(Re)evolution of the Test of Urgency for Interim Relief before the EU General Court – The Case of "Innocuous" Napropamide

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Case T-95/09 R, RII, and RIII United Phosphorus Ltd v. Commission[1]

The conditions of urgency for the granting of the interim suspension of a decision concerning the non-inclusion of an active substance in Annex I to Directive 91/414 should not be applied rigidly and mechanically and must be assessed in light of the specific circumstances of the case, in particular the progress of re-submission under Commission Regulation 33/2008, and be subject to a test of reasonableness (author's headnote).

I. Legislation

Articles 3, 4, 5 and 8(2) of Council Directive 91/414/EC of 15 July 1991 on the placing of plant protection products on the market, as last amended by Commission Directive 2010/92/EU of 21 December 2010; OJ 2010 L338/44 (hereinafter referred to as "Directive 91/414" or the "Directive").
Articles 1–3 of Commission Decision 2008/902/EC of 7 November 2008 concerning the non-inclusion of napropamide in Annex I to Council Directive 91/414/EEC and the withdrawal of authorizations for plant protection products containing that substance, OJ 2008 L326/35.

II. Facts

1. The review of napropamide

Napropamide is an active substance which fell within the transitional regime for review under Article 8(2) of Council Directive 91/414. It was supported in the review process by United Phosphorus Ltd ("UPL"). The Rapporteur Member State ("RMS"), Denmark, recommended the inclusion of napropamide in Annex I to Directive 91/414. However, following the identification by the European Food Safety Authority ("EFSA") of a number of critical areas of concern, on 7 November 2008, the Commission adopted a negative decision.[2] That decision (Commission Decision 2008/902) provided that napropamide shall not to be included as an active substance in Annex I to Directive 91/414 and that Member States were to withdraw authorisations for plant protection products containing napropamide by 7 May 2009, with an additional prohibition on the granting or renewal of such authorisations from the date of publication of the decision.[3] Recital 5 of the decision sets out the reasons for the non-inclusion.

On 16 December 2008, UPL re-submitted napropamide for assessment under the accelerated procedure provided for at Article 13 of Regulation 33/2008.[4] The re-submission dossier included data to address the specific issues which led to the non-inclusion decision.

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1 Case T-95/09 R *United Phosphorus v. Commission*, Order of the President of the Court of 28 April 2009, [2009] ECR II-47; Case T-95/09 RII *United Phosphorus v. Commission*, Order of the President of the Court of 15 January 2010, [2010] ECR II-3; Case T-95/09 RIII *United Phosphorus v. Commission*, Order of the President of the Court of 25 November 2010 (unreported).

2 Commission Decision 2008/902 of 7 November 2008 concerning the non-inclusion of napropamide in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance; OJ 2008 L 326/35.

3 Arts. 1–3 of Commission Decision 2008/902.

4 Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I; OJ 2008 L 15/5, hereinafter referred to as "Commission Regulation 33/2008".

2. Initiation of judicial review proceedings

On 26 February 2009, UPL filed an action for the annulment of Commission Decision 2008/902 which it claimed was based on a series of manifest errors of appraisal and was not adopted in accordance with the rights and principles guaranteed by the EU legal order. On 9 March 2009 the company also filed an application for interim measures to obtain suspension of the non-inclusion decision, pending the outcome of the judgment in the main case.

III. Interim relief

1. The conditions

Articles 278 and 279 of the Treaty on the Functioning of the European Union ("TFEU") (formerly Article 242 and Article 243 of the EC Treaty) allow the General Court to order the application of a contested act to be suspended, if it considers that circumstances so require. Article 104(2) of the General Court's Rules of Procedure[5] provides that as well as establishing a *prima facie* case, an application for such interim measures must state the circumstances giving rise to urgency. Where appropriate the judge must also weigh up the interests involved.[6]

According to settled case law, the urgency of an application for interim relief must be assessed in relation to the necessity of such an order to prevent serious and irreparable damage to the party requesting the relief.[7] The damage need not be established with absolute certainty, it is sufficient that the damage is foreseeable with a reasonable degree of probability.[8] The burden of proof lies on the applicant to prove the facts which are alleged to show the probability of serious and irreparable damage.[9]

Furthermore, financial damage is deemed generally not to be irreparable, except in exceptional circumstances, because in principle it may be compensated, for example via an action for damages under Article 340 TFEU (formerly Article 288 EC).[10] Where such financial damage occurs interim measures are justified only if "*it appears that, without such a measure, the applicant would be in a position that could imperil its existence before the main judgment*".[11]

2. Meeting the conditions – Examples from previous plant protection product cases

First, given that the non-inclusion of a substance in Annex I to Directive 91/414 leads to the mandatory removal of that substance from the EU market, it has been accepted by the General Court that damage is reasonably foreseeable.[12]

Secondly, the loss of market share resulting from that removal from the market has been held to equate to pure financial damage as it consists in the loss of income from sales of the active substance.[13] The loss of market share must be "*sufficiently large*"[14] to qualify as serious and, in order to be deemed irreparable, regaining that share must be impossible by reason of obstacles of a structural or legal nature.[15]

5 Consolidated Version of the Rules of Procedure of the General Court; OJ 2010 C 177/37.

6 Order of the President in Case C-445/00 R *Austria v. Council* [2001] ECR I-1461, para. 73.

7 Order of the President in Case T-346/06 R *IMS v. Commission* [2007] ECR II-1781, para. 121, and the case law cited; Order of the President in Case C-60/08 P(R) *Cheminova and Others v. Commission* [2009] ECR I-43, para. 62.

8 Order in Case T-346/06 R *IMS v. Commission*, *supra* note 7, para. 123 and the case law cited therein; Order of the President in Case T-31/07 R *Du Pont v. Commission* [2007] ECR II-2767, para. 144, and the case law cited therein; Order of the President in Case T-326/07 R *Cheminova and Others v. Commission* [2007] ECR II-4877, para. 97, and the case law cited therein.

9 Order in Case T-326/07 R *Cheminova and Others v. Commission*, *supra* note 8, para. 97, and the case law cited.

10 Order of the President in Case C-471/00 P(R) *Commission v. Cambridge Healthcare Supplies* [2001] ECR I-2865, para. 113.

11 Order of the President in Case T-475/07 R *Dow AgroSciences and Others v. Commission* [2008] ECR II-92, para. 71; Case T-326/07 R *Cheminova and Others v. Commission*, *supra* note 8, para. 99; Order of the President in Case T-349/07 R FMC *Chemical Sprl and Others v. Commission* [2007] ECR II-169, para. 100.

12 Case T-31/07 R *Du Pont v. Commission*, *supra* note 8, paras. 151 and 161. This case concerned the decision to include flusilazole in Annex I on a restricted basis for only 18 months. The Commission argued that damage was not imminent as the period of inclusion could hypothetically be extended. The President of the Court was not swayed by that argument and held that the imminence of the damage could not be ruled out.

13 Case T-475/07 R *Dow AgroSciences and Others v. Commission*, *supra* note 11, para. 75; upheld on appeal by Order of the President of 15 December 2009 in Case C-391/08 P(R) *Dow AgroSciences and Others v. Commission* (unreported), paras. 73–82; Case T-326/07 R *Cheminova and Others v. Commission*, *supra* note 8, para. 121, upheld on appeal in Case C-60/08 P *Cheminova and Others v. Commission*, *supra* note 7, paras. 62–76.

14 Case T-475/07 R *Dow AgroSciences and Others v. Commission*, *supra* note 11, para. 72; Case T-326/07 R *Cheminova and Others v. Commission*, *supra* note 8, para. 100; Case T-349/07 R *FMC Chemical Sprl and Others v. Commission*, *supra* note 11, para. 101.

15 Case T-326/07 R *Cheminova and Others v. Commission*, *supra* note 8, para. 100, upheld on appeal in Case C-60/08 P *Cheminova and Others v. Commission*, *supra* note 7, para. 64.

Thirdly, the seriousness of damage is assessed in light of the size and turnover of the applicant and the characteristics of the group of companies to which it belongs.[16] When assessing the gravity of damage, the Court looks for evidence of the market share/sales figures of the applicant relative to the substance concerned, and calculates that as a percentage of the total global turnover of the group of companies. Where such a calculation has been possible, it has been held that the loss of a market share which represents less than 1 % of the global turnover of a group of companies is not serious.[17] In a later case, it was held that financial damage amounting to 10 % of the turnover of the group of companies is not serious, in the absence of other special circumstances.[18]

Another factor influencing the seriousness of damage is whether the applicant holds marketing authorisations for substitute products. If such substitutes exist, even if not entirely appropriate for all purposes, the scope to recoup sales is taken into account and may diminish the seriousness of the damage.[19]

In relation to the irreparable nature of the loss, the availability of substitute products is again taken into account (i.e. if there are none, either produced by the applicant or its competitors, regaining the market upon a successful main action would be more likely). Further relevant factors are the views of customers as to whether they would return to using the substance and the profit margin on sales of the product (i.e. if high, upon return to the market, price could be cut as an incentive to win back customers).[20]

IV. The Napropamide orders

In Case T-95/09 R *United Phosphorus Ltd v. Commission,* interim measures were granted initially for a limited period of time and then subsequently twice extended by the President of the General Court (the "President") to reflect progress in the re-submission procedure under Regulation 33/2008.

1. Case T-95/09 R *United Phosphorus Ltd v. Commission,* Order of 28 April 2009

On 28 April 2009, the President ordered the suspension of Commission Decision 2008/902 until 7 May 2010, the end of the period of grace for the marketing and use of existing stocks of napropamide. That suspension was conditional upon the parties lodging comments on the progress of the re-submission procedure by 15 March 2010.[21]

The assessment of urgency in this case was approached by reference to the same legal principles and case law summarised above i.e. the applicant was required to demonstrate that it would suffer serious and irreparable damage if the interim measures requested were not granted. Nevertheless, the President widened his analysis to ensure that the particular circumstances of the case were taken into account.

a. Seriousness

Following previous case law, it was confirmed that damage from the loss of market share following the non-inclusion decision was purely financial in nature as it "*consists in the loss of the profits liable to be realised in the future on sales of the product in question.*"[22]

The next step was to establish the "seriousness" of that loss of market share. The President followed the established method, referred to above, of looking at the loss of the applicant against the total loss for the group of companies to which it belongs. The President avoided ruling that that certain percentage (between 1–10 %) was in itself sufficiently large to establish the seriousness of the harm but noted that it was higher than the percentage established as "not serious" in the *Cheminova* and *Dow* cases, i.e., 1 %.[23] Furthermore, it was noted that the harm caused could not be reduced by either sales of substitute products or export sales.[24]

16 Case T-31/07 R *Du Pont v. Commission*, *supra* note 8, para. 196, and the case law cited; Case T-475/07 R *Dow AgroSciences and Others v. Commission*, *supra* note 11, para. 77.

17 Case T-475/07 R *Dow AgroSciences and Others v. Commission*, *supra* note 11, para. 87; Case T-326/07 R *Cheminova and Others v Commission*, *supra* note 8, para. 121.

18 Order of the President of 30 April 2010 in Case T-71/10 R *Xeda v. Commission*, unreported, para. 55.

19 Case T-326/07 R *Cheminova and Others v. Commission*, *supra* note 8, para. 120.

20 Case T-326/07 R *Cheminova and Others v. Commission*, *supra* note 8, para. 129, and the subsequent appeal in Case C-60/08 P *Cheminova and Others v. Commission*, *supra* note 7, paras. 67–68.

21 Case T-95/09 R, *supra* note 1, operative Arts. 1 and 2.

22 Case T-95/09 R, *supra* note 1, para. 64.

23 Case T-95/09 R, *supra* note 1, para. 67.

24 Case T-95/09 R, *supra* note 1, para. 68.

The President then developed the scope of the analysis by declaring 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 of each case* [...] *and to bring them into relation, when taking his decision, with the harm occasioned in terms of turnover*".[25]

One such circumstance found to be relevant by the President was the global financial crisis and its impact on the Indian economy. The President referred to data provided by the applicant which showed that the group of companies to which it belongs had, at the end of March 2009, lost more than half of its value in terms of market capitalisation. The President held that "*in those specific circumstances*" he was "*obliged to acknowledge that the applicant has established the gravity of the harm which it will suffer in the event of the total withdrawal of napropamide and napropamide-based products from the Community market if the interim measures sought are not granted.*"[26]

b. Irreparability

The President referred to previous case law in which it had been held that financial damage is in principle reparable as it may be the subject of compensation by way of a damages action under Article 288 EC. However, the President then stated that the fact that such compensation would only be obtained after several years must not be "*overlooked*".[27]

Echoing his reasoning as regards the seriousness of harm, the President emphasised that he should not apply "*mechanically and rigidly*" the condition relating to the irreparable nature of the financial harm but must take account of the factual and legal circumstances specific to the case. He then proceeded to examine whether there were any "*specific circumstances*" which could justify a finding of urgency.[28] Circumstances which were found to be relevant included the fact that the applicant had, in December 2008, submitted napropamide to be re-assessed for inclusion in Annex I of Directive 91/414 under the procedure provided by Article 13 of Regulation 33/2008. It was possible that that re-submission procedure could be concluded shortly after the deadline contained in the contested decision for Member States to withdraw national authorisations (7 May 2009). Furthermore, the President noted that since in the re-submission procedure the applicant had taken the opportunity to submit the data it claimed had been improperly ignored by the Commission and EFSA, "*it cannot be ruled out* [...] *that the applicant's prospects of success will be greater*" under the re-submission procedure than under the first assessment.[29]

Crucially, the President held that "*it would be unreasonable to allow the prohibition of the marketing of a product in respect of which it is not improbable that its marketing will be authorized only a few months later*".[30]

A further *"specific circumstance"* taken into account by the President was that the applicant had demonstrated that it only had one production plant whose production is practically all used in the EU. Accordingly the President found that "*it appears sufficiently probable that the enormous fall in its production by reason of the banning of those sales would lead to the immobilisation of that plant for several years, or even its complete closure.*"[31] While noting that it was not necessary to determine whether they were "*real (long term) obstacles of a legal nature*", the President took account of the fact that even if napropamide were eventually included in Annex I, obtaining new national authorisations could take up to one year.[32] On that basis the President held that a return to the market by the applicant appears to be "*problematic by reason of the fact that, at the crucial point in time, it would probably not have available to it any source for the supply of ready-to-use napropamide.*"[33]

On those grounds it was concluded that there were "*specific circumstances*" establishing the existence of urgency.[34]

Lastly, on the question of the balance of interests, the President took note of the fact that there had been considerable delays in the assessment of napropamide for inclusion in Annex I which, together with the phase out period up to 7 May 2010, indicated

25 Case T-95/09 R, *supra* note 1, para. 69.

26 Case T-95/09 R, *supra* note 1, para. 71.

27 Case T-95/09 R, *supra* note 1, para. 73.

28 Case T-95/09 R, *supra* note 1, para. 74.

29 Case T-95/09 R, *supra* note 1, para. 77.

30 *Ibid.*

31 Case T-95/09 R, *supra* note 1, para. 78.

32 Case T-95/09 R, *supra* note 1, para. 79.

33 Case T-95/09 R, *supra* note 1, para. 81.

34 Case T-95/09 R, *supra* note 1, para. 82.

that the Commission did not itself consider there to be serious risks to public health or the environment if the product were not withdrawn from the market as soon as possible. In that regard the President also took into account the fact that the RMS had recommended inclusion of napropamide in Annex I.[35]

2. Case T-95/09 RII *United Phosphorus Ltd v. Commission*, Order of 15 January 2010

On 15 December 2009, UPL applied for an extension of the period of suspension of Commission Decision 2008/902 which was due to expire on 7 May 2010. The applicant demonstrated that while the re-submission procedure was progressing positively, as demonstrated by the RMS's favourable conclusion in its additional report, issued on 29 June 2009, the procedure was unlikely to be completed before the end of November 2010. In the face of objections from the Commission, the President extended the suspension of the non-inclusion decision until 31 November 2010.[36]

3. Case T-95/09 RIII *United Phosphorus Ltd v. Commission*, Order of 25 November 2010

The re-submission procedure for napropamide was successful and by the end of October 2010 the Commission was in the process of adopting an inclusion directive for napropamide by which it would be added to Annex I to Directive 91/414. However, given that that inclusion directive was only foreseen to come into force on 1 January 2011, that the interim measures against the original non-inclusion decision were to expire on 31 November 2010, and that, under the provisions of the new inclusion directive, holders of authorisations for plant protection products containing napropamide would need to re-apply for such national authorisations with certain new data, the result would be a gap of several months during which plant protection products containing napropamide would be required to be off the market.

Therefore, on 2 November 2010, UPL applied for a second extension of the interim measures in order to avoid such a gap occurring and the consequent undermining of the *effet utile* of the interim measures already granted. The Commission objected to that request.

The President ruled in favour of the applicant and granted the requested extension of interim relief. He noted that the new inclusion directive would enter into force on 1 January 2011 and, recalling his reasoning in the previous Orders that it would be "*unreasonable*" to allow the prohibition of the marketing of a product which would be authorised only a few months later, held, first, that the suspension of the original non-inclusion decision should be extended until 1 January 2011, as concerns the inclusion of napropamide in Annex I to Directive 91/414.[37] Secondly, with regard to plant protection products containing napropamide, the President took note of the practical consequences of the requirement to re-apply for national authorisations under the new inclusion directive, a procedure which the applicant had demonstrated can take more than a year, the fact that the new inclusion directive did not repeal the contested original non-inclusion decision and did not provide for a transitional period between the end of the expiry of the suspension of the contested original non-inclusion decision and the implementation of the new directive, and the fact that napropamide had been revealed to be "*innocuous*" following the re-submission assessment.[38] The President then held that the suspension of Commission Decision 2008/902 should be extended until 31 December 2011, or until the date of adoption of the judgment in main annulment action, if that were to be earlier.[39]

V. Comment

The Orders in this case demonstrate the President's willingness to apply a degree of flexibility to the strict conditions for obtaining the interim suspension of an EU measure. That approach is underlined by the repeated affirmation that the conditions for interim relief must not be applied "*mechanically and rigidly*". By allowing an examination of the specific circumstances applying to each individual applicant, in particular the seriousness and irreparability of financial damage, companies are afforded a greater

35 Case T-95/09 R, *supra* note 1, paras. 85–87.

36 Case T-95/09 RII, *supra* note 1, paras. 1–16.

37 Case T-95/05 RIII, *supra* note 1, paras. 11–15.

38 Case T-95/09 RIII, *supra* note 1, paras. 16–18.

39 Case T-95/09 RIII, *supra* note 1, para. 20.

chance of meeting the conditions of "urgency" required to obtain interim relief.

While the President himself has been at pains to state that the first Order in this case does not represent a departure from previous case law, emphasising that this case turned on the procedural circumstance of the ongoing re-submission procedure,[40] the fact that that circumstance fell to be considered as part of a "reasonableness" assessment is a welcome development.

In practice, as a consequence of the Orders in this case, the applicant UPL, a producer of napropamide, has been able to continue to sell napropamide and to maintain its plant protection product authorizations in place, despite the initial negative decision against the active substance, during the re-submission procedure and will continue to be able to place its napropamide products on the market while it seeks the granting of new authorisations under the re-submission inclusion directive, which entered into force on 1 January 2011.[41] Other companies selling napropamide also benefit from the Orders. Accordingly, this case demonstrates the practical benefit of seeking interim relief in the notoriously slow moving arena of EU judicial review.

40 Marc Jaeger, "Le référé devant the président du Tribunal de l'Union européene depuis septembre 2007", *Journal de droit européen* (Septembre 2010), pp. 197 *et sqq.*, at pp. 207–208 (paras. 65 and 71).

41 Commission Directive 2010/83/EU of 30 November 2010 amending Council Directive 91/414/EEC to include napropamide as active substance, OJ 2010 L 315/29.