Patently Unsatisfactory?: Community Legislative Competence and the ECJ Biotech Decision

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I. Introduction

[1] On 9 October 2001, the European Court of Justice dismissed (1) a challenge by the Netherlands with the support of Italy and Norway against the Community Directive on the legal protection of biotechnological inventions. (2) Although the Biotech Directive relates to a wide range of public concerns and the Application for its annulment was based on a half-dozen different pleas, the following article will focus on the case as it relates to European Community treaty limitations. It will critically examine the perspectives on the principles of harmonisation and subsidiarity presented in the Application, the Advocate General's Opinion and the Court's Judgment within the broader context of the Community/Union's past and future development. The examination will reveal that in this case the Court has foregone a good opportunity to delimit 'positive integration'. (3) It could have made an important contribution to the on-going discussion about power-sharing between the national and supranational levels. While the judgment does strongly affirm the positive integration paradigm, the margins of the EU's legislative policy competences remain blurred due to its oft-opaque reasoning. The judgment raises, directly and indirectly, as many questions as it answers.

[2] This outcome from the proceedings is unfortunate: it is "of the essence" of a regulatory order such as the EU's "that the powers exercisable at the centre be clearly demarcated." (4) A greater degree of clarity in the EU's policy competences would be desirable not only according to the well-known principle of legal certainty but also from the political perspective of legitimacy. A widespread suspicion exists even in traditionally more positive member states about the EU's ambition of "an ever-closer union". (5) Many people fear the extension of the integrationists' project into all walks of life, "gobbl[ing] up everything that gives substance to our sense of having separate national identities." (6) The extent of the EU's potential legislative reach is accordingly not an abstract issue; it is a live and sensitive one. Specifically, as regards biotechnological innovation, widespread concerns remain about the patenting of biological materials, particularly with respect to the propriety of patenting animals, plants and materials of human origin. (7) Given the failure of the European Court of Justice in cases such as the Biotech decision to address popular concerns, extra-judicial means, specifically revisions to the constitutive Treaties, may be the only means of providing a desirable degree of legal clarity in the EU's policy competences.

II. The Provisions of the Biotech Directive

[3] The Biotech Directive harmonises patent law among member states regarding biotechnology and ensures that the products of modern biotechnology are patentable throughout the Community. The Directive does so by establishing a detailed set of rules that apply to the patenting of biotechnological products and processes (including those involving materials of human origin) and to the scope of protection offered by those patents. It requires the Member States, through their patent laws, to protect biotechnological inventions according to these rules, whilst complying with their international obligations. (8)

[4] Approved by the Council and the European Parliament in July, 1998, after a decade-long debate, the Directive attempts both to encourage biotechnology innovation in Europe and to meet ethical concerns. The compromise struck failed to satisfy all member states. At the Council meeting convened for its approval, the Netherlands voted against the Directive, and Belgium and Italy abstained, but the proposal passed by a qualified majority. Four months after its publication, the Netherlands brought an action under Article 173 of the EC Treaty (now, after amendment, Article 230 EC) for its annulment. (9) Italy and Norway were subsequently granted leave by the Court to intervene in support of the Netherlands.

III. Harmonisation and Subsidiarity

[5] As noted, the Netherlands put forward six pleas. It pleaded that the Directive is incorrectly based on Article 100a of the EC Treaty (now Article 95 EC); it is contrary to the principle of subsidiarity laid down by Article 3b EC Treaty (now Article 5 EC); it infringes the principle of legal certainty; it is incompatible with obligations in international law; it breaches the fundamental right to respect for human dignity; and it was not properly adopted. The first two pleas relate specifically to Community treaty limitations, as the principles of harmonisation and subsidiarity concern the division of powers between the national and supranational levels. Although these were 'technical' grounds of

challenge, they were motivated by broader concerns that the irresponsible pursuit of biotechnological research may have ethically unacceptable consequences. Indeed, the fact that the Netherlands proceeded on largely technical grounds speaks significantly to the nature and dynamic of Community legislation. (10)

[6] The principles of harmonisation and subsidiarity have played a strong, formative role in the development of the Community/Union to date and look to influence its character in future. Article 100a of the EC Treaty had its origins in the efforts in the mid-1980s to complete the internal market. Member states agreed to embark on a massive harmonisation programme designed to provide common standards of protection of vital interests. In order to accelerate the legislative process, Article 100a was introduced into the EC Treaty. It provides for the harmonisation of provisions in Member States that have as their object the establishing and functioning of the internal market. The related Community measures are to be enacted by qualified majority vote in the Council, rather than by unanimity as heretofore under Article 100 of the EC Treaty (now Article 94 EC). Put otherwise, Article 100a was "designed to break through the perceived previous legislative impasse to completing the internal market." (11) As one observer noted, the harmonisation programme has been "largely successful." (12) Indeed, it was in a sense too successful: its effects caused constraints to be be placed on its operation. "The power ceded by Member States under Article 100a (new 95) EC proved wider than was anticipated, and more controversial." (13) Concern about a loss of national sovereignty and democratic legitimacy concomitant with a transfer of powers to the Community/Union has led Member States to be reluctant to commit themselves to further harmonisation, especially by qualified majority voting, and to be dilatory in implementing EC legislation. Subsidiarity, introduced into the EC Treaty at Maastricht as a general principle, is perhaps the most tangible manifestation of the new attitude to achieving the single market.

[7]While by now a well-known word, the precise meaning of subsidiarity remains uncertain and much debated. It may perhaps be best seen as composed of three elements: (a) attribution of powers, (b) subsidiarity per se, and (c) proportionality. (14) The first concerns the existence and extent of Community powers, the latter their exercise. (15) Briefly stated, the first paragraph of Article 3b of the EC Treaty (now Article 5 EC), namely "the Community shall act within the limits of the powers conferred upon it by the Treaty and the objectives assigned to it therein", confirms that the Community's powers are, in principle, limited and that such powers given it are to further specific objectives. In the context of a legal challenge to Community action, "[i]t is always necessary to know what is the legal basis of a Community measure, to make sure the objective in question can validly be pursued under that provision." (16) Where the Community may take action but does not have exclusive competence, supranational action must only be preferred to national action if this will bring demonstrable advantages. The subsidiarity principle is "to guide the decision whether the powers given to the Community should actually be used, in cases where the objective in question can also be pursued by the Member States individually, using their own powers." (17) Lastly, the so-called proportionality principle in the third paragraph of the Article is "about the intensity of the action the Community should take." (18) In particular, rather than prescribing their obligations in minute detail, the Community is simply to provide the outline, which the Member States are then to fill in.

IV. The Pleas Relied on in the Application, the Advocate General's Opinion (19) and the Judgment of the Court

[8] The pleas relating to Community treaty limitations will be consecutively considered as each was submitted by the Applicant, disputed by the Advocate General and settled by the Court. The intention is to uncover the legal justifications for the Community legislation.

A. Harmonisation

1. The Application

[9] In its application, the Netherlands claimed that the former Article 100a of the EC Treaty could not serve as the legal basis for the Directive as the Directive was not aimed at harmonising the internal market. The Directive ought to have been approved under Article 235 of the EC Treaty (now Article 308 EC) instead. This latter source of legal authority enables the Council to take appropriate measures where Community action is found necessary to attain, in the course of the operation of the common market, one of the objectives of the Community, and no specific power under the the Treaty is available for the purpose. The political significance in the selection of the legal basis for the harmonising measure lies in the different voting procedures: the former Article 100a requires the Council to adopt measures by qualified majority; the former Article 235 requires unanimity.

[10] Specifically, the Netherlands submitted that the Directive does not fall within the definition of measures for the approximation of the provisions laid down by law, regulation or administrative action in the Member States, which have as their object the establishment and functioning of the internal market, and was therefore incorrectly adopted. (20) The differences in the laws and practices of the Member States and the likelihood of their increasing and

creating barriers to trade do not exist or only concern secondary issues that do not justify harmonisation, according to the Netherlands. (21) The obstacles to trade cited in recitals five and six in the preamble of the Directive would at most be to trade with the United States and Japan, not within the internal market. (22) "In the absence of any evidence of differences in national laws or of effect on trade, harmonisation by way of a directive cannot be justified." (23) Second, "if the application by the Member States of the relevant provisions of international law left a measure of legal uncertainty [per recital 9 in the Directive preamble], it should have been removed not by Community harmonisation but by renegotiation of international legal instruments [*i.e.* the European Patent Convention or 'EPC']" in order to clarify the provisions. (24) Third, the Directive allegedly exceeded the definition of a measure for harmonisation of national legislation, as it creates "a new type of property right distinct in several respects from the rights previously covered by existing patent law." (25) Last, the Italian Government claimed that the Directive should have been adopted on the basis of Articles 130 and 130f (now Articles 157 and 163, all EC Treaty) since the principal aim is to support the industrial development of the Community and scientific research in the genetic engineering sector. (26) In the alternative, Italy contended that the former Article 100a could not be the legal basis for a harmonising measure in a field involving fundamental interests such as health and the environment unless the contents of the proposal conform to the former Article 100a(3) of the EC Treaty (now Article 95(3) EC), which requires the Commission to take as a base a high level of protection in its proposals. This high level had allegedly not been taken as a base. (27)

2. The Opinion

[11] AG Jacobs took the view as regards the Netherlands' first argument - *i.e.* that obstacles to trade had not been shown - that the Council and Parliament were entitled to consider that a harmonising measure was necessary to deal with disparities between Member States' laws concerning the patent protection of biotechnological inventions. Referring to the Court's rulings in Spain v Council as well as Germany v Parliament and Council, (28) the Advocate General asserted that recourse to the former Article 100a is justified where "harmonising measures are necessary to deal with disparities between the laws of the Member States in areas where such disparities are liable to create or maintain distorted conditions of competition (or) in so far as such disparities are liable to hinder the free movement of goods within the Community" and thus directly affect the establishment and functioning of the internal market. (29) The Advocate General qualifed the preceding to the extent that the emergence of such obstacles must be likely and that the proposal must designed to prevent them. (30) Applying this qualified principle to the legal protection of industrial and intellectual property rights, the Opinion claimed that the Court had already recognised that, in the absence of harmonisation, different levels of legislative protection for an identical product would lead to the fragmentation of the market into national markets where the product would be protected and others where it would not: "the common market would not be a single environment for the economic activities of undertakings." (31) The supplementary objective of avoiding any obstacles to trade with the United States and Japan can also lawfully guide the Community's action. Indeed, the desire to improve the competitive position of European undertakings internationally may be said to underlie the entire internal market programme. (32)

[12] The Advocate General likewise did not accept the second Dutch argument that Community harmonisation was inappropriate and ineffective. The Opinion began by noting that harmonisation at Community level often takes place against a background of international conventions whose parties include Member States and third countries. "The existence of that context does not [...] deprive the Community institutions of the competence in the area conferred upon them by the Treaty." (33) Moreover, in this particular instance, the Advocate General strongly doubted that amendent of the EPC would be feasible and that if feasible, it would guarantee harmonisation, as "important areas of patent law governed by the Directive are outside its scope" and as the Convention provides for no means of ensuring uniform interpretation of regulations in those areas covered. (34) The Directive would accordingly prove more effective than the Convention. The fact that the Directive leaves scope for non-harmonised national rules regulating in particular public health, safety and environmental protection does not militate against its effectiveness in contributing to the free movement of the products concerned: "a patent is a right merely to prevent others from infringing the patent and does not confer any absolute entitlement on the proprietor to exploit the patent: exploitation is always subject to national regulation." (35)

[13] The third Dutch argument was that the Directive creates a specific right by requiring Member States to protect biotechnological inventions under their patent law and therefore that it cannot be said simply to harmonise national principles. The Advocate General found that "the patentability of living material is not an innovation introduced by the Directive but the recognition of what is actually happening in conformity with national law." (36) Citing instances at the national, continental and international levels, the Opinion showed that applications for such patents have for decades been recognized and regulated by Member States. It cautioned in any event that the Dutch use of the term "patent on life" was "unhelpful and unclear" as it implies a right of ownership and unfettered rights to exploit. The Directive explicitly recognises numerous limits to patentability in line with national laws and international conventions as well as the ongoing obligation of patent-holders to comply with national regulatory requirements. (37)

[14] Last, Italy sought to characterize the Directive as not so much intended to ensure the smooth functioning of the internal market as to support industrial development and scientific research in the Community. It should therefore have been adopted on the basis of Article 130 and 130f (now Articles 157 and 163, all EC Treaty) and not the former Article 100a. The Advocate General reviewed the measure's aim and content as they appeared from its wording so as to ascertain its legal basis. (38) The Opinion observed that while some of the recitals in the preamble to the Directive refer to the importance of biotechnological inventions for the Community's industrial development and so forth, the emphasis was on the need to eliminate differences in national law and practice. (39) The Opinion noted further that the need could already be objectively seen in Member States' divergent approachs in this area. (40) For its part, the content of the Directive - in particular Article 1(1), which unequivocally requires Member States to adjust their national patent law to take account of its provisions - supported the conclusion that the principal aim was harmonisation. Inasmuch as the provisions of the Directive "will affect industrial development in the Community [...] the impact [...] is indissociably linked with its harmonising effect." (41) As the principal aim of the Directive was, the Opinion concluded, harmonisation, this aim was decisive in determining the correct legal basis, namely the former Article 100a. In any event, stated the Advocate General, the former Articles 130 and 130f do not confer any legislative power on the Community, even if measures taken under other Treaty provisions simultaneously pursue objectives falling within the Articles' scope. Recourse to the former Article 235 may only be had where the Treaty has not elsewhere provided the necessary powers to legislate. The Treaty has done so, however, under the former Article 100a. The Opinion dismissed the alternative argument that the proposal was not in line with the high level of protection required by the former Article 100a(3), stating that the Directive did not fall within the scope of the Article. Although biotechnological research and resultant inventions may have significant implications on these matters, "the proposal did not seek to regulate such research or use from the standpoint of health, safety or environmental or consumer protection"; this regulation was expressly left to other authorities. (42)

3. The Judgment

[15] As regards the Netherlands' first argument under this heading, the Court's statement of the appropriate test to be applied is relatively simple and straightforward: "recourse to Article 100a as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws provided that the emergence of such obstacles is likely and the measure in question is designed to prevent them." (43) Applying this test, the Court found not only that the proper operation of the internal market was threatened by the risk of divergent trends in practice and case-law but also that "marked differences with significant consequences were already apparent between national laws" in this area. (44) The Court held that by requiring the Member States to protect biotechnological inventions by means of their national patent law, the Directive does in fact aim to prevent the emergence of such future obstacles.

[16] The Court dismissed as unfounded the argument that any legal uncertainty resulting from Member States' application of the relevant provisions of international law should have been removed not by Community harmonisation but by renegotiation of the relevant instruments (e.g. the EPC). "The purpose of harmonisation is to reduce the obstacles, whatever their origin, to the operation of the internal market." Even if the obstacles derive from differing interpretations of international legal instruments, "there is nothing to prevent recourse to adoption of a Directive as a means of ensuring uniform interpretation." (45) In this instance, the Court observed, such an approach does not appear inconsistent with the Member States' honouring their obligations under the EPC, is suitable for achieving its objective of uniformity in patentability and, given the "more indirect and unpredictable approach of seeking to amend the wording of the EPC", may well be preferable. (46)

[17] As regards the third Dutch argument, the Court began by noting the Community's competence to harmonise national laws in the field of intellectual property pursuant to the former Articles 100 and 100a (now Articles 94 and 95, all EC Treaty). Moreover, the Community may create new rights superimposed on national rights, as it did with the Community trade mark. (47) The Court found that the patents to be issued under the Directive are national patents, "issued in accordance with the procedures applicable in the Member States and deriving their protective force from national law." (48) The creation of a Community patent is neither the Directive's purpose nor effect, notwithstanding the fact that some of the inventions concerned were not previously patentable in certain Member States and that the scope of patent protection has been variously clarified and derogated. Recourse to the legal basis afforded by the former Article 235 was therefore not required.

[18] Last, the Court agreed with Italy that the legal basis on which an act must be adopted should be determined according to its principal aim. (49) It also agreed that the Directive is intended to promote biotechnological research and development in the Community. Where the Court disagreed with Italy was the relative importance to be placed on the harmonisation of national legislation that the Directive effects. It argues that the way in which research and development are to be promoted is by removing the legal obstacles within the single market. Harmonisation is "therefore not an incidental or subsidiary objective of the Directive but is its essential purpose." The fact that research and development are to be promoted does not "make it inappropriate to use Article 100a of the Treaty as the legal

basis of the Directive." (50)

B. Subsidiarity

1. The Application

[19] In conjunction with its submissions as regards to harmonisation, the Netherlands claimed as its second plea in law that the Biotech Directive infringed upon the Subsidiarity Principle. The second paragraph of the fomer Article 3b states that in areas that do not fall within its exclusive competence, the Community is to act only and insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community. The Netherlands submitted that if the objectives of the Directive are to clarify the legal protection of biotechnological inventions in view of existing national differences, this objective should be effected through amending the EPC. "[N]ational patent law has been almost entirely harmonised by the [EPC...]. The Member States are thus perfectly able to achieve that objective." (51)

[20] In the alternative, the Netherlands claimed that the Directive does not state sufficient reasons to establish that the second paragraph of the former Article 3b was taken into account per the former Article 190 of the EC Treaty (now Article 253 EC). This article provides that measures jointly adopted by the Parliament and Council "shall state the reasons on which they are based and shall refer to any proposals or opinions which were required to be obtained pursuant to this Treaty."

2. The Opinion

[21] The Advocate General found no infringement of the principle of subsidiarity. As explained in the context of the first plea, the Directive was necessary in order to harmonise Member States' legislation. This harmonisation could be effected only by the Community, as amendment of the EPC would be "inappropriate, ineffective and possibly not feasible." (52) Moreover, the Community has exclusive competence in the approximation of national rules concerning the establishment and functioning of the internal market. (53)

[22] Although the Advocate General admitted that the Directive did not make express reference to the principle of subsidiarity, that the principle was respected is allegedly apparent in the preamble. Jurisprudence makes clear that "in such circumstances it is not necessar for the legislation to make express reference." (54) The alternative argument regarding subsidiarity was thus in the Advocate General's view groundless.

3. The Judgment

[23] The Court found that the principal aim of the Directive, the removal of the legal obstacles to the smooth functioning of the single market, "could not be achieved by action taken by the Member States alone." (55) As the scope of the protection of biotechnological inventions has an immediate impact on intra-Community trade, "it is clear that, given the scale and effects of the proposed action, the objective in question could be better achieved by the Community." (56) The principle of subsidiarity was thus not breached. Indeed, compliance with the principle of subsidiarity is, in the Court's view, necessarily implicit in the recitals of the preamble of the Directive, which state that, in the absence of action at Community level, the development of national laws and practices impedes the proper functioning of the internal market. "It thus appears that the Directive states sufficient reasons on that point." (57)

V. Analysis

[24] In filing its application, the Netherlands was acting at the express request of the national Parliament, "in light of the opposition expressed there to genetic manipulation involving animals and plants and to the issuing of patents for the products of biotechnological procedures liable to promote such manipulation." (58) It is unlikely that the approach taken by the Court to biotechnological innovation will assuage the Dutch Parliamentarians' concerns, regardless of how well reasoned the judgment is perceived to be. For those who will brook no compromise of their ethical and social concerns, the judgment must appear wrong-headed, if not positively offensive.

[25] The original impetus for the Directive was to address competition from abroad by "harmonising the technical patent law issues necessary to create a robust biotech industry." (59) Although the European Parliament was subsequently able to introduce ethical elements into the Directive, the Directive remains predominantly influenced by the Commission's original conception of harmonisation. The elucidation of the 'ordre public' or morality exception and the clarification of the application of patent standards to biotechnological innovations do not alter the fundamental nature of the Directive. (60) The Court has essentially followed the Commission's approach in characterizing the Directive: it has considered biotechnological innovation as primarily an industrial and not an ethical and social issue.

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Put otherwise, the starting point of its analysis of the Directive's validity is the state of the biotechnological industry in Europe rather than the role of biotechnology in society. The Court's approach is manifested at different turns in the judgment. The Court held variously that biotechnological innovation was fit for regulation under a conventional intellectual property regime, that the Directive's primary intent was harmonisation for the well-functioning of the internal market and that harmonisation was effected only by clarifying existing national legislation. If an ethics-based approach to biotechnological innovation is taken, however, the issue appears in a different light. At each turn in the judgment, the alternative approach casts a shadow over the validity of the Directive.

[26] First, it may well be the case, as the Court states, that the Community is competent under the former Article 100a to harmonise intellectual property laws. (61) If so, this provision would provide a better legal basis for the Directive than the former Article 235. This reasoning presumes, however, that biotechnological innovation is a matter fit for regulation under a conventional intellectual property regime. To what degree it is is a question precedent that the Court never addresses. A good counter-argument may be ventured that in view of the ethical and social concerns involved, biotechnological innovation should not be regulated like other intellectual property: inventions involving materials of human origin should be handled differently than those involving bits and bytes. Article 7 and Recital 44 of the Directive foresee a periodic review by an expert group of ethicists, the European Group on Ethics in Science and New Technologies, of the basic ethical aspects of biotechnology including in respect of patent law. The Directive confers only advisory power on this group. Expansion of its mandate to oversee developments in the area and to bring ethical considerations into policymaking would, for example, constitute an alternative regulatory mechanism.

[27] Following on the above, it is jurisprudentially clear that the former Article 100a provided a legal basis for Community action where the primary intent of that action was to harmonise measures of Member States so as to eliminate or prevent distortions in the internal market. The question then is the proper judicial characterization of the impugned Community action. This characterization, which will inevitably involve an element of subjectivity, is to be made in light of the proposal's aim and content: "a measure must be seen to be about contributing to the well-functioning of the internal market mechanism; and not about something else, however worthy". (62) The means cannot, however, be collapsed into the end: the Court is to judge the direct and incidental impact of the measure on the functioning of the internal market to ensure that the measure in fact pursues the objectives stated by the Community legislature. (63) In short, if a measure that has as its object the functioning of the market mechanism is likely to have a direct impact on the functioning of that market, then harmonisation is permissible. It may at this point, however, be asked whether the Court in this analysis risks giving priority to the well-functioning of the market mechanism over all other considerations. As a measure may have a dual working, there is the possibility that its impact on other aspects of Community life may be greater than its impact on the functioning of the market mechanism - however direct the latter impact may be. In this case, is harmonisation really the appropriate legal basis for legislation? The former Article 100a(3) does provide for a high level of protection where health, safety, environmental protection and consumer protection is concerned. However, this qualification neither circumscribes all the conceivable effects of a measure nor does it prevent the Community from legislating in the first place. (64) It is also true that a broad legal basis of the kind in Article 100a may be indispensible in order to "cater for the multifarious problems of ensuring an open and competitive market." (65) Nonetheless, the analysis, so framed, seems rather too narrow minded, being focussed on the functioning of the internal market. Specifically as regards the Biotech Directive, the fact that it is clear from internal evidence that it was always directed at harmonising patent law and from external evidence that it will have a direct impact on the functioning of the market should not alone determine the propriety of harmonisation as a legal basis for Community action in this field.

[28] Next, the Court held that the Directive does not create any new rights superimposed on national rights; its purpose is only to clarify existing patent law. The contrast is drawn in the secondary literature to the future creation of a Community patent, which would require legislative reference to Article 308, and in the judgment to the historical creation of the Community trade mark, which did refer to the predecessor Article 235. As harmonisation in this case is not "simply the first step in a grander Community scheme," (66) the former Article 100a is said to provide the Community with a sufficient legal basis to act. This finding comes notwithstanding the fact that the patentability of the subject-matter is being extended. (In the course of clarifying existing patent law, the Directive included as patentable certain plant and animal matter that was previously not patentable in some Member States such as the Netherlands.) Indeed, this fact was seen to justify the harmonisation of the national laws. The distinction thereby drawn between the types of Community action is a very fine one, a distinction, that may not always support the weight placed on it. In terms of the Biotech Directive, while harmonisation neither grants powers to a Community body nor creates any framework at the Community level with respect to patents, the Directive does stipulate at a Community level rules regarding patentability and puts the Community's institutional machinery behind their protection. To that significant degree power is transferred to the centre. Given this transfer and the inclusion of ethical elements in the Directive, it is arguable that Directive's approval in the Council should have been subject to a higher voting threshold (*i.e.* unanimous consent rather than qualified majority). As above, in the Community's choice of legal basis, "here is certain room for abuse, and thus a need for vigilance." (67)

[29] The preceding observations concern the way in which the Community under the Biotech Directive took action. That the Community acted in the first place may also be critically examined. According to the positive integration paradigm, differences in Member States' measures regarding biotechnological innovation are a 'bad thing', since they lead to the fragmentation of the internal market. Seen from a broader perspective, however, differences may be a 'good thing', as they represent a statement of a political community's values. From this broader perspective, the propriety of judging Member States' measures according to their relative efficiency is questionable. If different citizenries harbour different preferences regarding the regulation of biotechnology, they are on democratic principles entitled to them with all their consequences, even if these include economically sub-optimal outcomes.

[30] According to the principle of representative government, Member States are to determine in international policymaking the degree of cultural specificity justifying singular behaviour and the obstruction of universal applicability. In the context of supranational negotiations, both the terms and the ancestry of the subsidiarity principle may be read as requiring citizens' preferences to be considered in policymaking. Such consideration in the present case argues for the regulation of biotechnology by Member States singly, using their own legislative powers. On the terms of second paragraph of the former Article 3b, the Member States can "sufficiently achieve" - or at least the Community cannot "better achieve" - the objective in question. (The democratic deficit is at all events greater at the supranational than at the national level.) The scale and effects of Community action would not "produce clear benefits", as demanded by the protocol annexed to the Treaty of Amsterdam, rather the opposite. Since it is doubtful that Member States' citizenries would have agreed to harmonisation of biotechnological regulation, (68) Community policymaking is a priori unrepresentative of Member States' various ethical and social preferences. Furthermore, supranational policymaking per Article 5's ancestry constitutes "a disturbance of the right order," since "a larger and higher association [is] arrogat[ing] to itself functions which can be performed efficiently by smaller and lower societies." (69)

[31] In the alternative, it may be reasonably argued that the Biotech Directive breached the third paragraph of the former Article 3b, the so-called proportionality principle. The proportionality principle may be read as circumscribing the degree to which the Community may intervene in Member States' affairs generally as well as the type of action that the Community is to propose specifically. The Directive legislated as regards not only national economic interests but also national ethical and social concerns. Legislation was not necessary in the latter regard to achieve the objectve of the Directive, the well-functioning of the market mechanism, but went "beyond what is necessary". The Directive is thus excessively intrusive on the Member States.

VI. The Broader Context

[32] It should be noted that the majority of the other Member States, while not opposing the Biotechnology Directive like the Netherlands and Italy, have been tardy in transposing it into national law. The deadline of 30 July 2000 went by with only a few Member States having actually passed legislation to give the Directive effect. "For several countries the delay is due to nothing more than procrastination. For others, [...] the delay is due to ethical concern over the Biotech Directive." (70) Germany, which supported the Directive in the Council vote, is apparently taking a restrictive view of the patentability of biotechnological innovation in its preparation of legislation implementing the Biotech Directive. The German Minister of Research has announced that the government will issue interpretative comments on the legislation to ensure that patents are given a narrow interpretation. For its part, the German Council of Ministers has urged careful scrutiny of Member States' legislation and has suggested that modifications to the Directive might be necessary to address issues related to the scope of biotechnology patents. (71)

[33] This lack of enthusiasm on the part of Member States for Community legislation regarding intellectual property has also been manifested in their reaction to two related Commission initiatives. At their March 2000 summit in Lisbon, EU leaders pledged to put a common patent in place by the end of 2001. Reaching agreement on the details has, however, proven much more difficult than reaching agreement in principle. As one Commission official notes, all the countries involved remain "addicted" to their own national practices. (72) Commission President Romano Prodi is now urging agreement at next spring's summit in Barcelona. (73) The prospects of success are, judging from the long history of such efforts, not good. Creation of a new intellectual property right goes beyond harmonisation and would need to be based on Article 308. The story of the Biotech Directive should have demonstrated the difficulties in achieving the requisite unanimity thereunder. (74)

[34] Similarly, Member States have shown themselves distinctly cool towards genetically modified crops following several food scares. The lack of enthusiasm here comes despite the Commission's having identified biotechnology as a key area for growth in its declared quest to help make the EU the world's most competitive and dynamic economy by 2010. Specifically, EU environment ministers last month spurned the Commission's latest proposal to reactivitate the GMO authorisation process that has been stalled for three years in the face of a voluntary moratorium. The Ministers fear a consumer backlash due to the widespread perception that GMOs pose potential health risks. (75)

Under the EU's regulatory scheme, if governments fail to take any decision, the Commission is supposed to authorise any products once they are passed as safe. Approval has been given to 13 new GMO varieties by the EU's scientific advisers since the moratorium was declared, but the Commission has yet to authorise them. Although the Commission fears legal action from frustrated biotech groups if it fails to act, it is apparently "acutely aware of the public relations disaster if it chose to override the wishes of elected EU governments, particularly on an issue as sensitive as food safety." (76)

[35] In view of the experience with the Biotech Directive, the common patent and GMOs, it appears as if the Community is reaching the limits of cooperation regarding intellectual property. Further integration in this as in all other fields of Community policymaking is contingent on popular and political commitment. In the specific instance of biotechnological innovation, ethical and social concerns are directly implicated in policymaking. These are of great sensitivity and can be the subject of considerable disagreement within as well as between political communities. "The level of public concern and its effects on developing policy over biotechnology cannot be underestimated. As the Community further embraces the biotechnology industry, it would be wise to better consult with and take into account public attitudes toward biotechnology." (77) Attempting to proceed faster than participants desire risks not merely failure but provoking a backlash. Since the passage of the idealism of the immediate post-war years, European integration has been largely driven by 'economism', the language of economics. (78) The Commission and the Court's approach to the Directive with their overriding concern for the efficiency of the marketplace seem the latest examples of this trend. Like other utilitarian ideas, however, maximizing economic growth remains subject to certain overrides. The resistance of the Member States' governments and citizenries to further supranational cooperation regarding policymaking in this field may be an example of such an override in effect. Community regulation of biotechnological innovation that speaks first and foremost to shared values would prove far more acceptable to the peoples and politicians of the Member States.

VII. Conclusion

[36] In taking action under the present Article 95 of the EC Treaty, the Commission must always be mindful that there "a risk of the creeping extension of Community powers might lie." (79) Inevitably the competences in such a complex order as the EU's will to some degree remain unclear. The fact that a precise meaning cannot be given to the principles of harmonisation and subsidiarity places, however, a responsibility on all parties to `play fair´. It is responsibility of all "interpretative communities" (80) - but especially of the European Court of Justice, the final arbiter of the existing Treaties - to maintain an appropriate balance beween the Community's and the Member States' powers. To maintain this balance, these institutions must take into account prevailing political sensitivities as well as the constitutive Treaties' terms and practise self-restraint in the exercise of their powers.

[37] It is not clear that in the case of the Biotech Directive the Court - and the Commission before it - acted as they should have. They were not as careful in invoking the former Article 100a of the EC Treaty as a legal basis for action as they might have been. "While the Commission may have believed, at first, that the Biotech Directive was simply addressing technical difficulties within patent law, this was a grave misreading of the public's attitudes toward biotechnology." (81) The Court in its recent judgment has to an unfortunate extent repeated the Commission's mistake. By considering biotechnological innovation primarily as an industrial and not an ethical and social issue, it has engaged in an overly functionalist analysis. The Directive's validity hinged on its direct impact on the region's biotech industry rather than on European society. If, however, an alternative, ethics-based approach to biotechnological innovation had been taken by the Court, the issue would have appeared in quite a different light and the validity of the legislative framework with it.

[38] Although the legal challenge to the Biotech Directive failed, it "may not have been fruitless", as the Advocate General noted, (82) but for reasons other than he cited. The Opinion argued that the Dutch action "highlights the importance of regulating at national level the use of biotechnological material, precisely because such use, since it falls outside the parameters of patentability, is not - indeed cannot be - regulated by the Directive." (83) The Directive and the judgment do represent the start, rather than the end, of discussions about ethical and social questions regarding biotechnology in Europe. These discussions are, however, not likely to take place at the national but at the supranational level. Moreover, they may be expected to centre on the propriety of the EU legislating matters of considerable sensitivity and disagreement rather than on the use of biotechnological material. A clearer, politically and popularly more satisfactory demarcation of EU competence may be their ultimate outcome.

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(1) EC, Case C-377/98: Judgment of the Court of Justice of the European Communities in The Kingdom of the Netherlands v European Parliament and Council of the European Union; online: http://europa.eu.int/cj/index.htm; hereinafter 'Judgment'. For a press report on the decision, *see* "EuGH weist Klage gegen Gen-Richtlinie ab", NEUE

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JURISTISCHE WOCHENSCHRIFT, 9 October 2001, archived at newspaper website without page citation.
(2) EC, Directive 98/44 of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, OJ L (1998) No L213 at 13, hereinafter 'the Biotech Directive' or 'the Directive'.
(3) The harmonisation programme exemplified by the Directive is an instance of 'positive integration', as opposed to the 'negative integration' achieved by ECJ decisions rendering 'inapplicable' domestic provisions contrary to EC law.
(4) Alan Dashwood, The Limits of European Community Powers, (1996) 21 E.L. Rev. 113, p. 114.
(5) Article 1(2), EU Treaty.
(6) Dashwood, p 113.
(7) The interaction between ethics and patent policy is a complex issue, which will not be treated here. Hopefully it suffices to note that public uncertainty may arise not only out of the ethics of using patented inventions but also out of the ethics of a market-based patent system that has the potential to "encourage the development of morally suspect activity." E.R. Gold and A. Gallochat, The European Biotech Directive: Past as Prologue, European Law Journal, Vol. 7, No. 3, September 2001, 331, p. 333.
(8) The discussion here will focus on the jurisdictional foundations of the Directive rather than on the provisions themselves. For a more detailed description of the provisions, *see, ibid.*, p. 343ff.
(9) EC, Case C-377/98: Action brought on 19 October 1998 by Kingdom of the Netherlands against European Parliament and the Council of the European Union, OJ Information (1998) No 98/C378/13.
(10) This theme will be treated more extensively later in this article.
(11) Gabriel Gloeckler et al., Guide to EU Policies, Blackstone: London, 1998, p. 20.
(12) Josephine Steiner and Lorna Woods, Textbook on EC Law (6th ed.), Blackstone Press: London, 1998, p. 123.
(13) Ibid., p. 124.
(14) Dashwood, p. 114.
(15) Ibid., p. 115.
(16) Ibid., p. 116.
(17) Ibid., p. 115.
(18) Ibid.
(19) EC, Case C-377/98: Opinion of the Advocate General, F.G. Jacobs, 14 June 2001; hereinafter 'Opinion'.
(20) Judgment at paragraph 13.
(21) Judgment at paragraph 14.
(22) Opinion at paragraph 45.
(23) Ibid.
(24) Judgment at paragraph 19.
(25) Judgment at paragraph 23.
(26) Judgment at paragraph 26.
(27) Opinion at paragraph 64.
(28) See infra.
(29) Opinion at paragraph 46.
(30) Opinion at paragraph 47.
(31) Opinion at paragraph 48.
(32) Opinion at paragraph 50.
(33) Opinion at paragraph 52.
(34) Opinion at paragraphs 52-53.
(35) Opinion at paragraph 55.
(36) Opinion at paragraph 67.
(37) Opinion at paragraph 70.
(38) Opinion at paragraph 58.
(39) Opinion at paragraph 59.
(40) Opinion at paragraph 60.
(41) Opinion at paragraph 61.
(42) Opinion at paragraph 65.
(43) Judgment at paragraph 15. The supporting jurisprudence is found in Case C-350/92 Spain v Council [1995] ECR I-1985, paragraph 35, and Case C-376/98 Germany v Parliament and Council [2000] ECR I-8419, paragraph 86.
(44) Judgment at paragraph 17.
(45) Judgment at paragraph 20.
(46) Judgment at paragraph 22.
(47) Judgment at paragraph 24; with reference to point 59 of Opinion 1/94 of 15 November 1994 ([1994] ECR I-5267).
(48) Judgment at paragraph 25.
(49) Judgment at paragraph 27, with reference to paragraphs 19 to 21, Case C-155/91 Commission v Council [1993] ECR I-939.
(50) Judgment at paragraph 28, with reference to paragraphs 18 to 20, Case C-62/88 Greece v Council [1990] ECR I-1527. The Court did not explicitly consider Italy's alternative argument under the former Article 100a(3) EC Treaty.

(51) Opinion at paragraph 79.
(52) Opinion at paragraph 83.
(53) Opinion at paragraph 81.
(54) Opinion at paragraph 82.
(55) Judgment at paragraph 32.
(56) Ibid.
(57) Judgment at paragraph 33.
(58) Judgment at paragraph 4.
(59) Gold, p. 332.
(60) Ibid., Part II generally.
(61) See Spain v Council, above.
(62) Dashwood, p. 120.
(63) In the 'Tobacco Advertising' decision, the Court characterized a directive approximating national measures relating to the advertising and sponsorship of tobacco products as an invalid attempt to regulate public health. The invalid Directive did not contribute to the elimination of obstacles to the free movement of goods and services or to the elimination of the distortion of competition. See Germany v Parliament and Council above.
(64) As one observer noted, "the real battlefield is regulation by the Community in areas in which Member States may feel that they do not want any regulation at all" and not how high the level of protection in the Community harmonising measures is. J.H.H. Weiler, The Constitution of Europe, 1999, p. 71.
(65) Dashwood, p. 122.
(66) Gold, p. 352.
(67) Dashwood, p. 122.
(68) Gold, p. 361f.
(69) Pope Pius XI in his Encyclical of 1931, Quadragesimo Anno, as quoted in Dashwood, p. 115.
(70) Gold, p. 343.
(71) Ibid., p. 351.
(72) ECONOMIST, 3 November 2001, p. 68.
(73) FINANCIAL TIMES, 13 November 2001, p. 8.
(74) The Community has been trying since 1975 to create Community-wide patents. As Gold notes, many difficulties plague the most recent proposal, the draft Council Regulation of 2000. These include language (the proposal would require the patent to be filed in either English, German or French with subsequent translation into the other two languages) and the jurisdiction of courts (the proposal calls for the creation of a centralised judicial system). "It is therefore unlikely that a Community Patent will come into existence anytime soon." Gold, pp. 334 and 354.
(75) FINANCIAL TIMES, 10/11 November 2001, p. 6.
(76) Ibid.
(77) Gold, p. 361.
(78) Larry Sidentop, Democracy in Europe, Allen Lane The Penguin Press: London, 2000, p. 217.
(79) Dashwood, p. 120.
(80) Weiler, p. 43 *inter alia.*
(81) Gold, p. 361.
(82) Opinion at paragraph 226.
(83) Opinion at paragraph 228.