Review, Risk, Legality and Damages

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Case C-221/10 P, Artegodan GmbH v European Commission and Federal Republic of Germany[1]

I. Introduction

This case represents the latest stage in a legal saga that spans a decade. Some background is therefore necessary to understand the legal argumentation in the instant case.

Artegodan is the holder of a marketing authorization for Tenuate Retard, a medicinal product, which contains amfepramone, an amphetamine-like anorectic substance. There was however a re-evaluation of amfepramone at the request of a Member State, and this led the Commission to adopt the contested decision on the basis of Article 15a of Directive 75/319.[2]

This Directive established a system of mutual recognition, whereby an authorization granted in one Member State had to be recognized in other Member States. There were however not surprisingly qualifications to this regime, and it was open to a Member State pursuant to Article 15a to press for the withdrawal of the authorization on the ground of public health concerns. The schema was for the Member State to refer the matter to the Committee for Proprietary Medicinal Products, CPMP, although it was open to the Member State in cases of urgency to suspend authorization of the product in its territory pending this final decision. The CPMP issued a reasoned opinion which would be forwarded by the European Agency for the Evaluation of Medicinal Products to the Member States, the Commission and the person responsible for placing the medicinal product on the market, with a report describing the assessment of the medicinal product and stating the reasons for its conclusions.[3] It was then for the Commission, within 30 days of receipt of the CPMP's opinion, to prepare a draft decision. Where exceptionally the draft decision was not in accordance with the opinion of the EMA it was incumbent on the Commission to provide a detailed explanation of the reasons for the differences.[4]

The Commission decision ordered the Member States to withdraw the national marketing authorizations for amfepramone, in reliance on scientific conclusions attached to the CPMP's final opinion in August 1999. This was challenged by Artegodan, which argued, inter alia, that the Commission lacked competence and that the decision infringed Directive 65/65.[5] The GC annulled the contested decision in 2002 on the ground that the Commission lacked competence, and held moreover that even if the Commission had competence the decision infringed Article 11 of Directive 65/65.[6] The GC's decision was upheld on appeal. The ECJ held that the Commission lacked competence to adopt the contested decision, but did not rule on the other arguments concerning Directive 65/65.[7]

Artegodan then sought damages for the losses it had suffered in the three year period that the product had been withdrawn from the market while the legal proceedings contesting the legality of the withdrawal were being heard. The Commission rejected the claim in 2004, arguing that the conditions for non-contractual liability were not met, because there was no sufficiently serious breach of EU law. Artegodan then began proceedings in 2005 seeking damages, but the GC dismissed the action under what is now Article 340 TFEU, on the ground that the applicant had not established a sufficiently serious breach of EU law.[8]

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1 Judgment 19 April 2012, Third Chamber, n.y.r.

2 Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products [1975] OJ L147/13.

3 Directive 75/319/EEC, Art. 13.

4 Directive 75/319/EEC, Art. 14.

5 Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products [1965-66] OJ English Special Edition p. 24.

6 Joined Cases T74/00, T76/00, T83/00 to T85/00, T132/00, T137/00 and T141/00, *Artegodan and Others v Commission* [2002] ECR II-4945.

7 Case C-39/03 P, *Commission v Artegodan and Others* [2003] ECR I-7885.

8 Case T-429/05, *Artegodan v Commission* [2010] ECR II-491.

It held that the Commission's lack of competence and infringement of Article 11 of Directive 65/65 were accepted by the GC in 2002 and the ECJ in 2003 and therefore should be regarded as established. The fact that the ECJ in 2003 did not consider it necessary to examine the plea alleging breach of Article 11 of Directive 65/65 by the GC in 2002 was said to be irrelevant. The GC nonetheless concluded that the conditions for non-contractual liability were not met.

It held that the rules contained in Directive 75/319 delimiting the areas of competence of the Commission and the Member States were not intended to confer rights on individuals, but were rather intended to organize the division of powers between the national authorities and the Commission, as regards the procedure for the mutual recognition of national marketing authorizations.

It held moreover that the infringement of Article 11 of Directive 65/65 did not constitute a sufficiently serious breach for the purposes of damages liability. The GC decided that Article 11 did not confer any meaningful discretion on the Commission in the application of the substantive criteria for suspension or withdrawal of a marketing authorization.[9] It nonetheless concluded that infringement of Article 11 did not suffice to show a sufficiently serious breach for the EU to incur liability. This was because the EU courts had to take into account the legal and factual complexity of the situation to be regulated, notwithstanding the fact that Article 11 accorded priority to the protection of public health. Thus while the GC was clear that the error regarding Article 11 warranted annulment of the withdrawal of the authorization, it was necessary in adjudicating damages liability 'to take into account the particular difficulties to which the interpretation and application of that article give rise in this case'.[10] The GC continued in the following vein.[11]

> Having regard to the lack of precision of Article 11 of Directive 65/65, the difficulties related to the systematic interpretation of the conditions for withdrawal or suspension of a marketing authorization laid down by that article in the light of the whole Community system for the prior authorization of medicinal products (Artegodan v Commission paragraphs 187 to 195) could reasonably explain, in the absence of any similar precedent, the error of law committed by the Commission in accepting the legal relevance of the new scientific criterion applied by the CPMP, even though it was not supported by any new scientific data or information.

The GC reinforced this conclusion by adverting to the nature of the decision-making in this area. The practical reality was that the CPMP made the assessment, this was accepted by the EMA and the Commission then made the formal decision in the light of this recommendation. If the Commission were to disagree with the recommendation it had to provide detailed reasons. The GC felt that it would in any event have been very difficult for the Commission to acquaint itself with the scientific reasoning that informed the CPMP's conclusions. This reinforced the legal and factual complexity in the instant case and meant that the Commission's error did not amount to a sufficiently serious breach for the purpose of damages liability.[12]

II. The CJEU

1. Division of competence, protection of individual rights and sufficiently serious breach

Artegodan not surprisingly contested the finding of the GC that the rules on the division of competence between the Commission and the Member States resulting from Directive 75/319 were not of such a kind as to cause the EU to incur non-contractual liability on the ground that they were not intended to confer rights on individuals. It contended that such rules did confer rights on individuals in circumstances where exercise of the relevant power could lead, as in this case, to restrictive measures being taken against undertakings.

The CJEU upheld Artegodan's argument, although its judgment is nonetheless unclear in certain respects. The Court held that failure to observe the division of powers between the EU institutions, where the aim is to ensure that the balance between the institutions provided in the Treaties is maintained, and not to protect individuals, does not suffice per se to render the EU liable towards the traders concerned.

9 Article 11 of Directive 65/65 provides that: 'The competent authorities of the Member States shall suspend or revoke [a marketing authorization] where that product proves to be harmful in the normal conditions of use, or where its therapeutic efficacy is lacking, or where its qualitative and quantitative composition is not as declared. Therapeutic efficacy is lacking when it is established that therapeutic results cannot be obtained with the medicinal product.'

10 Case 429/05, para. 108.

11 Case 429/05, para. 108.

12 Case 429/05, paras. 109-111.

However the position was different if a measure of the EU was adopted that not only disregarded the division of powers between the institutions 'but also, in its substantive provisions, disregarded a superior rule of law protecting individuals'.[13]

The CJEU concluded that the GC made an error of law by holding that infringement by the Commission of the rules governing the division of competences between the Commission and the Member States resulting from Directive 75/319 was not of such a kind as to cause the EU to incur non-contractual liability on the ground that those rules are not intended to confer rights on individuals, because the GC had not taken into account the point of principle in the previous paragraph, 'according to which such an infringement, when it is accompanied by an infringement of a substantive provision which has such an intention, is capable of giving rise to that liability'.[14]

The CJEU does not, however, identify the superior of law for the protection of the individual that was disregarded in the instant case. This part of the judgment is therefore somewhat Delphic. There has to be something in addition to the infringement of the rules relating to the division of power between the institutions that can qualify as the superior rule of law. It may be that the CJEU regarded the GC as having committed an error of law simply because it did not investigate this possibility, without the CJEU itself reaching any conclusion as to what such a superior rule of law might be. The alternative reading of the judgment is that the superior rule of law might have been Article 11 of Directive 65/65, although the difficulty with this reading is that the CJEU held ultimately that the Article had not been infringed.

2. Infringement of Article 11 of Directive 65/65, discretion and sufficiently serious breach

Artegodan also contested the GC's reasoning concerning Article 11 of Directive 65/65, more especially its refusal to find that the breach of this Article constituted a sufficiently serious breach of EU law. It argued, inter alia, that the complexity of a legal or factual situation should not necessarily lead to the conclusion that there is an absence of any sufficiently serious breach.

The CJEU's consideration of this aspect of the appeal was rendered more complex by the fact that discussion of damages liability was interwoven with the issue of whether the ECJ in 2003[15] had pronounced on Article 11 of Directive 65/65. The CJEU reiterated the importance of res judicata in EU law, regarding it as important to ensure stability of the law, and the sound administration of justice: 'judicial decisions which have become definitive after all rights of appeal have been exhausted, or after expiry of the time-limits provided to exercise those rights, can no longer be called into question'.[16] However res judicata extended 'only to the matters of fact and law actually or necessarily settled by the judicial decision in question'.[17] The legal reality was that the ECJ's 2003 ruling was premised on the Commission's lack of competence, and the ECJ did not, as noted earlier, rule on the Article 11 issue. The CJEU therefore concluded that the Article 11 issue had not yet been addressed and that the 2003 ruling was only res judicata in relation to the competence issue.[18] Insofar as the GC in the case under appeal had found that the Article 11 issue had been determined and was thus res judicata, it had made an error of law.[19]

The hopes of success that Artegodan might have harboured at this point were however to prove short lived, because the CJEU drew on the principle that if the GC erred in law the decision could nonetheless be upheld if the operative part of the decision could be shown to be well founded on other legal grounds.

This was held to be so here. Article 11 of Directive 65/65 was intended to confer rights on undertakings which held a marketing authorization. It was nonetheless still necessary for the applicant to show a sufficiently serious breach of the substantive criteria for the withdrawal of a marketing authorization in Article 11. It was open to the Commission to take a long term view of whether a medicinal product lacked therapeutic efficacy. It was equally open to the Commission when undertaking the benefit/risk assessment that would inform the long term view to take account of views within the medical

13 Case C-221/10 P, para. 81, relying on Case C-228/90, *Industrieen Handelsonderneming Vreugdenhil BV v Commission* [1992] ECR I-1937, paras. 20-22.
14 Case C-221/10 P, para. 82.
15 Case C-39/03 P.
16 Case C-221/10 P, para. 86.
17 Case C-221/10 P, para. 87.
18 Case C-221/10 P, para. 92.
19 Case C-221/10 P, para. 93.

community. The CJEU concluded in the following vein.[20]

> In the present case, the Commission's decision to use the criterion of long-term efficacy in order to assess the therapeutic efficacy of amfepramone in the treatment of obesity and to withdraw the marketing authorization concerning the medicinal products containing that substance is based on the existence of a consensus within the medical community regarding a new assessment criterion of that therapeutic efficacy, according to which an effective therapy in the treatment of obesity must be for the long-term, on the questioning of the therapeutic efficacy of that substance, and also on the finding, in the light of that new assessment criterion, of a negative benefit/risk assessment of that substance.

It followed said the CJEU that the Commission did not fail to comply with the substantive criteria for the withdrawal of a marketing authorization of a medicinal product laid down in Article 11 of Directive 65/65.[21] There had been no breach of Article 11 and hence there was no sufficiently serious breach for the purposes of damages liability.[22] It followed also that the errors of law committed by the GC were not such as to invalidate the contested judgment, given that the conclusion could be justified on the grounds specified above.

III. Conclusion

Artegodan is a difficult case, primarily because of the admixture of legal issues that came before the CJEU, more especially the conjunction of discourse concerning the application of the sufficiently serious breach test with that concerning res judicata. There are two issues that should be highlighted by way of conclusion, which are related albeit distinct.

1. Sufficiently serious breach

The first relates to application of the sufficiently serious breach test. It has never been easy to prove the conditions for damages liability against the EU, although the test has become somewhat less restrictive than it was in the earlier years.[23] The need to prove the existence of a sufficiently serious breach of EU law has always been the principal stumbling block in this respect, and the hurdle may be especially difficult to surmount in relation to the types of case that arise in the context of risk regulation. It may be felt that the EU courts were harsh on the claimant insofar they held that even though Article 11 of Directive 65/65 did not entail meaningful discretion the legal and factual complexity surrounding its application meant that the applicant had not proven the existence of a sufficiently serious breach of EU law for the purposes of damages liability. The temptation to reach this conclusion should nonetheless be resisted for the following reason.

It is clear that Article 11 was mandatory, since it provides that the competent authorities of the Member States *shall* suspend or revoke a marketing authorization where the product proves to be harmful in the normal conditions of use, or where its therapeutic efficacy is lacking, or where its qualitative and quantitative composition is not as declared. Article 11 further stipulates that therapeutic efficacy is lacking when it is established that therapeutic results cannot be obtained with the medicinal product. There is thus no meaningful discretion whether to suspend or revoke the marketing authorization. This must be done when the conditions mentioned in Article 11 exist.

The reasoning of the GC and the CJEU relating to Article 11 was different, but it was informed by a common rationale, this being that although Article 11 was mandatory in the preceding sense, there could well be differences of opinion as how to test for harm or for therapeutic efficacy. This is a common problem. It is frequently the case that a regulation may impose a mandatory obligation to achieve a particular objective, but for there to be real interpretive choices as to how those objectives should best be attained. In such instances there is discretion not as to whether to pursue a particular objective, but as to how the objective should best be measured or realized.

This was acknowledged by the GC and the CJEU, although they reacted to it in different ways. The GC,

20 Case C-221/10 P, para. 104.
21 Case C-221/10 P, para. 108.
22 Case C-221/10 P, para. 109.
23 H.G. Schermers, T. Heukels, and P. Mead, (eds), *The NonContractual Liability of the European Communities* (Martinus Nijhoff, 1988);T. Heukels and A. McDonnell (eds.), *The Action for Damages in Community Law* (The Hague: Kluwer, 1997); C. Hilson, "The Role of Discretion in EC law on Non-Contractual Liability", 42 *CMLRev* (2005), p. 677 *et sqq*; P. Oliver, "Enforcing Community Rights in the English Courts", 50 *MLR* (1987), p. 881 *et sqq*; T. Tridimas, "Liability for Breach of Community Law: Growing Up and Mellowing Down?", 38 *CMLRev* (2001), p. 301 *et sqq*.

as we have seen, held that the earlier decisions of the EU courts had established the breach of Article 11 of Directive 65/65, which could not therefore be re-opened in the later litigation about damages. It also decided that this Article did not contain any meaningful discretion as to the substantive criteria for revocation or withdrawal of the authorization. The GC nonetheless concluded that the applicant had not proven the existence of the sufficiently serious breach, because of the legal and factual complexity involved in the application of the criteria in Article 11. The CJEU by way of contrast held that the earlier litigation had not established the breach of Article 11, which was not therefore res judicata for the purposes of the present case. It acknowledged moreover the choices as to how the conditions concerning harm and therapeutic efficacy might be measured. Its conclusion was that the Commission's long-term perspective when judging this issue was a legitimate interpretation of Article 11, hence there was no breach and a fortiori no sufficiently serious breach of that Article.

2. Appeals, errors and alternative legal grounds

The CJEU decided that the GC had committed errors of law, but that its substantive conclusion would not be overturned because it could be sustained on the grounds set out in the preceding analysis.

This approach has a long pedigree in the CJEU's case law, and it is premised on sound normative arguments. The underlying assumption is that it would be wasteful of time and resources if the case were to be remitted back to the GC following annulment of its decision, if the CJEU felt that the decision could be upheld on different grounds. This strategy is moreover especially attractive where the CJEU has a view as to the proper interpretation of the contested provision, since it is able to set down that interpretation in a binding judgment, which will then be relevant for later cases.

This is fine, provided that the applicant has the opportunity to contest the alternative legal ground advanced by the CJEU. The applicant's arguments before the CJEU will of course be directed towards revealing the errors that it believes to be present in the GC's judgment. It may become aware during the course of argument of some alternative legal argument that finds favour with the CJEU, but it may not. The alternative ground preferred by the CJEU may well make sense, and indeed this was so in *Artegodan* itself. This does not alter the point of principle being made here, which is that other things being equal basic precepts of due process require that parties have an opportunity to respond to arguments that will be dispositive of the case.