ORDER OF THE PRESIDENT OF THE COURT
25 July 2000 *

In Case C-377/98 R,

Kingdom of the Netherlands, represented by M.A. Fierstra, Head of the European Law Department in the Ministry of Foreign Affairs, acting as Agent, of 67 Bezuidenhoutseweg, The Hague,

applicant,

supported by

Italian Republic, represented by Professor U. Leanza, Head of the Legal Department in the Ministry of Foreign Affairs, acting as Agent, assisted by D. Del Gaizo, Avvocato dello Stato, with an address for service in Luxembourg at the Italian Embassy, 5 Rue Marie-Adélaïde,

intervener,

* Language of the case: Dutch.

European Parliament, represented by J. Schoo, Director in its Legal Service, and E. Vandenbosch, acting as Agents, with an address for service in Luxembourg at the General Secretariat of the European Parliament, Kirchberg,

and

Council of the European Union, represented by R. Gosalbo Bono, Director in its Legal Service, and G. Houttuin and A. Lo Monaco, Legal Advisers, acting as Agents, with an address for service in Luxembourg at the office of E. Uhlmann, Director-General of the Legal Affairs Directorate of the European Investment Bank, 100 Boulevard Konrad Adenauer,

defendants,

supported by

Commission of the European Communities, represented by T. van Rijn and K. Banks, Legal Advisers, acting as Agents, with an address for service in Luxembourg at the office of C. Gómez de la Cruz, of its Legal Service, Wagner Centre, Kirchberg,

intervener,

APPLICATION for suspension of the operation of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13), alternatively for other interim measures,

THE PRESIDENT OF THE COURT

makes the following

Order

1 By application lodged at the Court Registry on 19 October 1998, the Kingdom of the Netherlands sought annulment, pursuant to Article 173 of the EC Treaty (now, after amendment, Article 230 EC), of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13, hereinafter 'the Directive').

2 By a separate document, lodged at the Court Registry on 6 July 2000, the Kingdom of the Netherlands applied pursuant to Articles 242 EC and 243 EC for suspension of the operation of the Directive pending delivery by the Court of judgment on the substance of the case, alternatively for the adoption of such other interim measures as it may regard as reasonable and appropriate.

3 The Kingdom of the Netherlands also applied, pursuant to Article 84(2) of the Rules of Procedure, for suspension of the operation of the Directive prior to the submission by the defendants of their observations.

4 On 17 July 2000 the European Parliament and the Council submitted their written observations on the application for interim measures.

5 By application lodged at the Court Registry on 12 July 2000, the Commission sought leave to intervene in the present proceedings for interim relief in support of the form of order sought by the defendants. By application lodged at the Court Registry on 18 July 2000, the Italian Republic sought leave to intervene in support of the form of order sought by the applicant.

6 Pursuant to the first and fourth paragraphs of Article 37 of the EC Statute of the Court of Justice and Article 93(1) and (2) of the Rules of Procedure, the applications for leave to intervene in the proceedings for interim relief must be granted.

7 The parties presented their oral observations on 18 July 2000.

Arguments of the parties

The existence of a prima facie case

8 The parties were requested to concentrate, in the proceedings for interim relief, on the questions of the urgency of the application and the balance of the interests at stake; consequently, the arguments set out below are taken, as far as may be necessary, from the documents exchanged in the written procedure relating to the application by the Kingdom of the Netherlands for annulment of the Directive.

9 The applicant states that the essential reason for its opposition to the Directive is that that measure makes it possible for patents to be granted in respect of living

organisms, which conflicts with the fundamental ethical policy pursued by the Kingdom of the Netherlands. It reiterates the six pleas on which its application for annulment of the Directive is based.

10 By its first plea, it asserts that the legal basis chosen for the adoption of the Directive is incorrect. The fifth to ninth recitals in the preamble to the Directive purport to justify recourse to Article 100a of the EC Treaty (now, after amendment, Article 95 EC) by reason of differences between the laws of the Member States relating to the legal protection of biotechnological inventions, which could well become more pronounced, to the detriment of the proper functioning of the internal market, and on account of the fact that, whilst there is no need to create a separate body of law in place of the rules of national patent law, those rules should nevertheless be harmonised, since certain concepts of national law based on international conventions have created uncertainty. The applicant maintains, first of all, that no differences between the laws of the Member States were in fact established in the statement of the reasons for the proposal for the Directive, second, that Community-wide harmonisation does not constitute an appropriate means of eliminating the uncertainties created by international conventions such as the Convention on the Grant of European Patents signed in Munich on 5 October 1973 ('the Munich Convention') and, finally, that, far from simply harmonising national systems, the Directive creates a separate body of law with regard to patents of Community origin, which is specific in terms of both the sources to which it refers and the extent of the protection which it establishes.

11 The defendants maintain that Article 100a of the Treaty constitutes an appropriate legal basis, since there exists, as between the legal systems of the Member States, a risk of disparities which are liable to distort competition. National differences relating to patentability inevitably constitute an obstacle to intra-Community trade. Moreover, it is possible objectively to identify certain distortions of competition. In addition, harmonisation within the internal market cannot be achieved by a revision of the Munich Convention, to which the Community is not a party. Lastly, by merely laying down express rules governing the patentability of biotechnological products and processes and the exceptions to such patentability, the Directive does not affect the essential criteria for the

patentability of an invention, as they emerge from the existing law in the Member States. It therefore falls within the Community's powers of harmonisation in intellectual property matters, which are based on Article 100a of the Treaty.

12 By its second plea, the applicant alleges, primarily, an infringement of the principle of subsidiarity laid down in Article 3b of the EC Treaty (now Article 5 EC). There is nothing to indicate that the objectives pursued by the Directive could be better achieved by the Community than by the Member States. In the alternative, the applicant argues that, contrary to Article 190 of the EC Treaty (now Article 253 EC), the Directive does not contain an adequate statement of reasons concerning its conformity with Article 3b. The reasoning provided by the Directive in that connection is insufficient, especially in relation to its objective of clarifying the legal protection of biotechnological inventions, having regard to the harmonisation of the laws of the Member States which has already been achieved on the basis of the Munich Convention.

13 According to the defendants, the principle of subsidiarity does not apply to an area of competence reserved exclusively to the Community, such as the power of harmonisation conferred by Article 100a of the Treaty. In any event, the objective of harmonisation cannot be adequately attained by action on the part of the Member States. As to the reasoning contained in the Directive on that point, this is clearly set out in the third, fifth to seventh and ninth recitals in its preamble.

14 By its third plea, the applicant claims that the Directive infringes the Community principle of legal certainty, in that it creates fresh uncertainties regarding the protection of biotechnological inventions, contrary to its declared objective of removing those uncertainties which already exist. The Directive in fact confers on the competent national courts discretionary powers for the application of principles formulated in general and equivocal terms. In addition, the relationship between certain of its provisions is ambiguous, particularly as regards the patentability of plant varieties.

15 As regards the excessive leeway which the Directive allegedly gives the national courts, particularly as regards the application of the exception relating to *ordre public* and morality, the defendants consider that the use of general terms is perfectly compatible with the essential purpose of a directive, which is to allow the Member States a certain latitude as to the form and methods by which it is to be implemented. In the present case, moreover, the Directive provides guidelines for the interpretation of the concepts which it contains, unlike the instruments previously existing. As to the patentability of plant varieties, no ambiguity can be discerned in the correlation between the provisions in issue, as clarified by the recitals in the preamble to the Directive.

16 The fourth plea alleges infringement of the obligations imposed by public international law, as laid down in the Munich Convention and in the Convention on Biological Diversity which was signed in Rio de Janeiro on 5 June 1992 ('the Biodiversity Convention') and approved on behalf of the European Economic Community by Council Decision 93/626/EEC of 25 October 1993 (OJ 1993 L 309, p. 1). First, an invention regarded as incapable of being patented under the Directive could nevertheless be incorporated into the legal orders of the Member States by means of a European patent. Second, the Directive does not afford the Member States the possibility of complying — for example, by limiting the rights of patent-holders — with the obligations arising under the Biodiversity Convention as regards the equitable sharing with developing countries of knowledge of, and of the benefits offered by, genetic resources.

17 The defendants argue, first, that Community acts cannot be rendered unlawful on account of the infringement of rules of international law which, either because the Community is not a party to the act containing them or because they have no direct effect, are not binding on the Community. They consider, in the second place, that no incompatibility can be said to exist between the provisions of the international conventions invoked by the applicant and the obligations which the Directive imposes on the Member States.

18 By its fifth plea, the applicant maintains that, by affronting human dignity, the Directive infringes the obligation incumbent on the Community institutions to

respect fundamental rights. To allow isolated elements of the human body to be patented would be tantamount to reducing living human matter to a mere commodity and would constitute an assault on the dignity of mankind, *a fortiori* since no provision is made for any safeguard measure such as a requirement that authorisation be given by the donor and there is nothing in the Directive which would allow a patient to refuse a treatment involving matter obtained by biotechnological means.

19 According to the defendants, the Directive takes account of the ethical considerations referred to by the Kingdom of the Netherlands, in particular by excluding from patentability certain processes relating to human beings. Furthermore, it does not automatically follow that the grant of a patent concerning substances of human origin would be contrary to human dignity, as was acknowledged, in particular, by the European Commission's advisory group on the ethics of biotechnology in its opinion of 25 September 1996. Lastly, as regards the right of human beings to retain control over their own bodies, the Directive does not in any way affect the provisions which may apply in that connection at national level.

20 By its sixth plea, the applicant claims that the Commission's proposal, as considered by the Parliament and the Council, was adopted in breach of the combined provisions of Article 100a and Article 189b(2) of the EC Treaty (now, after amendment, Article 251(2) EC), inasmuch as no information has been provided to the Parliament, the Council or the Court of Justice enabling them to satisfy themselves as to fulfilment of the essential procedural requirement regarding the collegiality of the Commission's deliberations.

21 The defendants, for their part, maintain that all formal and procedural requirements needing to be fulfilled prior to adoption of the Directive have been satisfied and that the applicant has furnished no concrete evidence raising any doubt as to the validity of the act adopted pursuant to the co-decision procedure by the Parliament and the Council.

Urgency

22 The applicant maintains that the obligation to transpose the Directive by 30 July 2000 at the latest will cause serious harm which could not be remedied even if it were to succeed with its application for annulment.

23 First, in view of the fundamental nature of the objections raised against the Directive, the Netherlands legislature cannot be expected to transpose the Directive by adopting and bringing into force the corresponding national legislation.

24 Second, once the Directive has been transposed in the Netherlands, patents will be granted for certain inventions which are not currently patentable and the patentability of which, according to the applicant, is in any event undesirable. If the Directive were to be annulled, the measures transposing it in the Netherlands would be cancelled; this is not a requirement imposed by Community law, but it nevertheless constitutes the logical consequence of the institution by the Kingdom of the Netherlands of proceedings before the Court for annulment of the Directive.

25 In those circumstances, if the validity of the patents already granted were to be called in question, the protection on which the holders of those patents thought they could rely, and on the basis of which they had decided to make investments, would no longer be guaranteed, which would give rise to unacceptable legal uncertainty.

26 If, on the other hand, the validity of the patents already granted were not called in question, that would mean that equal treatment would not be afforded to biotechnological inventions produced after delivery of the judgment annulling the Directive. Moreover, the applicant would then have to make the best of a situation in which, despite its objections, biologically modified animals and plants could be protected by a patent.

27 The defendants observe, as a preliminary point, that the applicant's assertions are extremely vague. In their view, the existence of a real risk of serious and irreparable damage has not been established.

28 As regards the fundamental objections expounded by the applicant, the Parliament takes the view that these relate to matters of policy or ethics, and that they cannot be equated with serious and irreparable damage.

29 As to the specific damage alleged, the Parliament and the Council note, first, that the application contains no details of the applicable Netherlands legislation. No indication is given as to the respects in which the Directive allegedly goes further than the legislation currently in force in the Netherlands. According to the Council, it is apparent from the information provided by the Netherlands Government to the Chamber of Deputies that transposition of the Directive would not fundamentally alter the criterion of *ordre public* and morality currently applying. By the same token, no information has been provided regarding the patents granted by the Netherlands Patent Council in respect of biological substances or processes by which such substances are obtained, or as to the numerous European patents in force in the Netherlands in the field of biotechnology.

30 Second, the Parliament and the Council deny that annulment of the Directive would have the consequences alleged by the applicant with regard to patents granted in the interim pursuant to the transposing legislation. Even if the Directive were to be annulled, Community law would not necessarily require the repeal of the national legislation, and no problems of legal uncertainty would therefore arise. Furthermore, even if the national legislation were to be repealed, Community law would not require the withdrawal of any patents already granted.

31 The defendants further observe that the application for suspension provides no specific indication as to the applications which might be affected by the action for annulment, particularly those which are already currently pending before the Netherlands Patent Council in respect of inventions the patentability of which would, according to the applicant, be undesirable. According to the Council, there can only be a very limited number of applications for patents currently under examination. As to applications which may be lodged after 30 July 2000, these cannot be taken into consideration, in view of the fact that it takes between 18 and 24 months for a patent to be granted.

32 The defendants also maintain that it is not open to the Kingdom of the Netherlands to invoke possible damage arising from the withdrawal of patents granted pursuant to the transposing legislation, since that damage would not be suffered by the applicant itself. The damage in question would affect only a limited group of individuals, not an entire sector of the Netherlands economy. Moreover it would not be irreparable, since operators who were prejudiced could bring proceedings for compensation for any damage suffered.

33 Finally, as regards the unequal treatment which might be afforded to biotechnological inventions, depending on their date, the Parliament argues that this is a normal consequence of any change in the law and that such inequality could certainly not be classified as prohibited discrimination on the part of the Netherlands authorities.

The balancing of interests

34 The applicant maintains that the balancing of the interests at stake in the present case favours the grant of the suspension sought, since the effects of such a suspension would be relatively limited.

35 It is true that, if the operation of the Directive in the Netherlands were suspended, the benefit of patent protection would not extend in that country to biotechnological inventions relating to products consisting of or containing biological matter or to processes enabling such matter to be obtained, processed or used. However, this would not affect the legal protection afforded to biotechnological inventions in other Member States or the possibility of making a profit on investment, or indeed the possibility of applying for a European patent for such inventions. Nor would there be any obstacle to the importation into the Netherlands of products enjoying patent protection in other Member States. Lastly, the exportation to other Member States of goods legally produced in the Netherlands would not prejudice biotechnological patents issued in those States.

36 The applicant also observes that, in many Member States, the Directive will not in any event have been transposed by 30 July 2000; consequently, suspension of its operation in relation to the Kingdom of the Netherlands would not in any way affect a uniform system in force in all the other Member States.

37 The defendants consider that the balance of interests is such that the suspension sought should not be granted. First, it is not necessary in order to prevent the applicant from suffering grave and irreparable damage. Second, such a suspension would itself have serious repercussions. It would give rise to legal uncertainty for all concerned, both public authorities and individuals, and could result in the refusal of applications for patents in the Netherlands during the period in question, which could in turn discourage numerous investment projects in the sector of biotechnology. It would also have the effect of delaying the establishment of the internal market, having regard in particular to the distortion of competition which it would generate.

38 As regards the applicant's allegation that the Member States will not have implemented the Directive by the due date, the Council states that it has already been transposed by one Member State and that it is likely to be transposed by five others within the prescribed period. In any event, that allegation ignores the possible direct effect of certain provisions of the Directive.

Assessment

39 Under Articles 242 EC and 243 EC, the Court of Justice may, if it considers that the circumstances so require, order that application of the contested act be suspended or prescribe any necessary interim measures in any cases before it.

40 Article 83(2) of the Rules of Procedure requires applications pursuant to Articles 242 EC or 243 EC to state the subject-matter of the proceedings, the circumstances giving rise to urgency and the pleas of fact and law establishing a prima facie case for the interim measures applied for.

41 It is settled case-law that the judge hearing an application for interim relief may order suspension of operation of an act, or other interim measures, if it is established that such an order is justified, prima facie, in fact and in law and that it is urgent in so far as, in order to avoid serious and irreparable harm to the applicant's interests, it must be made and produce its effects before a decision is reached in the main action (order of 21 March 1997 in Case C-110/97 R *Netherlands* v *Council* [1997] ECR I-1795, paragraph 24). Where appropriate, the judge hearing such an application must also weigh up the interests involved.

42 In the present case, the urgency pleaded by the applicant is said to be due to the fundamental objections to which the contents of the Directive give rise in the Netherlands and to the legal uncertainty which would arise, for the Netherlands legal order in general and for certain patent-holders in particular, from the implementation of the Directive prior to delivery by the Court of its ruling on the application for annulment.

43 As regards, first of all, the allegations concerning the unacceptable nature of the contents of the Directive regarding the patentability of living matter, it must be observed that that issue does not fall within the scope of the assessment of the urgency of the suspension sought.

44 If the principle that an action for annulment cannot have suspensory effect is not to be called in question, it must be acknowledged that the purpose of proceedings for interim measures is not to remedy damage of an ethical nature, as alleged in the present case, but to ensure that the judgment delivered in the substantive proceedings is fully effective, in order to avoid a lacuna in the legal protection afforded by the Court.

45 Whilst a breach of a higher-ranking legal rule may affect the validity of the Directive, it cannot be sufficient on its own to establish that any damage caused is serious and irreparable (order of 25 June 1998 in Case C-159/98 P(R) *Netherlands Antilles* v *Council* [1998] ECR I-4147, paragraph 62). It is not enough to allege infringement of fundamental rights in the abstract for the purposes of establishing that the harm which could result would necessarily be irreparable (order of 15 April 1998 in Case C-43/98 P(R) *Camar* v *Commission and Council* [1998] ECR I-1815, paragraph 47).

46 Next, as regards the overall prejudice to legal certainty in the Netherlands, the applicant claims that the only means of remedying such uncertainty is to order that the operation of the Directive be suspended pending delivery of the decision on the substance of the case, and that such suspension should be ordered either generally or solely in respect of the Netherlands. In the latter regard, the representative of the Kingdom of the Netherlands stated at the hearing that he would leave it to the judge hearing the application for interim measures to decide on the scope to be given to the suspension sought.

47 It must be observed in that connection that legal uncertainty necessarily arises in some respects where proceedings challenging the legality of a measure are brought. Moreover, the legal uncertainties which the applicant seeks to avoid can be circumvented only at the cost of creating a corresponding degree of legal uncertainty amongst the other Member States, particularly those which have already taken the necessary steps to transpose the Directive into their own legal orders, regardless of the scope to be given to any suspension of operation of the Directive.

48 The general considerations formulated by the applicant with regard to legal certainty are not enough, therefore, to establish the existence of an urgent need to suspend operation of the Directive.

49 Lastly, it is necessary to consider the specific damage described in the application, namely the consequences which would arise from the grant, following the transposition of the Directive, of patents in respect of living organisms, which are not currently patentable under Netherlands law, if the Directive were subsequently to be annulled.

50 It should be borne in mind in that regard, as a preliminary point, that it is for the party alleging serious and irreparable damage to establish that such damage will be sustained (see, to that effect, the order of 18 November 1999 in Case C-329/99 P(R) *Pfizer Animal Health* v *Council* [1999] ECR I-8343, paragraph 75).

51 Whilst it is true that, for the purposes of establishing the existence of such damage, it is not necessary to prove beyond all possible doubt that the damage in question will arise, and although it is enough to show that it is sufficiently likely to occur, the applicant is nevertheless required to prove the facts on the basis of which it is alleged that such serious and irreparable damage is foreseeable (order of 14 December 1999 in Case C-335/99 P(R) *HFB and Others* v *Commission* [1999] ECR I-8705, paragraph 67).

52 In the present case, it must be held that the applicant has not succeeded, either in its written application or at the hearing, in establishing that the alleged damage is not purely hypothetical, that it is sufficiently serious in qualitative or quantitative terms or that it is of an irreparable nature.

53 As regards applications for patents which are currently pending before the Netherlands Patent Council, the applicant has furnished no concrete particulars whatever as to the existence or number of applications in respect of inventions concerning animals or plants which would not be patentable on the basis of Netherlands law as it currently stands but which would be patentable under the Directive.

54 With regard to applications of that kind which might be lodged after 30 July 2000, the applicant has stated that it would in principle take approximately 18 months before the results of such applications were published, which means that there is no imminent danger of any damage arising.

55 It is true that the applicant stated at the hearing that such applications were capable of producing legal effects as soon as they were lodged, since a party lodging such an application already enjoys some protection during that period and may grant a licence in respect of the patent applied for. At first sight, however, it appears that those effects remain subject to the adoption of a final, positive decision by the competent authority.

56 The irreparable nature of the damage which might be suffered by the holders of the patents in issue is likewise questionable. It appears that, if any such damage were to materialise in the event of annulment of the Directive, it would in most cases take the form of financial loss for which monetary compensation could, where appropriate, be awarded.

57 Furthermore, as the defendants and the Commission rightly stated at the hearing, it seems that the Netherlands authorities would be able to take steps to prevent the alleged damage from arising.

58 As the representative of the Kingdom of the Netherlands acknowledged at the hearing, the Netherlands authorities could lawfully provide, in the context of the transposition of the Directive into the Netherlands legal order, for mechanisms, such as the grant of patents subject to conditions precedent or subsequent, which would make it possible to prevent the holders of certain patents from suffering damage in the event of annulment of the Directive.

59 The applicant has also conceded that it would be possible for the Netherlands authorities, in the event of annulment of the Directive, to adopt legal measures permitting annulment of patents which had been granted pursuant to the Netherlands legislation transposing the Directive.

60 It appears, therefore, that the Netherlands authorities are themselves able to mitigate the adverse effects on which they rely in the present proceedings in order to show the existence of a risk of serious and irreparable damage.

61 That conclusion cannot be countered by the argument that the implementation of such national measures with effect from 30 July 2000 is no longer feasible since they require the adoption of legislation. First, it has not been denied that such measures could be adopted, at the latest, when the Directive is actually transposed; and, second, the applicant cannot rely on its own tardiness in the performance of its obligations under Community law in order to establish the existence of a risk of serious and irreparable damage justifying the grant in its favour of an order suspending the operation of the Directive.

62 Moreover, the fact that it does not appear feasible — having regard to the stage currently reached in the procedure before the national authorities and the

politically sensitive nature of the matter — for measures transposing the Directive into Netherlands law to be adopted and implemented in the near future constitutes a further factor rendering the alleged damage to the holders of certain patents still more hypothetical. As stated in the written application lodged by the applicant, the possibility of such damage being suffered is based on the premiss of the Directive having previously been transposed into Netherlands law.

63 The considerations regarding the possible direct effect of the Directive, which were raised for the first time by the applicant at the hearing, are not enough to justify a different assessment. In the absence of any solidly based arguments, the question of the possible direct effect of certain provisions of the Directive cannot be dealt with directly in the context of proceedings for interim measures, *a fortiori* since the damage to which such direct effect may give rise has not been specified.

64 The applicant has not, therefore, put forward sufficient arguments, either in its written application or at the hearing, to support its allegations concerning the existence, seriousness and irreparability of the damage which it claims may be suffered by the holders of certain patents relating to biotechnological inventions.

65 In those circumstances, it is clear that the urgency of the need for the suspension sought has not been established.

66 It follows that the application for interim measures must be dismissed.

On those grounds,

THE PRESIDENT OF THE COURT

hereby orders:

1. **The application for interim measures is dismissed.**

2. **The costs are reserved.**

Luxembourg, 25 July 2000.

R. Grass
Registrar

G.C. Rodríguez Iglesias
President