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Artificial Intelligence and Biotechnology's Use in Health: In Need of a Common Cure in Europe

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"The development of full artificial intelligence could spell the end of the human race."[1] Quoted Stephen Hawking, a globally renowned British physician, about artificial intelligence on an interview to the BBC held on 1st of May 2014. Other physicians such as Max Tegmark, Stuart Russell and Frank Wilczek share his point of view.[2]

On another hand, biotechnologies are perceived as unnatural, subject to fatal errors, and possibly catastrophic for Humankind. One can fear a Human genome irreversible degradation, biotechnological weapons leading to humankind self-destruction etc. are fears one can have towards this flourishing technology.[3]

Could we be facing two major apocalyptic and destructive technologies leading towards the end of our civilisation? Reality may not be that Manichean, as if the truth were that obvious research on both these domains would have been stopped and declared forbidden well before meeting a market and being commercialised. Therefore, there must be some good in these technologies that balances humanity's feelings about them.

Following a long scientific development characteristic of the second half of the 20th Century, these two technologies emerged in parallel. Even before they were technologically achievable, they met in the foundational thoughts of cybernetics where Louis Couffignal, a French mathematician, defined the machine, yet in 1938 as "a consortium of unanimated or partially animated beings capable of replacing mankind".[4] This definition does not exclude the conception of

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1) Rory Cellan-Jones, "Stephen Hawking warns artificial intelligence could end mankind", *BBC News* (2014) in : https://ww.bbc.com/news/technology-30290540 [28 October 2019].

2) Jean-Gabriel Ganascia, *Le mythe de la Singularité. Faut-il craindre l' intelligence artificielle?*, Le Seuil, 2017.

3) Gaëlle Le Dref, *Théories de l'évolution et biotechnologies : d'une controverse à l'autre*, PhD thesis, (dir.) B. Ancori, (2017), Université de Strasbourg.

4) Bernard Claverie, "De la Cybernétique aux NBIC: l'information et les machines vers le↗

"biological" machines, where the genes and their expressions are the pieces constituting the whole machinery nor does it exclude the conception of "immaterial" machines, where code lines replace genes. A unique definition defined artificial intelligence and biotechnologies well before they both existed.

Tomorrow's technologies will likely disrupt the economy and society, as we know it.[5] The fourth industrial revolution gave rise to an exponential trend towards the hyper-connection of society in all of its aspects: the objects of everyday domestic life, as well as connected factories' means of production or connected cities. Undeniably, health is also connected, the practice of medicine is being transformed.[6] It is precisely in this domain that the combination of biotechnology and artificial intelligence shows its greatest innovative potential, as evidenced by the, combination of the pharmaceutical and artificial intelligence industries.[7]

The virtuous links between the two materials are very simple to understand. Artificial intelligence makes it possible to establish more efficient diagnoses and eliminates the human error factor; and biotechnologies produce inordinate volumes of data, including gene-stored data, which are useful for the autonomous development of artificial intelligence which can then help biotechnology development creating a virtuous innovation loop. However, this data must be legally exploitable. In that context, the regulatory role of legal standards on new technologies must be taken into account first. The protection of personal data in Europe is based on an endemic definition of property and privacy, which has its legal roots in texts consented and adopted by European society.[8]

↘déplacement humain", *Hermès, la Revue*, (2014), n° 68 pp. 95-101: "un ensemble d'êtres inanimés ou partiellement animés capables de remplacer l'homme".

5) Cheryl Martin et al., *Readiness for the Future of Production Report 2018*, World Economic Forum's System Initiative on Shaping the Future of Production, (2018) ; Jacques Lucas, "Le médecin et le patient dans le monde des data, des algorithmes et de l'intelligence artificielle", *Innovations en santé publique, des données personnelles aux données massives (big data) : aspects cliniques, juridiques et éthiques*, (dir.) Christian Hervé et Michelle Stanton-Jean, Dalloz, (2018), pp. 89-91.

6) Aicha Guelli*, La médecine à l'ère de l'intelligence artificielle*, PhD thesis, (dir.) M. Zouhdi, (2018), Université Mohammed V - Rabat.

7) Lina Habbal*, L'intelligence artificielle: nouveau levier de croissance pour les industries pharmaceutiques*, PhD thesis, (dir.) F. Devred, (2017), Université Aix-Marseille; Ivan Capechi, "L'IA au service des médicaments de demain", *L'ADN*, (2017), *in* https://www.ladn.eu/nouveaux-usages/etude-marketing/comment-lia-va-permettre-de-creer-les-medicaments-de-demain/ [28 October 2019]

8) Olivier Iteanu, *Quand le digital défie l'État de Droit*, Eyrolles, 2016.

This (over) protected data can be an obstacle to the development of Industry 4.0's technologies, raising the imperative question of the role of the normative framework in the regulation of artificial intelligence and biotechnologies.

Within which limits should the normative framework regulate the virtuous development of new technologies, even though their consequences are uncertain. Is the combination of artificial intelligence and biotechnology a sustainable process in relation to health development: what are its limits?

The simultaneous use of biotechnologies and artificial intelligence in the health domain creates a virtuous circle of innovation where each of them stimulates the development of the other but normative framework is a double constraint to its valorisation (I). However, the deregulation of the economic and legal normative framework as such, is not enough to foster innovation, since the innovative duo faces another constraint: social opposition supported by strong legal obstacles, as the two technologies are among the toughest to be socially embraced (II).

I. A self-stimulating duo constrained by norms

The combination of two sectors with exponential innovative potential can only be as mathematically successful as it is. Nevertheless, the comments concerning the self-stimulation of artificial intelligence and biotechnologies must obviously be tempered since these are still different sectors which only meet occasionally. Indeed, scientific research, although based on a solid body of knowledge, is nonetheless still carried out by subdivided scientific sectors, and within these sectors themselves, there are subdivisions into sectors of applicability.[9] Thus, in many cases it is more relevant to approach a given topic from a specific angle of applicability, to this instance human health. Likewise, with regard to the economy, it is widely accepted that the meeting of innovative sectors is propitious for growth. However, this growth can be based on the competition between several scientific domains for the same market – each technology improving in order to respond to a problem faced. Therefore, one of them can annihilate the other: leading to the end of the research in one scientific discipline, and the appropriation of the applicability domain by the other one,[10] breaking the virtuous innovation circle of simultaneous application.

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9) *OECD Reviews of Innovation Policy: France 2014*, OECD Review of Innovation Policy, OECD (2014).

10) Jean-Luc Gaffard, "Concurrence et innovation en Europe: le dilemme de la compétitivité", *OFCE*, n° 102 (2017), pp. 353-379.

Such considerations cannot, in any way, jeopardize the fact that there is a virtuous stimulating link, potentially durable if correctly supported, that arises from the interaction between artificial intelligence and biotechnologies by using mutual data (A), as well as a strong innovative potential.[11] This link must undoubtedly be valued, and the preferred instrument seems to be intellectual property – and more specifically patents[12] – and the options it provides (B), not without legal boundaries.

A. The fragile simultaneous use throughout mutual data exploitation

New technologies when used simultaneously are part of a global innovation context that is beneficial to their own growth as well as to global growth. This hypothesis is empirically proven when applied to biotechnology and artificial intelligence,[13] two domains that at first glance would seem to opposed, but which in reality were built on common ideas, and are equally useful in the field of health.[14]

It is therefore necessary to approach their relationship through the prism of the health sector, particularly with regard to the development of artificial intelligence using health data (1). In return, it would appear that artificial intelligence impact on the biotechnology sector is broader and has repercussions on the entire scientific research area (2).

1. *Health data as a developer of artificial intelligence*

According to INSERM (*Institut National de la Santé Et de la Recherche Médicale*, French national research institute on health), there are six fields of application of artificial intelligence in medicine: predictive medicine, precision medicine, decision support, companion robots, computer-assisted surgery, and prevention.[15] Complementary to biotechnologies, which provide an efficient treatment, the applications of artificial intelligence allow rapid diagnoses and

11) Jacques Lucas, ibid., pp. 89-91.

12) Vincent Diebolt et al., "«Intelligence artificielle» : quels services, quelles applications, quels résultats et quelle valorisation aujourd'hui en recherche clinique? Quel impact sur la qualité des soins? Quelles recommandations?", *Therapies*, vol. 74, issue 1 (2019), pp. 141-154.

13) Lucie Cluzel-Metayer, " L'Assistance Publique-Hôpitaux de Paris : un «hôpital-entreprise» ?", *RDSS*, Dalloz, (2016), p. 1061.

14) Aicha Guelli, ibid.

15) INSERM - Jean Charlet, "Intelligence artificielle et santé : des algorithmes au service de la médecine", INSERM (2018), in https://www.inserm.fr/information-en-sante/dossiers-information/intelligence-artificielle-et-sante [29 october 2019].

appropriate treatment[16] (surgical or biological).

Artificial intelligence is a complex technology with many facets and variations. Among these, self-learning artificial intelligence relies on data analysis for its success[17]. Three variables are thus necessary for its development: human programming, computing power and data.[18] If the first two cannot be linked to the health domain, data analysis can be conducted on medical and genetic data. There is a lot of health-related data, ranging from rare disease registries and reactions to treatments, to the personal data collected by connected health devices and inherent to persons. All these raw materials are undeniably useful for artificial intelligence.

A particular application may be, for instance, the use of deep learning software to detect melanomas in skin photos, or detect diabetic retinopathies before they are incurable, and automatically decide on the appropriate treatment.[19] In some cases, such as the use of the artificial intelligence *IBM Watson*, they are even able to cross-reference patient data with all the published – and constantly updated – scientific data and make a diagnosis based on considerable amounts of medical discoveries.[20] The development of such systems requires a prior analysis of a large amount of genuine medical data, which is described as sensitive data and may be difficult to exploit. In the hypothetical context of a machine capable of detecting a disease, it is obviously essential that the machine is networked and capable of cross-referencing its data with other machines all over the world: learning is done through mass experiencing. However, once these machines and the personal data they use are released passed the research boundaries, they are no longer part of a scientific research but are in fact used commercially by the entity making them available and selling or exploiting them. Therefore, in this situation, an excessive protection of health-related data would inevitably lead to a loss of performance for such technologies.

The solution then seems to be data anonymization; keeping only two variables in the example of skin photo analysis. The photograph itself, and the associated response "infected"/"healthy". In this way, the machines can continue to improve without compromising patients' privacy and the data's use and commercialisation.

16) Yves Poullet, "Le droit face aux développements de l'intelligence artificielle dans le domaine de la santé" (part. 1), *RLDI*, n° 152, (2018), § 3.

17) Jean-Gabriel Ganascia, ibid.

18) Yves Poullet, ibid., § 1.

19) INSERM - Jean Charlet, ibid.

20) Aicha Guelli, ibid.

In order to perfectly function the photograph in question must not indeed be considered as personal data, not leading to the identification of an individual, which seems to be the approach taken by the General Data Protection Regulation (GDPR) in its Article 4.[21] This means the data would have to remain isolated and as such.

However, the main strength of artificial intelligence use in the medical field is in the personalisation and cross-referencing of data relating to a particular individual. For instance, there are specialised programs in patient data mining that establish a risk probability and adapt treatments to their medical situation,[22] and even according to their lifestyle.[23] It is therefore easy to understand that the difficulty here is the possible identification of the patient as an individual, and thus the qualification as "personal data". Although this identification were to be encrypted, it can be argued that the data remains "identifiable" in the sense of the GDPR.[24] Even though this qualification were not retained, the mere requirement of strong and costly security measures protecting this data on the users and their potential liability in the event their system fails is sufficient to weaken their willingness to act, unless the sanctions are lower than the potential gain. However, it is equally easy to understand that the protection of such data is essential for patients,[25] who could suffer serious consequences if such data were to come into the hands of third parties, particularly insurance companies.

Thus, it is established that the use of data is beneficial to the development of artificial intelligence in this sector. However, this data must still be able to be freely exploited without legal obstacles, without undermining the peculiar European concept of privacy,[26] which is the first limit to the virtuous development.

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21) Article 4 (1), (13), (14), (15), Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), *OJUE,* (2016).

22) INSERM – Jean Charlet, ibid.

23) Yves Poullet, ibid., § 3.

24) Article 4 (1), Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), *OJUE,* (2016).

25) Shane O'Sullivan et al., "Legal, regulatory, and ethical frameworks for development of standards in artificial intelligence (AI) and autonomous robotic surgery", *Int. J. Med. Robotics Comput. Assist. Surg*, vol 15, issue 1 (2019).

26) Olivier Iteanu, ibid.

A balance therefore remains to be established between common progress and individual freedom. On the other hand, it should be stressed that the simultaneous development of the two technologies is also and more widely beneficial to the development of biotechnologies, the complexity of which can be clarified by the assistance of artificial intelligence.

2. *Artificial Intelligence as an assistant of biomedical research*

The use of biotechnology in health is complex and composed by several techniques ranging from genetic modification to enzymatic treatment. Biological research is intricate and expensive. Like any scientific research, it involves the formulation of a hypothesis and its validation through an experiment. One cannot discover a truth one can only invalidate a lie: that is the essence of scientific reasoning. Artificial intelligence invalidates multiple lies faster than any man does.

Artificial intelligence has already proved its worth in the field of biological research, particularly in studies on cell mutation linked to neurodegeneration.[27] This application, based on the analysis of microscope images, is controlled by an automatic artificial intelligence which improves with use in order to detect flawed samples.

Nevertheless, this research support cannot stop there. It is then possible to imagine, as soon as the legal limits related to data analysis are lifted, an artificial intelligence that will analyse genetic data by crossing them with given empirical data. It would be possible to establish a correlation between a gene and its expression, or to observe and understand the functioning of the genome using self-taught software or help to discover the relation between genetics and illnesses.[28] This use would allow researchers to save considerable time on their research by reducing the scope of their hypotheses with respect to the correlations established by automatic data analysis, and would allow laboratories to reduce their research costs.[29] Once again, the limits of the European limitations on personal data – either social or legal – will undeniably be a limit to such development.

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27) L'Atelier BNP-Paribas, "L'intelligence artificielle au service de la biologie", BNP-Paribas (2012), in: https://atelier.bnpparibas/smart-city/article/l-intelligence-artificielle-service-biologie

28) Davide Cirillo et al., "Big data analytics for personalized medicine", *Current Opinion in Biotechnology*, n° 58, (2019), pp. 161-167.

29) Lincoln Tsang, Daniel A. Kracov, Jacqueline Mulryne, Louise Storm, Nancy Perkins, Richard Dickinson, Victoria M. Wallace and Bethan Jones, "The impact of Artificial Intelligence on Medical Innovation in the European Union and United States", *Intellectual Property & Technology Law Journal*, Vol. 29 Issue 8, (2017), pp. 12-20.

This point of view is further understandable when taking into consideration the risks and impacts of data crossing, and more specifically when it implies ethnicities or social groups or communities associated with religious beliefs. A simple empirical link between a disease, or a gene malfunction and a social group – leading therefore to a difference of treatment from insurance companies for instance – would not be permissible in light of the European fundamental rights and equality principles, which find their sources in the highest supra-legislative norms whether they be International Treaties or national Constitutions. Even though no "personal" identification as such occurs, a "group" identification – or even worse "classification" – would not be possible although scientifically proven.

The European legal regulations refuse to choose between risks on the one hand – to their patients on behalf of individual protection – and innovation on another hand – which leads to better standards of life when wisely developed throughout economic growth. Still risk and innovation are the two faces of the same coin,[30] and finding the equilibrium so it can stay on its edge is not easy. However, a step towards this balance needs to be highlighted on the data mining exception adopted by the European Union throughout articles 3 to 7 of the Directive on copyright and related rights in the Digital Single Market,[31] which helped to surpass the other limit on data use that was copyright. Maybe scientific and medical exceptions could be an option the European Union should explore.

It is therefore demonstrated that the virtuous relationship between artificial intelligence and biotechnology is highly beneficial and produces positive externalities for research and innovation. Nevertheless, this momentum can be broken if researchers cannot benefit from their work. The two technologies must be mutual assistants in each other's developments, and tools made available to researchers to promote innovation, particularly with regard to health. This innovation that must be able to be enhanced by intellectual property tools.

B. Valorisation by Intellectual Property tools

Intellectual property rights are key elements in the promotion of scientific research. The mere granting of a patent, or any other instrument conferring a monopoly, allows the research carried out to be made profitable and the innovation

30) Patrick Perreti-Watel, "Risque et innovation: un point de vue sociologique", *Innovations* 2003/2 n° 18, (2003), pp. 59-72.

31) Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019, on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC, *OJEU*, (2019), articles 3 and 7.

to be diffused in exchange for compensation on its discovery. However, the logic of old intellectual property instruments comes up against its own limits when confronted with new technologies such as artificial intelligence or biotechnology.

Indeed, artificial intelligence is software, and for the vast majority (excluding robots) it is dissociated from particular machines. The patentability of artificial intelligence as such is, in fact, very difficult if we follow the logic of intellectual property law.[32] In addition, artificial intelligence is protected by copyright, which may be transferable in its economic provisions. But patent protection can also protect the technical invention resulting from the software and not only the software as such.[33] Yet patenting an artificial intelligence, although done in practice, is criticized since it involves the exploitation of a legal loophole and should not occur as expressly prohibited by law on the patentability of software as such in the spirit of European intellectual property.[34] Furthermore, when dealing with medical inventions, the European Patent Convention states that "diagnostic methods practised on the human (…) body"[35] are not patentable, adding another limit to the patentability of artificial intelligence regarding medical applications and therefore its valorisation.

Similarly, the exploitation of biological technologies by intellectual property law instruments is just as sensitive since it raises the question of whether it is possible - and to what extent - to patent living organisms. With regard to inventions resulting from essentially biological processes, there is a specific intellectual property title, the Plant Variety Certificate; but for inventions resulting from non-plant living organisms the question of patentability is tricky. In reality, discoveries, natural creations, are not protectable as they did not generate any effort of invention from the researcher. Nonetheless, fundamental research is essential, but it is difficult to value it through intellectual property rights - hence the importance of state support. This is why living organisms cannot in principle be

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32) Jean-Marc Deltorn, "La brevetabilité des applications de l'intelligence artificielle et de l'apprentissage automatique: la pratique de l'Office européen des brevets", *Propriété industrielle*, n° 3, doss. 4, (2019).

33) Jean-Marc Deltorn, ibid.

34) Article 52 (2) (c), *European Patent Convention*, as amended since its 16th edition, June 2016; article L611-10 (2) (c), *French Intellectual Property Code*, as amended by law n° 2008-776, (2008); article 4 (4) (c), *Ley 24/2015, de 24 de julio, de Patentes (Spain)*, BOE n. 177, (2015); section 1 (3) (c), *Patentgesetz (Germany),* as amended by act of 8 October 2017, BGBI. I S. 3546, (2017).

35) Article 53 (c), *European Patent Convention,* ibid.

patented. However, the patentability of individual elements is possible under Directive 98/44/EC of the European Parliament of 6 July 1998,[36] provided that it meets the general conditions of patentability and that it is an individual element for industrial application concretely set out in the claims. The isolated nature is essential as its state allows human intervention to be justified: from the technical processes isolating it, a different state is created from the one in which it occurs in nature.[37] In addition to the technical limits, the patentability of living organisms is also hampered by ethical limits, thus prohibiting the patentability of human embryos, among others.[38]

Naturally, the combined use of these two technologies is subject to the legal limits of both. Consequently, there are only two ways for researchers wishing to protect their inventions: circumventing legislation by patenting on a different argument, or finding an alternative.

The alternative to Intellectual Property's valorisation would therefore be the valorisation by social acceptation. Diffusing the innovation in order to create a new market throughout the prism of a new created social need. However, this solution is also bounded by another limit that are the ethical regulations especially hard when dealing with health, or biotechnology and artificial intelligence.

This leads to well-defined limits to the valorisation of joint development through intellectual property rights. The barriers to both are an additional difficulty to overcome, but the legal standard has the duty to ensure the comfort of the researchers using them. However, the facility of protection provided to researchers must be balanced with the social interest and the rights of third party beneficiaries - or not - from the innovation. It is difficult to predict the technological impacts and therefore the legal limits.

II. The social acceptation of the innovation: ethical regulations

Legal limits on innovation are only imposed as a result of the societal will through which it is created. Law is - in theory and without taking into account certain nuances - a representation of a people's will that produces it. This is the Social Contract as mentioned by Rousseau in the 18th century. Even if there were

36) Directive 98/44/CE of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, *OJEC*, (1998), article 5.

37) Béatrice Ores, Fabienne Paris and Lionel Vial, *La brevetabilité du vivant*, CNCPI, (2015), déc.

38) CJUE, 18 October 2011, C-34/10 *Olivier Brüstle v. Greenpeace eV*, Christian Byk, *JDI* (2013); Hélène Gaumont-Prat, *Propriété industrielle*, (2011), n° 6, p. 6, n 42.

to be a softening of the rules in favour of innovation, some inventions, innovations and research could not be accepted since they did not correspond to the needs of the sovereign majority at the moment they were created. Innovation is not necessary, it is proposed then accepted. Yet, artificial intelligence and biotechnology are oddly enough two technologies that meet a plethora of social needs, but which are paradoxically mistrusted by consumers.[39)]

That is where information is central. It is the responsibility of legal standards not only to protect the suspicious consumer, but also to ensure that they are offered remedies by stimulating innovation. Over-regulation through ethics is only an unbalanced inhibitor of innovation. (A) Indeed, innovation in the health sector, among other things, by merging the sectors of artificial intelligence and biotechnology, is too important to be simply rejected. (B)

A. Ethical and preventive regulations: an innovation inhibitor

Research on the human body is limited by legal norms that protect not only the body but also the integrity of the person to whom it belongs. This protection is also in the general interest: forbidding human enhancement and suffering human beings as the result of poorly supervised experiments, experiments or scientific attempts carried out by persons either malicious or not willing to pursue an objective of real improvement of human life. The legal framework for biotechnological research is a general interest protection in the personal interest of the holders of new biotechnologies, creating an essential need.

However, at an early research stage, it is impossible to distinguish which technologies will be potentially destructive from those that will be potentially life saving. The Oviedo Convention - signed and ratified by a majority of Council of Europe member states with the significant exception of Austria, Belgium, Germany, Ireland, the United Kingdom and the European Union - formally prohibits the violation of human integrity. It is therefore legally prohibited to carry out genetic selection, gene therapies modifying the germ line, or the profitable use of human material. These are laudable objectives in that they value the primacy of the human being. According to Article 2 of the Oviedo Convention, "the interest and welfare of the human being shall prevail over the sole interest of society or science"[40)]. But

39) Mady Delvaux, *Report with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103 (INL))*, Committee on Legal Affairs, European Parliament, Plenary sitting, 27 January 2017.

40) 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,↗

this is a principle whose application becomes impossible when pushed to its limits. Indeed, the interest and well-being of a person may depend on the use of genetic material or research carried out on another; this is a philosophical bias responding to the historical consequences of experiments during and after the Second World War, with complicated legal application.[41] The same philosophical issues arise when dealing with artificial intelligence,[42] even though no international treaty rules these uses yet, arising thus the question of human security against it.

European Union law has also addressed bioethics and medical research issues. This may seem surprising in that these are provisions resulting from the application of fundamental rights and therefore traditionally dealt with by the Council of Europe, but as previously demonstrated, the health market is necessarily social, political and economic, and in its prerogatives are necessarily affected by European Union law. The European Union based its legal actions on the basis of the Charter of Fundamental Rights. The provisions of Article 3 of the Charter[43] are essentially the same as those of the Oviedo Convention. They consist of a main principle: the informed consent of the subjects; and three prohibitions: the prohibition of eugenics, the prohibition of taking advantage of the human body, and the prohibition of reproductive cloning. The informed consent of the patient is also needed while using health data; complicating their use as previously demonstrated. Furthermore, the prohibition of article 3 (2) (c) "on making the human body and its parts as such a source of financial gain"[44] could be a supplementary boundary when dealing with genetics if one considers that genetic information encoded in DNA is a part "as such" of the human body. Ethical considerations on behalf of Human Rights jeopardise scientific research and valorisation.

However, this framework is an untouchable consequence of fundamental rights, but not a fundamental rights issue itself. It is an interpretation of these rights that is subject to change. Indeed, the question of biomedical research and its applications cannot have a restricted dual answer saying authorisations or

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↘Oviedo, 4 April 1997, *European Treaty Series*, (1997), n° 164, article 2.

41) Anne Laude, "La réforme de la loi sur les recherches biomédicales", *Dalloz*, (2009), p. 1150, § 2.

42) Shane O'Sullivan et al., "Legal, regulatory, and ethical frameworks for development of standards in artificial intelligence (AI) and autonomous robotic surgery", *Int. J. Med. Robotics Comput. Assist. Surg*, vol 15, issue 1 (2019).

43) Charter of Fundamental Rights of the European Union (2012/C 326/02), *OJEU*, (2012), article 3 (2).

44) Charter of Fundamental Rights of the European Union, ibid.

prohibitions; it must necessarily be based on a free research principle, and framed by ethical authorities in order to maintain a balance between effective research and its benefits, and the protection and application of irrevocable fundamental rights. This is why the legislative framework should be permissive and adapted in the context of research.

It is therefore easy to see that ethical regulation preventing the drifts of innovation creates a barrier sometimes impassable, for the desirable innovation needed among the masses. This inadequate filter can have the first effect of aborting innovation, and paradoxically, of encouraging unethical innovation at the international level by opening up the possibility of a profitable monopoly for foreign competitors.

B. Towards a new definition of innovation?

As it stands, science allows a great understanding of genetics. However, it is not the understanding, but the possible and future actions that are already available that are subject to research today. Although one cannot exist without the other, it is possible to note a turning point in the scientific literature, but also in the information field: there is uncertainty and division about the future application of biotechnology and, in the same way that artificial intelligence - which has been around for years - nowadays arouses many fantasies, they are attracting scientific interest. Indeed, the combined use of both this almost science fiction technology, shall be the solution to incurable diseases - among other industrial applications -, which piques the interest of the economic sector[45]. A change, or even creation, of a new market is emerging and its structural changes are already underway.

The economic domain evolves in correlation with the scientific domain according to the application sector of the technologies resulting from it. Only from their union can innovation be born. Indeed, it has multiple definitions: it can be from an economic point of view perceived as "the successful marketing of a new product, process or service"[46], but also from an internal point of view to innovation actors as "everything that is new for the company, which allows it to acquire a

45) Isabelle Poirot-Mazères, "Robotique et médecine: quelle (s) responsabilité (s)?", *Journal international de bioéthique*, vol 24, n° 4, (2013), pp. 99-124; Filippo Pesapane, Marina Codari et al., "Artificial intelligence in medical imaging: threat or opportunity? Radiologists again at the forefront of innovation in medicine", *European Radiology Experimental*, 2:35 (2018).

46) Thierry Lucidarme, *Valoriser et développer l'innovation*, Vuibert, (2013), p. 206 "la mise sur le marché réussie d'un produit, procédé ou service nouveau".

sustainable competitive advantage in response to a market need."[47] Innovation is an invention that has become a reality. Invention which itself is a "discovery in the field of the mind"[48].

Thus, science - discoveries of the world - and innovation - the concretisation of discoveries of the mind - are intimately linked. Indeed, it is the discoveries of the physical world resulting from observations that give the necessary knowledge to the discovery of the mind which is acheived by the meeting of a market. This gives rise to a chronological axis that cannot be ignored in the innovation process: research, invention, meeting a market. Innovation is the process by which scientific discovery is transformed into a market product.

This logic is also found in intellectual property, where the patent is only the title that guarantees the protection of industrial application and not scientific discovery. The patent protects industrial application and not innovation, invention nor discovery[49]. The patent is then the legal tool that serves the economy in its quest to meet a market. This is why it would seem that innovation is governed only by the economy and the willingness of economic agents to value their intangible assets for profit. Scientific and legal instruments are only tools in an economic process.

The possibility of future commercialization then relegates research to the rank of economic investment, which is then given a certain importance and - to a certain extent - financial value. Indeed, at the same time, the economy is a driving force, a tool, a research tool and therefore at the service of scientific discovery. In the same way that Man and Nature are a tangle of causes and consequences, so are science and economics.

The valorisation is made by the fusion of technologies as well, therefore certainly by the construction of multi-technology parks and the communication of knowledge beyond the materials in which they were acquired. It is up to the legal world to ensure the right mix of innovative sectors by stimulating the positive aspects and limiting uncontrolled and therefore potentially dangerous innovation.

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47) Patricia Guiraudie and Laure Merland, "Le centre régional d'innovation et de transfert de technologie - chimie - formulation - matériaux (CRITT chimie), exemple d'institution d'aide à l'innovation en PACA", Droit et innovation, PUAM, (dir.) J. Mestre and L. Merland, (2013), pp. 83-88 "tout ce qui est nouveau pour l'entreprise, qui permet d'acquérir un avantage compétitif durable en réponse à un besoin de marché."

48) Thierry Lucidarme, (2013), ibid. "une découverte dans le domaine de l'esprit".

49) Marie-Christine Piatti, "La nature, source d'innovations techniques Le chercheur, l'ingénieur et le juriste", *Droit et innovation*, (dir.) J. Mestre and L. Merland, PUAM, (2013), pp. 101-122.