Reports of Cases

ORDER OF THE PRESIDENT OF THE GENERAL COURT

11 July 2018 *

(Application for interim measures — Medicinal products for human use — Directive 2001/83/EC — Suspension of the marketing authorisation for contrast agents containing gadolinium for human use — Application for suspension of operation of a measure — Lack of urgency)

In Case T-783/17 R,

GE Healthcare A/S, established in Oslo (Norway), represented by D. Scannell, Barrister, G. Castle and S. Oryszczuk, Solicitors,

applicant,

v

European Commission, represented by K. Mifsud-Bonnici and A. Sipos, acting as Agents,

defendant,

APPLICATION pursuant to Articles 278 and 279 TFEU for the suspension of operation of Commission Implementing Decision C(2017) 7941 final of 23 November 2017, concerning, in the framework of Article 31 of Directive 2001/83/EC of the Parliament and of the Council, the marketing authorisations for gadolinimum-containing contrast agents for human use which contain one or more of the active substances 'gadobenic acid, gadobutrol, gadodiamide, gadopentetic acid, gadoteric acid, gadoteridol, gadoversetamide and gadoxetic acid',

THE PRESIDENT OF THE GENERAL COURT

makes the following

Order [1]

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Law

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* Language of the case: English.

1 Only the paragraphs of the present order which the Court considers it appropriate to publish are reproduced here.

Urgency

22 In order to determine whether the interim measures sought are urgent, it should be noted that the purpose of the procedure for interim relief is to guarantee the full effectiveness of the future final decision, in order to prevent a lacuna in the legal protection afforded by the EU judicature. To attain that objective, urgency must be assessed in the light of the need for an interlocutory order to avoid serious and irreparable harm to the party requesting the interim measure. That party must demonstrate that it cannot await the outcome of the main proceedings without suffering serious and irreparable damage (see order of 14 January 2016, *AGC Glass Europe and Others* v *Commission*, C-517/15 P-R, EU:C:2016:21, paragraph 27 and the case-law cited).

23 Furthermore, according to well-established case-law, there is urgency only if the serious and irreparable harm feared by the party requesting the interim measures is so imminent that its occurrence can be foreseen with a sufficient degree of probability. That party remains, in any event, required to prove the facts that form the basis of its claim that such harm is likely, it being clear that purely hypothetical harm, based on future and uncertain events, cannot justify the granting of interim measures (see order of 16 February 2017, *Gollnisch* v *Parliament*, T-624/16 R, not published, EU:T:2017:94, paragraph 25 and the case-law cited).

24 In addition, under Article 156(4), second sentence, of the Rules of Procedure, applications for interim measures 'shall contain all the evidence and offers of evidence available to justify the grant of interim measures'.

25 Thus, an application for interim measures must be sufficient in itself to enable the defendant to prepare its observations and the judge hearing the application to rule on it, as necessary, without any other supporting information, since the essential elements of fact and law on which the application is based must be found in the actual text of that application (see order of 6 September 2016, *Inclusion Alliance for Europe* v *Commission*, C-378/16 P-R, not published, EU:C:2016:668, paragraph 17 and the case-law cited).

26 It is also settled case-law that, to determine whether all the conditions referred to in paragraphs 22, 23 and 25 above are fulfilled, the judge hearing the application for interim measures must have specific and precise information, supported by detailed, certified documentary evidence, which shows the situation in which the party seeking the interim measures finds itself and enables the probable consequences, should the measures sought not be granted, to be assessed. It follows that that party, in particular when it relies on the occurrence of financial harm, must produce, with supporting evidence, an accurate overall picture of its financial situation (see order of 29 February 2016, *ICA Laboratories and Others* v *Commission*, T-732/15 R, not published, EU:T:2016:129, paragraph 39 and the case-law cited).

27 Lastly, although the application for interim measures can be supplemented, on specific points, by references to documents annexed thereto, those documents cannot compensate for the failure to set out the essential elements in that application. It is not the task of the judge hearing the application for interim measures to seek, in place of the party concerned, those matters contained in the annexes to the application for interim measures, in the main application or in the annexes to the latter which might support the application for interim measures. Imposing such an obligation on the judge hearing the application would, moreover, render redundant Article 156(5) of the Rules of Procedure, which provides that the application for interim measures must be made by a separate document (see, to that effect, order of 20 June 2014, *Wilders* v *Parliament and Others*, T-410/14 R, not published, EU:T:2014:564, paragraph 16 and the case-law cited).

28 It is in the light of those criteria that it must be examined whether the applicant has succeeded in demonstrating urgency.

The serious nature of the harm

29 In order to demonstrate the seriousness of the alleged harm, the applicant puts forward, in essence, first, the inevitable loss of its market share currently held on the GdCA market in the Member States concerned and, secondly, damage to its reputation.

30 In the first place, so far as concerns the seriousness of the harm due to the loss of market share, the applicant states that, in 2016, its shares of the GdCA and X-ray contrast agents markets were approximately 8.2% and 36.8% respectively. The applicant alleges that GE Healthcare's competitors are readying themselves to inherit a market that they could not have conquered in the absence of the contested decision.

31 In that regard, as the applicant notes, the loss allegedly sustained is purely financial. It is settled case-law that the market share held by a company indicates only the percentage of all the products present on the market in question which were sold by that company to customers over the course of a specified reference period. Consequently, the loss of that market share consists in the loss of the profits liable to be realised in the future on sales of the product in question. A market share can thus clearly be represented in financial terms, as the holder of that market share can benefit from it only in so far as it generates profit for him (see order of 30 April 2010, *Xeda International* v *Commission*, T-71/10 R, not published, EU:T:2010:173, paragraph 41 and the case-law cited).

32 Regarding the seriousness of the financial loss relied upon, it is well-established case-law that the interim measure sought will be justified only if it appears that, without such a measure, the applicant would be in a position that could imperil its existence before final judgment is given in the main action (see order of 30 April 2010, *Xeda International* v *Commission*, T-71/10 R, not published, EU:T:2010:173, paragraph 42 and the case-law cited).

33 In the present case, the applicant states expressly that it does not maintain that the harm that it may suffer could imperil its existence or that of any related company. It does claim, however, that the harm would be serious in view of the irremediable nature of the loss of its share of the GdCA market in each of the Member States and countries within the European Economic Area (EEA) where Omniscan has a marketing authorisation, owing to the structural and legal barriers to market re-entry for its product.

34 While, in the case-law, account has also been taken of the fact that, if the measure sought were not granted, the applicant's market share would be irremediably affected, it must be pointed out that this situation can be placed on an equal footing with that of the risk of disappearance from the market and justify adoption of the interim measure sought only if the irremediable effect on market share is also of a serious nature. It is therefore not sufficient that a market share may be irremediably lost by an undertaking; rather, it is necessary for that market share to be sufficiently large in the light of, in particular, the size of that undertaking, regard being had to the characteristics of the group to which it belongs through its shareholders (see order of 30 April 2010, *Xeda International* v *Commission*, T-71/10 R, not published, EU:T:2010:173, paragraph 43 and the case-law cited).

35 In the present case, although the applicant provides some information concerning the financial significance of its activity relating to Omniscan — the applicant states that, for the year 2016, the turnover generated by the sales of Omniscan amounted to 80 million United States dollars (USD) and that the total turnover for Omniscan and its related markets amounted to USD 968 million, yielding a gross margin of USD 662 million — it does not, however, indicate the scale of that activity in the light of its overall turnover. Nor has any specific information been provided as to the size of its undertaking or the group's structure and characteristics. In its observations on the present application, the Commission states that, for the year 2016, the EU revenue attributed to Omniscan was less than 0.1% of the revenue of the GE group, which was close to USD 124 billion.

36 This lack of information is, moreover, recognised and accepted by the applicant, who takes the view that little purpose would be served by producing detailed accounting evidence setting out the turnover and profitability of the undertakings related to it since it is accepted that such evidence would reveal healthy figures under each head.

37 Nevertheless, the fact remains that, in accordance with the case-law cited in paragraphs 25 to 27 above, it is for the applicant to put the defendant and the judge hearing the application for interim measures in a position to assess the seriousness of the harm, by providing specific and precise information. That is not the case here.

38 Thus the applicant has failed to provide information of such a nature as to allow an assessment of the seriousness of the harm allegedly suffered on account of the loss of the market share that it currently holds in the GdCA markets in the Member States concerned.

39 As the applicant submits in its observations of 16 January 2018, it should however be noted that it has been accepted –– in the order of 28 April 2009, *United Phosphorus* v *Commission* (T-95/09 R, not published, EU:T:2009:124, paragraph 69) –– that, in the evaluation of the seriousness of the harm, the judge hearing the application for interim relief cannot confine himself to having recourse, in a mechanical and rigid manner, solely to the relevant turnover, but must also examine the circumstances particular to each case and bring them into relation, when taking his decision, with the harm occasioned in terms of turnover.

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49 In that context, it should be noted that, whilst the applicant states, in its observations of 16 January 2018, that, since the lodging of the application for interim measures, the former Yugoslav Republic of Macedonia, Malaysia and the United Arab Emirates have adopted measures suspending authorisations for Omniscan in their jurisdictions, it has, however, failed to produce any evidence in support of its assertion that those measures have been adopted 'to reflect the Commission's decision'. Furthermore, even if that allegation were to prove to be founded, that would not call into question the fact that those decisions were adopted by independent authorities (see paragraph 46 above) and that it falls to the applicant potentially to bring the appropriate actions in those legal systems in order to challenge the lawfulness of those decisions.

50 As a result, the consequences envisaged by the applicant as to its activity related to Omniscan outside the European Union do not constitute particular circumstances from which the seriousness of the harm may be inferred.

51 Secondly, according to the applicant, the suspension of the Omniscan MA will mean that GE Healthcare will no longer be able to offer a full range of contrast agent products, thus leading a substantial number of hospitals and other healthcare service providers to turn to other suppliers for GE Healthcare's non-GdCA products. In that regard, the applicant adds that it would be excluded from public tendering procedures run by hospitals and other public institutions for the provision of all contrast agents as a large number of those procedures require that the tenderer provide a full range of contrast agent products. Furthermore, the applicant stresses the fact that, as it is currently a party to a large number of multi-year contracts concluded with major groups providing diagnostic services in a large number of Member States and third countries and relating generally to the supply of full ranges of imaging products, it would have to procure supplies, at additional expense to itself and for the healthcare providers concerned, from its competitors to replace its own GdCAs in order to honour those contracts.

52 First of all, it should be noted that, contrary to the case-law cited in paragraphs 23 to 26 above, the applicant has failed to provide the President of the General Court with the essential elements enabling him to examine the seriousness of the alleged effects so far as concerns the contractual obligations to

which the applicant is subject and the costs resulting from the need to replace Omniscan in that context. In that connection, the applicant merely makes general assertions without stating, for example, the size of the contracts at issue in the light of its activity as a whole, the estimated amount of the costs attributable to the substitution of the banned product or the penalty incurred on account of the possible failure to perform those contracts.

53 Next, although the lack of information concerning the substitution costs generated by the contractual obligations referred to by the applicant does not allow the increase in the alleged harm to be assessed, the existence of the contracts at issue nevertheless suggests that, to a certain extent, the applicant has a means of reducing the scale of that harm and preserving the market share that it fears it will lose on the markets for similar products in the Member States concerned and outside the European Union. In that respect, it is worth noting that the contracts in question are, as the applicant points out, multi-year contracts and, consequently, seem to guarantee it a certain degree of stability as to its competitive position with its customers, save for the possibility of the other parties to those contracts incurring liability as a result of a breach of their obligations under the contracts. In that context, it may be observed that, in the light of the average duration of proceedings before the General Court, the judgment on the substance in the present case will probably be delivered within two years (see, to that effect, order of 21 July 2017, *Polskie Górnictwo Naftowe i Gazownictwo* v *Commission*, T-130/17 R, EU:T:2017:541, paragraph 47). Consequently, depending on the term of those contracts, the applicant may potentially know where it stands on the lawfulness of the contested decision before their expiry.

54 Lastly, it is apparent from the material in the case file that, since 2017, the applicant has held an MA within the European Union for another GdCA, Clariscan, the marketing of which is unaffected by the contested decision. In that connection, the applicant states that Clariscan is not a precise substitute for Omniscan owing to the fact that (i) that generic medicine is available only on 13 EU markets, (ii) cannot rely on Omniscan's improved safety profile and (iii) does not benefit from Omniscan's specialised indication for myocardial perfusion imaging. The Commission contends, on the other hand, that (i) neither the PRAC nor the CHMP was able to confirm or agree that Omniscan had an improved safety profile and (ii) the EMA's scientific committees considered that, as it is authorised for imaging the entire human body, Clariscan can be used in myocardial perfusion imaging. Consequently, while it can be reasonably accepted, at this stage, that Clariscan will probably not be able to replace Omniscan completely, that generic medicine will nevertheless reduce the impact of the disadvantages feared by the applicant by allowing it, to some extent, to participate in tendering processes that require a full range of contrast agent products.

55 It must therefore be stated that the present case does not present any particular circumstance which, assessed in the light of the incomplete figures provided by the applicant (see paragraphs 35 to 38 above), would lead the President of the General Court to conclude that the alleged harm is serious on account of the loss of the applicant's market share on the GdCA market.

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On those grounds,

THE PRESIDENT OF THE GENERAL COURT

hereby orders:

1. The application for interim measures is dismissed.

2. The costs are reserved.

Luxembourg, 11 July 2018.

E. Coulon
Registrar

M. Jaeger
President