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OPINION

Brain Patents as a Legal or Societal Challenge?

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Abstract Patents relating to the human brain and its functions regularly fulfil the general patent requirements. In some cases, however, the inventions in question reveal considerable risks for the rights of individuals, but also for society as such, which have a hitherto unknown dimension and which have not been discussed so far. Due to the limited scope of application of the *ordre public* clause, patent law is fundamentally not in a position to respond adequately to the challenges that exist here. The ratio of patent law and the lack of resources and also, above all, competence of the patent offices for a more extensive ethico-legal analysis mean that patent law is not the right setting for dealing with the existing challenges. Instead, the international organisations responsible for the protection of human rights and their relevant bodies are in particular demand here, although they have so far been unaware of the difficulties that are evident in the area of brain patents. What is needed is the development and establishment of mechanisms that enable the flagging and communication of critical patents, so that the responsible bodies are enabled to fulfil their tasks.

Keywords Brain patents · Neurolaw · Neuroethics · Human rights · Ordre public · Misuse

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1 Introduction

In recent years, neuroethics and neurolaw have established themselves as disciplines with their own *raison d'être*. Numerous monographs and journal articles,¹ the activities of the International Neuroethics Society,² the investigation of the interdependencies between neuroscientific findings and the US legal system funded by the MacArthur Foundation,³ and the institutionalised study of ELSA aspects within the framework of both the Human Brain Project⁴ and the BRAIN Initiative⁵ impressively demonstrate the breadth and depth of the scientific discourse. However, despite these exponentially increasing activities, the implications and challenges of patent law have so far remained almost unnoticed. One could attribute this finding to the fact that brain patents do not represent any special features compared to patents on genes and gene sequences. In fact, this view was held in the early stages of the neuroethical and neuroregulatory discourse.

In the meantime, however, more and more voices are being raised to point out the numerous special features of neuroscientific research and the patents granted in this field. For example, the philosopher Matthew Liao, who teaches at NYU, states: "The current IP framework is designed for existing technologies and might be unable to cope with neurotechnologies and data being collected from our brains. These new technologies might force us to reconsider our intellectual property, privacy and data protection legal regimes".⁶ Nevertheless, there is currently no structured or even interdisciplinary examination of the existing challenges. The same applies to patent law itself, which, due to its numerous specifics, has traditionally been rather reluctant to take up suggestions from other areas of law. The patent law discourse has thus not yet discovered the topic of brain patents. Against this background, the project International Neuroethics Patent Initiative (INPI) is dedicated to the first structured recording and analysis of brain patents. Patents granted in the field of neuroscience can cover such diverse areas as medical neurological methods, neurological diagnostic methods, neurological devices, data processing of neurological signals, or computational models of a neurological network/system/cell. The project at hand examines in the necessary brevity the patents already granted, classifies them into the applicable patent law, poses the question of the viability of patent law and necessary gap-filling, and then devotes itself above all to the conceivable risks for the individual and society.

¹ See, for instance: Levy (2009); Illes (2013); Clausen and Levy (2014); Spranger (2014); Racine and Aspler (2018); Picozza (2018); Spranger (2022), p. 241 et seq.

² https://www.neuroethicssociety.org/.

³ https://www.lawneuro.org/.

⁴ https://www.humanbrainproject.eu/en/.

⁵ https://braininitiative.nih.gov/.

⁶ Cf. http://www.ip-watch.org/2015/10/19/the-brain-is-the-next-frontier-bioethics-futurist-says-raising-new-societal-challenges/.

2 Foundations and Legal Assessment

Relevant patents were identified using a customised algorithm developed by our collaborating team in Canada.⁷ The algorithm was a modification of Edris-Roskams et al., revealing neuromodulatory methods patents in the five-year period between 2016–2020.⁸ The legal analysis focussed on the examination of those patents that were identified as potentially particularly controversial. On the one hand, these were patents that required the use of invasive techniques. On the other hand, patents were examined whose commercial exploitation raises human rights issues due to the statements in the patent description. In this way, a total of 58 brain patents – 41 of them US patents and 17 EU patents – were identified and analysed.

Within the scope of the analysis, it could be shown that all patents fulfilled the respective patent grant requirements. It also turned out that in each case the scope of application of the patent law "*ordre public* clause" was not misunderstood. As is well known, Art. 27(2) of the TRIPS Agreement states:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

However, the applicability of these and all comparable patent barriers is linked to the fulfilment of strict conditions and is therefore only considered in rare exceptional cases.

In its official "Guidelines for Examination", the European Patent Office states the following with regard to Art. 53a EPC which corresponds to Art. 27(2) TRIPS:

Any invention the commercial exploitation of which would be contrary to "ordre public" or morality is specifically excluded from patentability. The purpose of this is to deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour. Antipersonnel mines are an obvious example. (P)ractical examples under Art. 53(a) arise from the fact that not everything can be done to human beings that can be done to other living beings. For example, the avoidance of offspring that are unwanted because of certain properties (sex, colour, health) and for economic reasons may be quite legitimate for domestic animals but when applied to human beings it would be contrary to "ordre public" or morality. This provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable. If it is clear that this is the case, an objection is raised under Art. 53(a); otherwise not. The mere possibility of abuse of an invention

 $[\]overline{^{7}}$ Rotenberg et al. (forthcoming).

⁸ Roskams-Edris et al. (2017), p. 119; Illes et al. (2019), p. 19.

is not sufficient to deny patent protection pursuant to Art. 53(a) EPC if the invention can also be exploited in a way which does not and would not infringe "*ordre public*" and morality.⁹

None of the patents examined exceeded this barrier, as the scope of application focussed on in the patent application always met the aforementioned requirements. This is particularly true in view of the fact that in all patent law systems, the *ordre public* clause only comes into operation if any commercial exploitation of the invention in question that comes into consideration would constitute such a violation of *ordre public* or morality. Thus, as soon as even one "non-critical" exploitation can be found, the patentability exception does not apply. The EPO makes this perfectly clear:

Special attention must be paid to applications in which the invention has both an offensive and a non-offensive use, e.g. a process for breaking open locked safes, where use by a burglar is offensive and use by a locksmith in an emergency non-offensive. In such a case, no objection arises under Art. 53(a). Similarly, if a claimed invention defines a copying machine with features resulting in an improved precision of reproduction and an embodiment of this apparatus could comprise further features (not claimed but apparent to the skilled person) the only purpose of which would be that it also allows reproduction of security strips in banknotes strikingly similar to those in genuine banknotes, the claimed apparatus would cover an embodiment for producing counterfeit money which could be considered to fall under Art. 53(a). There is, however, no reason to consider the copying machine as claimed to be excluded from patentability, since its improved properties could be used for many acceptable purposes.... However, if the application contains an explicit reference to a use which is contrary to "ordre public" or morality, deletion of this reference is required under the terms of Rule 48(1)(a).¹⁰

From the perspective of patent law, it is therefore first of all completely correct to grant a patent that also – but not exclusively – opens up critical application options. Nevertheless, the explanations given in some patent descriptions make one listen attentively. To illustrate the challenges that arise here and the overall social dimension of the issue, three examples will be presented in the following.

Patent EP 3331434 B1 relates to the technical field of behaviour modulation in a subject, particularly a mammal, e.g. rodent and human. More particularly, the invention relates to a method and a device for modulating fear and/or anxiety.¹¹ The patent description then states:

"Modulating fear and/or anxiety" should be understood as meaning either decreasing the feeling of fear or anxiety down to complete suppression or increase of the feeling of fear or anxiety. Increasing the feeling of fear in a subject is particularly interesting for research purposes or as a therapy to

⁹ Guidelines for Examination in the European Patent Office, March 2022, Part G, sub 4.1.

¹⁰ Guidelines for Examination in the European Patent Office, March 2022, Part G, sub 4.1.2.

¹¹ Patent EP 3331434 B1, sub 0001.

repress unwanted behaviour comprising but not limited to sexual offenders, violent individual and any antisocial behaviour, whereas decreasing the feeling of fear or anxiety can be interesting for research or practical purposes such as helping an anxious person to feel less anxious and more generally treating anxiety related disorders including but not limited to generalised anxiety disorder, panic disorder, agoraphobia, other specific phobias (notably those listed above), social anxiety disorder, obsessive-compulsive disorder, post-traumatic stress disorder, separation anxiety, exposure anxiety, anticipatory anxiety inducing sleep disorders.¹²

Patent US 10869628 B2 protects a method and apparatus for a whole-mind cognitive interface. Such a system includes a bodily integrated artificial cranium, computer, RF antenna, and transceiver array to seamlessly augment the human brain with artificial intelligence (AI) and permit enhanced cognitive functions, and human host feedback-based neurological rewiring.¹³ The invention shall, *inter alia*, be able to locally suppress negative neuron activity (for example, bad memories), causing positive activity to dominate and reducing PTS (Post Traumatic Stress),¹⁴ form a short movie of a natural thought that may be replayed,¹⁵ and lead the "brain owner" to answering questions in such a way that "artificially-induced action potentials ... may be indistinguishable from the natural conclusion".¹⁶

Patent US 9729252 B2 relates to an invention that comprises methods and systems for modulating the activity of the brain using transcranial ultrasound energy (bioTU) in humans and other organisms for the purpose of communication.¹⁷ The patent description states that communication content can be transmitted (unnoticed) to the recipients in a way that alters their perceptions at all levels:

Communication via brain stimulation by bioTU represents a novel technique for the delivery and exchange of messages, including information or inducement of a physiological, behavioral, attentional, or emotional response in another. Methods and systems of the present invention permit communication wherein the brain stimulation modulates neuronal activity in a manner such that the recipient perceives a message which can, for example, modify the recipient's cognitive, emotional, physiological, or attentional state according to the sender's message.¹⁸

The conceivable areas of application are then outlined as follows:

(1) New modalities of communication such as direct communication of an emotional state; (2) Communication of subjective experiences; (3) Concurrent communication of a concept and an emotional response such as a visual image

¹² Patent EP 3331434 B1, sub 0043.

¹³ Patent US 10869628 B2, sub 0002.

¹⁴ Patent US 10869628 B2, sub 0072.

¹⁵ Patent US 10869628 B2, sub 0078.

¹⁶ Patent US 10869628 B2, sub 0085.

¹⁷ Patent US 9729252 B2, sub 0034.

¹⁸ Patent US 9729252 B2, sub 0053.

of a person, place, or object and a feeling of satisfaction or desire; (4) Faster communication, for instance by communicating a higher order concept directly to the brain that would otherwise require 10s to 100s of milliseconds or seconds or longer for the brain to process; (5) Communication that affects behavior such as brain stimulation that modulates the risk-taking behavior for a soldier or trader in the financial markets; (6) Parallel communication in multiple sensory domains that circumvents our general limitation of being able to attend to a limited number of sensory stimuli (e.g. circumventing our limited ability to listen to two spoken conversations concurrently by using brain stimulations that cannot be eavesdropped upon; and (8) Numerous additional beneficial aspects described herein that relate to entertainment, cognitive enhancement, improved decision-making, cognitive processes related to learning and memory, the quality of sleep, physiological arousal, sexual arousal, attention, mood, emotions, creativity, and other applications.¹⁹

The examples mentioned partly point to challenges that are already the subject of the neuroethical and neurolegal debate. This applies, for example, to the possibilities of improving human abilities, which are discussed under the umbrella term of neuroenhancement. It seems, however, that the possible applications of some inventions in the field of brain research go far beyond what has been discussed in expert circles so far. This applies, for example, to the possibility of generating fear for the purpose of controlling behaviour in the case of "antisocial behaviour", regardless of how this is to be understood, to the "remote control" of people through the transmission of external thoughts or commands to act, to accessing and modulating thought content that has so far been closed to the outside world, or even to the merging of the human brain with an AI, which goes beyond the already known cyborg or bionics discussion. Whereas the already known debates concern the "technical upgrading" of a human being, a fusion with an AI that ultimately acts as a black box, even for the original programmer, results not only in the unpredictability but also in the irreversibility of the processes once initiated.

All this gives reason to take a more comprehensive look at the legal implications of such brain patents. Clarification of the existing challenges is unlikely to be achieved through patent law instruments. This is the case because the "neutrality of patent law",²⁰ which is due to the special nature of the subject matter, cannot be overcome without serious disruptions in the system: since patent law only seeks to protect an intellectual achievement underlying the invention and rewards the associated increase in knowledge of the general public, an examination that goes beyond the fulfilment of the patenting requirements is not possible there²¹ – apart from the *ordre public* clause, which is to be interpreted narrowly. Furthermore, the patent offices simply do not have the ethical-legal expertise that would be necessary to ensure such a more comprehensive examination in practice; for this reason, as is

¹⁹ Patent US 9729252 B2, sub 0107.

²⁰ See, for instance, Spranger (2000), p. 373 et seq.

²¹ See, for instance, Recital 14 of Directive 98/44/EC.

well known, the attempt to supplement the "classical" patent law examination with an ethical consideration, as set out in Recital 39 to Directive 98/44/EC, failed.

As a result, a detailed analysis of the possible individual threats, but also of the challenges and risks for society as a whole, is required in the light of human rights instruments such as the Universal Declaration of Human Rights (UDHR), the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (UNCAT), the European Convention on Human Rights (ECHR), the Convention on Human Rights and Biomedicine, or the Universal Declaration on Bioethics and Human Rights of UNESCO. The international organisations responsible for the relevant international legal instruments and their bodies, but also other stakeholders such as scientific societies, are called upon to critically and constructively accompany the developments in the field of brain patents described above.

In this respect, the dissemination of knowledge plays a central role: for the reasons mentioned above, the patent law assessment of potentially critical brain patents cannot go beyond the narrow scope of the ordre public clause. However, international organisations concerned with the protection of human rights and their bodies have - as far as can be seen - not yet become aware of such critical developments in the field of brain patents. Thus, an interdisciplinary, translational approach is needed, which above all also enables a transfer of knowledge from the patent offices to the international organisations active in human rights issues. One conceivable outcome here would be an adaptation of procedural regulations of the patent offices that implement corresponding reporting or notification obligations in the event that the public policy clause was examined more closely, but in the end did not prevent the granting of a patent because an uncritical field of application was found in addition to critical fields of application. In such constellations, there are at least certain indications that an invention gives rise to a more comprehensive examination – which, however, is not and cannot be carried out in patent law for the reasons given above.

3 Summary and Outlook

Brain patents are not problematic as such in terms of patent law. The vast majority of the numerous patents that deal directly or indirectly with the human brain and its functioning do not raise any particular legal questions. However, a few patents are a serious exception in this respect, because despite the small quantitative dimension, the questions arising here are extremely important from a qualitative point of view. The emerging possibilities of influencing the cognitive, emotional, physiological, or attentional state of the person concerned not only give rise to hitherto unrecognised risks for the individual, but also for society as a whole. Also, in view of the fact that brain research seems to show a stronger tendency to generate results that have a dual use or misuse dimension,²² there is considerable societal interest in clarifying the questions that arise. A structured identification and transdisciplinary analysis of the

²² Cf. Aicardi et al. (2021); Mahfoud et al. (2018), p. 73 et seq.; Burton et al. (2018), p. 129 et seq.

incriminated patents is an indispensable prerequisite for this. The creation of a corresponding reporting system, preferably embedded in procedural law, should be considered to ensure that the relevant international organisations and their bodies become aware of potentially critical developments.

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