Human donors' right to consent to patenting biochemical inventions: is it real?

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'Whatever you do or don't, the
European Patent Office is on
your side!'

'No it isn't!' – 'Yes it is!'

Lawyers are often considered to be gifted with extensive exonerative capabilities, used to set their clients (and themselves?) free from any unforeseen and unwanted consequence of their expressions. Capabilities that may, however, be required by the fact that in law, $1 + 1$ may equal anything, depending on the circumstances in which the sum is made. Then again, the rules may be fixed, but circumstances always change. Lawyers thus focus on the specifics of a particular case, and so tend to sum up circumstances, but may not generally be endowed with the mathematical skills necessary for summing – unlike the many readers of this editorial, who conversely need such skills to go about and do their jobs. Since the question contained in the title of this editorial is legal in kind, it may so be inevitable that the one and only possible answer is: 'it depends!' The answer depends on the legal perspective one takes when answering the question. On one hand it will show that the right of donors of human biochemical materials to (withhold) consent to patenting inventions somehow related to that material certainly is not real, at least if looked at from within a patent law perspective. On the other hand, the right to (withhold) such consent is very real indeed, if looked at from within a human rights perspective. This ambivalent situation, which may astonish the ones who focus on reality instead of on the rules that may apply thereto, derives from an asymmetry – perhaps even a divide – between the human rights law and the patent law framework. Whereas the question posed is inherently legal, and the answer provided thus must be of the same kind, it is of profound practical importance to the ones engaged in genomics and personalized medicine. Numerous healthcare professionals engaged in a large variety of distinct activities may be held to inform donors of biochemical materials at very preliminary stages of their work regarding future uses – including patenting – that may be made

thereof. This editorial introduces the aforementioned legal perspectives, the contradictions they may entail, and the consequences thereof for said healthcare professionals. Its conclusion sets forth issues that need to be resolved, and includes my promise to do so in a future Perspective article to be published in this journal.

Biochemical material: the fuel for genomics

The enhancement of genomics, and the manner in which the knowledge it sets forth feeds into the area of healthcare that is generally called personalized medicine, creates daunting, unprecedented prospects for individually tailored preventive, diagnostic and curative methods and products. Genomics will enable divergence from the 'one-size-fits-all-approach' that has determined healthcare for so long. It also necessitates a departure from the same approach in R&D, most notably when it hinges on the inquiry, modification, recombination and application of biochemical compounds for individualized diagnostic, therapeutic and pharmaceutical purposes. Both genetically delineated groups and individuals will become increasingly important to the endeavors of the host of public and private entities that engage in research, and ultimately pursue to deliver products and services. One needs their biochemical material to study, to investigate its characteristics and workings and subsequently develop knowledge and applications accordingly. Access to, and exchange of information about, such material and its workings should be achieved at increasingly preliminary stages of contact with said groups and individuals, and must be continued throughout the R&D phases thereafter. The genetic and other biochemical material of these patients/research-subjects/donors is the fuel of the scientific engine that drives genomics and personalized medicine.

Patent law: the turbo for genomics

Whereas the material concerned may be the fuel of the engine of knowledge that drives the genomics R&D, a particular legal regime is generally considered to provide it with its boost. Patent law is often regarded as the turbo of

R&D, particularly also in the field of the life sciences that incurs such high costs and huge risks. Patent law is an economic instrumental regime that should continuously stimulate technological progress. Its mechanism makes use of private interests to safeguard a public one. Progress is to be stimulated by conveyance of proprietary rights with regard to inventions and, on the other hand, publication of information regarding them. The international legal framework of intellectual property law, of which patent law is a part, is determined by the Agreement on Trade Related Aspects of Intellectual Property Rights (1994) (the TRIPs Agreement) [1]. The requirements for patentability can be found in, among others, articles 27, 28 and 33 of the TRIPs Agreement [1]. They may equally be found in the European Patent Convention (1973), particularly in articles 52–57, 63 and 64. It is noted that the European patent system is two-tiered. A patent conveyed pursuant to the European Patent Convention comprises a bundle of national patents of the designated member states (i.e., articles 2(2) and 64(1) of the European patent Convention) [2]. The requirements for patentability are set forth in the European Patent Convention, and some of the effects of conveyed patents are also stipulated. Others may, however, be determined by national patent statutes. From the aforementioned requirements, it follows that inventors of novel, inventive and industrially applicable inventions, which have been disclosed and can be reduced to practice, may obtain a patent. The patent to the invention concerned is valid for a period of 20 years, and conveys a right to exclude anyone from commercially using the invention without prior consent (e.g., a license) by the patentee. This allows the patentee to recoup investments, without risking commercial free-riding and appropriation by others. Given the fact that information regarding the patent and the underlying invention is published by the patent office, others may seek to develop the invention – knowledge – further, and so yet again reach novel, inventive and industrially applicable inventions. A timeless cycle of innovation is initiated – or at least one hopes so. Often heard assertions regarding the innovation inhibiting effects of patent law in the life sciences should be taken seriously, but don't negate that many participants in R&D, among which are many universities, continue to make extensive use of this legal regime. Moreover, the allegations often seem to bypass the fact that most governments

in the world are not able or willing to take up full public funding of R&D, and that one has to (partially) rely on patent law to steer and stimulate activities in this respect. Also, many of the assertions seem to ignore the many restrictions and exceptions provided in (European) patent law that are particularly aimed at enabling follow-up activities. Given the scope of this editorial, this debate is, however, not further elaborated here. The same applies to the thought that it may be useless to patent the products and processes to be developed in the course of personalized medicine. It should just be mentioned that, whereas the individual use of such products and processes may bolster said thought, their characteristics and less individual potential applicability may prove otherwise, and may imply that patent law will continue to play an important role in this field also. This assumption is bolstered by the increasing number of patents conveyed and used in regard of inventions that are most relevant for personalized medicine too. The past decades have generally made clear that most inventions coming forth from the life sciences may be patented. This includes (partial) genetic sequences, proteins and other biochemical substances and their applications. Rules 26–29 of the Implementing Regulations to the European Patent Convention explicitly say so. Rule 27(1) provides that:

'[B]iotechnological inventions shall also be patentable if they concern: (a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature.'

Rule 29(2) specifies this with regard to human material.

Inventors & facilitators

The proprietary rights associated with patents are limited though. The duration of the patent is restricted in time. Upon lapse of the patent, anyone can freely and fully make use of the invention. Furthermore, the rights associated with the patent apply to, so to say, commercial use of the invention only. Most patent regimes contain additional exceptions, such as research exemptions and compulsory license provisions, for example, for dependency of follow-up inventions. However, the most important substantive limitation to patents derives from the principal focus of patent law. It applies to inventions. Hence, whereas the attainment of an invention

may require both intangible (knowledge) and tangible (material) inputs from a vast array of sources, the patent can only be conveyed with regard to the ultimate invention, which always is a novel, inventive technological idea that can be reduced to practice in an industrial context and for a particular purpose. Patent law so disregards most inputs given to reach such idea. They are never eligible for patent protection. Whereas this may leave a lot of room to maneuver in R&D – most of the knowledge and materials somehow related to an invention are irrelevant for patent law purposes – it also has another impact. Other rights could pertain to those intangible or tangible contributions; rights which are disregarded in patent law too. The latter's regime narrowly focuses on the patentability of inventions. That's it and that's all. Obviously, this may profoundly affect the interests of providers of biochemical resources, which may be individual human donors, traditional knowledge holders, biodiverse countries, botanical gardens, gene-banking and data-banking institutes and so forth. Insofar as the contribution concerns nonhuman material, the Convention on Biological Diversity (1993) and the International Treaty on Plant Genetic Resources for Food and Agriculture (2001) may apply [3,4]. Rights with regard to nonhuman materials are not further elaborated on here, given the scope of this editorial. Most important is, however, that the contributions of providers of said resources are generally not acknowledged within patent law. Facilitation of a molecule or – for that matter – a cup of coffee or a microscope, may be helpful in the course of conducting R&D, but it does not, as such, amount to inventing and thus does not conceptually bear upon the ultimate inventions, the subject matter of patent law. The aim and reach of the rights with regard to the facilitated biochemical material is, of course, at the heart of this editorial. It includes an individual donor's right to (withhold) prior-informed-consent to further use of his or her bodily material, including patenting, after it has been removed in the course of a (medical) intervention.

The reality of human rights law

The principle of prior-informed-consent to medical interventions on the human body is firmly rooted in human rights law. The principle emanates from the individual's human dignity and freedoms. It is explicitly recognized in article 7 of the International Covenant on Civil and Political Rights (1966):

'...no one shall be subjected without his free consent to medical or scientific experimentation'

See also the Preamble and article 1(1) of this Covenant; the Preamble and article 1 of the Universal Declaration of Human Rights (1948); and the Preamble and article 1(1) of the International Covenant on Economic, Social and Cultural Rights (1966). This right is repeated in article 5 of the Convention on Human Rights in Biomedicine (1997) (the Convention) [5,6]. The long-embraced customary pretext that the human body cannot be deemed an ordinary 'good' in the legal fashion, which may be owned and transferred for benefit is made explicit in article 21 of the Convention:

'[T]he human body and its parts shall not, as such, give rise to financial gain.'

Article 21 of the Convention, of course, does not reflect upon commercialization of (patents on) inventions deriving from or consisting in human biochemical materials. The make-up and application of patent law ensure that it is never the human body or its parts, as such, that are patented and commercialized; but perhaps a part not as such, and which is delivered through technical intervention and/or modification and to be applied in a certain way for a certain goal (e.g., diagnostics, pharmaceutical and so on). Article 21 merely implies that I may, so to say, not sell myself or my parts. However, article 22 of the Convention arguably stretches the reach of the prior-informed-consent right as it was recognized before, when it provides that:

'[W]hen in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.'

An expansive interpretation of this provision implies that use of a bodily part (e.g., further R&D, intervention, modification, application, transfer and patenting) is subject to said consent too. Human rights lawyers likely answer the question posed in the title of this contribution affirmatively: human donors of biochemical material have a right to (withhold) consent to future patenting of inventions related thereto. In the absence of consent, an inventor is held to refrain from patenting. Human rights lawyers may assert that this obligation should be given effect in patent law

too. The UN Economic and Social Council thus recently stated in its General Comment No. 17 (E/C.12/GC/17, 12 January 2006) that:

'[P]arties should prevent the use of scientific and technical progress for purposes contrary to human rights and dignity...e.g., by excluding inventions from patentability whenever their commercialization would jeopardize the full realization of these rights. States parties should, in particular, consider to what extent the patenting of the human body and its parts would affect their obligations...under...relevant international human rights instruments.'

No matter how forceful this statement is, it does not bear upon the reality of patent law.

The reality of patent law

The European Patent Convention does not contain a provision that acknowledges and gives effect to the aforementioned right to prior-informed-consent. In fact, it disregards any right or interest merely related to facilitation, not invention. It may, however, be asserted that article 53(a) of the European Patent Convention could be applied. This provision excludes inventions from patentability if their commercial exploitation would be contrary to *ordre public* or morality. Hence, in the absence of referenced consent to the further use, including patenting, an invention deriving from or consisting in human biochemical material would arguably fall within the scope of this exclusion. Although most patent lawyers agree that article 53(a) of the European Patent Convention should be applied marginally and restrictively – which is done by the European Patent Office – it may nonetheless appear self-evident that human rights bear upon morality, and so deserve to be assessed in this realm. Support for this proposition may perhaps be derived from the EC directive 98/44 on the legal protection of biotechnological inventions (1998) [7]. In Recital 26 of directive 98/44, it is provided that:

'[W]hereas 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...'

The Recital is not repeated in the main body of directive 98/44, and thus does not confer a binding obligation to the member states of the EU.

Whereas it is not legally binding, the fact that it was explicitly included in the directive renders it relevant. It cannot be deemed entirely detached from moral considerations, as implied in article 53(a) of the European Patent Convention. Hence, Recital 26 may offer guidance for acknowledgement of the prior-informed-consent concept and its effects in European patent law. Whereas directive 98/44 is only binding upon the member states of the EU – not including the European Patent Organization – it is important to observe that the main body of the directive was implemented in the European Patent Convention through inclusion in the Implementing Regulations (in Rules 26–34 of the Regulations). Because Rule 26(1) of those Regulations states that directive 98/44 can be used as an additional means of interpretation, it may give a helping hand in this respect. However, in a recent decision, the Technical Boards of Appeal of the European Patent Office has rejected the aforementioned arguments, and held that no right to prior-informed-consent is to be acknowledged within the framework of the European Patent Convention, including in the realm of article 53(a) [8]. This leaves legislative change as the only option to give in to a broad reach and effect of the human right to prior-informed-consent, as may be envisioned by human rights lawyers. There seems to be no inclination to adapt the European Patent Convention in this respect though. Some legislative action is taken in the course of the implementation of directive 98/44 at the national level. Italy, Denmark and Norway are among the very few European countries that legislatively implemented variations of Recital 26, and its counterpart contained in article 22 of the Convention.

A right = a right

Regardless of the patent law perspective, it could well be asserted that an expansive human right to (withhold) consent to further uses of removed and facilitated bodily material exists and can be enforced. The right is a right, and is therefore real anyhow – to swing back to the human rights perspective in answering the question contained in the title of this editorial. Arguably, the right may affect the legal position of the ones envisaging further use of a donor's biochemical material. Such a legal position may be conceived of with regard to the following situations. First, insofar as the human right to prior-informed-consent to further uses of removed bodily material has been implemented in other

(national) laws than patent law, one has to comply therewith. It may lead to sanctions outside of the patent law context, such as pursuant to medical or criminal law. Second, and dependent on, on the one hand, the behavior of healthcare professionals with regard to the material they have obtained and, on the other hand, dependent on the manner in which information was provided and the prior-informed-consent forms used were formulated, filled-out and signed by donors, one may envisage claims on the basis of the law of obligations (torts or contracts law). Third, donors whose human right, as contained in article 22 of the Convention and rooted in other human rights instruments, is violated may pursue to enforce it horizontally – i.e., in direct relation to the presupposed violator, thus the inventor, patent applicant or patentee. Even if at present the human right concerned may be unreal for patent law purposes, healthcare professionals may have to deal with it in their real world anyhow.

Conclusion: issues & reassurance

The answers provided to the question of whether the human donor's right to prior-informed-consent to patenting is real surely are unsatisfying – even for me, a lawyer. The answers 'yes' and 'no' are given simultaneously, but should of course mutually exclude each other. Furthermore, the fact that the right appears irrelevant from a contemporary patent law perspective does not negate that it surely is most relevant from other legal and practical perspectives. The sum should thus be remade. The ambivalence caused by the asymmetry of the legal regimes at hand triggers a host of important questions, the most practical one of

which certainly pertains to the appropriate set-up and application of prior-informed-consent mechanisms used by healthcare professionals and researchers. They are left wondering in the dark, which will surely negatively affect their daily work, R&D endeavors and the position of individuals whose bodily material may be of interest too. Other, perhaps more fundamental, questions pertain to the appropriate interaction between the legal regimes at hand.

These questions pertain to, among others: the generally acceded superiority of human rights law over any other type of law and the legal effects and relevancy thereof in this case; the degree and extent of divergence of patent law from human rights law; possible ways to solve aforementioned ambiguities and the practicalities of one and other. These questions are not further elaborated here, but will be addressed fully in an upcoming Perspective 'Human donors' right to consent to patenting biochemical inventions: should it be real? – to appear in *Personalized Medicine* later this year. In the mean time, the ones engaged in genomics and personalized medicine may be reassured: whatever you do or don't, the European Patent Office is on your side! It must be acceded, however, that the reassurance is rather elusive.

Financial & competing interests disclosure

The author has no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending or royalties.

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• See Technical Boards of Appeal of the European Patent Office in Case T 1213/05, September 27, 2007 (Breast and ovarian cancer/University of Utah, UT, USA) (at 46–51 of the Reasons).