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ABSTRACT

This paper responds to an invitation by the editors to consider whether the intellectual property (IP) regime suggests an appropriate model for protecting interests in detached human body parts. It begins by outlining the extent of existing IP protection for body parts in Europe, and the relevant strengths and weaknesses of the patent system in that regard. It then considers two further species of IP right of less obvious relevance. The first are the statutory rights of ownership conferred by domestic UK law in respect of employee inventions, and the second are the economic and moral rights recognized by European and international law in respect of authorial works. In the argument made, both of these species of IP right suggest more appropriate models of sui generis protection for detached human body parts than patent rights because of their capacity better to accommodate the relevant public and private interests in respect of the same.

INTRODUCTION

Detached human body parts have substantial commercial value and will therefore be exploited, whether legally or not. For this reason alone one might argue that there exists a need to regulate their exploitation, and that statutory rights of property such as those conferred by the intellectual property (IP) regime are a mechanism well suited to that end because of their ability to accommodate a range of private and public interests. The question which then arises is whether any aspect of the IP regime in particular suggests an appropriate model for protection.
The European IP regime covers a diversity of rights, each with its own juridical and theoretical basis,[1] making it preferable to focus on specific IP rights rather than the IP regime in general when answering this question. The relevance of such rights can then be determined having regard to the specific interests which it is sought to protect, and to the aim of legal protection in general.

The IP rights of most obvious relevance are those conferred by the patent system, which already protects detached human body parts in most developed jurisdictions. In this paper I start by considering the extent of that protection in Europe, and the relevant strengths and weaknesses of the European patent system.[2] I then consider two further species of IP right of less obvious relevance. The first are the statutory rights of ownership conferred by domestic United Kingdom law in respect of employee inventions, and the second are the economic and moral rights recognised by European and international law in respect of authorial works. In the argument made, both of these species of IP right suggest more appropriate models of sui generis protection for detached human body parts than patent rights because of their capacity better to facilitate the law’s recognition and accommodation of the different public and private interests in respect of the same. This is consistent with my suggestion elsewhere[3] that while patents ought to be available for subject matter involving elements of the human body, they are not appropriate for the protection of such elements as products as such.

**THE PATENT REGIME: MONOPOLY RIGHTS IN RESPECT OF HUMAN BODY PARTS**

*The availability of patents for human body parts*

The purpose of the patent system is commonly understood as being to promote innovation by rewarding contributions to the technical arts with the grant of limited monopoly rights. Those rights give the grantee a limited period of exclusivity within which to exploit his or her patented invention on the understanding that at the end of the period it will enter the public domain.
In Europe and elsewhere, patents have long been available for isolated elements of the human body. By contrast, non-isolated elements are expressly excluded from protection. The reason for the patentability of isolated elements is the technical character of all acts of isolation, and thus (it is said) of all isolated elements themselves, which are consequently “inventions” within the meaning of patent law. It follows that provided an element satisfies the other patentability requirements, it is capable of supporting a European patent.

The main “other patentability requirements” are novelty, inventive step, susceptibility of industrial application, and sufficient disclosure. The combined effect of the novelty and inventive step requirements is to limit the availability of body part patents to newly isolated parts such as gene sequences, stem cells, and other biological materials. The need for an invention to be susceptible of industrial application requires at least an “educated guess” as to how the isolated part might benefit industry.

In addition to satisfying these requirements, for a subject matter to be patentable in Europe its commercial exploitation must not be contrary to ordre public or morality. Among other things, and by express provision of Directive 98/44/EC on the legal protection of biotechnological inventions (and associated European and domestic instruments), this requires the exclusion of processes for cloning and modifying the germ line genetic identity of human beings, and of uses of human embryos for industrial or commercial purposes.

Before 2009, patentability in Europe was treated as an essentially technical enquiry, and the morality(ordre public) exclusion interpreted restrictively. That approach was established in the 1994 case of HOWARD FLOREY/Relaxin, which involved an application for a European patent for a DNA sequence which the applicant had isolated from the human body for the first time using known recombinant techniques. The application was opposed before the European Patent Office (EPO) on the ground, among others, that DNA represents “life” the patenting of which is immoral and therefore prohibited under European law, and that to allow a patent
for the invention in question would have involved an abuse of the pregnant women from whose bodies the mRNA had been isolated, a return to slavery, and “the piecemeal sale of women to industry”. The argument was “emphatically rejected” on four central grounds: first, that the women from whose bodies the mRNA had been isolated had consented to donate their tissue “within the framework of necessary gynaecological operations”; second, that patents confer rights of exclusion rather than use, and are incapable of conferring “any rights whatever to individual human beings”; third, that DNA is not “life” but rather “a chemical substance which carries genetic information and can be used as an intermediate in the production of proteins which may be medically useful” and fourth, that the ordre public/morality exclusion of patent law does not permit enquiry into the intrinsic immorality or inappropriateness of gene patents, on the ground that patentability is a matter of law rather than ethics, and ethical enquiries are beyond the proper remit of European patent tribunals. All the EPO could do was consider whether “the opponents’ general assertions concerning the alleged intrinsic immorality of patenting human genes” were made out, which it decided they were not, as there existed no “overwhelming consensus” among the EPC Contracting States that the patenting of human genes, including the use to that end of consensually detached human body parts, is abhorrent.

Consistent with this, the Patent Office in Howard Florey interpreted the ordre public/morality exclusion narrowly, as existing merely to ensure “that patents … not be granted for inventions which would universally be regarded as outrageous” such as (it was suggested) a letter bomb and perhaps (it was implied) an invention devised using human body parts detached without free and informed consent. An earlier decision that the exclusion provides a mechanism for balancing competing interests in relation to the protection of transgenic animals and other biotechnological subject matter by requiring that the usefulness of the invention be weighed against the environmental and other ethical risks of its exploitation was all but rejected by the Office. On the other hand, the possibility of the exclusion being used to regulate the conduct of pre-
patent research was clearly recognized by the EPO’s treatment of donor consent as relevant to patentability.

Howard Florey was decided nearly 20 years ago, four years before the Biotech Directive was introduced and the ordre public/morality exclusion extrapolated in the terms described above. Nonetheless, it is only since the decisions in WARF/Stem Cells and Brüstle v Greenpeace that its approach to the patenting of human body parts has been successfully challenged. The result has been a sea change in European patent law. Rather than an essentially technical enquiry in which considerations of ethics have no role beyond ensuring that the grant of a patent would not be universally regarded as outrageous, patentability must now take full account of human dignity as one of the values underpinning both the Biotech Directive and European law and culture more generally. Thus it was that the Warf and Brüstle tribunals construed the ordre public/morality exclusion expansively, with a view to achieving one of its motivating purposes of preventing the commodification of human embryos. As a result of their decisions, European (including national) patents must now be refused for human stem cells and other isolated materials the preparation of which involves the use of human embryos, even if the subject matter for which the patent is claimed does not itself include an embryo and is intended exclusively for research (as distinct from commercial or industrial) purposes, and even if the embryos are obtained and used with the donors’ free and informed consent. The decisions restrict significantly the availability of patents for detached human body parts, and raise the spectre of further restrictions on conceptions of patentability with reference to European conceptions of morality and public policy in the future. They also invite a reconception of European patent law and its relationship to human rights, including the right to respect for and protection of human dignity and the integrity of the person.

One important issue of uncertainty concerning that relationship is whether the patent system may validly be used as a vehicle for regulating the conduct of pre-patent research in the manner in which Howard Florey suggested that it might. On one hand,
Recital (26) of the Biotech Directive provides a legal basis for such use in its statement that

...if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law.

In addition, the Court of Justice of the European Union (CJEU) has expressly recognized that “the right to human integrity” encompasses the right of a person to have the opportunity to give free and informed consent to the use of his or her biological material and other body parts, consistent with Article 3 of the European Charter on Fundamental Rights. On the other hand, it has also rejected the relevance of this right to issues of patentability. In its opinion, such right is “clearly misplaced as against a directive … whose scope does not … extend to activities before and after … grant, whether they involve research or the use of the patented product”.

Aside from the availability of patents for human body parts, one must consider the scope of protection which such patents confer, including the uses which they preclude of the patented body part. Until recently that scope was expansive, extending to the isolated part and, in the case of genetic products, to “all material, save as provided in [Biotech Directive Art 5(1)] in which the product is incorporated and in which the genetic information is contained and performs its function”. However, this was scaled back by the CJEU, consistent with the wider shift in European law and culture described above. As a result, gene patents in Europe now only protect the gene when able to perform the specific function for which it was patented. The result challenges the Howard Florey view above by supporting a restrictive interpretation of the scope of protection conferred by a product patent with reference to that which merits the patentee his or her monopoly protection.

There remains the ability of the owner of a patent in the biological or medical field to enforce his or her rights in a manner which restricts public access to the relevant invention. According to
decision-makers in other jurisdictions, the right to human dignity encompasses a right to health care services, which in turn requires that patents not be used to deny citizens access on reasonable terms to essential medicines.[30] Among other things, the view underlines the potential for human rights to restrict the enforceability of patents for detached human body parts, and the significance of such patents in transforming a protected body part into “public property”, viz, an essential commodity to which the public has a right of access.

The strengths and weaknesses of the patent system for the protection of interests in detached human body parts

The strengths and weaknesses of the patent system for the protection of interests in detached human body parts depend on the reasons for conferring the protection at all. One legitimate reason would seem to be to protect the autonomy of persons from whose body the parts are detached, and society against the commodification and commercialization of the human body. Another would seem to be to permit if not encourage the donation of human body parts to medical science, and remove existing legal and social obstacles to their use in medical research, including by ensuring to researchers the rights necessary to pursue their work.[31] If this is accepted, the suitability of any form of legal protection must depend on its capacity to accommodate appropriately the range of private and public interests which these reasons suggest; and in this connection the patent system has certain obvious strengths. They include strong exclusionary rights in the form of limited monopoly protection on such grounds and subject to such conditions as the legislature deems appropriate (including, perhaps, the condition that any biological material of human origin incorporated into an invention have been obtained and used with the donor’s free and informed consent[32]); a central register of grants to facilitate the transfer of patents and the commercial exploitation of the subject matter to which they relate; a forum for lawmakers to consider and “balance” the competing interests in and issues raised by such exploitation; the recognition of certain “public interest” exceptions to infringement (covering for example acts done privately for non-commercial purposes and in certain experiments); and the provision of a compulsory licensing mechanism (to ensure,
for example, that patented inventions be made available to the public on reasonable terms). In short, the patent system offers considerable flexibility to resolve the competing public and private interests in the protection of detached human body parts.

On the other hand, it also has certain important constraints which limit its suitability to that end. Above all, they derive from its focus on rewarding contributions to the technical arts, and the consequential restriction of patent grants to inventors and employers responsible for detaching or using the body parts. Among other things, this makes the system unsuitable as a means for promoting personal autonomy interests by prohibiting interference with others’ bodies other than via such patentability exclusions as considered above. On the other hand, the current interpretation of these exclusions is widely regarded as going too far in its discouragement of medical research. Related to these points, the focus of the patent system on advancing the technical arts requires that patents be limited to “technical” subject matter which satisfy the requirements of novelty, inventiveness, and susceptibility of industrial application, with the result that the vast majority of detached human body parts will not in any case be patentable. In addition, even where they are patentable, the protection conferred by the patent will not include property rights in the body part itself, and nor will it extend – directly at least – to the commercial interests of the persons from whose body the part was isolated. Finally, even where available patents last for a limited period of 20 years, after which the protected subject matter enters the public domain.

For these reasons, it may be considered that the patent system is ill-suited to protect detached human body parts as such. The reason is its inability, on its own at least, to accommodate sufficiently the various public and private interests outlined above.

The question remains whether there might be other IP regimes of relevance. One contender in the United Kingdom is the regime of statutory ownership which exists in respect of employee inventions irrespective of their patentability. The primary significance of that regime for current purposes is two-fold: first, it
confers an additional and more direct form of protection in respect of detached human body parts than that conferred by the patent system; and second, it provides a model for the creation of a new species of property right in respect of detached human body parts as between the person from whose body the parts were detached and the person responsible for detaching them.

THE EMPLOYEE INVENTION REGIME: OWNERSHIP RIGHTS IN RESPECT OF HUMAN BODY PARTS

The vast majority of inventions are devised by employees, raising the question who is entitled to patent them?

Historically, in the United Kingdom, a patent could only be granted to a “true and first inventor”. While employers were not “true and first inventors” by virtue of their position as such, they did have contractual rights to the benefits of their employees’ labour, including their employees’ inventive labour. Over time this led the courts to recognise that employers had equitable property rights in any inventions which their employees had been employed to make (and had in fact made). That was the position in the 1970s, which the UK Government sought to codify in the current (1977) Patents Act subject to the inclusion of certain protections for employees. The result was sections 39 to 43, which in combination achieve three things. First, they allocate property rights in employee inventions “as between” employee and employer. Second, they give an employee whose invention is owned by his employer a right to compensation calculated in accordance with section 41 if, having regard to the circumstances of the case, including the size and nature of the employer’s undertaking, “the invention or the patent for it (or the combination of both) is of outstanding benefit to the employer”. And third, where an invention is owned by an employee, they protect him against the contractual diminution of his rights in the innovation and any associated patents by his employer, and against his employer’s use of copyright or design right in materials concerning the invention to obstruct its working, performing, or patenting; the latter protection extending also to third parties.
The significance of sections 39 to 43 for current purposes lies in the right they confer on a research company or other employer of a person who isolates a body part to exclude third parties from the unauthorized use of the part in its isolated form. Importantly, that right is potentially unlimited in duration and does not depend for its existence or enforcement upon registration or compliance with other requirements, including the patentability requirements described above. This emerges clearly from *LIFFE Administration & Management v Pinkava*,[38] which involved methods of doing business for which neither UK nor European patents could have been validly granted, and which were accepted by the parties and the Court to be subject to the section 39 right all the same. The reason for that acceptance seems to have been the view, previously accepted by the courts, that “[o]nly when there is self-evidently no bone should the dogs be prevented from fighting over it”.[39]

Perhaps more important than their direct protection of human body parts is the example which sections 39 to 43 offer of a statutory property regime based in considerations of equity, and the recognized need to prevent inventors from exercising their rights and freedoms to the detriment of certain interested third parties. The introduction of that regime ended the judicial practice of imposing a constructive trust in any situation in which the interests of recognizing an employee to have rights in respect of an invention s/he had devised were believed to be outweighed by the interests of recognizing his or her employer to have rights in respect of the same.[40] Hence my argument, that just as a regime of ownership has long existed to balance competing interests in respect of employee inventions, so one might be created to balance competing interests in respect of human body parts. Following the model of sections 39 to 43, and taking account of the rights of respect for and protection of human dignity and the integrity of the person recognized in the European Charter, such a regime could be constructed to achieve three things. First, to confer ownership or other property rights in respect of detached human body parts (and innovations involving the same) on the person responsible for detaching them in certain specified situations (for example, where the part is detached in the course of an authorized investigation following satisfaction of
appropriate information and consent procedures) or, in all other situations, on the person from whose body the part is detached. Second, to entitle a person whose body part has been used for a commercial or industrial purpose, but who has no rights of ownership in relation to it, to a statutorily-determined amount of compensation in respect of such use (for example, “a fair share of the benefit” which the person who detached the body parts has derived, or could reasonably be expected to derive, from their commercial exploitation). And third, to protect individuals against the contractual diminution of their statutory rights of property and compensation in respect of their detached body parts. In this way, sections 39 to 43 could provide a model for a new regime of statutory rights in respect of detached human body parts. Such a regime would have the principal advantages of securing exclusionary rights in respect of body parts from the point of their detachment as between detacher and donor alone, and of conferring on the latter a right in certain pre-defined circumstances to share in any benefits resulting from exploitation of the same. By allocating rights in respect of detached body parts independent of their patentability, it would help to remove the existing social and legal obstacles to their use by means of a nuanced, human rights-informed and equity-based regulatory regime.

**THE COPYRIGHT REGIME: ECONOMIC AND/OR MORAL RIGHTS IN RESPECT OF HUMAN BODY PARTS**

My focus to here has been on the potential relevance of patent and associated property rights for the protection of detached human body parts. While that focus makes sense in a system in which isolated elements of the human body are conceived as technical subject matter appropriate for commercial and industrial exploitation, other conceptions are equally if not more appropriate, and also suggest other models of legal protection. One such conception is as part of a person’s self or personhood, analogous to the expressive subject matter of authors’ economic and moral rights.

In Europe, authors’ rights have their basis in moral or natural law arguments, epitomized by the 1791 statement of Le Chapelier
that “[t]he most sacred, the most legitimate, the most unassailable, and, I may say, the most personal of all properties, is the work which is the fruit of a writer’s thoughts.”[42] To be sure, the premise of this argument is open to critique, as are some or all of the ideas which may be attributed to it, including the ideas that writers deserve rights in the fruits of their thoughts, require rights for reasons of autonomy and personhood or in recognition of their natural law rights in their body, and/or will be harmed emotionally or financially by being denied property or other rights. On the other hand, even if these ideas are not accepted for authorial works, the second and third in particular might be accepted for detached human body parts; for, and as an objective matter, there would seem to be few things more expressive or constitutive of a person than his or her body. If accepted, this suggests another model for protection in the form of authors’ economic (property) rights and moral (personal) rights. Following the lead of European law, the former might confer something less than the monopoly protection of a patent grant, such as a transferable right to prevent the commercial exploitation or cloning of detached body parts during the life of a person plus 70 years, and be subject to certain de minimis and other public policy exceptions. Following the lead of international law, the latter might confer a non-transferable (but potentially waivable) right to object to derogatory treatments of one’s detached body parts – meaning treatments prejudicial to the person’s honour or dignity – augmented perhaps by rights of privacy.[43] As with a regime of statutory ownership rights the details would need to be carefully worked out. On the other hand, in contrast to a regime modelled on industrial rights, their starting point would be the intimate connection which presumptively exists between a person and certain aspects of his or her body, and the moral or natural law rights which s/he consequently ought to be recognised as having to prevent unauthorised uses of the same.

CONCLUSION

The European IP regime provides limited protection for detached human body parts in the form of patent grants for certain technical
subject matter ("inventions") and statutory ownership rights. In recent years the limits on the first of these species of protection have become more pronounced due to the increasing importance within Europe of fundamental rights, including rights of respect for and protection of human dignity and the integrity of the person. While the emergence of such rights gives the patent regime new relevance as a site in which non-technical issues raised by the protection of detached human body parts and other subject matter are required to be considered by the courts, the result of such consideration can only be reduced patent protection for inventors and their employers, and a corresponding chilling effect on medical research. Of itself, neither the grant nor denial of patent protection recognises third party rights in respect of body parts, including of the person from whose body the parts are detached, other than indirectly via such conditions on patentability and protection as may be imposed for his or her benefit. For these reasons alone, the weaknesses of the patent system may be thought to outweigh its strengths as a means of regulating the commercial exploitation of detached human body parts.

Running through the discussion above is the appropriate conception of the human body. This has been a persistent question in patent law, where the availability and scope of protection for human genetic material has depended largely on the courts’ conception of such material as life, information, chemical substances or something else.[44] It is submitted that this issue may be an appropriate starting point for considering the best form, if any, of legal protection for detached human body parts.[45] For example, conceiving the human body in expressive or personal rather than technological terms is more likely to support a form of protection akin to authors’ economic and moral rights, focused on protecting the autonomy of the person from whose body the relevant parts derive. When combined with other forms of legal protection, such rights could appropriately recognise the various economic and moral interests which persons may be expected to have in their physical selves, while also being limited to reflect the interests of society in supporting medical and biotechnological research in a way which does not involve the commodification or commercialization of the human body as such.
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2 By “European patent system” and “European patent law” is meant the system and law established by the European Patent Convention 1973/2000 (EPC) as supplemented, for the 27 EPC Contracting States which are also Member States of the European Union (EU), by EU law.


4 See Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions (Biotech Directive) Article 5(1) and European Patent Convention 1973/2000 (EPC) Rule 29(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.” The availability of patents for isolated elements is confirmed in Biotech Directive Article 5(2) and EPC Rule 29(2) as follows: “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.”

5 See EPC Arts 52–57, 83; Biotech Directive Art 5(3); EPC Rule 29(3).

See Biotech Directive Art 6(1) (“Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation”) following EPC Art 53(a).

See Biotech Directive Article 6(2) and EPC Rule 28: “On the basis of paragraph 1, the following, in particular, shall be considered unpatentable: (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.”


See [1995] EPOR 541,[6.3.1].

[1995] EPOR 541,[6.3.1].

[1995] EPOR 541,[6.3.3].

[1995] EPOR 541,[6.3.4].

[1995] EPOR 541,[6.3.1], [6.4.3].

[1995] EPOR 541,[6.4.3].

[1995] EPOR 541,[6.2.1].

See [1995] EPOR 541,[6.3.1].


Biotech Directive Art 6(2); EPC Rule 28.

G_2/06 *WARF/Stem cells* [2009] EPOR 15 (EBA).

C–34/10 *Oliver Brüstle v Greenpeace eV* (CJEU 2011).
Prior to these cases the EPO had also rejected an application for a patent for modified human and animal stem cells on *ordre public/morality* grounds as contrary to EPC Rule 28(c).

In support of this the Board referred to the EU’s selective policy of funding for stem cell research.

See Charter of Fundamental Rights of the European Union OJ C 83/02 (30.03.2010) (European Charter) Arts 1 (“Human dignity is inviolable [and] must be protected and respected”), 3 (“Everyone has the right to respect for his or her physical and mental integrity”) which, since the Treaty of Lisbon, has the constitutional status of primary European law (see The Treaty on European Union OJ C 83/13 (30.03.2010) Art 6(1)).


See European Charter Art 3(2): “In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law; the prohibition of eugenic practices, in particular those aiming at the selection of persons; the prohibition on making the human body and its parts as such a source of financial gain; the prohibition of the reproductive cloning of human beings.”


See Natco Pharma Ltd v Bayer Co. (Controller of Patents, March 9, 2012), 24, discussed in Pila J. Reflections on Method and Policy in the Crowded House of European Patent Law and their Implications for India (n9). The right to health care services is also recognized in the European Charter, in Article 35 (“Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.”)
On the importance of patent protection in this regard see Human Genome Sciences Inc v Eli Lilly & Co [2011] UKSC 51,[99].

But see n 27.

Patents Act 1977 (PA) ss 60(5), 48–48B.

See, eg, Sample I. European Court outlaws patents on embryonic stem cell techniques. The ban will stifle research investment in potential stem cell treatments for conditions such as dementia, say scientists. The Guardian 18 October 2011. www.guardian.co.uk/science/2011/oct/18/european-patents-embryonic-stem-cells (last accessed 17 June 2012).

In other jurisdictions individuals have successfully negotiated patent shares in consideration for their provision to a patentee of biological materials.


PA s40.

[2007] 4 All ER 981 (CA).


This is particularly if it is accepted, as the European Charter and Biotech Directives suggest, that the rights of respect for and protection of human dignity and the integrity of the person require a “prohibition on making the human body and its parts as such a source of financial gain” (European Charter Art 3(2)).

This is the position under UK law; see Copyright, Designs and Patents Act 1988 (CDPA) s85. For the UK definition of "derogatory treatment" see CDPA s80(2), adapting Article 6bis of the Berne Convention for the Protection of Literary & Artistic Works 1886, as amended.

Cf, eg, the 2010 and 2011 decisions of the US Southern District Court of New York and the Court of Appeals for the Federal Circuit in Association for Molecular Pathology v United States Patent and Trademark Office.