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The Intellectual Property Rights (IPR) elements of the DIME Network currently focus on research in the area of patents, copyrights and related rights. DIME's IPR research is at the forefront as it addresses and debates current political and controversial IPR issues that affect businesses, nations and societies today. These issues challenge state of the art thinking and the existing analytical frameworks that dominate theoretical IPR literature in the fields of economics, management, politics, law and regulation- theory.



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The Discovery of Invention Gene Patents and the Question of Patentability

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Introduction

The development of patent protection for gene sequences has provoked both much debate and a considerable amount of concern and indeed misunderstanding. But in so far as intellectual property protection is afforded to products in order to develop and sustain certain markets, any misunderstanding cannot be dismissed. The very nature of the intellectual property bargain with the public is such that the relationship with the consumer underpins the legitimacy of the law. So-called gene patents are arguably no different.

So what is the controversial nature of patenting this kind of technology? Apart from the suspicion of commercial monopolies over material considered to be the natural building blocks of humanity, as it were, the very nature of genetic research appears to be confounded by the way in which patent protection and the scope of the subsequent monopolies conferred.

Genetic sequencing is in a way an incomplete exercise without the subsequent analysis to identify protein-coding sequences, and the nature and function of those proteins. The so-called central dogma of genetics refers to the functional interrelationships between DNA (the basic template), RNA (the transcription), and finally the protein encoded. The central dogma is this direction of the transmission of information.

Thus, the mere location of the sequence does not provide the technical information for any useful application. A gene sequence is simply the ordering of amino acids or nucleotides – it is simply identifying the information, a product of nature. The understanding of that word, the analysis and identification of the function, is where the skill and research is critical. And it is this understanding that generates a sense of

contribution to knowledge that, in the context of the intellectual property paradigm, is put forth as justifying recognition. The problem is that, as the law is currently interpreted in Europe, the identification of one function may result in protection of all possible and potential functions.

This paper considers the problematic scope of so-called gene patents and identifies factors, both within the legal framework and in terms of the socio-economic policies underpinning intellectual property, that support a restricted purpose-bound approach to patent protection of gene sequences.

Patenting Biotechnology in Europe

According to the European Patent Convention (EPC), for subject matter to be patentable it must be new, inventive (that is, not obvious),¹ sufficiently disclosed in the patent specification,² and have industrial application (also known as utility).³

In Europe, newness, that is, novelty must be absolute.⁴ In other words, the subject matter must not have been previously used or published anywhere in the world. But with respect to gene patents, the question of inventiveness (or non-obviousness) is more difficult to translate from other technologies.

Of particular interest in the case of gene patents, is the way in which “inventiveness,” as it were, is achieved for the purposes of patentability. What is sometimes criticised as a patent for a discovery (the gene sequence), is “inventive” by virtue of the identification of the application or function. In other words, there is a kind of critical nexus between utility and inventiveness, in this respect. Back in 1994, efforts to patent gene sequences in the United States were defeated by lack of utility.⁵ Importantly, as many commentators and researchers have made clear, it is not the isolation and identification of the sequence that is critical to the technological development, but rather, it is the identification of the function and application of the protein coded by that sequence that is the useful and industrious aspect.

In this respect then, for patents in this area of technology, the industrial application is critical. While the sequencing of the human genome has become relatively easy, the “inventiveness,” as it were, is to be found in the ingenuity and skill required to identify the “use” or application of the particular gene sequence. In other words, in the case of gene patents, it is the identification of a use or application for the gene sequence that

¹ European Patent Convention, Art 52(1)

² EPC 2000 Article 83.

³ European Patent Convention, Art 52(1)

⁴ EPC 2000 Art 54(2).

⁵ Gershon D (1994) “US and British Researchers Agree not to Seek Gene Fragment Patents,” 367 *Nature* 583. See also the discussion in Pottage A (1998) “The Inscription of Life in Law: Genes, Patents, and Bio-Politics,” in R Brownsword et al (eds) *Law and Human Genetics: Regulating a Revolution*, Oxford, Hart: 148 at 156.

renders the sequence patentable⁶ and defines that invention through what are known as “functional claims.”⁷ The question of “inventiveness” might be understood as being linked to the “discovery” of that use.⁸

As Recital 23 of the Biotechnology Directive⁹ explicitly states:

Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention.

The European Patent Convention and the European Biotechnology Directive require that the use or industrial application is disclosed in the patent application. This might include the function performed by that sequence or the protein produced¹⁰ (but not a merely predicted function¹¹), which would then be relevant to understanding potential therapeutic or diagnostic uses.¹² In other words, the patent relates to the function rather than the structure of the sequence – the identification of an application and use rather than the mere information. The human effort or intervention in an otherwise natural substance (and thus, unpatentable subject matter) is deemed to be found in the technical change that is brought about by the otherwise discovery of the gene sequence and its function. Change is thus invention. Investment can thus be inventive.

The concern among commentators on the patentability of gene sequences is that this interpretation of patent protection is not necessarily compatible with the nature of technological innovation in genetic research. In particular, as the law is currently applied, identification of *a* use for a gene sequence will be sufficient to render the subject matter patentable, but the patent will grant control over *all* uses of the patented sequence.¹³ Therefore, whatever conceptualisation of the actor in which the original rights must vest (whether it is the skill and labour of the inventor or the investment of the entrepreneur),

6 To show industrial applicability, it is sufficient that the invention is susceptible or capable of industrial application, that is, it has the potential for application in industry. Bently and Sherman argue that this implies that it is not necessary to show actual use. See the discussion in Bently L & Sherman B (2004) *Intellectual Property Law*, 2nd ed, Oxford, OUP: 386.

7 Functional claims in other areas of technology raise concerns of ultimately “broader” claims, thus limiting the entry of competitors through important substitution in the market.

8 Recital 23 of the European Biotechnology Directive states “Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention.”

⁹ Directive of the European Parliament and of the Council on the legal protection of biotechnological inventions (98/44/EC).

¹⁰ Recital 24: “Whereas, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs.”

¹¹ *Icos Corporation / Seven transmembrane receptor* [2002] OJEP 293. See further, the UK Patent Office, *Biotechnology Examination Guidelines* (Sept 2002), para 33-35.

¹² See Bently & Sherman (2004): 387.

¹³ Bently & Sherman (2004): 387.

the effort that is expended is that which leads to the identification of the function and application identified in the claim. Therefore, control over all uses might suggest that this kind of interpretation of patent protection would arguably limit the interest in pursuing research into subsequent and significant identification of future applications for a particular sequence. In this way, it would be contrary to the cultural and technical specificity of genetic research.

The problem then is whether classical patent protection of gene sequences balances incentives for initial analysis of the function of a particular gene sequence with ongoing research based upon identified gene sequences. In other words, the so-called dynamic efficiency of this system may in fact be compromised because of the impact of an inappropriately broad interpretation of the scope of gene sequence patents, effectively deterring entry of later players in the market and inhibiting follow-on innovation.

Arguably, this is also contrary to the principles of patent law, in that the claimed invention is not sufficiently disclosed in the patent specification. In other words, the patentee is obtaining protection for uses that are not disclosed in the description and claims of the patent, thus defying the basic bargain of patent protection – a monopoly in return for the disclosure of the invention for others to experiment upon and use, thus driving further innovation and technological progress.

Current debate suggests that the scope of the biotechnological invention should be limited to the disclosure of the “invention,” as it were. That is, the scope should be limited to the industrial application or function that is disclosed in the patent. In this way, the patent recognises and protects the technical contribution of the inventor, rather than providing what is arguably an indirect monopoly over the natural substance and all its future uses. In other words, a classical interpretation of the subject matter could inadvertently lead to a monopoly over all subsequent examination and analysis of the functions of the coded protein, potentially limiting investigation for the life of the patent.

However, there are also problems with a purpose-bound approach. Potentially, if a new patent is granted for each new function or application that is identified, there is the opportunity for perpetual protection of a particular gene sequence. This is also contrary to policy objectives and compromises follow-on innovation for that particular gene sequence. But purpose-bound approaches cannot be dismissed, if one is to consider the possible contribution of protection for particular new applications as incentives to subsequent research. The critical articulation of these various interests, therefore, would seem to be the question of infringement.

Since the decision of the House of Lords in *Kirin-Amgen Inc v Hoechst Marion Roussel*,¹⁴ however, it is worth asking whether a patent for a gene sequence will now be interpreted as limited to those uses which a person skilled in the art would have reasonably considered to have been disclosed in the application. That is, the uses anticipated by a so-called gene patent might be limited by the state of the art at the time

14 [2004] UKHL 46.

of the application; it would be limited to what would be reasonable to expect of a person skilled in the art at that time.

What might be the most appropriate mechanism for protection and the delivery of incentives in genetic research, is a reliance upon Swiss-Type Claim patents. Swiss claims (or so-called Mobil claims, named after the leading case) refer to the novelty of purpose patents under the European Patent Convention, as considered by the United Kingdom Enlarged Board of Appeal in *Mobil/Friction reducing additive*.¹⁵ The usefulness of a new purpose (identified by Mobil) for a known substance had not previously been known, but the Enlarged Board of Appeal held that using an old substance in a new way may be novel, but using an old substance in an old way to produce a new purpose would not. In other words, doing the same thing but with a different purpose in mind will not be novel. This decision was noted in the House of Lords decision in *Merrell Dow Pharmaceuticals v HN Norton*,¹⁶ where the court described it as making it difficult to apply the traditional doctrine of infringement in the UK.¹⁷ So what is required is a solution to this question of infringement in the case of purpose-bound patents. Arguably, that solution, as anticipated in the literature and in case law, relies upon the question of “intention,” introducing a new proximity between the patentee/inventor and the consumer that has been otherwise deferred by traditional applications of the doctrine of infringement, a proximity which neatly re-inscribes the creativity of the inventor, albeit in the context of an entrepreneurial rendition of the invention.

In this context, a recent decision of June this year of the Canadian Federal Court of Appeal, in *Pharmascience v Sanofi-Aventis*,¹⁸ (so just 3 months ago) goes some way to confronting these complicated policy questions, even if it does not ultimately decide them. Although this is a decision on drug patents, it provides an important insight into the possible limitations of purpose-bound protection for gene patents by explaining the problematic application of infringement claims in the context of products with multiple uses.

Sanofi-Aventis produce and market ramipril capsules under the trade name Altace, used in the treatment of hypertension and cardiac insufficiency. Pharmascience is the manufacturer of ramipril capsules which are marketed for use only in the treatment of hypertension, although the capsules would be therapeutically equivalent to Altace. Pharmascience argued that it would not infringe the Aventis patents because it was seeking approval and marketing only in the treatment of hypertension. Aventis rejected this and successfully obtained a photibion order in the Federal Court, prohibiting the Minister from issuing a notice of compliance to Pharmascience. Pharmascience appealed,

¹⁵ *Mobil/Friction reducing additive* G2/88 [1990] EPOR 73.

¹⁶ *Merrell Dow Pharmaceuticals Inc v HN Norton & Co* [1996] RPC 76.

¹⁷ See also the discussion in Thorley S et al (2005), *Terrell on the Law of Patents*, 16th Ed, London, Sweet and Maxwell on intention in Mobil claim: “The court has not yet had to grapple with the issue, and it remains to be seen whether the principle of absolute liability, or the validity of MOBIL-type claims, will be compromised.” Page 302.

¹⁸ *Pharmascience v Sanofi-Aventis* (2006) FCA 229.

asking for the prohibition order to be set aside or varied, but the appeal was dismissed with costs.

However, it is not the decision in this case that is of particular significance to the present discussion. Rather, it is what this case has to say about infringement on the part of doctors and patients that is of interest.

In relation to one of the particular patents in question, Pharmascience proposed a narrower interpretation of the scope of protection. Specifically, Pharmascience proposed a narrower reading of subparagraph 5(1)(b)(iv) of the relevant Regulations (the *Patented Medicines (Notice of Compliance) Regulations*), relying on *AB Hassle v Canada (Minister of National Health and Welfare)*.¹⁹ The relevant subparagraph reads:

5. (1) Where a person files or has filed a submission for a notice of compliance in respect of a drug and compares that drug with, or makes reference to, another drug for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics and that other drug has been marketed in Canada pursuant to a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the person shall, in the submission, with respect to each patent on the register in respect of the other drug,

..

(b) allege that

...

(iv) no claim for the medicine itself and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by that person of the drug for which the submission for the notice of compliance is filed.

Pharmascience argued that the Regulations did not require it to address the possibility or probability of infringement by patients (that is, end users), of the patent in question, arguing that without such limitation on the interpretation, there would be an inadvertent extension to the monopolies of patent holders:

If there was any likelihood that a patient could consume a generic product for a patented use, then the generic product would not be approved. This would prevent new uses from being approved for existing drugs because there is always the possibility that someone somewhere will use the drug for the prohibited, patented purpose. This would result in a real injustice: since a generic company cannot possibly control how everyone in the world uses its product, the prevention of the generic from marketing the product would further fortify and artificially extend the monopoly held by patent holders. *The patent holder would, therefore,*

¹⁹ *AB Hassle v Canada (Minister of National Health and Welfare)* [2002] FCA 421.

*effectively control not just the new uses for the old compound, but the compound itself, even though the compound itself is not protected by the patent in the first place.*²⁰

Pharmascience alleged non-infringement of the patent, arguing that its decision to seek approval and market the capsules for a specific use (the treatment of hypertension only) and its plans to label the packaging such that this intention for a more limited use was explicit on the part of the manufacturer justified this. Although ultimately the point need not be decided, as the patent had expired, thus lifting the prohibition order, the court concluded that this narrower interpretation was correct.

Thus, this recent decision raises the question of public health policy and the negative impact of the traditional application of the doctrine of infringement in these cases. Finding infringement in the actions of doctors and patients who, when using drugs for one purpose also obtained benefits from the other purpose (a kind of beneficial side effect) would be contrary to basic policy both in terms of public health and patent monopolies and innovation. This case suggests that questions of infringement should be limited to manufacturers and distributors in this kind of situation.

This is relevant to efforts to resolve the need to avoid monopolies over gene sequences, through limiting scope to disclosed use, while at the same time avoiding perpetual protection of gene sequences and the confusion of cross-licensing, through a proliferation of patents each relating to a particular use.

In other words, where research and development can, in theory, amount to an attack on one's own market (thus limiting the incentive), research and development bound to the particular function and application creates a new market. Research and development on a particular gene function is not technical improvement on the original product because, in a purpose-bound approach, the gene sequence or even the protein coded is not the product, as it were. Rather, it is the function that is marketed by the manufacturer and it is the function that is the significant subject matter of the patent. Thus, the question of technical obsolescence, as it were, does not necessarily take hold.

So, in a very interesting kind of way, the role of the consumer is literally intrinsic to the patentability of the new technology in so far as that patentability is tied to use, is tied to its market. I find this fascinating in the context of current intellectual property law debates.

At the recent ATRIP Congress at the beginning of this month, Josef Drexler made a presentation rejecting the efficiency-oriented approach in intellectual property law, arguing that the dynamic efficiency of investment in innovation (arguably what is being measured in conventional analyses of incentives to innovation) cannot be measured, because the subject matter of that measurement (innovation) is a literally unknown and

²⁰ *AB Hassle v Canada (Minister of National Health and Welfare)* [2002] FCA 421: para 57. Emphasis added.

unpredictable quantity. Rather than profit coming directly from market investment, Drexl argues that it comes from market success. In other words, it is consumers which drive the intellectual property system. Those unwilling to pay have been branded pirates, thieves, and so on. But as Drexl maintains, these are potential customers that need to be convinced.

In other words, what is lost cannot be measured because the negative impacts on innovation are necessarily unknown. This is the nature of innovation. What is lost is the opportunity and incentive to take risk. It is perhaps this “risk” that is the critical turn in the entrepreneurial narrative of innovation and the creation of new markets. In particular, the entrepreneurial model of innovation provided by Joseph Schumpeter is somewhat instrumental in deciphering the inventiveness of research in this area. In a Schumpeterian model of dynamic efficiency, what is at stake is the driving and motivating of new consumer choices, new changes in the market, rather than responding to consumer demand. In other words, it is about risk. And these new markets are in the hands of the convinced consumer. Consumers provide the financial incentive, rather than the patent. The patent does not guarantee the value of the investment; rather, it is its use. Significantly, it is the question of “use” (and infringement) which defines the debate in gene patents. And it is other users (whether end-users or traditional consumers, or other innovators as other users of the gene sequence) that drive innovation.

Culturally and politically, in the context of intellectual property frameworks more broadly, this criterion of utility distances the nature of the “patent” from a sense of creative activity and the quality of the “inventor” as a creator. The “patent” describes an industrial and technical product rather than qualifying the outcome of creative and intellectual activity. Other qualities of reward – such as the esteem and reputation of the inventor or researcher – do not register within this system.²¹ And in this way, current debates over the relationship between the human right of the right to benefit, and the mechanism for delivering that right (intellectual property rights), do not seem willing to negotiate the possibility that inventors should enjoy a similar right to benefit.²² And indeed, patent rules defy the individual and independent creativity of the inventor, whether the rule is first-to-file or first-to-invent, and patent administration is of late criticised as precluding the access of inventors to that potential right to benefit (through high costs and the need to assign rights to commercialisation partners).

²¹ For instance, Sir John Sulston has suggested that “esteem” should be recognised as a legitimate reward in the context of incentives to innovation. See his discussion, RSA Adelphi Charter Launch, 13 October 2005.

²² In fact, in current debates over the relationship between intellectual property rights and human rights, the “right to benefit” discussed in the General Comment issued by the United Nations Committee on Economic, Social and Cultural Rights, is rarely attributed to inventors. Rather, it is usually reserved for discussions of authors and copyright creators. Economic and Social Council. Committee on Economic, Social and Cultural Rights. 35th Session. Geneva, 7-25 November 2005. General Comment No 17 (2005). 12 January 2006. E/C.12/GC/17.

In other words, the creativity or originality of copyright is not translated in patent law.²³ The creativity at stake in patent law is increasingly that of the entrepreneurial risk rather than the creativity of the inventor – that is, it is the investment in technology that is perhaps emphasised rather than the use and diffusion of that technology. Indeed, I would argue that in the context of patents, the efficiency of the system is frequently measured in terms of the number of new patents granted each year. But this provides little information on the diffusion of new technologies, or the use of that technology: “Patent indices are, however, a measure of new technology generated and not new technology used.”²⁴

I would suggest that this is as relevant in the context of patentable subject matter, not merely in terms of the obvious relationship between brand loyalty and trust and pharmaceutical markets, but also in terms of a more implicit relationship between consumer markets and the architecture of the intellectual property law system. In other words, consumers are not only merely end-users or patients, but also intermediate consumers (including practitioners).

Returning to the question of infringement, which appears to be critical in this context, this brings in current discussions advocating an emphasis not on infringement, but on balance transactions in a competitive market. The identification of new uses for a coded protein might be interpreted, therefore, as a type of competition by substitution.

And it is towards this purpose-bound approach, that the European Parliament is proceeding.

European Parliament Resolution

In its sitting of last October, the European Parliament adopted a resolution on the patents for biological inventions. In this resolution, the European Parliament referred to the Council of Europe’s Convention on Human Rights and Biomedicine²⁵ as well as the Commission Implementation Report of 2005, entitled “Development and implications of patent law in the field of biotechnology and genetic engineering.”²⁶

23 Drassinower, ATRIP 2006. Drassinower explains this difference in terms of the difference between invention (as the manipulation of nature and the technical space between self and world) and the author (as communicating with others and within the cultural space between humans). In this way, Drassinower suggests that invention is an addition to culture whereas authorial activity is engaging with culture “in one’s own voice.” He argues that “novelty” in patent law explicitly conjures up this notion of “additions” to culture. What is useful about this observation in the context of gene patents, is that this notion of an addition to culture, that is, a substantive contribution on the part of the inventor, coincides with the argument for restricted “purpose-bound” protection.

²⁴ Stoneman P (2002) *The Economics of Technological Diffusion*, Oxford, Blackwell: 251.

²⁵ Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, signed in Oviedo, Spain, in 1997.

²⁶ Report from the Commission to the Council and the European Parliament, “Development and implications of patent law in the field of biotechnology and genetic engineering,” COM(2005)0312 final. The Commission also launched a study, undertaken by the University of Sussex Science and Technology

The 2005 implementation report analyses the patenting of sequences of genes that have been isolated from the human body, and the patentability of human embryonic stem cells and cell lines. With regard to the patenting of gene sequences, the Report was concerned with the scope of protection and whether this would be classical protection that would thus cover future uses, or protection restricted to the specific use disclosed in the application (referred to as “purpose-bound protection”).

In that report, it was considered that Article 5(3) of the Biotechnology Directive, together with Recitals 23 and 25, might allow for a more limited scope of protection restricted to the disclosure of a specific industrial application. In the first Implementation Report on the Biotechnology Directive,²⁷ it was announced that a Group of Experts had been established to advise the Commission for future Reports, by examining relevant issues.²⁸ Meeting informally in 2003, the Group of Experts considered there to be no difference between DNA sequences and chemical inventions that would justify a different regime of patent protection. However, commentators have suggested that the proliferation of functions and uses that attend one particular gene sequence is not comparable to the few functions identified with other patentable products, including chemical substances. In other words, biological materials contain an enormous quantity of known and unknown information, as distinct from chemical and mechanical inventions. Genes and genetic sequences are indeed exactly that – portfolios of information. Patents are not to be awarded simply for information, but rather, for the technical solution to a problem – the deciphering of that information. Arguably, patentability should relate to the state of the inventor’s knowledge at the time, not the state of the product (the gene sequence itself). With classical protection of gene sequences, and thus protection of future and unknown use, there is a problematic patenting of information as such and, in effect, the patenting of discovery.

And indeed, the Group of Experts subsequently identified additional considerations that may justify different treatment for gene sequences. First, they raised ethical questions and noted the implementation of the Biotechnology Directive in France and Germany, where purpose-bound protection is provided.²⁹

But of particular interest in the current discussion, the Group of Experts identified the economic impact of classical protection in this area of technology, raising the question of freedom of research (in addition to exemptions for research and experiment) and, more significantly perhaps, the question of a proportionality or proximity between the

Policy Research (SPRU) analysing the extent of human DNA patenting in Europe in the context of research and innovation. I note also our Chair here today, Nick von Tunzelmann, who is from SPRU.

²⁷ Report from the Commission to the European Parliament and the Council. Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering. 7 October 2002. COM(2002) 545 final.

²⁸ *Ibid*, p 28.

²⁹ In France, purpose-bound protection is provided where the subject matter includes material isolated from the human body, and in Germany, purpose-bound protection is provided for inventions concerning human/primate gene sequences.

investment and the potential reward.³⁰ Again, the reward of the market is the most useful quantification and it is the consumer that qualifies the value of this market.

Although the Report ultimately did not take a position, its identification of the basis for limiting scope nevertheless provided an important foundation for the Parliament's Resolution, which supports the more restricted "purpose-bound protection" and calls upon the European Patent Office and Member States "to grant patents on human DNA only in connection with the specific disclosed application.

The Resolution also calls on the Commission to examine whether an amendment to the Biotechnology Directive, in the form of an amendment to Article 5, will be necessary to achieve these objectives.

Recalling the text of Article 5:

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Conclusion

Returning to the entrepreneurial model of innovation, and the critical nexus of application in the context of gene patents, in this way, consumers are innovators in this market. Arguably, innovation comes from branding. The marketing of gene research, the identification of function, the "labelling" of the intention of a product, as it were, will ensure the technical progress of biotechnology innovation – that is, the necessary creative destruction to make way for new innovation in the field of gene research.

³⁰ On this point, the European Commission has launched a study to undertake an economic analysis of human DNA patenting in Europe, the results of which are expected later this year.