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Review, Risk, Legality and Damages

Paul Craig*

*Case C-221/10 P, Artegoda GmbH v European Commission and Federal Republic of Germany*¹

I. Introduction

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

Artegoda is the holder of a marketing authorization for Tenuate Retard, a medicinal product, which contains amfepramone, an amphetamine-like anorectic substance. There was however a re-evaluation of amfepramone at the request of a Member State, and this led the Commission to adopt the contested decision on the basis of Article 15a of Directive 75/319.²

This Directive established a system of mutual recognition, whereby an authorization granted in one Member State had to be recognized in other Member States. There were however not surprisingly qualifications to this regime, and it was open to a Member State pursuant to Article 15a to press for the withdrawal of the authorization on the ground of public health concerns. The schema was for the Member State to refer the matter to the Committee for Proprietary Medicinal Products, CPMP, although it was open to the Member State in cases of urgency to suspend authorization of the product in its territory pending this final decision. The CPMP issued a reasoned opin-

ion which would be forwarded by the European Agency for the Evaluation of Medicinal Products to the Member States, the Commission and the person responsible for placing the medicinal product on the market, with a report describing the assessment of the medicinal product and stating the reasons for its conclusions.³ It was then for the Commission, within 30 days of receipt of the CPMP's opinion, to prepare a draft decision. Where exceptionally the draft decision was not in accordance with the opinion of the EMA it was incumbent on the Commission to provide a detailed explanation of the reasons for the differences.⁴

The Commission decision ordered the Member States to withdraw the national marketing authorizations for amfepramone, in reliance on scientific conclusions attached to the CPMP's final opinion in August 1999. This was challenged by Artegoda, which argued, *inter alia*, that the Commission lacked competence and that the decision infringed Directive 65/65.⁵ The GC annulled the contested decision in 2002 on the ground that the Commission lacked competence, and held moreover that even if the Commission had competence the decision infringed Article 11 of Directive 65/65.⁶ The GC's decision was upheld on appeal. The ECJ held that the Commission lacked competence to adopt the contested decision, but did not rule on the other arguments concerning Directive 65/65.⁷

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

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

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

³ Directive 75/319/EEC, Art. 13.

⁴ Directive 75/319/EEC, Art. 14.

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

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

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

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

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

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

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

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

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

II. The CJEU

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

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

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

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

¹⁰ Case 429/05, para. 108.

¹¹ Case 429/05, para. 108.

¹² Case 429/05, paras. 109-111.

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

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

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

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

Artegoda also contested the GC's reasoning concerning Article 11 of Directive 65/65, more especial-

ly its refusal to find that the breach of this Article constituted a sufficiently serious breach of EU law. It argued, inter alia, that the complexity of a legal or factual situation should not necessarily lead to the conclusion that there is an absence of any sufficiently serious breach.

The CJEU's consideration of this aspect of the appeal was rendered more complex by the fact that discussion of damages liability was interwoven with the issue of whether the ECJ in 2003¹⁵ had pronounced on Article 11 of Directive 65/65. The CJEU reiterated the importance of *res judicata* in EU law, regarding it as important to ensure stability of the law, and the sound administration of justice: 'judicial decisions which have become definitive after all rights of appeal have been exhausted, or after expiry of the time-limits provided to exercise those rights, can no longer be called into question'.¹⁶ However *res judicata* extended 'only to the matters of fact and law actually or necessarily settled by the judicial decision in question'.¹⁷ The legal reality was that the ECJ's 2003 ruling was premised on the Commission's lack of competence, and the ECJ did not, as noted earlier, rule on the Article 11 issue. The CJEU therefore concluded that the Article 11 issue had not yet been addressed and that the 2003 ruling was only *res judicata* in relation to the competence issue.¹⁸ Insofar as the GC in the case under appeal had found that the Article 11 issue had been determined and was thus *res judicata*, it had made an error of law.¹⁹

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

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

13 Case C-221/10 P, para. 81, relying on Case C-228/90, *Industriellen Handelssondemering Vreugdenhil BV v Commission* [1992] ECR I-1937, paras. 20-22.

14 Case C-221/10 P, para. 82.

15 Case C-39/03 P.

16 Case C-221/10 P, para. 86.

17 Case C-221/10 P, para. 87.

18 Case C-221/10 P, para. 92.

19 Case C-221/10 P, para. 93.

community. The CJEU concluded in the following vein.²⁰

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

It followed said the CJEU that the Commission did not fail to comply with the substantive criteria for the withdrawal of a marketing authorization of a medicinal product laid down in Article 11 of Directive 65/65.²¹ There had been no breach of Article 11 and hence there was no sufficiently serious breach for the purposes of damages liability.²² It followed also that the errors of law committed by the GC were not such as to invalidate the contested judgment, given that the conclusion could be justified on the grounds specified above.

III. Conclusion

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

1. Sufficiently serious breach

The first relates to application of the sufficiently serious breach test. It has never been easy to prove the conditions for damages liability against the EU, although the test has become somewhat less restrictive than it was in the earlier years.²³ The need to prove the existence of a sufficiently serious breach of EU law has always been the principal stumbling block

in this respect, and the hurdle may be especially difficult to surmount in relation to the types of case that arise in the context of risk regulation. It may be felt that the EU courts were harsh on the claimant insofar they held that even though Article 11 of Directive 65/65 did not entail meaningful discretion the legal and factual complexity surrounding its application meant that the applicant had not proven the existence of a sufficiently serious breach of EU law for the purposes of damages liability. The temptation to reach this conclusion should nonetheless be resisted for the following reason.

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

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

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

20 Case C-221/10 P, para. 104.

21 Case C-221/10 P, para. 108.

22 Case C-221/10 P, para. 109.

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

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

2. Appeals, errors and alternative legal grounds

The CJEU decided that the GC had committed errors of law, but that its substantive conclusion would not

be overturned because it could be sustained on the grounds set out in the preceding analysis.

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

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

From Status to Impact, and the Role of National Legislation: The Application of Article 34 TFEU to a Private Certification Organisation in *Fra.bo*

Barend van Leeuwen*

Case C-171/11, Fra.bo SpA v Deutsche Vereinigung des Gas- und Wasserfaches eV (DVGW) – Technisch-Wissenschaftlicher Verein (Judgment of 12th July 2012, nyr)

In Fra.bo, it was held by the Court of Justice of the European Union (“CJEU”) that “Article 28 EC¹ must be interpreted as meaning that it applies to standardisation and certification activities of a private-law body, where the national legislation considers the products certified by that body to be compliant with national law and that has the effect of restricting the marketing of products which are not certified by that body”² (author’s headnote).

I. Facts

Fra.bo SpA (“Fra.bo”) is an Italian business which manufactures and sells copper fittings. These copper fittings are used to connect two pieces of piping for water or gas. They have sealing rings made of malleable material at the ends to make them water-tight.

In Germany, the Deutsche Vereinigung des Gas- und Wasserfaches eV (“DVGW”) makes standards which lay down the technical requirements with which such copper fittings have to comply. It is an association established under private law. German legislation has provided that products in connection with the supply of water can be lawfully brought on the German market if they have a CE mark. If they do not have a CE mark, the alternative is for products to be certified by DVGW. In fact, DVGW uses a sub-contractor for its certification activities, for which its own technical standards are used.

Fra.bo applied for certification of its copper fittings by DVGW in 1999. In 2000, Fra.bo was award-

ed a certificate for the duration of five years. The certification assessment itself had been subcontracted by the German laboratory which was normally used and approved by DVGW to a non-approved Italian laboratory. During the five-year period in which the certificate was valid DVGW received complaints by third parties which resulted in a re-assessment procedure, directly undertaken by the approved German laboratory. In 2005, DVGW informed Fra.bo that its fittings had not passed the ozone test, but that it was free to submit its own assessment report within three months. Fra.bo then had another assessment done by a non-approved Italian laboratory, which found that its fittings did pass the ozone test. However, DVGW refused to recognise this report because it had not been undertaken by one of its approved laboratories. As a consequence, it cancelled Fra.bo’s certificate in June 2005. Therefore, Fra.bo was no longer able to place its copper fittings on the German market.

After the cancellation of the certificate, Fra.bo brought an action against the cancellation before the Landgericht Köln, which dismissed its claim. It then appealed to the Oberlandesgericht Düsseldorf, which decided to stay the proceedings to make a preliminary reference to the Court of Justice of the European Union (“CJEU”). Its main question was whether Article 34 TFEU (ex Article 28 EC), which provides for

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1 Now Article 34 TFEU

2 Case C-171/11, *Fra.bo SpA v Deutsche Vereinigung des Gas und Wasserfaches eV (DVGW) – Technisch-Wissenschaftlicher Verein* (Judgment of 12th July 2012), para 34.

the right to free movement of goods, was applicable to the standardisation and certification activities of DVGW. If the answer to this question was negative, its alternative question was whether DVGW's standardisation and certification activities constituted "economic activity" for the purposes of Article 101 TFEU (ex Article 81 EC).

II. Judgment

It is appropriate to start with the Opinion of Advocate General (AG) Trstenjak. She argued that it was already clear from the CJEU's case law on the applicability of the free movement provisions to private parties that it had moved to an approach based on the *effects* of the rules created by collective regulators. Although the previous cases had not expressly dealt with the free movement of goods, and it had been argued that horizontal direct effect of the free movement of goods had been excluded by the CJEU, as a matter of principle it would not be right to take a different approach to free movement of goods vis-à-vis the other fundamental freedoms.³ Given that DVGW had obtained a position of significant power in the certification market as a result of the German legislation, it was virtually impossible to bring the fittings on the market without a certificate awarded by DVGW. This effect was reinforced by the fact that the referring Court had found that the copper fittings were not covered by a harmonised European technical standard, which meant that this was not a case in which Fra.bo could obtain a CE mark. Certification by DVGW was then the only alternative. AG Trstenjak argued that given this *de facto* competence to decide which products could be lawfully brought on the market, which had been granted to DVGW by the German legislation, its activities had to be caught by the provision on free movement of goods.⁴

The CJEU more or less followed the arguments of AG Trstenjak. In a relatively short judgment it, first of all, found that the copper fittings in question were not covered by a harmonised European technical standard. As such, Member States were free to adopt their own technical standards, which would still have to comply with the free movement of goods.⁵

The CJEU then focussed exclusively on the applicability of Article 34 TFEU. Although DVGW was a private law association over which the German State did not exercise any decisive influence, this in itself

did not constitute a reason not to apply the free movement provisions to its activities. Therefore, the question for the CJEU to answer was whether the activities of DVGW could have "the effect of giving rise to restrictions on the free movement of goods in the same manner as do measures imposed by the State".⁶

The CJEU answered this question in the affirmative and, in reaching its conclusion, used three key arguments.⁷ First of all, German legislation had provided that goods certified by DVGW would be compliant with national law and could be lawfully brought on the market. Secondly, DVGW was the only body which certified copper fittings in Germany. As a result, the only possibility for business to obtain a certificate of compliance was through certification by DVGW. Thirdly, a lack of certification by DVGW would result in serious difficulties to place products on the German market. Almost all German consumers bought copper fittings which had been certified by DVGW.

On the basis of these three arguments, the CJEU held that "a body such as the DVGW, by virtue of its authority to certify the products, in reality holds the power to regulate the entry into the German market of products such as the copper fittings at issue in the main proceedings"⁸ and that, consequently, Article 34 TFEU was applicable to its standardisation and certification activities. This meant that it was not necessary to answer the question on the applicability of Article 101 TFEU.

III. Comment

It should not come as a surprise that the CJEU held that DVGW's activities were caught by the provision on the free movement of goods. In the past decade, the CJEU has gradually moved from deciding the applicability of the free movement provisions on the basis of the public or private *status* of the regulator to the actual *impact* of the regulatory actions on the

3 Opinion of AG Trstenjak in Case C-171/11, *Fra.bo SpA v Deutsche Vereinigung des Gas und Wasserfaches eV (DVGW) – TechnischWissenschaftlicher Verein*, paras 43-45.

4 *Ibid.*, paras 49-50.

5 Case C-171/11, *Fra.bo SpA v Deutsche Vereinigung des Gas und Wasserfaches eV (DVGW) – TechnischWissenschaftlicher Verein* (Judgment of 12th July 2012), paras. 18-20.

6 *Ibid.*, para 26.

7 *Ibid.*, paras 27-30.

8 *Ibid.*, para 31.

internal market. This approach has been taken to improve the effectiveness and uniformity of EU law.⁹ Public and private regulators act in the same internal market and while some of the Member States still have public regulators, others have delegated powers to private regulators. If Member States could escape the application of EU law by delegating regulatory powers to private parties, this would be highly detrimental to the effectiveness of the free movement provisions.

This rationale was clearly recognised by AG Trstenjak and can also be seen in the judgment itself. The move towards an effects-based application of the free movement provisions is very clear from the structure of the judgment. The CJEU justified the application of the provision on the free movement of goods to DVGW by reference to three main arguments outlined above. These arguments were provided *after* the CJEU referred to the definition of a restriction of the right to free movement of goods based on the *Dassonville* formula.¹⁰ Traditionally, the determination of the applicability of the free movement provisions preceded the determination of a restriction. In this case, the issue of applicability is determined on the basis of the identification of a restriction. To put it in simple terms, Article 34 TFEU was held applicable to DVGW *because* its actions constituted a restriction of the free movement of goods. Therefore, it is clear that the free movement of goods provision was applied to DVGW's activities because of the impact its activities had on the internal market, not because of its public or private status as regulator. It is not entirely clear how this effects-based application can be reconciled with the CJEU's own statement in *Fra.bo* that the measures must give rise to restrictions to the free movement of goods imposed "in the same manner as do measures imposed by the State".¹¹ This would appear to be a somewhat formalistic return to

a distinction based on whether or not measures can be attributed to the State or are similar to measures taken by the State.

If it is not really surprising that the free movement provisions were held applicable to DVGW's activities, why is *Fra.bo* still such an interesting case? This is because many EU lawyers were interested to find out whether the application of the free movement provisions to DVGW was considered to be horizontal or vertical direct effect by the CJEU. However, the CJEU was very careful not to touch on that issue in its judgment. One could argue that it no longer makes sense to distinguish between horizontal and vertical direct effect, since all that matters is the impact of the regulatory conduct on the internal market. This was the position taken by AG Maduro in his Opinion in *Viking*.¹² While it is correct that it does not make any difference when deciding on the applicability of the free movement provisions, the horizontal or vertical nature of the proceedings might still have an impact of the issue of responsibility or liability. If the Oberlandesgericht Düsseldorf were to find that the activities of DVGW constituted an obstacle to *Fra.bo*'s right to free movement, would DVGW be required to compensate *Fra.bo* itself, or would it be able to forward the bill directly to the German State? After all, the effect of the German legislation was a decisive factor in the CJEU's decision to apply the free movement provisions to DVGW.

In that respect, the *Fra.bo* case is illustrative of a recent series of cases in which the private regulator to which the free movement provisions were applied had a clear link to the State and to national legislation. Although the German State had no direct influence on the activities of DVGW, DVGW's activities would not have had an important regulatory impact if the German legislation had not singled out DVGW as the main certification body in the market. As such, this case in a way challenges the CJEU's previous rationale for extending the application of the free movement provisions to private parties. In the traditional series of cases based on *Walrave en Koch*,¹³ the CJEU focussed on two functional criteria. The first was that the private party had to be engaged in collective regulation; the second was that it was exercising legal autonomy. In *Fra.bo*, there appears to be a tension between these two criteria. They did not cause any difficulties in cases like *Walrave en Koch* or *Bosman*,¹⁴ in which the private regulators in question, the UCI and the UEFA, were clearly powerful

9 Stefaan van den Bogaert, "Horizontalty: the Court Attacks?", in Catherine Barnard and Joanne Scott, (eds.), *The Law of the Single European Market: Unpacking the Premises*, (Oxford: Hart Publishing, 2002), pp. 123–152.

10 Case C-171/11, *Fra.bo SpA v Deutsche Vereinigung des Gas und Wasserfaches eV (DVGW) – TechnischWissenschaftlicher Verein* (Judgment of 12th July 2012), para 22.

11 *Ibid.*, para 26.

12 Opinion of AG Maduro in *Viking*, Case C-438/05, *International Transport Workers' Federation and Finnish Seamen's Union v Viking Line ABP et al.*, [2007] ECR I-10779, paras 38–40.

13 Case C-36/74, *Walrave and Koch v Association Union cycliste internationale and others*, [1974] ECR 1405.

14 Case C-415/93, *Union Royale Belge des Sociétés de Football Association ASBL v Jean-Marc Bosman and others*, [1995] ECR I-4921.

private regulators which were entirely independent from the State. There was no link to national legislation. In *Fra.bo*, the collective regulation element of DVGW's activities derived from the German legislation. The collective impact of DVGW's certification activities would not have occurred but for the decision of the German legislature to refer to DVGW in the legislation. Therefore, it can be concluded that the collective regulation aspect of DVGW's activities was much more vertical than horizontal.

However, when we look at the criterion of legal autonomy the situation is quite different. DVGW was acting autonomously in its adoption of the rules which gave rise to the dispute in *Fra.bo*. The specific rules on the ozone testing had been adopted by DVGW itself without any State input. The same applied to its rules which provided that it would not accept reports from non-approved laboratories. In fact, the German legislation had given something of a "carte blanche" to DVGW to regulate according to its own standards and rules. It did not in any way prescribe *how* DVGW should exercise its standardisation and certification activities. Although the German legislation had placed DVGW in a position of regulatory power, the exercise of that regulatory power was not controlled by the legislation. From that perspective then, the application of the free movement provision would seem to be more horizontal than vertical.

This discussion is not purely theoretical, since it will have a real impact on the question of liability. If private regulators are increasingly going to be held liable under free movement law, the impact of the relationship between private regulators and the State on the issue of liability should be further clarified by the CJEU. This is not something which can simply be

left to national courts, as it is a matter of EU law when the free movement provisions should be applied to private parties and when they should be held liable. Further clarification of some of the concepts used by the CJEU is required. For example, in *Fra.bo*, if legal autonomy was to be the key criterion, it would be just to hold DVGW individually and solely liable for any breaches of free movement law. However, if the application of the free movement provisions was more based on the collective regulation aspect, then it would be just to hold the German State liable. This is a question of legal certainty for national private regulators which remains to be answered by the CJEU. It was not adequately dealt with in *Laval*,¹⁵ in which the CJEU failed to apply its discussion of the interaction between the trade union's actions and the Swedish legislation to the question of liability. As a consequence, the Swedish Labour Court was left to decide the issue of liability with very limited guidance.¹⁶ The outcome cannot be described as a success.¹⁷ Therefore, the CJEU should not simply continue to extend the application of the free movement provisions to private parties without providing more guidance on this issue.

15 Case C-341/05, *Laval un Partneri Ltd v Svenska Byggnadsarbetareförbundet et al.*, [2007] ECR I-11767.

16 *Arbetsdomstolens domar* (Judgments by the Labour Court) 2009 No. 89 of 2 Dec. 2009. Unofficial English translation by Jur. Dr Laura Carlson, available on the Internet at <<http://arbetsratt.juridicum.su.se/Filer/PDF/ErikSjoedin/AD%202009%20nr%2089%20Laval%20English.pdf>> (last accessed on 6 August 2013).

17 Barend van Leeuwen, "An illusion of protection and an assumption of responsibility: the possibility of Swedish State liability after *Laval*", in Catherine Barnard and Marcus Gehring (eds.), *The Cambridge Yearbook of European Legal Studies 2011-2012*, Volume 14, (Oxford: Hart Publishing, 2013), pp. 453-473. Others are more positive: Ulf Bernitz and Norbert Reich, "Case comment: The Labour Court Judgment in the Case *Laval et Partneri*", 48 *CML Rev* (2011), pp. 603-623.

The Product of Nature Doctrine in the Myriad Saga II

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*In June 2013, the U.S. Supreme Court decided *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, holding that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring”.*

This case note gives an overview of the U.S. Supreme Court’s decision, which is focused on the product of nature doctrine, and discusses its implications for the implementation of the criterion of isolation to DNA sequences and the United States Patent and Trademark Office’s long-standing practice of granting patents on isolated DNA sequences (author’s headnote).

I. The “Myriad Case” before the U.S. Supreme Court

On June 13, 2013, the Supreme Court of the United States decided *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*¹ (the “Myriad case”), and its holding may affect the United States Patent and Trademark Office’s (USPTO) long-standing practice of granting patents on *isolated* DNA sequences and the implementation of the concept of *isolation* in order to establish patent eligibility.

The Myriad case involves some very controversial patents in both Europe² and the United States on BRCA1 and 2 genes, whose mutations are linked to genetic breast and ovarian cancer. The BRCA1 gene, discovered in 1990, is a tumor-suppressor gene linked to genetic breast and ovarian cancer. Women who

have a mutation of this gene tend to have a high incidence of breast cancer, as well as ovarian cancer. In 1995 the BRCA2 gene was mapped and sequenced. While BRCA1 affects only women and also carries an increased risk of ovarian cancer, BRCA2 raises the risk of breast cancer alone, and can affect both women and men.³

Litigation started on May 12, 2009 when an assortment of medical organizations⁴ and a group of patients, researchers and genetic counselors working on the prevention and cure of breast cancer sued Myriad Genetics, the directors of the University of Utah Research Foundation, and the U.S. Patent and Trademark Office (USPTO). The plaintiffs challenged fifteen claims of seven patents owned or exclusively licensed to Myriad Genetics, a company involved in diagnostic testing, and asked for summa-

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1 See Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, 13 June 2013, 569 U.S. 12-398 (2013), available on the Internet at <http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf> (last accessed on 14 August 2013).

2 See Mariachiara Tallacchini, *Gene Patenting in Europe* (forthcoming): “In Europe, after two patents on BRCA1 (Patents EP0699754 and EP0705902) were granted by the EPO in January and November 2001, Switzerland’s Social Democratic Party, Greenpeace Germany, the French Institute Curie, Assistance Publique-Hôpitaux de Paris, the Belgian Society of Human Genetics, the Netherlands, the Austrian Federal Ministry of Social Security et al. filed an opposition with the support of the European Parliament.

Opponents argued that both inventions lacked novelty, inventive step and industrial application and posed ethical and policy concerns. One of the patents was revoked and the other was amended. After Myriad’s appeal and opposition they were restored, but in an amended form”.

3 G. De Wert, R. Ter Meulen, R. Mordacci and M. Tallacchini, *Ethics and Genetics. A Workbook for Practitioners and Students* (Oxford-New York: Berghahn Books, 2003). On the discovery of BRCA1 and 2 genes see also S. Parthasarathy, *Building Genetic Medicine. Breast Cancer, Technology, and the Comparative Politics of Health Care* (Cambridge MA: The MIT Press, 2007), at pp. 3-7.
4 (1) The Association of Molecular Pathology (AMP); (2) The American College of Medical Genetics (ACMG); (3) The American Society for Clinical Pathology (ASCP); (4) The College of American Pathologists (CAP).

ry judgment on their invalidity. These claims fall into two main categories: product claims⁵ and method claims.⁶

The public debate raised by these patents focuses on whether the claims are patentable subject matter according to Title 35 § 101 U.S.C.,⁷ since they include the so-called “wild type” sequences,⁸ namely DNA sequences not altered and mutated.⁹ These sequences are the basis for performing any kind of clinical genetic predisposition test for breast and ovarian cancer, in order to establish the actual existence of mutations in the BRCA1 and 2 genes of individuals.

The claims have been challenged on legal and constitutional grounds. According to the plaintiffs the claims fall within the judicial patentability exclusion affirmed in *Diamond v. Chakrabarty*¹⁰ on the laws of nature, natural phenomena and abstract ideas. Furthermore, they infringe the First Amendment,¹¹ which deals with liberty of expression and association, and Article I, section 8, clause 8 of the U.S. Constitution.¹²

Myriad was accused of having pursued, since the '90s, a commercial strategy aimed at gaining a monopoly on BRCA1 and 2 mutations testing:

1. Myriad patented several BRCA1 and 2 sequences, as well as the methods to compare them.
2. Then it enforced its patents and exclusive licenses against other researchers, clinicians and laboratories offering similar services, by sending cease

and desist letters and proposing collaboration licenses.

This monopolistic strategy was considered to have hindered clinical research on cancer, limited the performance of alternative/complementary clinical diagnostic tests for hereditary cancer predisposition, raised considerably the health insurance costs related to BRCA1 and 2 mutations testing and restrained access to health care for patients.

The District Court granted summary judgment to the petitioners on the composition claims and concluded that Myriad's claims, including the ones related to cDNA,¹³ were invalid since they covered products of nature.

On July 29, 2011, the Court of Appeals for the Federal Circuit held valid most of Myriad's patents on BRCA1 and 2 genes, reaffirming the USPTO's longstanding practice of granting patents on isolated DNA sequences. On the merits, the Court reversed the District Court's decision that Myriad's composition claims to “isolated” DNA molecules cover patent-ineligible products of nature under Title 35 § 101 U.S.C. since the molecules, as claimed, do not exist in nature. It reversed the decision that Myriad's method claim to screening potential cancer therapeutics via changes in cell growth rates is directed to a patent-ineligible scientific principle. It, however, affirmed the decision that methods claims directed to

5 The “product category” includes: (a) Claims that cover the isolated BRCA genes (claim 1 of the '282 patent, claim 1 of the '473 patent, and claims 1 and 6 of the '492 patent); (b) Claims that cover only the BRCA cDNA (claims 2 and 7 of the '282 patent and claim 7 of the '492 patent); (c) Claims that cover portions of the BRCA genes and cDNA as small as 15 nucleotides long (claims 5 and 6 of the '282 patent).

6 The “method category” encompasses method claims directed at comparing or analyzing a patient's altered BRCA sequence with the normal one or wild-type one to identify the presence of cancer-predisposing mutations (e.g. claim 1 of the '999 and '001 patents).

7 See 35 U.S.C. § 101 *Inventions patentable*, available on the Internet at <http://www.wipo.int/clea/docs_new/pdf/en/us/us007en.pdf> (last accessed on 14 August 2013).

8 Plaintiffs point out claims 1, 2, 5 and 6 of “patent '282”; claim 1 of “patent '492”. See *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, Complaint, 12 May 2009, available on the Internet at <<http://docs.justia.com/cases/federal/district-courts/new-york/nysdcce/1:2009cv04515/345544/1/0.pdf?ts=1243609964>> (last accessed on 14 August 2013), at pp. 20–21.

9 Scientists often use the term “wild-type” to refer to the normal gene sequence, i.e. the sequence of a gene without any variation, against which individuals' gene sequences are compared. *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, Case 1:09-cv-04515-RWS, 29 March 2010, available on the Internet <http://graphics8.nytimes.com/packages/pdf/national/20100329_patent_opin-

http://graphics8.nytimes.com/packages/pdf/national/20100329_patent_opinion.pdf?scp=3&sq=Myriad%20Genetics&st=cse> (last accessed on 14 August 2013), at p. 31. However, Senior Judge Sweet points out that “there is an increasing recognition that the notion of a single ‘normal’ gene sequence may not be entirely accurate in light of the high frequency of variations in a gene sequence between individuals”. See note 8, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, 29 March 2010, at p. 31.

10 U.S. Supreme Court, *Diamond v. Chakrabarty* (447 U.S. 303), 16 June 1980, the “Chakrabarty case”.

11 On the First Amendment of the U.S. Constitution see A. Roddey Holder and J.T. Roddey Holder, *The Meaning of the Constitution* (NY Hauppauge: Barron's, 1997), at p. 57.

12 Art. I, section 8, clause 8 states: “The Congress shall have the Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”. See A. Roddey Holder and J.T. Roddey Holder, *The Meaning of the Constitution*, *supra* note 11, at p. 28.

13 cDNA or complementary DNA is “a man-made copy of the coding sequences of a gene; cDNA is produced in a test tube – it is not a natural product. In a living cell, the protein-coding sequences of DNA are transcribed as mRNA. Molecular biologists use reverse transcriptase, an enzyme that makes DNA copies from RNA, to make copies of the mRNA. The resulting cDNA – a copy of a copy, so to speak – may then be analyzed by various methods”. See Daniel J. Kevles and Leroy Hood (eds.), *The Code of Codes: Scientific and Social Issues in the Human Genome Project* (Cambridge MA: Harvard University Press, 2000), at p. 376.

comparing or analyzing DNA sequences are not patent-eligible because such claims cover only abstract mental steps.¹⁴

On March 26, 2012, the U.S. Supreme Court granted the petition for a writ of certiorari on the case.¹⁵ This decision vacated the judgment of appeal and remanded the case to the United States Court of Appeals for the Federal Circuit for further consideration in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (the “Mayo case”).¹⁶ In the Mayo case the U.S. Supreme Court, in a unanimous opinion written by Justice Stephen Breyer, held invalid several patent claims, which concerned the use of thiopurine drugs to treat certain autoimmune diseases. The patented processes were not considered patent eligible as they claimed laws of nature, namely the correlations between thiopurine metabolite levels and the toxicity or efficacy of thiopurine drug dosages.

On remand, on August 16, 2012, the Court of Appeals affirmed the District Court in part and reversed in part, with each member of the panel writing separately. The Court agreed that only one petitioner, Dr. Ostrer, had standing.¹⁷ On the merits, it held that both isolated DNA and cDNA sequences were patent eligible under § 101.¹⁸ The Court reversed the District Court’s holding that Myriad’s method claim to screening potential cancer therapeutics via changes in cell growth rates of transformed cells is directed to a patent-ineligible scientific principle and affirmed that Myriad’s method claims directed to comparing or analyzing DNA sequences are patent-ineligible.¹⁹

The central issue discussed by the panel members was whether the act of isolating a DNA sequence, separating a sequence of nucleotides from the rest of the chromosome, is an inventive act that entitles the person who first did it to a patent or not. Each member of the panel had a different point of view on the question. While Judges Lourie and Moore agreed that Myriad’s DNA sequences were patent-eligible, but disagreed on the rationale, Judge Bryson dissented in part and argued that isolated DNA is not patent-eligible.

II. The product of nature doctrine applied to isolated DNA sequences

On November 30, 2012, the Supreme Court granted again petition for a writ of certiorari on the Myriad case, but limited it to one question presented by petitioners – “Are human genes patentable?” –²⁰ and dismissed the other two, which concerned Myriad’s method claims and petitioners’ standing.²¹ The Court’s judgment of June 13, 2013 has, therefore, dealt only with patent eligibility of DNA sequences and focused on whether they are patentable subject matter, according to Title 35 § 101 U.S.C., or fall within one of the implicit exceptions to this provision established for laws of nature, natural phenomena and abstract ideas. The rationale of these exceptions to patentability is that they represent “the basic tools of scientific and technological work”²² that lie beyond the domain of patent protection. The first two excep-

14 U.S. Court of Appeals for the Federal Circuit, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, 29 July 2011, available on the Internet at <<http://www.aclu.org/files/assets/10-1406.pdf>> (last accessed on 14 August 2013), at p. 8.

15 See U.S. Supreme Court Order 11-725, 26 March 2012, available on the Internet at <<http://www.supremecourt.gov/orders/courtorders/032612zor.pdf>> (last accessed on 14 August 2013).

16 U.S. Supreme Court, *Mayo Collaborative Services, Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc.*, 20 March 2012, 566 U.S. (2012), available on the Internet at <<http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf>> (last accessed on 15 July 2013).

17 U.S. Court of Appeals for the Federal Circuit, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, 16 August 2012, available on the Internet at <<http://www.ca9.uscourts.gov/images/stories/opinions-orders/10-1406.pdf>> (last accessed on 14 August 2013), at p. 7.

18 U.S. Court of Appeals for the Federal Circuit, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, 16 August 2012, *supra* note 17, at pp. 7-8.

19 U.S. Court of Appeals for the Federal Circuit, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, 16 August 2012, *supra* note 17, at p. 8.

20 See In the Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, on Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit, Petition for a Writ of Certiorari, 25 September 2012, available on the Internet at <<http://sblog.s3.amazonaws.com/wp-content/uploads/2012/11/12-398-Petition.pdf>> (last accessed on 14 August 2013), at p. i.

21 See In the Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, on Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit, Petition for a Writ of Certiorari, *supra* note 20, at p. i: “2. Did the Court of Appeals err in upholding a method claim by Myriad that is irreconcilable with this Court’s ruling in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) 3. Did the Court of Appeals err in adopting a new and inflexible rule, contrary to normal standing rules and this Court’s decision in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), that petitioners who have been indisputably deterred by Myriad’s “active enforcement” of its patent rights nonetheless lack standing to challenge those patents absent evidence that they have been personally threatened with an infringement action?”

22 *Mayo Collaborative Services, Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc.*, 20 March 2012, *supra* note 16, at p. 3, citing *Benson*, 409 U.S.

tions/exclusions to patentable subject matter, which regard the laws of nature and natural phenomena, result from the so-called product of nature doctrine, which can be traced back to the XIX century and was re-affirmed in *Diamond v. Chakrabarty*.²³ According to it, the laws of nature and natural phenomena are excluded from patent protection, whereas a non-natural occurring manufacture or composition of matter – a product of human ingenuity – is patent-eligible. In order to assess whether this doctrine could be applied to Myriad's composition claims on DNA's sequences, the Court examined what Myriad's invention consisted of and concluded that "Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13".²⁴ Confronting Myriad's gene claims with Chakrabarty's invention, it observed that Chakrabarty's bacterium was new, "with *markedly different* characteristics from any found in nature", whereas "Myriad did not create anything ... it found an important and useful gene, but separating that gene from its surrounding genetic materials is not an act of invention".²⁵ Justice Thomas, who delivered the opinion of the Court, argued that although isolating DNA from the human genome severs chemical bonds, Myriad's claims were not expressed in terms of chemical composition nor did they rely in any way on the chemical changes that result from isolation of a particular section of DNA.

The Judge pointed out that the claims, instead, focused on the genetic information encoded in the BRCA1 and 2 genes²⁶ because it is the genetic information that is valuable for Myriad. As a matter of fact, "if the patents depended upon the creation of a unique molecule, then a would be infringer could arguably avoid at least Myriad's patent claims on entire genes ... by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair". Since such a molecule would not be chemically identical to the molecule invented by Myriad, there would not be any patent infringement. However, as the Court argued, Myriad would resist that outcome, since its claims are concerned primarily with the information in the genetic sequence, not with the specific chemical composition of a particular molecule.

The Court, therefore, concluded unanimously that "genes and the information they encode are not patent eligible under § 101 simply because they have

been isolated from the surrounding genetic material".²⁷ This holding may have significant consequences on the USPTO long-standing practice of granting patents on *isolated* DNA sequences because, for the first time, the Supreme Court made clear that extensive research effort and the mere isolation of DNA sequences are insufficient to satisfy the demands of § 101.

The Court, however, deemed cDNA patent eligible under § 101 since it is not naturally occurring. As the U.S. Court of Appeals for the Federal Circuit explained,²⁸ DNA molecules can be also synthesized in the laboratory and one type of synthetic DNA molecule is complementary DNA or cDNA. cDNA is synthesized from mRNA using complementary base pairing in a manner analogous to RNA transcription. Because it is synthesized from mRNA, cDNA contains only the exon sequences (the coding regions for proteins) and none of the intron sequences (the non-coding regions) from a chromosomal gene sequence. The creation of a cDNA sequence from mRNA results in an exons-only molecule that does not exist in nature. Therefore, cDNA sequences were considered patent-eligible.

III. Comment

As regards DNA sequences, isolation and purification are scientific concepts that have acquired legal relevance in patent systems to distinguish non-patentable sequences from patentable ones.²⁹ In the

23 U.S. Supreme Court, *Diamond v. Chakrabarty*, 16 June 1980, *supra* note 10.

24 See Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, 13 June 2013, *supra* note 1, at p. 12.

25 See Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, 13 June 2013, *supra* note 1, at p. 12.

26 See Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, 13 June 2013, *supra* note 1, at pp. 14-15.

27 Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, 13 June 2013, *supra* note 1, at p. 18.

28 U.S. Court of Appeals for the Federal Circuit, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, 16 August 2012, *supra* note 17, at pp. 16-17.

29 In the European Union the criteria of isolation and purification were introduced (art. 5.2) with the approval of the European Parliament and Council Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, available on the Internet at <<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:213:0013:0021:EN:PDF>> (last accessed on 30 July 2013).

United States the introduction³⁰ into the USPTO's revised Utility Examination Guidelines³¹ of 2001³² of the criteria of isolation and purification has established the rationale to legally demarcate between naturally occurring DNA sequences and artificially isolated/purified ones. According to the Guidelines, "an isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound". The inclusion of these criteria in the USPTO's Utility Examination Guidelines has supported DNA sequences patentability, reducing the risks for DNA patent holders to incur the "product of nature" doctrine's objections.³³

Although the meanings of "isolation" and "purification" seem to be clear, the Myriad case has instead shown all the ambiguities related to their practical implementation. Genes, as Judge Sweet pointed out, are of a double-nature: on one hand, they are chemical substances or molecules and, on the other, they are carriers of information. In the Myriad case the

former viewpoint had to face the latter,³⁴ according to which "DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature".³⁵ If the latter is considered more scientifically and legally sound in describing the very nature of DNA sequences, it can be concluded that isolated DNA molecules fall within the "product of nature"³⁶ exception under 35 U.S.C. § 101 because such isolated DNAs are not "markedly different" from native DNAs.³⁷

The judges who decided the Myriad case expressed opposing views about what is DNA (a chemical molecule or information), whether it is better described by its structure or its function and what the criterion of isolation means within each of these different frames. For instance, Judge Lourie of the Court of Appeals for the Federal Circuit stated that the process of excising a selected portion of DNA from its cellular environment results in a molecule that is *structurally* different from native DNA, since each end of the isolated DNA segment is no longer bonded to the rest of the gene. According to him, the fact that "isolated DNA has been cleaved (i.e., had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA

30 As the U.S. Department of Justice explained in its brief for the United States as *amicus curiae* in support of neither party, in 2001 the USPTO issued its first written explanation of its practice of granting patents for isolated DNA molecules. In response to comments concerning proposed revisions to its Utility Examination Guidelines (66 Fed. Reg. 1092, January 5, 2001), the PTO held that an isolated DNA molecule is not a product of nature "because that DNA molecule does not occur in that isolated form in nature". See In the Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, Brief of the United States as *amicus curiae* in support of neither party, 31 January 2013, available on the Internet at <http://www.americanbar.org/content/dam/aba/publications/supreme_court_preview/briefs-v2/12-398_neither_amcu_us.authcheckdam.pdf> (last accessed on 14 August 2013), at pp. 27-28.

31 In 2001 the USPTO published a revised version of the Utility Examination Guidelines to be used by office personnel in their review of patent applications for compliance with the 'utility' requirement of 35 U.S.C. § 101, that became effective on January 5, 2001. See USPTO, <<http://www.uspto.gov/web/offices/com/sol/og/2001/week05/patutil.htm>> (last accessed on 14 August 2013).

32 After the controversial granting in the '90s of some patents on the so-called ESTs (expressed sequence tags), in 2001 the USPTO had to enact new Utility Examination Guidelines to stem the "far-west patent rush" to DNA sequences (see M.A. Heller and R.S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research", *Science*, 1 May 1998, Vol. 280, at p. 699). In the Guidelines were set forth the concepts of *isolation* and *purification* to discriminate non-patentable DNA sequences from patentable ones: "An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because

that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound" (USPTO, January 5, 2001, Utility Examination Guidelines, 66 Fed. Reg., at p. 1092).

33 The origin of the "product of nature" doctrine can be traced back to the XIX century, at least in 1889 when *Ex parte Latimer* [Comm. Dec. 123(1889)] was decided by the Commissioner of patents. See J. Wilson, "Patenting Organisms. Intellectual Property Law Meets Biology", in D. Magnus, A. Caplan, G. McGee (eds.) *Who Owns Life?* (Amherst NY: Prometheus Books, 2002) at pp. 47-48. For a critical historical reconstruction of the "product of nature" doctrine, see L.J. Demaine and A.X. Fellmeth, "Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent", in 55 *Stanford Law Review* (2002), at pp. 303-462.

34 See L.E. Kay, *Who Wrote the Book of Life? A History of the Genetic Code* (Stanford CA: Stanford University Press, 2000).

35 U.S. District Court for the Southern District of New York, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, 29 March 2010, available on the Internet at <http://graphics8.nytimes.com/packages/pdf/national/20100329_patent_opinion.pdf?scp=3&sq=Myriad%20Genetics&st=cse> (last accessed on 14 August 2013), at pp. 7-8.

36 The main substantive argument advanced by the plaintiffs and agreed on by Judge Sweet is based on the "product of nature doctrine". See U.S. District Court for the Southern District of New York, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, Complaint, *supra* note 8, at p. 18.

37 See U.S. District Court for the Southern District of New York, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, 29 March 2010, *supra* note 35, at p. 8.

molecule”³⁸ makes it “markedly different” from native DNA. Furthermore, he embraced a structural description of DNA sequences, pointing out that although “biologists may think of molecules in terms of their uses, genes are in fact materials having a chemical nature and, as such, are best described in patents by their structures rather than by their functions”.³⁹

Conversely, the U.S. Supreme Court endorsed the view that genes carry information and it is their information that makes them valuable for patent purposes. Like the U.S. Department of Justice, which wrote a brief for the United States as *amicus curiae* in support of neither party, the Court considered the structural difference between isolated DNA and native DNA (namely the isolated segment’s “snipped” ends) with no functional consequences, as the truncation does not alter the operative properties of the isolated DNA segment.⁴⁰ This perspective is focused on the function that DNA performs in the human body and in a laboratory. If the function performed is the same and the “additional utility” that isolation adds is simply the ability of researchers to study and exploit in a laboratory the inherent natural properties that isolated DNA shares with native DNA, isolated DNA sequences will not be patent eligible, according to the brief.⁴¹

The word “isolation” generally refers to “separating a specific gene or sequence of nucleotides from the rest of the chromosome”.⁴² However, in order to establish patent eligibility of a specific isolated DNA sequence, the patent examiner must ascertain whether isolation makes the sequence “markedly different” from the one found in nature or not. The USPTO issued patents on isolated DNA sequences for more than twenty years. This practice, as the United

States District Court for the Southern District of New York pointed out, was based on the analogy between DNA sequences and chemical compounds.⁴³ Nonetheless, if this view, grounded on the chemical analogy, is questioned, the boundaries between naturally occurring products and man-made inventions may change.

Although, according to Myriad, the USPTO’s past practice of awarding gene patents should be entitled to deference by the courts, the Supreme Court disagreed, recalling the Department of Justice’s brief. The brief made clear that the USPTO’s revised Utility Examination Guidelines do not have the force of the law and do not specifically address patents on DNA, but were revised to fix a standard for determining utility generally.⁴⁴ Moreover, Congress has never specifically considered the USPTO’s practice of granting patents on isolated DNA in its bills related to patents on genetic materials.⁴⁵ The correctness of the USPTO’s practice was never challenged in litigation prior to the Myriad case, but the Supreme Court designed an opposite frame to describe the “nature” of genes, centred on their biological information and function. Within this frame, in order to assess gene patent eligibility, the concept of isolation entails more than extensive research and economical investments to achieve the separation of a DNA sequence from the rest of the chromosome.⁴⁶ This choice in favor of defining genes by their informational character and function may, therefore, affect the application of the criteria of isolation in the future and bring about a substantial change in the USPTO’s practice of granting patents on native DNA sequences.

In deciding the case, the Supreme Court was guided by the consideration that “patent protection

38 U.S. Court of Appeals for the Federal Circuit, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, 16 August 2012, *supra* note 17, at p. 45.

39 U.S. Court of Appeals for the Federal Circuit, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, 16 August 2012, *supra* note 17, at p. 48.

40 In the Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, Brief of the United States as *amicus curiae* in support of neither party, 31 January 2013, *supra* note 30, at p. 22.

41 In the Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, Brief of the United States as *amicus curiae* in support of neither party, 31 January 2013, *supra* note 30, at p. 23.

42 Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, 13 June 2013, *supra* note 1, at p. 8.

43 U.S. District Court for the Southern District of New York, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, 29 March 2010, *supra* note 35, at p. 7.

Eisenberg explained why the chemical analogy was applied to genes in such a successful way. R.S. Eisenberg, “Why Gene Patenting Controversy Persists”, 77 *Academic Medicine* (2002), at p. 1381; R.S. Eisenberg, “Patenting Genome Research Tools and the Law”, 326 *Comptes Rendus Biologies* (2003), at p. 1116.

44 In the Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, Brief of the United States as *amicus curiae* in support of neither party, *supra* note 30, at p. 28.

45 See, for example, *Genomic Science and Technology Innovation Act of 2002* (H.R. 3966, 107th Cong., 2d Sess., 2002); *Genomic Research and Diagnostic Accessibility Act of 2002* (H.R. 3967, 107th Cong., 2d Sess., 2002); *Life Patenting Moratorium Act of 1993* (S. 387, 103d Cong., 1st Sess., 1993); *Consolidated Appropriations Act of 2004* (Pub. L. No. 108-199, § 634, 118 Stat. 101).

46 In the Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, Brief of the United States as *amicus curiae* in support of neither party, 31 January 2013, *supra* note 30, at p. 28.

strikes a delicate balance between creating ‘incentives that lead to creation, invention, and discovery’ and ‘imped[ing] the flow of information that might permit, indeed spur, invention’.⁴⁷ As the Department of Justice noted, “an overbroad conception of patent eligibility under §101 can impose significant social costs by requiring the public to pay to study and exploit that which ought to be ‘free to all men and reserved to none’”.⁴⁸ The product of nature doctrine exceptions to §101 reflect the public interest in avoiding undue restrictions imposed by patents that could preempt natural laws and substances. Unlike the USPTO’s long-standing practice, the Supreme Court struck a different balance of the opposite interests involved in patenting DNA sequences: access to genetic information by scientific researchers and clinicians, patients’ health care rights and intellectual property rights held by biotech companies.

IV. In the aftermath of the U.S. Supreme Court’s decision

On June 14, 2013, the day after the Supreme Court’s decision was issued, Myriad’s stock fell by 5.6%, and it became clear to analysts that, even though the company was partially successful before the Court, its market share in the genetic testing on BRCA1 and 2 genes was expected to decrease.⁴⁹

Shortly afterwards, Myriad Genetics, Inc., together with the University of Utah Research Foundation,

the Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership and Endorecherche Inc. filed a complaint for patent infringement and a Motion for Preliminary Injunctive Relief against two competitors, Gene by Gene Ltd⁵⁰ and Ambry Genetics Corporation,⁵¹ which announced that they would offer genetic testing on BRCA1 and 2 genes at a much lower price than Myriad had offered before the decision. As Myriad made clear in the Motion for Preliminary Injunctive Relief and Memorandum in Support against Defendant Ambry Genetics,⁵² before the Supreme Court’s ruling on June 13, 2013, Myriad held 24 patents containing 520 claims concerning BRCA1 and 2 genes. After the Court held that five patent claims covering isolated naturally occurring DNA were not patent-eligible, Myriad’s patent estate was reduced to 24 patents and 515 patent claims. Nonetheless, these two cases do not involve any of those five rejected claims,⁵³ but only methods-of-use and synthetic DNA patent claims concerning BRCA1 and 2 genes, which are valid and, therefore, enforceable.

As regards the first civil action, Myriad complained that Gene by Gene infringed and induced the infringement of, literally and/or under the doctrine of equivalents, several claims related to nine patents,⁵⁴ owned or exclusively licensed to Myriad and asked for damages. Gene by Gene began, in fact, offering its BRCA 1 and 2 analysis and clinical diagnostic and genomic services as part of its testing menu as soon as the Court’s opinion was issued, on June 13, 2013.⁵⁵

47 Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc.*, et al., 13 June 2013, *supra* note 1, at p. 11.

48 In the Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc.*, et al., Brief of the United States as *amicus curiae* in support of neither party, 31 January 2013, *supra* note 30, at p. 33.

49 See Johanna Bennett, “About Face on Myriad Genetics, Stock Falls 5.6%”, available on the Internet at <<http://blogs.barrons.com/stockstowatchtoday/2013/06/13/about-face-on-myriad-genetics-stock-falls-5-6/>> (last accessed on 30 July 2013).

50 In the United States District Court for the District of Utah, Central Division, *University of Utah Research Foundation, et al., v. Gene by Gene LTD*, Complaint Demand for Jury Trial, 10 July 2013, available on the Internet at <<http://files.priorsmart.com.s3.amazonaws.com/utdce/89792/Complaint.pdf?Signature=7Cgxn5Qlu%2FgM7jCmSRghLXeZl%3D&Expires=1375782713&AWSAccessKeyId=AKIAJWOP3U6XRH5BBMOA>> (last accessed on 31 July 2013).

51 In the United States District Court for the District of Utah, Central Division, *University of Utah Research Foundation, et al., v. Ambry Genetics Corporation*, Motion for Preliminary Injunctive Relief and Memorandum in Support, 9 July 2013, available on the Internet at <[http://www.patentlyo.com/myriad-](http://www.patentlyo.com/myriad-motionforpreliminaryrelief.pdf)

[motionforpreliminaryrelief.pdf](http://www.patentlyo.com/myriad-motionforpreliminaryrelief.pdf)> (last accessed on 31 July 2013), at p. 4.

52 See In the United States District Court for the District of Utah, Central Division, *University of Utah Research Foundation, et al., v. Ambry Genetics Corporation*, Motion for Preliminary Injunctive Relief and Memorandum in Support, 9 July 2013, *supra* note 51, at p. 4.

53 See In the United States District Court for the District of Utah, Central Division, *University of Utah Research Foundation, et al., v. Ambry Genetics Corporation*, Motion for Preliminary Injunctive Relief and Memorandum in Support, 9 July 2013, *supra* note 51, at p. 4.

54 Myriad alleged that Gene by Gene was infringing the following patents, owned or exclusively licensed to Myriad: U.S. patent No. 5,709,999 (the “999 Patent”); U.S. patent No. 5,747,282 (the “282 Patent”); U.S. patent No. 5,753,441 (the “441 Patent”); U.S. patent No. 5,837,492 (the “492 Patent”); U.S. patent No. 6,033,857 (the “857 Patent”); U.S. patent No. 5,654,155 (the “155 Patent”); U.S. patent No. 5,750,400 (the “400 Patent”); U.S. patent No. 6,951,721 (the “721 Patent”); U.S. patent No. 7,250,497 (the “497 Patent”).

55 In the United States District Court for the District of Utah, Central Division, *University of Utah Research Foundation, et al., v. Gene by Gene LTD*, Complaint Demand for Jury Trial, 10 July 2013, *supra* note 50, at p. 4.

Furthermore, on July 9, 2013, Myriad filed a Motion for Preliminary Injunctive Relief against Ambry Genetics, claiming that it could suffer immediate and irreparable harm if Ambry was not enjoined from infringing the activity of Myriad's patents.⁵⁶ Such harm consists of "price erosion and the loss of the benefit of Myriad's established pricing strategy; the loss of market share; reputational injury; and loss of the benefit of the remaining limited term of patent exclusivity and Myriad's patent business plans for that period".⁵⁷ Myriad asserted that it had created and nurtured to maturity a new market for clinical diagnostic testing for hereditary cancer predisposition.⁵⁸ Allowing Ambry to offer its BRCAPlus test for \$2,280, whilst Myriad's competing test is priced at \$4,040, would cause a decline in market prices for Myriad, since third party payers, such as insurers and/or Health Maintenance Organizations, would exert pressure on the company to lower its prices in response to Ambry. In addition, other competitors could potentially enter the market and, therefore, Myriad's market share would drop. As a consequence, Myriad argued, the overall quality of tests on BRCA1 and 2 would decrease, as the company contends that its tests are more reliable and accurate than Ambry's products.

By filing lawsuits against Gene by Gene and Ambry Genetics shortly after the Supreme Court's decision, Myriad sent a clear signal to potential competitors that, although the Court's ruling has potentially weakened its market advantage of being the only provider of tests on BRCA1 and 2 genes, the company is willing to fight any attempt to threaten its monopolistic market share over clinical diagnostic testing for hereditary breast and ovarian cancer predisposition. However, the reason why Myriad's patents became so controversial in the United States is that they are at the core of a monopolistic strategy that was considered to hinder clinical research on breast and ovarian cancer, raising health insurance costs related to BRCA1 and 2 mutations testing and restraining access to health care for patients. All these issues, which were raised by the plaintiffs in the Myriad case, involve public interests that had to confront Myriad's patent claims and its substantial investment towards developing genetic diagnostic testing. Not only is Myriad the owner of many patents related to BRCA1 and 2 genes, but it is also the exclusive licensee of others,⁵⁹ which are owned or co-owned by universities and are partially based on federally-funded research. Some of these exclusive licenses, together

with several patents granted to Myriad, were challenged in the Myriad case and are at present enforced against Gene by Gene and Ambry.

Since the 1980s the U.S. Congress has backed a policy to promote the utilization of federally-sponsored inventions with the passage of the Bayh-Dole Act⁶⁰ and the Stevenson-Wydler Technology Innovation Act.⁶¹ The goal of this legislation was to transform universities into major, active patent claimants for federally funded research, so that they could attract private investors that could transform their discoveries into commercial products and would become the exclusive licensees of their patents. In more than 20 years U.S. universities have taken the opportunities opened by this legislation and filed patent applications on basic research discoveries, such as DNA sequences and protein structures. Although this policy has largely fostered investments in biomedical research and favored impressive scientific results, in the long run it has entailed some problems, namely hindering subsequent research and limiting patients' access to health care, as the Myriad case and its aftermath show.

Addressing one of these issues, on July 12, 2013, U.S. Senator Patrick Leahy of Vermont sent a letter to the Director of the National Institutes of Health (NIH), Francis Collins, urging him to consider exer-

56 Myriad alleged that Ambry Genetics is infringing: claims 16 and 17 of patent '282, claims 29 and 30 of patent '492, claims 8 and 7 of patent '441, claim 4 of patent '857, claim 5 of patent '721, claims 2 and 4 of patent '155. See In the United States District Court for the District of Utah, Central Division, *University of Utah Research Foundation, et al., v. Ambry Genetics Corporation*, Motion for Preliminary Injunctive Relief and Memorandum in Support, 9 July 2013, *supra* note 51, at p. 15.

57 In the United States District Court for the District of Utah, Central Division, *University of Utah Research Foundation, et al., v. Ambry Genetics Corporation*, *supra* note 51, at p. 30.

58 In the United States District Court for the District of Utah, Central Division, *University of Utah Research Foundation, et al., v. Ambry Genetics Corporation*, *supra* note 51, at p. 3.

59 For example, U.S. patent No. 5,747,282 (the "282 Patent"), which is owned by the University of Utah, along with the Public Health Service, through the National Institutes of Health and is exclusively licensed to Myriad; U.S. patent No. 5,753,441 (the "441 Patent"), which is owned by the University of Utah and Public Health Service and exclusively licensed to Myriad. See In the United States District Court for the District of Utah, Central Division, *University of Utah Research Foundation, et al., v. Gene by Gene LTD*, Complaint Demand for Jury Trial, 10 July 2013, *supra* note 50, at pp. 6-7.

60 The Bayh-Dole Act was passed in December 1980 (Act of December 12, 1980, Pub. L. No. 96-516, § 6(a), 94 Stat. 3015, 3019-3028, 1980, codified as amended at 35 U.S.C. §§ 200-212, 1994). Its main purpose is "to use the patent system to promote the utilization of inventions arising from federally funded research or development ...". See 35 U.S.C. § 200.

61 The Stevenson-Wydler Technology Innovation Act was passed in 1980 (Pub. L. No. 96-480, § 2, 94 Stat. 2311-2320, 1980, codified as amended at 15 U.S.C. §§ 3701-3714, 2000).

cising “march-in” rights under the Bayh-Dole Act to ensure greater access to genetic testing for breast and ovarian cancer.⁶² As several patents held by Myriad are based in part on federally funded research, they are subject to the Bayh-Dole Act’s provisions. Under the Bayh-Dole Act, federal agencies, such as the NIH, can exercise march-in rights *ex post* to compel licensing of patents on inventions made through federally funded research. The federal agency can take this initiative only in some circumstances, such as when the “action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees.”⁶³

Senator Leahy highlighted the importance of Myriad’s genetic test for public health and the fact that the company is its only provider, because it is covered by patent protection, and charges between \$3,000 and \$4,000. Since, by exercising march-in rights, the NIH can require the patent holder to grant a license on reasonable terms (that can be non-exclusive, partially exclusive or exclusive), Senator Leahy claims that this initiative would meet the health needs of the public who cannot afford the testing provided by Myriad.

62 See Senator Patrick Leahy’s Letter addressed to Doctor Francis S. Collins, Director of the National Institutes of Health, available on the Internet at <http://www.leahy.senate.gov/download/07-12-13-pjl-to-nih-re_myriad-march-in> (last accessed on 14 August 2013), at p. 1.

63 See 35 U.S.C. § 203 March-in rights, available on the Internet at <<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title35/pdf/USCODE-2011-title35-partII-chap18-sec203.pdf>> (last accessed on 14 August 2013).

64 Arti K. Rai and Rebecca S. Eisenberg, “Bayh-Dole Reform and the Progress of Biomedicine”, in James Boyle (ed.), *Law and Contemporary Problems*, Vol. 66: 2003, Nos. 1 & 2, at pp. 289-314.

65 Arti K. Rai and Rebecca S. Eisenberg, “Bayh-Dole Reform and the Progress of Biomedicine”, *supra* note 64, at pp. 289.

66 See Arti K. Rai and Rebecca S. Eisenberg, “Bayh-Dole Reform and the Progress of Biomedicine”, *supra* note 64, at pp. 290-291.

67 See Arti K. Rai and Rebecca S. Eisenberg, “Bayh-Dole Reform and the Progress of Biomedicine”, *supra* note 64, at p. 294.

As early as 2003 Arti Rai and Rebecca Eisenberg,⁶⁴ discussing the Bayh-Dole’s reform and the progress of biomedicine, pointed out that biomedical tradition of open science has been eroded considerably over the past decades, since “proprietary claims have reached farther upstream from end products to cover fundamental discoveries that provide the knowledge base for future product development”,⁶⁵ and that this change is partially due to the narrowing of the conceptual gap between fundamental research and commercial application. According to them, the changes in the economic structure of research and in the case law, that adopted an expansive approach to patent eligibility while relaxing the standards for patent protection, such as utility and non-obviousness, may sometimes, in the long run, hinder rather than accelerate biomedical research.⁶⁶

As a response to the problems arising from the frenzy of patent claims on upstream research tools, they envisaged a set of solutions, which included the reinvigoration of the product of nature limitation on patent eligibility, so that discoveries of DNA sequences and proteins could be excluded from patent protection, and to fortify the utility standard to limit the patenting of broadly enabling research tools. In addition, they argued that march-in rights could be used by agencies to better assure the public interest in federally funded patented inventions, but the administrative hurdles are so cumbersome that the NIH has never exercised these rights.⁶⁷

In the Myriad case, the Supreme Court has already intervened decisively, reinvigorating the product of nature doctrine and reshaping the criterion of isolation. However, since citizens’ health interests at stake are so relevant, maybe for the first time the NIH would actually exercise march-in rights in order to serve and fulfill the public interest involved in federally funded inventions.