

Ethical and legal aspects of commercialization of individual human body parts

Salvador D. Bergel

Resumen

El trabajo expone reflexiones sobre la mercantilización del cuerpo humano, sus partes y sus productos. Centralmente toma el caso particular de las células humanas, que en sí no presenta mayores diferencias con otros, como el de los genes, proteínas, secuencias de genes, medicamentos biológicos etc., por cuya razón las conclusiones a las que arribemos deben reconocer un cierto grado de generalización. En las consideraciones finales se recuerda los enormes cambios en la idea de la comercialización del cuerpo humano, que evocaba la esclavitud y se hay pasado muy rápidamente a una situación donde ella está ligada a los progresos de la Medicina, rematando a la conclusión con la advertencia que el debate no puede quedar circunscripto a los derechos de propiedad industrial en la medida en que se encuentran comprometidos intereses de primer nivel como la salud y la dignidad humana.

Palabras-clave: Violaciones de los derechos humanos. Cuerpo humano - Comercio. Personas. Patentes. Leyes.

Resumo

Aspectos éticos e jurídicos da comercialização de partes separadas do corpo humano

Este trabalho expõe reflexões sobre a mercantilização do corpo humano, suas partes e produtos. Centralmente toma-se o caso particular das células humanas que, em si, não apresentam maiores diferenças com outros organismos como os genes, proteínas, sequência de genes, medicamentos biológicos etc., razão pela qual as conclusões as quais se chega podem ser em certa medida generalizáveis. Nas considerações finais são lembradas as enormes mudanças na ideia da comercialização do corpo humano, que evocava a escravidão e passou muito rapidamente a uma situação ligada ao progresso da medicina. Finalizando, conclui com a advertência de que o debate não pode ficar circunscrito aos direitos de propriedade industrial, uma vez que compromete interesses de primeiro nível, como a saúde e a dignidade humana.

Palabras-chave: Violações dos direitos humanos. Corpo humano - Comércio. Pessoas. Patentes. Leis.

Abstract

Ethical and legal aspects of commercialization of individual human body parts

This paper presents reflections on the commodification of the human body, its parts and products. It centrally takes the particular case of human cells, which in itself presents no major differences with other organisms, such as genes, proteins, gene sequences, biological medications, etc, for which reason the conclusions which can be reached, may be generalizable in some degree. In the final considerations the enormous changes in the idea of commercialization of the human body are reminded, which evoked slavery and passed very quickly to a situation linked to medical progress. The conclusion with the warning that the debate can not be confined to industrial property rights to the extent that compromises interests in the first level such as health and human dignity.

Key words: Human rights violations. Human body - Commerce. Persons. Patents. Laws.

Doctor s.bergel@zbv.com.ar – Cátedra Unesco de Bioética en la Universidad de Buenos Aires, Buenos Aires/CF, Argentina.

Correspondence

Florida 537 Piso 18^o C 1005AAK. Cidade Autônoma de Buenos Aires/CF, Argentina.

He declares that he does not have conflict of interest.

Historically, and perhaps unable to pinpoint its origin, it was considered that the human body was out of business, out of the market. Religious and ethical reasons worked to support such claim. The identification of the body with the person and the recognition of the inherent dignity of the human condition were based to keep such intangible principle in time. Dahl Rendtorff notes that the human body and its parts can be seen as something which affirms their dignity, as an expression of the human person and what, specifically, is from the man himself. Consequently, respecting the body and its parts is respecting human dignity¹.

When the evolution of biological sciences led to work and investigation of the separate parts of the body (including cells, tissues, genes, etc.), there was the concern on the need to give them a special status. Helgan Kuhse recalls in this respect that, historically, the human body and its parts have been of great importance, but now what counts is the use of human body parts in the results of medical and biological programs². Based on the unquestionable duality between the right person and thing, an interesting debate has emerged around the attribution of body parts to one of these categories, or in this case, on the uselessness of these categories to address the topic under discussion.

Recently, with the enactment of the French law on Bioethics, in 1994, the principle of exclusion of the body and its parts for trading is acquired citizenship status to the law. The French Civil Code, in its Article 16.1, states that the human body, its elements and its products cannot be the object of a property right³ also the *Convenio de Oviedo* on Biomedicine and Human Rights devotes Chapter VII to profit prohibition and use of a human body part⁴; establishing in its article 21 that the human body and its parts, as such, cannot be an object of profit.

The explanatory report of the mentioned article notes that it applies the principle of human dignity set out in the Preamble and Article 1. The article states that the human body and its parts, as such, cannot generate an economic benefit. Under this provision, the organs and tissues, including blood, cannot be bought or sold or generate any financial gain to the person from who they were extracted or a third party, either an individual or a company.

These principles, however, were received by the *Charter of Fundamental Rights of the European Union* (art. 3.2) and⁵ and they were considered as one of the fundamental rights of the person. The patentability of the body in its integrity seems to be a topic out of debate. No one can think wisely,

nowadays, to trade with the body. In contrast, for the separate parts of the body, the answer does not seem so peaceful.

A French philosopher, who integrated the National Ethics Committee, Lucien Seve⁶, asks himself at the moment he analyzes the limits of the person, not so much in time but in space, i.e., when we move from the whole body to its parts, which are smaller and smaller; if it is valid to maintain the same criteria regarding the status they deserve. The split body – he adds – is not the individual. Here there is a human being. To which extent is wise to recognize here the smallest segment of human and give it dignity? When the cell and genes are approached to the extent that all the specific treatment of humanity is eliminated, which is left from humanity? How to keep here the fundamental distinction between the person and the thing? Seve concludes his reflections arguing that it should take into account its social use than its biological expression.

On our part, we observed that the consideration which separated parts of the body deserve is not related, or, at least, it is not related to a significant relationship with the physical size of the part from which it comes. I raise the question on the gene or cell, which, in their tiny size, keeps essential information of human life. Since the time of the enactment of the French law on Bioethics, dated of 1994⁷, the trading of body parts was a palpable reality. It is that an organ, a tissue, genes, cells may serve in this new reality for utilitarian purposes, and this has aroused the economic interest by purchasing or trading, which led us to imagine the application of new legal criteria which justify them.

In essence, we believe that the body, in its entirety, as well as its separated parts, responds to the same reality, which allows applying similar principles regarding the consideration and treatment they deserve. Both gene and the cells, or tissues, are separated functional parts of the body and there are no arguments worthy of consideration that, once separated, may be distinctly considered of the body in its entirety.

It is that, the same reasons which keep the body away from the market and should act with respect to the parties in fact they are separated from it, if they really are recognized with an equal human nature. If the body, in its entirety, is out of the trade, with which arguments could it be argued that a separated part only by the effect of its segregation loses the character which is attributed to the whole? However, with the reasonableness of this approach, it is certain that, with an increasing intensity, we can

observe how the separated parts of the body have entered the market.

Rodotá ⁸, a distinguished jurist and professor of Bioethics, notes that it is precisely the economic compensation which reveals the inscription of the body and life in the context of ownership, abandoning their exclusive assignment with the personality dimension, supported by qualitatively different and stronger principles and guarantees. If the criterion is the market – he adds – words such as equality and dignity are distorted, lose their significance, and, with this reason, the autonomy of the person confined to the freedom to enter or exit the market is dissolved.

In the framework which we present, taking a separated part of the body as a simple “thing”, its entry into the commercial trafficking is authorized, distorting the consideration and respect for human dignity that connotes the body; consideration that – as we understand – means to extend to the separated parties. Here, it is not about only excluding the trading process, but also the patentability of cells, cell lines, mother cells, while the patent is an undeniable property content and it is the result of economic returns and it can be sold or licensed for consideration.

Although cells are not “people”, which is under the classical categorization of private law, it is not possible to call them as “things” without further additions. Cells – argues Wulpert Lewis ⁹– are the basis of any form of life. They are very small, but for their size, they are the most complex objects of the universe. This tells us that when we speak about a cell, we are not talking about anything, but something essential to life.

Edelman ¹⁰, who is a French philosopher and jurist, marks the consequences which should have such an assignment: there is a drastic difference between the fact of owning a property right in the body and to own a person. This striking difference is undoubtedly essential, if I sell my cell I sell myself, I would be reduced to slavery, but if my cells are “disposable”; if they are no longer anything from me, without being myself, consequently I could alienate them and staying free. In other words, only the fact of making such a difference requires that the individual was the owner of his body, which would have to distinguish between the person who is on the order of freedom and their bodily elements which are in the order of things.

This warns us that the traditional legal division between person and thing proves unsuited to the reality that the contributions of the contemporary

biology present to us. If, in view of this binary division, we can conclude that the separated parts are simply “things”, and the law is authorizing the sale and trading of organs, tissues, cells etc., which, in the view of any observer, seems immoral. The aforementioned separation between person and thing, which served and serves many purposes for the private law should be considered, at least that is in crisis. The category *person* refers exclusively to the human being in his entirety. The separated parts are not obviously “people”. Consequently, could it be argued that these are things which are in trade?

At the first sight, it seems to be unwise, which leads us to try other ways of approach. In this task, the lucid thought of M. A. Hermitte is very relevant, who, years ago, postulated the creation of a category, *things of human origin and with human purpose* ¹¹ to insert into its bosom the separated parts of the body and allow meeting in their consideration the respect for human dignity. Thus, the organs, tissues, cells, etc. would be outside the commerce and out of the market, which shows mercy with an approximated view of the dignity we attach to the body and its parts.

The property of human cells

The recognition of a property right of man on the constituent parts of the body is the necessary bridge to allow their trading. There is one case in the North-American jurisprudence, in which it was discussed the right that an individual had on his own tissues and cells, the famous Moore’s case. In 1976, John Moore was treated for a rare form of leukemia, a pathology for which the former physician advised him to extirpate the spleen. In the course of its further treatment is noted that Moore produced substances released by T lymphocytes: the lymphokines in quantities far higher than normal. Based on spleen cells, the doctor developed a cell line that patented in 1981 under the name of “cell MO”, giving the commercial exploitation rights to the Genetics Institute and Sandoz Pharmaceuticals. At the moment he knew about this, the patient Moore filed a lawsuit against the doctor, which comprised, among other requirements:

- conversion (unlawful consisting in seizing abandoned things);
- lack of informed consent;
- breach of the obligation of good faith in medical practice;
- liability.

Based on that, it was to set out to provide economic compensation for the commercial use of their cell line, which generated benefits to who patented them.

The process was refused at first instance upheld by the Court of Appeals and ultimately rejected by the Supreme Court of California. Importantly, the Court – after admitting that the doctor had hurt Moore when he explored without the consent, the patient’s cell lines – understood that it was useless to speak, but limitedly about a property right in body parts removed. Thus, the right to participate in the utilities and their exploitation by both the substantial absence of property rights, as considering that economic compensation would hurt human dignity, was denied.

The motivation of the Court, in the opinion of Tallacchini¹², leaves a strange void with respect to ownership of the materials, because these are objects of non-patrimonial autonomy acts, but, on the other hand, it is stated that the doctor had not even the property of tissues but rather on the rights of patents. Then, the issue about the disposal and acquisition modalities of cells, but with different consequences for the parties, is not resolved. Nobody owns the tissues, but the applicant cannot take any economic advantage of this “lack of law”, while the respondent (the doctor) can get an exclusive benefit.

In fact, rights are assigned and precisely they are assigned to who has the means to launch productive products on the market¹². Finding the rights originated from the patent in a different instance of the domain (civil property) is a hypocrisy. The court left unresolved which, in my opinion, is the most important issue of the dispute: the existence or non-existence of property rights over the separate parts of the body.

“Natural” cells and the ones obtained by technical procedures

The steady progress of biological sciences has led scientists to work on separated parts of the body, to modify them according to the search results directly usable by medicine, or simply to advance in research which, in the future, may help solving health problems.

Regenerative medicine, although it has a long way to go, it is definitely happening. This does not happen by chance to the market that, in the case of cells, introduced the difference between “natu-

ral cells” and “cell obtained by technical processes”. This distinction, as we shall see, is the starting point to incorporate them to the market. With regard to this issue, the position of the French Committee is very illustrative.

In Resolution 93 of the National Advisory Committee on Ethics in the Life Sciences and Health of France¹³, the ethical aspects of research on stem cells and their use are dealt. The resolution starts to make a distinction between two categories: the products separated of human bodies and unprocessed – on one hand – and the products derived from the human body – on the other hand. As a result, when it is referring to cells, the natural ones are differentiated from those obtained through technical procedures, *in vitro*, which, for the reason they are not similar to natural, are patentable. This division, in my judgment, is debatable.

The pretense of resembling a cell, as long as it is important for human intervention, to an artifact or a composition of matter to make it patentable is arbitrary. The “transformed” cell does not lose its association with the genre of life. It would be strange if the cell extract some element of its composition to industrialize it. Regarding the resolution, it is not a product of the cell or a part thereof, since the cell was destroyed. This is a “transformed” cell with greater or lesser intensity.

We understand that, for this reason, the essence of the human being is not lost and, consequently, such “transformed” cell should be out of the trade. Both natural cells, in the words of the Committee, as dealt with technical procedures remain separated parts of the human body. The day on which the man is able to create cells through technical procedures this opinion can be reverted. However, for the time being, it is not possible to achieve it, and *these cells should be outside the market as it is accepted as the guiding principle of the non-marketability of the body and its parts*.

The legal approach – framed in industrial property rights – should refer us the concept of patentable invention to grant or deny a patent on “derived” or “transformed” cells. A central condition for the acquisition of the exclusive right to grant a patent is the existence of a patentable invention, which is stated as a human creation, of a technical nature, to solve a technical problem. The “invention” would be patentable if it also meets the so-called objective requirements for patentability, i.e., if the contribution is something new which has not existed before, that the technical contribution has a certain height or merit that gender does not enter the the obvious,

and that, at the moment of request, the “invention” is industrially applicable.

In this case, the human cell preceded the known *transformed cell*. As much as it has been added this “transformation”, the resulting cells of the procedure should not lose their human status, even when the transformation procedure occurred *in vitro*. When this issue is taken into account, the inevitable distinction between the living and artificially created by man should be necessary.

About this subject, in particular, I refer to the clear thought of Duve, Nobel Prize in Medicine, who argues that, in the building of a house the workers build the projects designed by an architect. In the construction of a cell, where are the workers? Where is the architect? They do not exist. All this happens automatically according to written estimates in the molecules involved. The extraordinary thing regarding these phenomena is its spontaneity. Although there may be several hundred parts involved, since the assembly of a structure¹⁴, all of this occurs without external intervention¹⁴.

It should be thought that, if the transformed cells do not capture the essence of its constituent elements, the “inventor” would not need to use them, since it would be enough the *ex nihilo* creation of a “new cell”. What should be warned at this point of the statement is that the division between *natural cells* and *transformed cells* is a simple ploy to obtain a right to exclusivity (the patent), which clearly would not be obtained otherwise.

Tallacchini¹², with regard to the creation of products made from human biological material, but artificially processed to the point of being qualified as bio artificially constructed (bio artificial constructs), engineered bio products (bio engineered products), biological inventions (biological inventions), believes that the main problem for the body artifact consists on assessing if biotechnology change biological materials, to the point of considering them as artificial objects, which are definable as “inventions”¹². Here, it is worth to mention that biotechnologies, in my opinion, need an entity to transform a human element into an artificial object. Everything which is connected to life is natural, even if the operation of man is important on a “natural object”, it is not possible to achieve the category of “artificial object”.

In the discussion which allows patenting human elements “transformed”, there is a double circuit. Initially, the natural becomes “artificial”, closing the first one and then the “artificial” becomes “pat-

entable”, closing the second one. In order to move to the second circuit, there must be a construction that allows the distortion of the concept of “patentable invention”. The only human intervention, no matter how insignificant it may be, is for this sufficient design to allow the patentability.

For this, the fact that the vast majority of laws, including the international one (TRIPS Agreement of the WTO¹⁵), avoid setting the “invention” helps, which means that, depending on the circumstances of the case, an “invention” can be based on the simple fact of finding a micro-organism in nature, and segregates it from its natural environment, thus becoming “a patentable invention”. This is that – with no greater intellectual effort to note it – appears in the Article 3 of the European Law on Protection of Bio-Technological Innovations¹⁶.

A patentable invention presupposes a human creation. The needs of industrial companies have distorted the concept of the invention to inadmissible limits. Thus, when the Supreme Court of the United States resolved the Chakrabarty case, it considered that the scientist, who had been able to change the metabolism of a bacterium to endow it with certain characteristics, would have “created” a new body, transforming man into a kind of god¹⁷. Subsequently, the mentioned opinion of the French Bioethics Committee considers that as we define the biological entities taken into consideration, the ethical approach of trading has a different direction.

In this line of thought, a distinction is settled between a biological material in its *raw state* and a *chemical molecule*. At the Committee’s discretion, there are between the two a difficult zone to differentiate between biology and chemistry. This zone includes the *intermediate entities*, biological products, treated to such an extent that they lost part of their biological status, for example, cells, cell therapy products, the bioengineered cells and tissues etc. For such entities, the Committee adds, the issue of whether it may be considered as biological realities or as medicinal products or products industrially manufactured is open. From when it will be questioned which cellular elements can be considered as sufficiently separated and differentiated between them to be a trading object? Every separation parameter, every feature seems impossible to fix. Finally, something that is clear, a court does not have the same relationship on the individual than a cell or a molecule.

There is a criterion for the degree of transformation of which the biological material is subject, in order to obtain the desired cells. A minimal interven-

tion would consist of, for example, the conditioning of the cells to preservation; a maximum intervention consists on obtaining a cell by transferring its core. Most operations to which the cells are subjected are located between the two. It seems that we are facing a difficult conflict to overcome between the industrial property right, which aims to transform its contribution to the human appropriation, and biology, which aims to save the human essence.

The different view of law and medicine is not conflictive, according to the understanding of Labrousse Riou. The conflict arises from the use of bodies treated as things, and their scientific or medical instrumentation, which causes the person's "un-subjectivity", generates a life market. Thus, the body becomes raw material, an object of consumption or production, which leads to the author to ask questions whose answer requires a deep thought: what is the body to the law?, What is the nature of the rights on the body?; do scientific or medical means justify an unreasonable right? What we say about the body at this point of time must be transported to their separated parts and products¹⁸.

It should also be noted that a cell can be as or more important than any biological material, needing to value it according to size. A cell is in itself a microcosm and the cellular biology deals with its importance, which is nowadays one of the cornerstones of biology. The existence of "gray areas" between the natural parts of the body and *transformed parts that have lost part of their biological status*¹² is simply a rhetorical device to justify the market advance on the human.

The cell in its insignificant size, involves itself a part of human evolution that even in its last demonstrations continues to amaze us as a masterpiece that man could not create by his own means.

The mother cells in the market

¹⁹ In 1998 James Thomson¹⁹ and his collaborators managed, through an original procedure, to isolate and cultivate human embryonic stem cells. This, besides involving a remarkable scientific breakthrough, also sparked a remarkable controversy which goes beyond the academic subject. Thompson requested and obtained the intellectual property rights on the procedure and the products (included the stem cells); a right which was transferred to the University of Wisconsin. The patents granted covered both stem cells as the main techniques used to develop them.

This allowed the Wisconsin Alumni Research Foundation (WARF) prohibiting researchers to re-produce, use, sell, offer for sale, or importing the patented, as well as the use of the patented idea as a base to achieve another "invention". The contracts of WARF – rights holder – with scholars include critical limitations related to the purposes for which stem cells could be used. Preferably, two ways to control the market for human embryonic stem cells were used: licenses governing the use of patented material on the basis of the payment of a fixed amount, and perks for the sale of any product derived from the license. Given the abuses committed, WARF has been accused by the academic community to "choke" the market for stem cells²⁰.

A situation – which is somehow similar – is presented with the polls of Yakamata and colleagues at Kyoto University²¹, which are related to induced pluripotent cells that allowed cellular reprogramming, which allowed the patentability of the method used, as well as the reprogrammed cells. Here it is presented two issues in the ethics field:

- 1) submission to private rights of human cells and the procedures used for their cultivation, which requires them to enter the market as "patentable product";
- 2) the serious obstacle to scientific research which involves the establishment of economic barriers difficult to bear.

Final considerations

Through a concrete case – the commercialization and patenting of human cells and cell lines – we intend to show some notes highlighted of an evolving process called for transforming the components of the human body in raw material of industry. This is a silent process that failed to draw much attention from society, but once consolidated, it will be very difficult to be reviewed.

Here are committed ethical principles, which since formerly were signed and admitted without greater differences, such as non-commerciality of the human body and its parts; arrangements such as those linked to the limits of patentability, the status of fundamental research and the protection of human health. On an ethical level, although the commerciality of the human body in its entirety is not questioned, a substantial difference with respect to the separated parts is established, which are simply considered as things and enter the market.

On the legal field, the historic and main difference between invention and discovery is set aside, allowing, according to industry interests, the patentability of basic science discoveries that have very little to do with the technological creations, which is a field of the industrial property rights²². Thus the crucial difference between basic research and applied research enters a gloom area that, according to the interest of the case, allows the appropriation of their discoveries.

It is possible to apply to the results of the fundamental research instruments of protection industry excellence (patents) – Franceschi points out – but not without consequences for the internal logic of industrial property rights, or to changes in the research activity. Rereading the conditions for patentability, in order to grant the discovery qualifying invention, leads to disruption of the balance organized by patent law²³. The growing category of “biological medicines” also shows a tendency in which development the care and protection of human health may be blocked by the advance of market forces. These are not postcards of the future, but samples of a tangible

reality that cannot fail to observe without a growing concern.

Hermitte, in a study on the commercialization of the human body and its product, recalls that the Western world went quickly from a situation in which the idea of body trading evoked slavery to a situation in which it is connected to the fabulous medical or pharmacological progresses: blood, organs, substances, proteins, enzymes, hormones, antibodies, tissues, and genetic material; everything can be used for medical or scientific purposes, as well as purely commercial, making the body a source of raw materials for industry. The points of contact between these two distinct realities oblige to proceed with the utmost caution to avoid a return to forms of exploitation, which are not less violent, and not less detrimental to human dignity²⁴.

The debate cannot be confined to industrial property rights; it would be a terrible mistake if this would happen. To the extent that interests of first level are compromised such as human health, freedom of research, the unrestricted defense of non-commercial viability of the body and its separated parts must compromise our attention and our efforts.

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