the referring court points out, with effect from 1 May 2004, the CMA was required by Article 3 of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (OJ 2003 L 1, p. 1) to apply the EU competition rules at the same time as the national competition rules to an agreement which may affect trade between Member States. The CMA concluded that that was the case of the GUK Agreement in paragraphs 10.19 to 10.27 of the CMA decision.

16 See above, point 18 of the present Opinion.

17 Paragraphs 1.17 and 4.127 of the CMA decision; paragraph 377 of the CAT judgment.

18 See for that date, point 15 of the present Opinion, above.

19 Judgments of 18 October 1990, Dzodzi (C-297/88 and C-197/89, EU:C:1990:360, paragraphs 36, 37 and 41); of 14 March 2013, Allianz Hungária Biztosító and Others (C-32/11, EU:C:2013:160, paragraph 20); and of 15 November 2016, Ullens de Schooten (C-268/15, EU:C:2016:874, paragraph 53).

20 See above, points 14, 16 and 19 of the present Opinion. As regards the IVAX Agreement specifically, see, also, point 253 of the present Opinion below.

21 See above, points 22 and 27 of the present Opinion.

22 See above, points 10 and 11 of the present Opinion.

23 See, in particular, paragraphs 205, 321 and 333 of the CAT judgment. Without prejudice to the question of the time at which that issue should be assessed, it should be pointed out, for information purposes only regarding the facts that process claims in the Anhydrate Patent were (after the conclusion of the IVAX and GUK Agreements) held to be valid for the first time in the BASF proceedings and (after the conclusion of the IVAX, GUK and Alpharma Agreements) for the second time in the Apotex proceedings (see above, points 24 and 25 and footnote 8 of the present Opinion); however, it is not possible to determine whether that finally settled the question of the validity of those claims. In any event, the referring court, which has jurisdiction to assess the facts, assumes that at the time the agreements at issue were entered into it was uncertain whether the patent claims at issue were valid, and it is in any case uncertain whether the products of IVAX, GUK and Alpharma would have been found to have infringed them.

24 See, in particular, paragraphs 162, 242 to 244 and 320 to 326 of the CAT judgment.

25 See above, points 28 and 29 of the present Opinion.

26 See judgments of 1 July 2008, MOTOE (C-49/07, EU:C:2008:376, paragraph 30), and of 14 March 2013, Allianz Hungária Biztosító and Others (C-32/11, EU:C:2013:160, paragraph 29).

27 See judgments of the General Court of 29 June 2012, E.ON Ruhrgas and E.ON v Commission (T-360/09, EU:T:2012:332, paragraph 84), and of 8 September 2016, Lundbeck v Commission (T-472/13, EU:T:2016:449, paragraph 98).

28 Judgments of the General Court of 15 September 1998, European Night Services and Others v Commission (T-374/94, T-375/94, T-384/94 and T-388/94, EU:T:1998:198, paragraph 137); of 14 April 2011, Visa Europe and Visa International Service v Commission (T-461/07, EU:T:2011:181, paragraph 68); of 29 June 2012, E.ON Ruhrgas and E.ON v Commission (T-360/09, EU:T:2012:332, paragraph 85); and of 8 September 2016, Lundbeck v Commission (T-472/13, EU:T:2016:449, paragraph 99).

29 Judgment of 20 January 2016, Toshiba Corporation v Commission (C-373/14 P, EU:C:2016:26, paragraphs 31, 32 and 34); see, also, judgments of the General Court of 28 June 2016, Portugal Telecom v Commission (T-208/13, EU:T:2016:368, paragraph 181), and of 28 June 2016, Telefónica v Commission (T-216/13, EU:T:2016:369, paragraph 221).

30 See, to that effect, judgment of 28 February 1991, Delimitis (C-234/89, EU:C:1991:91, paragraph 21); as regards the conditions for categorising an undertaking as a potential competitor by the Commission, see judgments of the General Court of 15 September 1998, European Night Services and Others v Commission (T-374/94, T-375/94, T-384/94 and T-388/94, EU:T:1998:198, paragraph 137); of 14 April 2011, Visa

Europe and Visa International Service v Commission (T-461/07, EU:T:2011:181, paragraphs 68, 166 and 167); of 29 June 2012, E.ON Ruhrgas and E.ON v Commission (T-360/09, EU:T:2012:332, paragraphs 85 and 86); and of 8 September 2016, Lundbeck v Commission (T-472/13, EU:T:2016:449, paragraphs 99 and 100); see, also, paragraph 10 of the Commission's Guidelines on the applicability of Article 101 TFEU to horizontal cooperation agreements (OJ 2011 C 11, p. 1).

31 See, to that effect, judgments of the General Court of 14 April 2011, Visa Europe and Visa International Service v Commission (T-461/07, EU:T:2011:181, paragraph 168); of 29 June 2012, E.ON Ruhrgas and E.ON v Commission (T-360/09, EU:T:2012:332, paragraph 87); and of 8 September 2016, Lundbeck v Commission (T-472/13, EU:T:2016:449, paragraph 101).

32 Judgment of 20 January 2016, Toshiba Corporation v Commission (C-373/14 P, EU:C:2016:26, paragraphs 33 and 34); see, also, judgments of the General Court of 28 June 2016, Portugal Telecom v Commission (T-208/13, EU:T:2016:368, paragraph 180); of 28 June 2016, Telefónica v Commission (T-216/13, EU:T:2016:369, paragraphs 218 and 227); and of 8 September 2016, Lundbeck v Commission (T-472/13, EU:T:2016:449, paragraph 144).

33 Judgment of the General Court of 14 April 2011, Visa Europe and Visa International Service v Commission (T-461/07, EU:T:2011:181, paragraph 169); see, also, judgments of the General Court of 8 September 2016, Lundbeck v Commission (T-472/13, EU:T:2016:449, paragraph 144), and of 12 December 2018, Servier and Others v Commission (T-691/14, EU:T:2018:922, paragraph 342 et seq.).

34 See above, points 15, 16, 18 and 19 of the present Opinion.

35 See in that regard, above, points 40 and 41 of the present Opinion.

36 Judgment of the General Court of 8 September 2016, Lundbeck v Commission (T-472/13, EU:T:2016:449, paragraph 159).

37 See, in that regard, paragraph 29 of the Commission's Guidelines on the application of Article 101 TFEU to technology transfer agreements (OJ 2014 C 89, p. 3).

38 Judgment of the General Court of 1 July 2010, AstraZeneca v Commission (T-321/05, EU:T:2010:266, paragraph 362).

39 Judgments of the General Court of 8 September 2016, Lundbeck v Commission (T-472/13, EU:T:2016:449, paragraph 121), and of 12 December 2018, Servier and Others v Commission (T-691/14, EU:T:2018:922, paragraph 359).

40 Judgments of 31 October 1974, Centrafarm and de Peijper (15/74, EU:C:1974:114, paragraph 9); of 18 February 1992, Commission v Italy (C-235/89, EU:C:1992:73, paragraph 17); of 27 October 1992, Generics and Harris Pharmaceuticals (C-191/90, EU:C:1992:407, paragraph 23); and of 5 December 1996, Merck and Beecham (C-267/95 and C-268/95, EU:C:1996:468, paragraphs 30 and 31); see, also, judgment of the General Court of 8 September 2016, Lundbeck v Commission (T-472/13, EU:T:2016:449, paragraph 117).

41 Judgment of 25 February 1986, Windsurfing International v Commission (193/83, EU:C:1986:75, paragraphs 89 and 92), and judgment of the General Court of 8 September 2016, Lundbeck v Commission (T-472/13, EU:T:2016:449, paragraph 119).

42 See, inter alia, judgment of the General Court of 29 June 2012, E.ON Ruhrgas and E.ON v Commission (T-360/09, EU:T:2012:332, paragraph 89).

43 The *'at risk'* launch of a generic medicinal product refers to entry on the market of such a medicinal product despite the fact that the manufacturer of the originator medicinal product maintains that such launch is prevented by patent rights which continue to cover that medicinal product.

44 See above, points 15, 18, 24 and 25 of the present Opinion. See, also, for illustration purposes, judgment of 12 September 2019, Bayer Pharma (C-688/17, EU:C:2019:722), and Opinion of Advocate General Pitruzzella in Bayer Pharma (C-688/17, EU:C:2019:324).

45 See above, points 10, 11, 24, 40, 41 and 42 of the present Opinion.

46 See paragraph 140 of the CAT judgment.

47 See above, point 69 of the present Opinion.

48 See, on that point also, judgment of the General Court of 8 September 2016, Lundbeck v Commission (T-472/13, EU:T:2016:449, paragraph 171).

49 See, to that effect, judgment of 6 December 2012, AstraZeneca v Commission (C-457/10 P, EU:C:2012:770, paragraph 108); see, also, judgment of the General Court of 8 December 2016, Lundbeck v Commission (T-472/13, EU:T:2016:449, paragraph 163).

50 Judgment of 23 January 2018 (C-179/16, EU:C:2018:25, paragraph 48 et seq.); see, also, Opinion of Advocate General Saugmandsgaard Øe in F. Hoffmann-La Roche and Others (C-179/16, EU:C:2017:714, point 82 et seq.).

51 Judgment of 23 January 2018, F. Hoffmann-La Roche and Others (C-179/16, EU:C:2018:25, paragraph 60); see, also, Opinion of Advocate General Saugmandsgaard Øe in F. Hoffmann-La Roche and Others (C-179/16, EU:C:2017:714, point 88).

52 See, to that effect, judgment of 23 January 2018, F. Hoffmann-La Roche and Others (C-179/16, EU:C:2018:25, paragraph 64); see, also, Opinion of Advocate General Saugmandsgaard Øe in F. Hoffmann-La Roche and Others (C-179/16, EU:C:2017:714, points 85 to 87 and 90).

53 Judgment of 7 February 2013, Slovenská sporiteľňa (C-68/12, EU:C:2013:71, paragraphs 14 and 19 to 21).

54 Opinion of Advocate General Saugmandsgaard Øe in F. Hoffmann-La Roche and Others (C-179/16, EU:C:2017:714, point 89 and footnote 47).

55 See, also, to that effect, judgment of the General Court of 12 December 2018, Servier and Others v Commission (T-691/14, EU:T:2018:922, paragraph 244).

56 See, also, to that effect, judgment of the General Court of 12 December 2018, Servier and Others v Commission (T-691/14, EU:T:2018:922, paragraph 244).
57 See above, point 72 of the present Opinion.
58 See above, points 10, 11, 24, 40, 41 and 42 of the present Opinion.
59 See above, points 59 and 60 of the present Opinion.
60 See, to that effect, judgment of 20 January 2016, Toshiba Corporation v Commission (C-373/14 P, EU:C:2016:26, paragraphs 33 and 34).
61 See paragraph 96 et seq. of the CAT judgment.
62 See above, points 15 and 18 of the present Opinion.
63 See judgments of the General Court of 14 April 2011, Visa Europe and Visa International Service v Commission (T-461/07, EU:T:2011:181, paragraphs 171 and 189), and of 12 December 2018, Servier and Others v Commission (T-691/14, EU:T:2018:922, paragraph 386); see, also, footnote 9 of the Commission's Guidelines on the applicability of Article 81 of the EC Treaty to horizontal cooperation agreements (OJ 2001 C 3, p. 2), paragraph 10 and footnote 6 of the Commission's Guidelines on the applicability of Article 101 TFEU to horizontal cooperation agreements (OJ 2011 C 11, p. 1), and paragraph 34 of the Commission's Guidelines on the application of Article 101 TFEU to technology transfer agreements (OJ 2014 C 89, p. 3).
64 See judgment of the General Court of 8 September 2016, Lundbeck v Commission (T-472/13, EU:T:2016:449, paragraph 163).
65 See above, points 71 to 74 of the present Opinion.
66 See above, point 74 of the present Opinion.
67 See, for the acknowledgement of such barriers, for example, judgment of the General Court of 29 June 2012, E.ON Ruhrgas and E.ON v Commission (T-360/09, EU:T:2012:332, paragraphs 89 and 94 to 103).
68 See paragraph 143 of the CAT judgment.
69 See above, points 15, 16, 18 and 19 of the present Opinion.
70 See, to that effect, judgment of 20 January 2016, Toshiba Corporation v Commission (C-373/14 P, EU:C:2016:26, paragraphs 33 and 34).
71 Judgments of 30 June 1966, LTM (56/65, EU:C:1966:38, p. 236); of 4 June 2009, T-Mobile Netherlands and Others (C-8/08, EU:C:2009:343, paragraph 28); and of 16 July 2015, ING Pensii (C-172/14, EU:C:2015:484, paragraphs 29 and 30); see, also, my Opinion in T-Mobile Netherlands and Others (C-8/08, EU:C:2009:110, point 42).
72 See, on that point, my Opinion in T-Mobile Netherlands and Others (C-8/08, EU:C:2009:110, point 42 and the case-law cited).
73 See judgment of 11 September 2014, CB v Commission (C-67/13 P, EU:C:2014:2204, paragraphs 49 to 51 and the case-law cited).
74 See judgment of 11 September 2014, CB v Commission (C-67/13 P, EU:C:2014:2204, paragraphs 53 and 54 and the case-law cited); see, also, my Opinion in T-Mobile Netherlands and Others (C-8/08, EU:C:2009:110, point 38 et seq. and the case-law cited), and Opinion of Advocate General Wahl in CB v Commission (C-67/13 P, EU:C:2014:1958, point 40 et seq. and the case-law cited).
75 See judgment of 26 November 2015, Maxima Latvija (C-345/14, EU:C:2015:784, paragraphs 18 to 23); see, also, to that effect, Opinion of Advocate General Bobek in Budapest Bank and Others (C-228/18, EU:C:2019:678, point 40 et seq.).
76 See judgment of 11 September 2014, CB v Commission (C-67/13 P, EU:C:2014:2204, paragraph 52 and the case-law cited).
77 Judgment of 20 November 2008 (C-209/07, EU:C:2008:643).
78 See above, point 102 of the present Opinion.
79 See above, points 47 and 48 of the present Opinion.
80 See above, points 51 and 52 of the present Opinion.
81 See regarding those agreements, respectively, above, points 15 et seq. and 18 et seq. of the present Opinion.
82 Although, in the present case, it is apparent from the file that the expected duration of the agreements (points 15 and 18 above) did not go beyond the unexpired period of validity of the patent in question (point 11 above), it is less clear whether the scope of the restrictions imposed by the agreements did not actually go beyond that of the patent at issue: thus, as the CAT states, in essence, in paragraph 245 of its judgment, the scope of the patent protects only against products which infringe it while, in the present case, it has not been properly determined whether the generic manufacturers' products infringed GSK's Anhydrate Patent; moreover, it is not clear from reading the terms of the agreements that they prohibited solely the marketing of paroxetine manufactured in accordance with processes which continued to be protected by that patent, since it appears, rather, that those agreements prohibited any marketing of paroxetine (other than that manufactured by GSK) (see points 16 and 19 above). It is nevertheless possible (subject to the findings of the referring court in that respect) that it may be apparent from the context and duration of the agreements that they concerned only paroxetine manufactured in accordance with the processes at issue with which GUK and Alpharma were preparing to enter the market (in particular because the duration of the agreements would not have enabled those manufacturers to find another process for manufacturing the API concerned or another supplier which manufactured that API with a process other than those used by them).
83 See, to that effect, judgments of 13 July 1966, Consten and Grundig v Commission (56/64 and 58/64, EU:C:1966:41, p. 346), and of 25 February 1986, Windsurfing International v Commission (193/83, EU:C:1986:75, paragraph 46).
84 Thus, in the judgments of 6 October 1982, Coditel and Others (262/81, EU:C:1982:334, paragraph 15), and of 4 October 2011, Football Association Premier League and Others (C-403/08 and C-429/08, EU:C:2011:631, paragraph 137), the Court limited itself to noting that, as far as concerns agreements to licence intellectual property rights, the mere fact that the right holder has

granted to a sole licensee the exclusive right to broadcast protected subject matter from a Member State, and consequently to prohibit its transmission by others, during a specified period, is not sufficient to justify the finding that such an agreement has an anticompetitive object. Similarly, in the judgment of 19 April 1988, Erauw-Jacquery (27/87, EU:C:1988:183, paragraph 10), the Court limited itself to stating that, in relation to plant variety rights, an operator who has developed varieties of basic seed which may be the subject matter of such rights must be allowed to protect himself against any improper handling of those varieties by prohibiting, inter alia, a licensee from selling and exporting basic seed, so that a provision to that effect falls outside the prohibition on anticompetitive agreements. Finally, in the judgment of 30 January 1985, BAT Cigaretten-Fabriken v Commission (35/83, EU:C:1985:32, paragraph 33), the Court did no more than state that, although it acknowledges that agreements are lawful and useful if they serve to delimit the respective spheres within which different trademarks may be used, those agreements are not however excluded from application of Article [101 TFEU] if they also aim to divide up the market or restrict competition in other ways.

85 Judgments of 18 February 1971, Sirena (40/70, EU:C:1971:18, paragraph 9), and of 8 June 1982, Nungesser and Eisele v Commission (258/78, EU:C:1982:211, paragraph 28).

86 Judgment of the General Court of 12 December 2018, Servier and Others v Commission (T-691/14, EU:T:2018:922, paragraph 241).

87 See, regarding those objectives, Opinion of Advocate General Pitruzzella in Bayer Pharma (C-688/17, EU:C:2019:324, points 31 and 55).

88 OJ 2004 L 157, p. 45.

89 See recital 12 of Directive 2004/48; see, also, on that point, judgment of the General Court of 12 December 2018, Servier and Others v Commission (T-691/14, EU:T:2018:922, paragraph 240).

90 See above, point 69 of the present Opinion.

91 See above, point 68 of the present Opinion.

92 Judgment of 7 February 2013, Slovenská sporiteľňa (C-68/12, EU:C:2013:71, paragraph 20).

93 See paragraphs 229 to 242 of the CAT judgment.

94 See in that regard, above, point 67 of the present Opinion.

95 Judgments of 16 December 1975, Suiker Unie and Others v Commission (40/73 to 48/73, 50/73, 54/73 to 56/73, 111/73, 113/73 and 114/73, EU:C:1975:174, paragraphs 173 and 174); of 8 July 1999, Commission v Anic Partecipazioni (C-49/92 P, EU:C:1999:356, paragraphs 116 and 117); of 8 July 1999, Hüls v Commission (C-199/92 P, EU:C:1999:358, paragraph 159); and of 4 June 2009, T-Mobile Netherlands and Others (C-8/08, EU:C:2009:343, paragraph 32).

96 See, to that effect, judgments of 16 December 1975, Suiker Unie and Others v Commission (40/73 to 48/73, 50/73, 54/73 to 56/73, 111/73, 113/73 and 114/73, EU:C:1975:174, paragraph 26); of 31 March 1993, Ahlström Osakeyhtiö and Others v Commission (C-89/85, C-104/85, C-114/85, C-116/85, C-117/85 and C-125/85 to C-129/85, EU:C:1993:120, paragraph 63); and of 4 June 2009, T-Mobile Netherlands and Others (C-8/08, EU:C:2009:343, paragraph 26).

97 See, in that regard, paragraph 242 of the CAT judgment.

98 See, in that regard, above, point 27 of the present Opinion.

99 In order to calculate the amount transferred, the referring court must take into account all the value transfers made between the parties, whether monetary or not, and therefore also, in particular, the added value to be realised by GUK and Alpharma when selling the paroxetine supplied by GSK or the waiver, by those manufacturers, of the cross-undertakings in damages previously given by GSK.

100 See above, point 66 of the present Opinion.

101 See above, points 66 et seq. and 110 et seq. of the present Opinion.

102 See above, point 77 et seq. of the present Opinion.

103 Judgment of 27 September 1988, Bayer and Maschinenfabrik Hennecke (65/86, EU:C:1988:448, paragraphs 14 to 16).

104 See, in that regard, judgment of 1 June 1999, Eco Swiss (C-126/97, EU:C:1999:269, paragraphs 37 to 39).

105 See above, points 47 and 48 of the present Opinion.

106 See paragraph 324 of the CAT judgment.

107 Judgments of 11 July 1985, Remia and Others v Commission (42/84, EU:C:1985:327, paragraphs 19 and 20); of 12 December 1995, Oude Luttikhuis and Others (C-399/93, EU:C:1995:434, paragraphs 12 to 15); and of 11 September 2014, MasterCard and Others v Commission (C-382/12 P, EU:C:2014:2201, paragraph 89).

108 See above, point 22 of the present Opinion.

109 See above, points 21 and 22 of the present Opinion.

110 See paragraphs 283, 292 and 325 of the CAT judgment.

111 See above, point 23 of the present Opinion.

112 See, to that effect, judgments of 13 July 1966, Consten and Grundig v Commission (56/64 and 58/64, EU:C:1966:41, pp. 342 and 343); of 28 January 1986, Pronuptia de Paris (161/84, EU:C:1986:41, paragraph 24); of 20 November 2008, Beef Industry Development Society and Barry Brothers (C-209/07, EU:C:2008:643, paragraph 21); and of 11 September 2014, MasterCard and Others v Commission (C-382/12 P, EU:C:2014:2201, paragraphs 93 and 180); see, also, judgment of 13 July 1966, Italy v Council and Commission (32/65, EU:C:1966:42, pp. 405 and 406) (*'to grant the benefit of Article [101(3)] to a given agreement presupposes that this agreement falls within the prohibition imposed by Article [101(1) TFEU]'*).

113 See, to that effect, judgment of 8 July 1999, Montecatini v Commission (C-235/92 P, EU:C:1999:362, paragraph 133), and judgments of the General Court of 18 September 2001, M6 and Others v Commission (T-112/99, EU:T:2001:215, paragraphs 72 to 74); of 23 October 2003, Van den Berg Foods v Commission (T-65/98, EU:T:2003:281, paragraph 107); of 30 June 2016, CB v Commission (T-491/07 RENV, not published, EU:T:2016:379, paragraph 67 et seq.);

and of 24 September 2019, HSBC Holdings and Others v Commission (T-105/17, EU:T:2019:675, paragraph 154).

114 See judgment of 13 October 2011, Pierre Fabre Dermo-Cosmétique (C-439/09, EU:C:2011:649, paragraph 39 et seq. and the case-law cited).

115 See judgments of 19 February 2002, Wouters and Others (C-309/99, EU:C:2002:98, paragraph 97 et seq.); of 18 July 2006, Meca-Medina and Majcen v Commission (C-519/04 P, EU:C:2006:492, paragraph 42 et seq.); of 18 July 2013, Consiglio Nazionale dei Geologi (C-136/12, EU:C:2013:489, paragraph 53 et seq.); and of 4 September 2014, API and Others (C-184/13 to C-187/13, C-194/13, C-195/13 and C-208/13, EU:C:2014:2147, paragraph 46 et seq.); see, also, previous judgments of 15 December 1994, DLG (C-250/92, EU:C:1994:413, paragraph 33 et seq.), and of 21 September 1999, Albany (C-67/96, EU:C:1999:430, paragraph 59 et seq.).

116 Judgment of 15 December 1994, DLG (C-250/92, EU:C:1994:413, paragraph 33 et seq.).

117 Judgment of 19 February 2002, Wouters and Others (C-309/99, EU:C:2002:98, paragraph 97 et seq.).

118 Judgment of 18 July 2006, Meca-Medina and Majcen v Commission (C-519/04 P, EU:C:2006:492, paragraph 42 et seq.).

119 It is on this point that the situation envisaged by the line of case-law at issue differs from that which may give rise to an acknowledgment that a restriction of competition is ancillary to an operation which is not in itself a restriction of competition; see in that regard, above, point 140 of the present Opinion.

120 See above, points 143 and 144 of the present Opinion.

121 See above, points 16 and 19 of the present Opinion.

122 See above, point 101 of the present Opinion.

123 See, inter alia, my Opinion in T-Mobile Netherlands and Others (C-8/08, EU:C:2009:110, point 48); Opinion of Advocate General Wahl in CB v Commission (C-67/13 P, EU:C:2014:1958, point 41); or Opinion of Advocate General Bobek in Budapest Bank and Others (C-228/18, EU:C:2019:678, point 46).

124 See my Opinion in T-Mobile Netherlands and Others (C-8/08, EU:C:2009:110, point 43), and Opinion of Advocate General Bobek in Budapest Bank and Others (C-228/18, EU:C:2019:678, point 27).

125 Judgment of 11 September 2014, CB v Commission (C-67/13 P, EU:C:2014:2204: paragraphs 49 to 51).

126 See Opinion of Advocate General Bobek in Budapest Bank and Others (C-228/18, EU:C:2019:678, points 41 to 49, specifically point 48) (emphasis in the original).

127 See, to that effect, judgments of 4 June 2009, T-Mobile Netherlands and Others (C-8/08, EU:C:2009:343, paragraph 31), and of 14 March 2013, Allianz Hungária Biztositó and Others (C-32/11, EU:C:2013:160, paragraph 38).

128 See my Opinion in T-Mobile Netherlands and Others (C-8/08, EU:C:2009:110, point 45).

129 See, to that effect, the case-law cited above, in point 102 of the present Opinion.

130 See, to that effect, judgment of 11 September 2014, CB v Commission (C-67/13 P, EU:C:2014:2204, paragraph 74 et seq.), and of 26 November 2015, Maxima Latvija (C-345/14, EU:C:2015:784, paragraphs 22 to 24); see, also, to that effect, Opinion of Advocate General Bobek in Budapest Bank and Others (C-228/18, EU:C:2019:678, points 50 and 78 et seq.).

131 See above, points 47, 48, 106 and 141 of the present Opinion.

132 See above, points 143 and 144 of the present Opinion. The findings made in relation to the present point are without prejudice to the question of the point in time at which these effects must be assessed and whether it is possible to take into account actual effects observed after the entry into the agreements or only effects foreseeable at the time when they were entered into. In any event, in the present case the positive effects at issue were in all cases foreseeable at the time when the agreements were entered into, due to the terms of the agreements.

133 See above, points 47 and 48 of the present Opinion, and the paragraphs of the CAT judgment cited therein.

134 See, for examples of cooperation between undertakings having such characteristics, the case-law cited in point 164 of the present Opinion.

135 See above, points 17 and 20 of the present Opinion.

136 See, to that effect, paragraph 213 of the CAT judgment.

137 Judgments of 4 June 2009, T-Mobile Netherlands and Others (C-8/08, EU:C:2009:343, paragraphs 38 and 39); of 6 October 2009, GlaxoSmithKline Services and Others v Commission (C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, EU:C:2009:610, paragraph 63); and of 19 March 2015, Dole Food and Dole Fresh Fruit Europe v Commission (C-286/13 P, EU:C:2015:184, paragraph 125); see, also, my Opinion in T-Mobile Netherlands and Others (C-8/08, EU:C:2009:110, points 58 to 60).

138 See above, points 116 to 118 of the present Opinion.

139 See above, points 124 to 128 of the present Opinion.

140 See above, points 15, 16, 18 and 19 of the present Opinion.

141 See above, point 128 of the present Opinion.

142 See above, points 22 and 27 of the present Opinion.

143 See above, points 99 and 100 of the present Opinion and the case-law cited therein.

144 See the arguments of Advocate General Bobek in his Opinion in Budapest Bank and Others (C-228/18, EU:C:2019:678, point 18 et seq., especially point 29).

145 Judgments of 30 June 1966, LTM (56/65, EU:C:1966:38, p. 249); of 20 November 2008, Beef Industry Development Society and Barry Brothers (C-209/07, EU:C:2008:643, paragraph 15); and of 14 March 2013, Allianz Hungária Biztosító and Others (C-32/11, EU:C:2013:160, paragraph 34).

146 Judgments of 30 June 1966, LTM (56/65, EU:C:1966:38, p. 250); of 6 April 2006, General Motors v Commission (C-551/03 P, EU:C:2006:229, paragraph 72); and of 11 September 2014, MasterCard and Others v Commission (C-382/12 P, EU:C:2014:2201, paragraph 161).

147 Judgments of 11 December 1980, L'Oréal (31/80, EU:C:1980:289, paragraph 19), of 23 November 2006, Asnef-Equifax and Administración del Estado (C-238/05, EU:C:2006:734, paragraph 49), and of 11 September 2014, MasterCard and Others v Commission (C-382/12 P, EU:C:2014:2201, paragraph 165); see, also, to that effect, judgment of 28 February 1991, Delimitis (C-234/89, EU:C:1991:91, paragraphs 19 to 22).
148 Judgment of 11 September 2014, MasterCard and Others v Commission (C-382/12 P, EU:C:2014:2201, paragraph 166) (emphasis added).
149 See above, points 77 to 82 of the present Opinion.
150 See above, points 83 to 88 of the present Opinion.
151 See above, point 77 of the present Opinion.
152 See above, points 67 to 71 of the present Opinion.
153 See above, points 73 to 75 of the present Opinion.
154 See above, points 75 to 77 of the present Opinion.
155 See above, points 83 to 88 of the present Opinion.
156 See judgments of 17 November 1987, British American Tobacco and Reynolds Industries v Commission (142/84 and 156/84, EU:C:1987:490, paragraph 54); of 28 May 1998, Deere v Commission (C-7/95 P, EU:C:1998:256, paragraph 77); and of 23 November 2006, Asnef-Equifax and Administración del Estado (C-238/05, EU:C:2006:734, paragraph 50).
157 See above, point 76 of the present Opinion.
158 See above, points 47, 48, 106 and 141 of the present Opinion.
159 See above, points 122 to 127 of the present Opinion.
160 See above, points 67 to 70 and 77 to 82 of the present Opinion.
161 See above, point 187 of the present Opinion.
162 Judgments of 9 July 1969, Völk (5/69, EU:C:1969:35, paragraph 7); of 21 January 1999, Bagnasco and Others (C-215/96 and C-216/96, EU:C:1999:12, paragraph 34); and of 13 December 2012, Expedia (C-226/11, EU:C:2012:795, paragraph 16).
163 See above, point 188 of the present Opinion.
164 See judgments of 12 December 1967, Brasserie de Haecht (23/67, EU:C:1967:54, p. 416); of 11 December 1980, L'Oréal (31/80, EU:C:1980:289, paragraph 19); and of 28 February 1991, Delimitis (C-234/89, EU:C:1991:91, paragraph 14); and order of 28 September 2006, Unilever Bestfoods v Commission (C-552/03 P, EU:C:2006:607, paragraph 53).
165 On that point, see above, points 27, 40, 41, 72, 76 and 85 of the present Opinion.
166 See above, points 10 to 12 of the present Opinion.
167 See above, points 28 and 29 of the present Opinion.
168 Paragraph 4.97 of the CMA decision.
169 See above, point 9 of the present Opinion.
170 See paragraphs 395, 402, 407 and 409 of the CAT judgment.
171 See paragraphs 395 to 409 of the CAT judgment.
172 Judgments of 14 February 1978, United Brands and United Brands Continentaal v Commission (27/76, EU:C:1978:22, paragraph 65), and of 13 February 1979, Hoffmann-La Roche v Commission (85/76, EU:C:1979:36, paragraph 38).
173 Judgments of 13 February 1979, Hoffmann-La Roche v Commission (85/76, EU:C:1979:36, paragraph 28), and of 23 January 2018, F. Hoffmann-La Roche and Others (C-179/16, EU:C:2018:25, paragraph 51).
174 See judgments of 9 November 1983, Nederlandsche Banden-Industrie-Michelin v Commission (322/81, EU:C:1983:313, paragraph 37); of 1 July 2008, MOTOE (C-49/07, EU:C:2008:376, paragraph 32); and of 23 January 2018, F. Hoffmann-La Roche and Others (C-179/16, EU:C:2018:25, paragraph 51); and judgments of the General Court of 1 July 2010, AstraZeneca v Commission (T-321/05, EU:T:2010:266, paragraph 30), and of 29 March 2012, Telefónica and Telefónica de España v Commission (T-336/07, EU:T:2012:172, paragraph 111). See, also, to that effect, judgments of 21 February 1973, Europemballage and Continental Can v Commission (6/72, EU:C:1973:22, paragraph 32), and of 14 November 1996, Tetra Pak v Commission (C-333/94 P, EU:C:1996:436, paragraph 13).
175 OJ 1997 C 372, p. 5.
176 See, to that effect, judgment of 6 December 2012, AstraZeneca v Commission (C-457/10 P, EU:C:2012:770, paragraph 38 et seq.).
177 See judgments of 1 July 2008, MOTOE (C-49/07, EU:C:2008:376, paragraph 30), and of 14 March 2013, Allianz Hungária Biztosító and Others (C-32/11, EU:C:2013:160, paragraph 29).
178 See above, points 67 to 70, 77 and 94 of the present Opinion.
179 See above, points 77 to 82 of the present Opinion.
180 See, to that effect, judgments of 7 February 2013, Slovenská sporitel'ňa (C-68/12, EU:C:2013:71, paragraphs 14 and 19 to 21), and of 23 January 2018, F. Hoffmann-La Roche and Others (C-179/16, EU:C:2018:25, paragraph 48 et seq.); see, also, Opinion of Advocate General Saugmandsgaard Øe in F. Hoffmann- La Roche and Others (C-179/16, EU:C:2017:714, point 85 et seq.).
181 OJ 1997 C 372, p. 5.
182 See above, points 219 to 221 of the present Opinion.
183 See judgment of 21 February 1973, Europemballage and Continental Can v Commission (6/72, EU:C:1973:22, paragraph 33); as well as judgments of the General Cour of 7 July 1999, British Steel v Commission (T-89/96, EU:T:1999:136, paragraph 84); of 28 April 2010, Amann & Söhne and Cousin Filterie v Commission (T-446/05, EU:T:2010:165, paragraph 57); and of 29 March 2012, Telefónica and Telefónica de España v Commission (T-336/07, EU:T:2012:172, paragraph 130); see, also, paragraph 20 et seq. of the Commission Notice on the definition of the relevant market for the purposes of Community competition law (OJ 1997 C 372, p. 5).
184 Judgment of the General Court of 30 September 2003, Atlantic Container Line and Others v Commission (T-191/98 and T-212/98 to T-214/98, EU:T:2003:245, paragraph 834).
185 Judgment of the General Court of 29 March 2012, Telefónica and Telefónica de España v Commission (T-336/07, EU:T:2012:172, paragraph 123).

186 On the inclusion of IVAX for the purposes of applying the prohibition of abuse of a dominant position, see above, points 28, 29 and 49 of the present Opinion.
187 See above, point 220 of the present Opinion.
188 See above, points 10, 11, 27, 40, 41, 42, 72, 85 and 119 of the present Opinion.
189 See above, points 95, 96 and 142 of the present Opinion.
190 Judgment 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); see, also, judgments of 13 February 1979, Hoffmann-La Roche v Commission (85/76, EU:C:1979:36, paragraph 116); of 11 April 1989, Saeed Flugreisen and Silver Line Reisebüro (66/86, EU:C:1989:140, paragraph 37); and judgment of the General Court of 10 July 1990, Tetra Pak v Commission (T-51/89, EU:T:1990:41, paragraphs 21, 25 and 30).
191 Judgment of 13 February 1979, Hoffmann-La Roche v Commission (85/76, EU:C:1979:36, paragraph 116).
192 Judgment of 21 February 1973, Europemballage and Continental Can v Commission (6/72, EU:C:1973:22, paragraph 25).
193 Judgment 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 34).
194 Judgments of 9 November 1983, Nederlandsche Banden-Industrie-Michelin v Commission (322/81, EU:C:1983:313, paragraph 57); 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 37); and of 27 March 2012, Post Danmark (C-209/10, EU:C:2012:172, paragraph 21).
195 Judgments of 17 February 2011, TeliaSonera Sverige (C-52/09, EU:C:2011:83, paragraph 24), and of 27 March 2012, Post Danmark (C-209/10, EU:C:2012:172, paragraph 21).
196 Judgments of 9 November 1983, Nederlandsche Banden-Industrie-Michelin v Commission (322/81, EU:C:1993:313, paragraph 57); 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 37); and of 27 March 2012, Post Danmark (C-209/10, EU:C:2012:172, paragraph 23).
197 Judgment of 14 November 1996, Tetra Pak v Commission (C-333/94 P, EU:C:1996:436, paragraph 24).
198 Judgments of 13 February 1979, Hoffmann-La Roche v Commission (85/76, EU:C:1979:36, paragraph 91); of 3 July 1991, AKZO v Commission (C-62/86, EU:C:1991:286, paragraph 69); and of 6 December 2012, AstraZeneca v Commission (C-457/10 P, EU:C:2012:770, paragraph 74).
199 Judgments of 3 July 1991, AKZO v Commission (C-62/86, EU:C:1991:286, paragraph 70); of 6 December 2012, AstraZeneca v Commission (C-457/10 P, EU:C:2012:770, paragraph 75); and of 6 September 2017, Intel v Commission (C-413/14 P, EU:C:2017:632, paragraph 136).
200 See, to that effect, judgments of 21 February 1973, Europemballage and Continental Can v Commission (6/72, EU:C:1973:22, paragraphs 24 to 26 and 29), and of 13 February 1979, Hoffmann-La Roche v Commission (85/76, EU:C:1979:36, paragraphs 120 and 125); and also judgments of the General Court of 10 July 1990, Tetra Pak v Commission (T-51/89, EU:T:1990:41, paragraph 24), and of 23 October 2003, Van den Bergh Foods v Commission (T-65/98, EU:T:2003:281, paragraphs 159 and 160).
201 See above, point 141 of the present Opinion.
202 See above, points 28, 29 and 49 et seq. of the present Opinion.
203 See above, point 14 of the present Opinion.
204 See judgment of 14 February 1978, United Brands and United Brands Continentaal v Commission (27/76, EU:C:1978:22, paragraph 189).
205 Judgments of 5 October 1988, Volvo (238/87, EU:C:1988:477, paragraphs 8 and 9); of 29 April 2004, IMS Health (C-418/01, EU:C:2004:257, paragraphs 34 and 35); and of 16 July 2015, Huawei Technologies (C-170/13, EU:C:2015:477, paragraphs 46 and 47).
206 See above, point 251 of the present Opinion.
207 See, to that effect, also, the case-law cited above, in points 245 and 249 of the present Opinion.
208 See above, points 208 and 209 of the present Opinion.
209 See above, points 28 and 49 of the present Opinion.
210 See on those points, already, above, points 207 to 210 of the present Opinion.
211 See, to that effect, judgments of 19 April 2012, Tomra Systems and Others v Commission (C-549/10 P, EU C:2012:221, paragraphs 19 and 20), and of 6 September 2017, Intel v Commission (C-413/14 P, EU:C:2017:632, paragraphs 50 to 57).
212 See above, point 243 of the present Opinion.
213 See above, points 143 and 144 of the present Opinion.
214 See above, point 23 of the present Opinion.
215 See above, point 250 of the present Opinion.
216 See, to that effect, judgment of 19 April 2012, Tomra Systems and Others v Commission (C-549/10 P, EU:C:2012:221, paragraphs 19 to 21).
217 See judgment of 6 September 2017, Intel v Commission (C-413/14 P, EU:C:2017:632, paragraphs 138 to 141).
218 Judgment of 27 March 2012, Post Danmark (C-209/10, EU:C:2012:172, paragraphs 40 and 41 and the case-law cited); see, also, judgment of 6 September 2017, Intel v Commission (C-413/14 P, EU:C:2017:632, paragraph 140).
219 Judgment of 27 March 2012, Post Danmark (C-209/10, EU:C:2012:172, paragraph 42); see, also, point 28 et seq. of the Communication from the Commission — Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (OJ 2009 C 45, p. 7).

220 See above, points 169 and 170 of the present Opinion.

221 Judgment of 21 February 1973, Europemballage and Continental Can v Commission (6/72, EU:C:1973:22, paragraph 26); of 17 February 2011, TeliaSonera Sverige (C-52/09, EU:C:2011:83, paragraph 24); and of 27 March 2012, Post Danmark (C-209/10, EU:C:2012:172, paragraph 20).

222 See above, points 177 and 178 of the present Opinion.

223 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).