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Neuroenhancement Patentability and the Boundaries Conundrum in Psychiatric Disorders

Comparative Regulatory Inquiries from China and the West

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Abstract

Patent offices worldwide deny patentability to innovations which stand against the *ordre public*: does enhancement represent a value-laden societal threat? Patent offices also reject applications for therapeutical methods: when is enhancement also a therapeutical method? One specific class of enhancers, i.e. pharmaceutical neuroenhancers, is particularly complex in this respect: certain molecules can potentially function both as treatment for neuropsychiatric disorders and as recreational enhancers for non-patients' brain. Hence, the present work advances the debate on enhancement patentability in two directions: *ratione loci*, by scrutinising China's stances on enhancement's safety and morality, compared to the most frequently explored Western jurisdictions, namely the EU and the US; and *ratione materiae*, by illuminating the porous bioethical boundaries between treatment and enhancement in the domain of neuropsychiatry. It challenges patent offices' *de facto* regulatory role in defining and policing citizens' access to neuroenhancing substances through misplaced or pseudo-scientific intellectual-property narratives of innovativeness and morale.

Keywords

Chinese-Western comparative regulatory frameworks – molecular innovativeness – neuropsychiatric disorders – patentability exceptions – pharmaceutical neuroenhancement – public morals and public order

1 Introduction

Suppose you intend to commercially exploit a molecule. If it is found in nature and retrieved with reasonably negligible effort, it will not be patentable. If, instead, you have synthetised it thanks to your skills and instruments, you may proceed to patent it *inter alia* as a medical drug or a neuroenhancing substance, provided that two main conditions apply. First, you will need to abide by the relevant jurisdiction's public morals, as well as by the applicable public-health requirements. Second, the molecule will need to prove innovative enough to stand by itself rather than merely representing an alternative way to treat patients (therapeutical method) with a substance already being used—and possibly patented—for other purposes (e.g. to treat another disorder, but also, indeed, as neuroenhancement). But what is a neuroenhancing substance, and why are the controversial scientific interfaces between those substances and medical drugs so salient for legal and medical practice?

Humans have long aspired to overcome their bodily and cognitive limits by taking their psychophysical fate in their own hands, but for the longest fraction of human history, the boldness of their dreams has been far outsmarting the pace of technological and scientific advancement. This unevenness seems to be gradually but remarkably reversing nowadays, with some of our wildest horizons being turned into reality thanks to techno-scientific progress across a wide range of discipline, including medical diagnostic and treatment. The most visionary applications are early-stage, and their effects mild, so much that unconceding optimism has been replaced by more cautionary tales;[1] and yet, compared to any past point in human history, medico-pharmaceutical and neuroscientific knowledge unfolds fast, with biomedical engineering and therapeutical applications following suit. All-round health is a new (yet not *so* new) terrain for discrimination and domination, with ultra-high-net-worth individuals trying to secure the safest vanguard treatments for themselves while outsourcing large-scale experimentations onto the indigent and less educated. As a result, healthcare has possibly never proven so contested, and its limits so fragmented. Whereas it claims the ability to prepare our brains for a futuristic post- or trans-human age, "neuroenhancement" techniques stand exactly at the crossroad of these controversial revolutions, coming to interact with the porous boundaries of medical treatment in neurology—and psychiatry even

1 See e.g. Stephan Schleim and Boris B. Quednow, "How Realistic Are the Scientific Assumptions of the Neuroenhancement Debate? Assessing the Pharmacological Optimism and Neuroenhancement Prevalence Hypotheses", *Frontiers in Pharmacology* 9(3) (2018) 1–7, 1.

more pertinently. When is a substance a form of neuroenhancement, and when is it medical treatment instead? What is the neuroethics of psychiatric treatment and cognitive enhancement? These are intricate questions for lawyers, regulators, political philosophers, and bioethicists as much as they are so for physicians, pharmaceutical chemists, clinicians, or biomedical engineers, with implications spanning broadly throughout the legal domain, not least as far as intellectual property rights (IPRs) are concerned.

The present article contributes to the burgeoning literature on law and neuroenhancement in at least three distinct ways. To begin with, it offers an account of the Chinese definitory and policy stances on neuroenhancement, comparing it to Western narratives thereabout—and particularly to the United States of America (US) and European Union (EU)'s ones, which differ significantly even just between themselves. This represents the first-ever academic account of China's views on this matter in English language, and to the best of my knowledge, the most specialised and complete account thereof in any language (including Mandarin and Cantonese). China's centrality in shaping pharmaceutical policies on the international plane cannot be neglected, and its rapidly changing medical and patent landscape in this field is reviving the interest of scholars from around the planet,[2] not least due to the increasingly interconnected research on standard technology-intensive "Western" medicine and Chinese traditional herbal "medicine".[3] Despite the *objective* magnitude of China in this field as a market, a techno-scientific research and educational powerhouse, as well as a geopolitical actor, major international multidisciplinary publications on human enhancement in English language mention this jurisdiction *not even once*.[4] Second, this

2 Refer, most recently, to P.K. Yu, "China's Innovative Turn and the Changing Pharmaceutical Landscape", *The University of the Pacific Law Review* 51(3) (2020) 593–620.

3 *See also* E.J. Vargo and A. Petróczi, ""It Was Me on a Good Day": Exploring the Smart Drug Use Phenomenon in England", *Frontiers in Psychology* 7 (2016) 779, 2. One meaningful exemplification of traditional Chinese medicine being conceptually and practically at the crossroad between "Western" medicine and neuroenhancement comes from patent application CN:201911333940:A ("Traditional Chinese medicine composition and application for improving memory and strengthening the brain"), submitted to China's patent examiners on 23 December 2019. The clinical trials it underwent are not comparable to those which are compulsory for medical drugs *stricto sensu*, but this compound is advertised and "scientifically toned" as Chinese medicine while clearly phrased in neuroenhancing language. The present paper will indeed illustrate how narratives on "medicine" vs "enhancement" can shape the marketability, public-morals compliance, and thus the very patentability of substances addressed to the human brain.

4 To exemplify, check E. Hildt and A.G. Franke (eds.), *Cognitive Enhancement: An Interdisciplinary Perspective* (Springer, 2013).

study reviews the patentability[5] of neuroenhancement from a public-policy perspective (public order, public health, and public morals) in China contrasted to the other two West-"representative" jurisdictions, updating and significantly expanding on the (West-intensive) available literature[6] in a comparative fashion. Third, it focuses on a specific class of neuroenhancement, namely neuroenhancing drugs,[7] to scrutinise how patent offices and related authorities in China, the EU, and the US address (or should or might want to address) the distinction between psychiatric treatment and neuroenhancing substances, and to emphasise why such distinction matters in practice. In this case, too, this paper represents the very first scholarly attempt to extensively examine this subject from a double legal-scientific perspective, illuminating both the role of patent offices as *de facto* regulatory bodies, as well as the scientific uncertainty surrounding the definition and identification of "psychiatric treatment". It links medical-ethical debates on the osmotic influences between psychiatry and neurology—in light of the most recent neuroscientific discoveries—with more general appreciations of neuroenhancement's complexity which have already surfaced in legal literature in recent years. One scholar in particular, Ana Nordberg, has produced ground-breaking scholarship in this field law-wise, which also analyses a fairly extensive amount of case-law, but her analysis has

5 Certain English-language doctrines distinguish between "patentability" and "patent eligibility"; I deem this distinction superfluous, therefore I will stick to the first term throughout this work. Regardless of these terminological contentions, what matters—especially in the pharmaceuticals sector—is that abstract inventions or natural discoveries cannot be granted a patent; refer e.g. to the *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* case, as recounted *in* T.P. Sheehan, "*Mayo v. Prometheus*: The Overlap Between Patent Eligibility and Patentability", *Bright Ideas* 21(2) (2012) 3–8.

6 See most recently T.M. Spranger, "Brain Patents as a Legal or Societal Challenge?", *IIC—International Review of Intellectual Property and Competition Law* 54(2) (2023) 268–275; also check I. Schneider, "To be or not IP? Exploring limits within patent law for the constitutionalization of intellectual property rights and the governance of synthetic biology in human health", *Revista de derecho y genoma humano* 37(1) (2012) 193–233; E. Bonadio, "Patents and Morality in Europe", in: I. Calboli and S. Ragavan (eds.), *Diversity in Intellectual Property Identities, Interests, and Intersections* (CUP, 2015) pp. 149–168; A. McMahon, "Patents, Governance and Control: Ethics and the Patentability of Novel Beings and Advanced Biotechnologies in Europe", *Cambridge Quarterly of Healthcare Ethics* 30(3) (2021) 529–542.

7 Pharmaceutical neuroenhancement is a sub-category of neuroenhancement, which in turn stands as a subgroup of human enhancement. Refer generally to J. Daubner et al., "Pharmacological Neuroenhancement: Current Aspects of Categorization, Epidemiology, Pharmacology, Drug Development, Ethics, and Future Perspectives", *Neural Plasticity* (2021) https://doi.org/10.1155/2021/8823383; G. Fond et al., "Neuroenhancement in Healthy Adults, Part I—Pharmaceutical Cognitive Enhancement: A Systematic Review", *Journal of Clinical Research & Bioethics* 6(2) (2015).

consistently confined itself to the European regulatory landscape and Western sociolegal thinking; furthermore, it has never focused on the tangled and porous interfaces between psychiatry and neuroenhancement. Through this article, my purpose is to bridge both these jurisdictional and subject-wise shortcomings. In fact, her scholarship emanates from two research questions: first, (when) does enhancement represent a threat for society overall? and second, given the fact that patent offices reject applications for therapeutical methods,[8] when is enhancement also a *therapeutical method*? As for Nordberg's first research question,[9] I am going to address the same issue but from such an underexplored (and unmissably prominent) Eastern viewpoint as China's. As for Nordberg's second research question,[10] I believe it is meaningful for other forms of human enhancement but not particularly relevant to neuroenhancement, therefore I will rather address a slightly different, two-fold question, namely: when is neuroenhancement also *medical treatment*, and *psychiatric* treatment more specifically? Where to draw the boundaries between the two, and why is this crucial from a practical standpoint? In sum, my two interconnected research questions are as follows: 1) Is neuroenhancement a threat to public order or morale for patentability purposes in China, compared to Western stances? 2) How may patent offices and regulators attempt to distinguish between neuroenhancing substances and neuropsychiatric drugs, and what might the operative implications of said distinction in China and the West be?

Following the present introductory Section (1), Section 2 explores the definitory challenges policymakers, physicians, drug producers, and regulators face when engaging in neuroenhancing practices and debates. After commenting upon the definitions employed in the present paper, it concisely recounts the terminological understandings of neuroenhancement as retrievable from Chinese policy and legal documents, compared to European

8 Briefly explained, this means that patents can normally not be granted for therapeutical methods, but they can be granted for neuroenhancing solutions *which are not just therapeutical methods* as long as they meet, *inter alia*, the above-mentioned public-order requirement. In other words, *therapeutic and non-therapeutic effects of a substance are severable for the sake of patentability assessments*; for a case-law exemplification, refer to M. Hazes, "BCI and BMI: Therapeutic treatment or human enhancement? A comparative study on the exclusion of patentability of methods of treatment using brain-computer and brain-machine interfaces under Article 53c EPC and US patent law", Unpublished LLM Thesis in Law and Technology at Tilburg University (2018), 23.

9 She mainly addresses this question in A. Nordberg, "Patentability of human enhancement: From ethical dilemmas to legal (un)certainty", in: T. Pistorius (ed.) *Intellectual Property Perspectives on the Regulation of New Technologies* (Edward Elgar, 2018) 54–92.

10 This question principally features in A. Nordberg, "Patentability of methods of human enhancement", *Journal of Intellectual Property Law & Practice* 10(1) (2015) 19–28.

and American understandings as found in Western literature. Building on these lax and confusing definitory frameworks, regulators across all regions have endeavoured to further their acquaintance with the phenomenon and outline the main societal stances towards these novel techno-scientific tools, in line with the prevailing cultural traits in each society. For the sake of this analysis, I will succinctly report in Section 3 some examples of institutional and governmental positions from China, to be contrasted with those from the EU and the US. The subsequent Section (4) digs deeper into the patentability affair, scrutinising neuroenhancement's compliance with the public-order requirement as interpreted by patent offices in harmony with the prevalent societal values in the three aforementioned jurisdictions. Upon recalling the main trends and controversies in psychopharmacology, including the topical (and yet scientifically obsolete) distinction between psychiatric and neurological treatment (Section 5), the analysis proceeds in Section 6 to eviscerating several lines of reasoning which could mark a watershed between neuroenhancement and psychiatric (or neuropsychiatric) treatment. Attempting a distinction is of the essence regulatorily *lato sensu* as well as patent-wise *stricto sensu*, as it discloses a range of practical implications in terms of IPRs but also for market governance, medical practice, competition regimes, and consumer behavior. Selected exemplifications of these implications for legal strategy, chiefly addressed at court litigators, policy officials, and other practitioners, are enucleated in Section 7. Section 8 concludes.

2 Definitory and Conceptual Hurdles

To start with, terminologically, this phenomenon and its stimulating products have been labelled in a variety of ways, with no coherence having been achieved (or even sought) internationally so far. One may easily count dozens of expressions, including "human re-engineering", "human enhancement", "cognitive enhancement", "nootropics", "smart drugs", "lifestyle drugs", "cosmetic neurology", "brain doping", "brain optimisation", "neuropushers", "brain boosters", "neuro-empowerment", and so forth[11]—and blossoming translations do not help achieve standardisation, either.

I will stick to the most widely accepted expression—"neuroenhancement"—to identify the phenomenon; indeed, I reckon it is most essential to identify the

11 Refer e.g. to Nordberg, *supra* note 9, 56–57; Italian National Bioethics Committee, 'Opinions 2013–2014', https://bioetica.governo.it/media/3518/9_opinions_2013-2014.pdf, 47; Schleim and Quednow, *supra* note 1; Daubner et al., *supra* note 7.

conceptual perimeter of the phenomenon itself rather than its nomenclature per se. This will also help confine my investigation to interventions which modify the brain or anyway humans' neurological and psychic dimensions rather than other human organs, systems, or apparatuses.[12] Differently from a number of papers in sociology and other social sciences,[13] I will refer to neuroenhancement as what *scientifically is*—as opposed to what is *perceived to be or experienced as*—enhancing human cognitive functions. And yet, the reader will realise that this dichotomy is only somewhat tenable for healthy subjects, while it scratches untenability in the domain of psychiatry, where at times the biochemical effectiveness (or lack thereof) of a drug partly depends on patients' experiential perceptions and expectations.

In many ways, neuroenhancement is a responsibilising project implying that 'aspects of human life previously beyond our control—the biological foundations of cognitive development and decline—are now malleable by deliberate human action'.[14] Just as persuasively, one could argue that in fact it *de*responsibilises humans *as they are* while moulding an "enhanced version" thereof. It can be reckoned as an anthropological and somewhat "anthropolitical" quest for exceeding and overcoming the human, theoretically by improving on it both individually and socially.[15]

Some thinkers hypothesise that neuroenhancement would artificially alter the course of natural-selection and evolutionary pathways, which is probably why Nordberg herself suggested to use the expression "induced human evolution":[16] not to posit that *Homo sapiens* has ceased to evolve naturally, but to theorise that artificially triggered alteration will be added to the natural course of our species' evolution, eventually deviating it to a certain extent. Indeed, neuroenhancement might be assumed to catalyse evolution in such a way that our brains come to match our contemporary lifestyle more closely.

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12 Because not all forms of enhancement of our cognition are performed through substances, this scope could be more technically referred to as "pharmacological neuroenhancement", but I will mostly stick to the term "neuroenhancement" for the sake of readability.

13 Check e.g. C. O'Connor and S.K. Nagel, "Neuro-Enhancement Practices across the Lifecourse: Exploring the Roles of Relationality and Individualism", *Frontiers in Sociology* 2(1) (2017) 2.

14 *Ibid*., 3.

15 Check e.g. E.A. Williams, 'Good, Better, Best: The Human Quest for Enhancement—Summary Report of an Invitational Workshop Convened by the Scientific Freedom, Responsibility and Law Program American Association for the Advancement of Science', June 1-2 (2006), available at: https://www.aaas.org/sites/default/files/s3fs-public/HESummaryReport.pdf.

16 See Nordberg, *supra* note 9, 58.

The latter did evolve rapidly but only on the cultural-professional side (and most notably in "developed countries"), while our bodies are still designed for the primitive cave.[17] In this overly broad sense, which I do *not* fully propound here but is still worth exploring, neuroenhancement would resemble a sort of "adaptive therapy" for our species—assuming we do enjoy and would prefer to keep our modern hectic and superficially hyperconnected lifestyle, which many societies are in fact coming to despise and find unreasonably toxic as well as unsustainable.[18] Regrettably, 'the inability to cope with information overload characterizes the mental *conditio humana* in the age of neurocapitalism'.[19]

In the present piece, "therapy" will not be entrusted with such a broad—however justified—anthropobiological scope; instead, I will refer to its most standard, medical meaning. This choice also owes to the assumption that discussing evolution seems improper here: apart from genetic editing (e perhaps genic therapies, purportedly leading to the "edited human")[20], human enhancements cannot be immediately passed onto one's prole; hence, they fail to permanently partake in our evolutionary path. This holds true unless one relaxes its inspection up to encompassing transhumanist technologies (such as integrated chips or special suits and helmets) as extended bodies, but even then, not our biological essence, but its technological substratum alone, would undergo sensible change. Irrefutably, what distinguishes the self-declared *Homo sapiens* from other species is *inter alia* its acquired mastery

17 Read for instance S.S. Ilardi, *The Depression Cure: The 6-Step Program to Beat Depression Without Drugs* (Hachette, 2009) p. 6.

18 One curious facet of this trend is that upon having spent centuries, or at least decades, striving towards equality (in economic terms, but most recently along genderised and racialised arguments), we have ended up being all so "equal" that caste-based or élite-driven societies have resulted in an even fiercer free-for-all competition whereby literally everyone competes against each other in any given aspect of their family, academic, professional lives, and even in their spare times. Because of this hectic and all-comprehensive, constant arguing grounded in all-round negotiation on every daily-life decision, no one seems to enjoy any more time and space to breathe beyond their virtual bubble and digitised reality-show. To survive this condition of perennial competition catalysed by human-rights entitlement whereby anyone can finally aspire to "the top", each of us is busy trying to find a distinctive element that may make them stand out from the crowd (a crowd of billion equally-qualified competitors which, in turn, is getting longer every day). From the backdoor of equality, we are back to a situation whereby the wealthy will afford their evolutionary privilege (i.e. enhancing tools) while all others will succumb to hyper-competition and eutrophication of their life-time.

19 J-C. Bublitz, "My Mind Is Mine!? Cognitive Liberty as a Legal Concept", in: E. Hildt and A.G. Franke (eds.), *Cognitive Enhancement: An Interdisciplinary Perspective* (Springer, 2013) pp. 233–264, 235.

20 Refer to Nordberg, *supra* note 9, 62.

of technology,[21] but that cannot simplistically equate to concluding that our natural evolution—put aside intervening on our genome directly—can be forced to follow the pace of technological advancement and application.[22] More truthfully, and perhaps paradoxically, "enhancing" ourselves too steadily could make us biologically (e.g. immunologically) weaker as animals: as the COVID-19 pandemic has evidenced, the natural environment we live in and depend on is not accommodating our desired "development" at the pace and as smoothly as we would like, so that enhancing our nature uncontrollably may make us weaker and weaker compared to the natural challenges our bodies were supposed—and equipped—to tackle. What is more, "imperfection" is an integral, essential, and instrumental drive of evolution, not a mistake thereof or an accident therein;[23] "enhancing" us up to possibly elide all imperfections might turn out to be a boomerang in evolutionary terms—though these are mere suppositions.

By all means, as a departure point for any serious discussion, it is important to ask ourselves what the "human" is, or what makes us so.[24] In fact, any

21 Check e.g. *ibid*., 59.

22 See *ibid.*, 60, Nordberg writes that '[t]he posthuman future will not long for the return of the *Homo sapiens*, no more than we wish to revert to the *Homo neanderthalensis*', which is an analogical tenet I must disagree with: attaching technologies to our minds and bodies, even to such an integrated and permanent extent that we get used to it (which is far away from us still …), does not make human bodies evolutionarily different *stricto sensu*. In terms of biological species, we would remain *Homo sapiens* for a very long time, as we would not be born with such technology into our bodies already, and our genes—unless we play around with them, too—would not "speak its language". In truth, evolution's timings are unconceivably slow-paced. Even when evolution skips intermediary species and manifests a progression less gradual than usual, it still operates over hundred-thousand or million years; refer further to C. Bryant and V.A. Brown, *Cooperative Evolution: Reclaiming Darwin's Vision* (ANU Press, 2021); J.M. Ziman, *Technological Innovation as an Evolutionary Process* (Cambridge University Press, 2000). However, most recently, cf. eg. R. Bonduriansky and T. Day, E*xtended Heredity: A New Understanding of Inheritance and Evolution* (Princeton University Press, 2018). What holds always true, instead, is that social values constantly change, accompanying humans' evolutionary path in a gradual fashion, with phases of progressiveness and others of retraction that keep alternating and subverting each other unpredictably; refer extensively to F. De Waal et al., *Evolved Morality: The Biology and Philosophy of Human Conscience* (Brill, 2014); T. Pievani, *Homo sapiens e altre catastrofi: Per un'archeologia della globalizzazione* (Meltemi, 2006).

23 Refer extensively to T. Pievani, *Imperfezione: Una storia naturale* (Raffaello Cortina, 2019).

24 See also B. van Beers, '"The Obsolescence of Human Beings" and the Non-obsolescence of Law's Natural Persons: Transformations of Legal Personhood Through the Lens of "Promethean Shame"', in: M. de Leeuw and S. van Wichelen (eds.) *Personhood in the Age of Biolegality: Brave New Law* (Palgrave, 2020) pp. 187–204, 202.

attempt at defining the "enhanced" human should arguably start from defining the non-enhanced, generally "sane", or "current" one. In debating the ordinary human, splitting scientific and legal-ethical definition is of no assistance, not least because any attempt at doing so would repropose obsolete dichotomic thinking which is not well placed to navigate the systemic complexity we are currently living in.[25] Resultantly, in perusing Chinese institutions' definitory exercises and contrasting them with Euro-American views, and unless a piece of legislation provides for the ultimate and supreme—for a lawyer, at least—definition, I will endeavour to identify a synthesis between medical and policy literature.

No matter what jurisdiction one considers, multiple features of what we might deem "enhancement" will remain undefined. Are neuroenhancing interventions on the human inherently preventative or remedial, integrative or corrective? One may instinctively lean towards an understanding of it as *ex ante* intervention rather than reality-driven remedy, but then what would the difference with medical pursuits of preventative genomics—or even eugenics—be all about? One firm consideration is that enhancement bears a functional shade that exceeds mere aesthetics—although even this has been enough of a controversy in the past, insofar as some aesthetic treatments can display non-secondary functional outcomes.[26] It might be helpful to think of enhancement as being not just functional, but essentially performative, too—a conscious transformation of the self which metamorphosises our sense of relational identity with ourselves and others. While this not solve the dilemma of when an altering performance amounts to a restorative/repairing (and thus therapeutical) intervention rather than an integrative (and thus inherently enhancing) one, nor of—borrowing from another research context—'what lives should be enhanced or enabled',[27] focusing on relational identity and drawing the line between a *before* and an *after* does require one to isolate a commonly accepted definition of "normalcy".

At this point, the domain of psychiatry complexifies all efforts further, by introducing the human-individuality factor: because humans showcase

25 On the obsolescence of dichotomies in legal-ethical thinking, check e.g. R.J. Neuwirth, "The "Letter" and the "Spirit" of Comparative Law in the Time of "Artificial Intelligence" and other Oxymora", *Canterbury Law Review* 26(1) (2020) 1–32.

26 Refer to Nordberg, *supra* note 9, 59.

27 See also N. Ehlers, "Racial Futurity: Biolegality and the Question of Black Life", in: M. de Leeuw and S. van Wichelen (eds.), *Personhood in the Age of Biolegality: Brave New Law* (Palgrave, 2020) pp. 109–123, 113.

remarkable variability in their spectrum of psychiatric disorders and in the way they suffer and heal from them, any attempt at isolating "normalcy" seems to fade miserably.[28] On top of that, one shall mention the plasticity of our brains as one more reason to assert that variability is not only an individual feature *tout court*, but an individual feature *across one's own lifetime*—which is, in turn, lengthening. I will revert to these variables in Section 6 of the present work.

3 Society-wide Institutional and Regulatory Stances

What we have learnt so far is that definitory exercises are irredeemably controversial. How does China endeavour to disentangle this controversy? And how does neuroenhancement in China compare to Western definitions thereof? Comparing jurisdictions appears particularly meaningful here as the matter is a truly ethics-intensive, ideology-charged, and value-laden one; as it weighs benefits and challenges of neuroenhancing technologies, techniques, and—most relevantly here—substances, this investigation calls into question scientific and bioethical complementary inspections into humans' ideal positioning before life.

Among other ideal and practical challenges, the risk of the unknown is pre-eminent.[29] Some would stand sympathetic with pushing the boundaries of our nature to such a degree that our biological limits do not bother us or constrain our agency anymore, but they seem to ignore that those limits are not *actually* going to be overcome—just more or less temporarily sided—unless our genome is artificially altered on a fairly large scale. And if the latter scenario concretises, one is left to wonder what plan would be enacted as soon as our aiding technology becomes unreliable, unavailable, or fought for just like people fight today over non-renewable energy sources, pristine lands, or drinkable water. These insights fit into the more general debate on how far new technologies should be regulated,[30] and whom by, given that most of them are dual-use in design and/or deployment, necessarily carrying both harms and benefits to societies. As perilous as it sounds, one hardly gets to appreciate their benefits without experimenting with their harms beforehand; moreover, the non-marginal role serendipity plays is not confined to

28 Refer also to R.S. Downie and J. Macnaughton, *Bioethics and the Humanities: Attitudes and perceptions* (Routledge, 2007) pp. 66–68; 79.

29 Nordberg, *supra* note 9, 60.

30 See also *ibid.*, 63.

research: it encompasses technologies' potential applications as well, some of which were never conceived of by their discoverers or inventors. In fairness, during psychiatry's golden age, numerous

> psychiatric breakthroughs were achieved somewhat accidentally. Chlorpromazine was synthesized during research related to nausea and allergies. And the first antidepressant was created by a man in Switzerland after many tests that would be considered unorganized by today's standard.[31]

I will refrain from reviewing in detail all ethical challenges brought about by neuroenhancement; this has been done *ad nauseam* by other authors[32] and I feel the debate in that direction is exhausted—not because it is settled, but upon realising that there is no paradigm-turning argument to advance to support either camp, and thus it is "just" a matter of finally positioning oneself along the spectrum of already available arguments.

As a general take, one may nonetheless note that just like in many policy areas (yet not necessarily in other spheres of medical law), the US' stances on neuroenhancement are laxer and more liberal compared to its European counterpart. This might originate in their long-standing tradition about freedom of expression, whereby 'the freedom to think and remember without state interference [is] so important that [Americans] protect freedom of thought generally without attempting to assess the value of particular thoughts',[33] as restated in 2003 by the US Supreme Court in *Lawrence v. Texas*.[34]

As for China, the prominent parameter to assess is its potential regional representativeness. Is China's an "Eastern"—or at least "(South-)East Asian"—approach? If one compares its stances to those of, say, Japan or South Korea, they will answer in the negative. An extensive perusal of these jurisdictions' policy preferences falls outside the scope of this work, but a superficial glance

31 ktMINE, 'The Patents Behind Psychiatry' (February 2019) https://www.ktmine.com/the-patents-behind-psychiatry/.

32 Most recently, see M.C. Errigo, "Neuroenhancement and Law", in: A. D'Aloia and M.C. Errigo (eds.), *Neuroscience and Law: Complicated Crossings and New Perspectives* (Springer, 2020) pp. 189–214.

33 A.J. Kolber, "Criminalizing Cognitive Enhancement at the Blackjack Table", in: L. Nadel and W.P. Sinnott-Armstrong (eds.), *Memory and Law* (Oxford University Press, 2012) p. 320.

34 See *ibid.*, p. 318.

suffices to conclude that China's policing in this field is indeed peculiarly Chinese. In India, for instance,

> enhancement of the self [...] has had to be legitimized in a society that had kept Gandhian and socialist principles of maintaining a distinctive national identity alive in the face of western capitalist expansion, and a strong culture of empathizing with disenfranchised groups such as peasants, the workers, members of lower castes, and tribal groups. [... Legitimising] measures have proven to be successful, as consumption has become the dominant mode of expressing progressive, democratic values that urban elites espouse in the country.[35]

As the reader will appreciate *infra*, the "enhancement of the self", at least formalistically, is not yet liberalised to the same extent in China—despite the seemingly unconstrained consumerism that so manifestly characterises today's Chinese society.

4 Patentability-determining Moral Compass and Security Concerns

Despite the definitory and conceptual controversies surrounding neuroenhancement, one would assume that the issue has little to do with IPRs. However, that enhancement is acceptable cannot be taken for granted patent-wise, either, due to long-standing exceptions from patentability (also known as "exclusionary grounds").[36]

In Europe, Article 53(a) of the European Patent Convention (EPC) averts the patentability of unethical inventions which run contrary to the European *ordre public*.[37] Notably, this ethical scrutiny is a disjointed assessment, thoroughly

35 J. Talukdar, "The Science of Robust Bodies in Neoliberalizing India", in: D.L. Kleinman and K. Moore (eds.), *Routledge Handbook of Science, Technology, and Society* (Routledge, 2014) pp. 140–154, 143.

36 For a useful flowchart of patentability exclusionary grounds in the pharmaceutical sector, refer to K. Victoria Barker, 'Subject-Matter Eligibility at the EPO: Life Sciences' (2021), available at: https://www.finnegan.com/en/insights/blogs/european-ip-blog/subject-matter-eligibility-at-the-epo-life-sciences.html.

37 The reader might wonder what the relationship between public morals and *ordre public* is, that is, why it is being mentioned here at all. Roughly translatable into English as "public order", *ordre public* is a legal "term of art" that "socialised" from the most doctrinally conservative public international law onto human rights and other domains—refer to T. McKenzie, "*Ordre Public* (Public Policy)", in: Christina Binder et al.

independent from contracting parties' domestic laws and regulations. Not only this should probably *not* be the case, but indeed there is no need for it to be the case: even in the absence of more explicit and/or binding inputs, it is legit for the European Patent Office (EPO) to draw inspiration from authoritative sources,

(eds.), *Elgar Encyclopedia of Human Rights* (Elgar, 2022) pp. 607–614—and it is frequently listed in patent laws alongside "public morals" (or the like) as a bar to patentability. The expression is technically concerned with issues that might undermine or disrupt the security of a State and the safety of its citizens, but it has admittedly loosened its definitory boundaries (in the IP realm and beyond) up to encompass all those (perceived or actual) threats to the "core identity" or "orderly management" of a national society, under an all-pervasive mantra of "risk prevention". In practice, it is hardly distinguishable from public morals nowadays, especially towards patentability assessments—so much that the two expressions are often deployed together or interchangeably. This holds even truer in those jurisdictions, such as indeed China, where the public discourse is highly "securitised", meaning that an extremely wide array of public dossiers and administrative/policy domains are portrayed in national security terms or appraised against national security objectives—on securitisation in Chinese narratives around innovation, see further R. Vecellio Segate, "Horizontalizing Insecurity or Securitizing Privacy? Two Narratives of a Rule-of-Law Misalignment between a Special Administrative Region and Its State", *The Chinese Journal of Comparative Law* 10(1) (2022) 56–89; R. Vecellio Segate, "Securitizing Innovation to Protect Trade Secrets between "the East" and "the West": A Neo-Schumpeterian Public Legal Reading", *UCLA Pacific Basin Law Journal* 37(1) (2020) 59–126. Extensive literature exists on references to *ordre public* towards patentability assessments, as often coalesced with morality arguments; some of the most salient exemplifications, ranging from environmental protection to food safety, are reported in S. Sterckx and J. Cockbain, *Exclusions from Patentability: How Far Has the European Patent Office Eroded Boundaries?* (Cambridge University Press 2012) pp. 243–308; V. Prifti, "The limits of "*ordre public*" and "morality" for the patentability of human embryonic stem cell inventions", *The Journal of World Intellectual Property* 22(1) (2019) 2–15; D. Matthews et al., "Balancing Innovation, "*Ordre Public*" and Morality in Human Germline Editing: A Call for More Nuanced Approaches in Patent Law", *European Journal of Health Law* 29(4) (2022) 562–588; E. Demir and E. Stamhuis, "Patenting human biological materials and data: Balancing the reward of innovation with the *ordre public* and morality exception", *Journal of Intellectual Property Law & Practice* 18(7) (2023) 546–553; J. Straus, "*Ordre public* and morality issues in patent eligibility", in: T. Takenaka (ed), *Intellectual Property in Common Law and Civil Law* (Elgar, 2013) pp. 19–49; A. Bonfanti, "Environmental Risk in Biotech Patent Disputes: Which Role for *Ordre Public* before the European Patent Office?", *European Journal of Risk Regulation* 3(1) (2012) 47–56; J. Pila, "Adapting the *ordre public* and morality exclusion of European patent law to accommodate emerging technologies", *Nature Biotechnology* 38 (2020) 555–557; E. Bonadio, "Patents as a tool to encourage the production of healthier food", in: A. Alemanno and E. Bonadio, *The New Intellectual Property of Health: Beyond Plain Packaging* (Elgar, 2016) pp. 305–331; K.W. Lindroos, "Fairness and *ordre public* in certified global food chains", in: D.J. Gervais (ed), *Fairness, Morality and* Ordre Public *in Intellectual Property* (Elgar, 2020) pp. 195–213. Interestingly, in reviewing the monograph *Patent politics: Life forms, markets, and the public interest in the United States and Europe* by Shobita Parthasarathy for the *Journal of Responsible*

no matter it being under no obligation to refer to such external sources.[38] As for IP regulators, while the EPC offers no assistance on what *ordre public* is supposed to stand for, guidance is retrievable from the EPC Implementing Regulations as well as from the EPO Board of Appeal's case-law.[39] One example of application which was deemed contrary to public order as reported in Rule 28 of the EPC Implementing Regulations is that of 'processes for modifying the germ line genetic identity of human beings'. This application might well have concerned a human enhancement technique,[40] and even a *neuro*enhancement one if those modifications were meant to bear effects on our brain, but again, this is not immediately relevant here as I am focusing on neuroenhancement via intake of substances. To date, no official guidelines exist on when exactly (if ever) pharmacological neuroenhancement[41] should be considered publicly unethical, immoral, or unsafe for patentability purposes.

A reminder seems crucial: being an independent treaty under public international law (PIL), the EPC is not governed by EU law; in particular, '[t]he EPO Boards of Appeal are not a national court of an EU member and the EPO is not an EU organization, nor is there a correspondence between EPC members and the members of the EU'.[42] Nevertheless, all EU Member States (MSs) are parties to the EPC, therefore one may safely assume that EPO's holdings are representative of EU MSs' patent-law stances with regards to the subject-matter of the present paper. Definitory and conceptual harmonisation among Members is not facilitated by the current configuration of the European patent system, whereby patent entitlements approximate to bundles of domestically enforceable patent rights rather than to a Europe-wide enforceability system.

Innovation, J.C. Lai (at 112) laments that 'the author occasionally seems to conflate *ordre public* and morality, when these are distinct legal concepts', which is abstractly true but operationally false: in fact, neither legislators nor courts, perhaps out of inertia, seem keen on drawing (much-needed) context-sensitive and/or procedural distinctions between the two. Read further Å. Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (Stockholm University, 2015) p. 89; C.H. Farley, "A Research Framework on Intellectual Property and Morality", in: I. Calboli and M.L. Montagnani (eds), *Handbook of Intellectual Property Research: Lenses, Methods, and Perspectives* (OUP, 2021) pp. 791–806.

38 Refer e.g. to Nordberg *supra* note 9; 69, 73.

39 See also *ibid*., 71.

40 See also D. So et al., "Disease Resistance and the Definition of Genetic Enhancement", *Frontiers in Genetics* 8(40) (2017), available at: https://doi.org/10.3389/fgene.2017.00040; Nordberg *supra* note 9, 69, 75–78.

41 This expression should not be confused with medical terminology such as "dopamine enhancer" and the like, where "enhancer" simply stands for the opposite of "blocker" or "inhibitor"—quantitatively.

42 Nordberg *supra* note 9, 70.

As for the proposed Unified Patent Court which would represent a major step forward towards a unitary system, the process is in a stalemate, and its future precarious.[43] As a tangential note, it matters to underline that definitory issues in patent law impact societies and the economy far beyond the IPR domain, easily turning to wider questions of competition. It should not surprise anyone if the US academy and business diplomacy, for example, will soon become more assertive in "exporting" their application of patentability doctrines to neuroenhancers overseas: it will represent a normative-projection move whose underlying rationale is fundamentally competitive.

The US displays more relaxed an approach compared to the European one,[44] also because no constitutional and statutory bar to patentability exists on grounds of public order—judicial doctrines on the subject do fill the void, but their application remains discretionary and somewhat erratic.[45] It was indeed the EU, and not the US, to advocate for the inclusion of morality bars to patentability within Article 27(2) of the TRIPS Agreement,[46] which merely accepts that States '*may* exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality'.[47] Contrariwise, in the law of the People's Republic of China (PRC law), the corresponding exception is reported in Article 5 of the Patent Law—out of legal transplant, but also in genuine pursuit of Chinese long-standing views on value-regulated society; in pursuance thereof, as far as public order is concerned, neuroenhancement might be banned. I will now explore this option in more detail.

43 See generally A. Plomer, "The Unified Patent Court and the Transformation of the European Patent System", *IIC—International Review of Intellectual Property and Competition Law* 51(7) (2020) 791–796; R. Vecellio Segate, "The Unified Patent Court and the frustrated promise of IP protection: Investors' claims in (post-)Brexit Britain", *Maastricht Journal of European and Comparative Law* 27(1) (2020) 75–104; A. Wszołek, "Still Unifying? The Future of the Unified Patent Court" *IIC—International Review of Intellectual Property and Competition Law* 52(9) (2021) 1143–1160.

44 Read further Z. Warso et al., "Analysis of the legal and human rights requirements for Human Enhancement Technologies in and outside the EU" (2019) Deliverable for the SIENNA [Stakeholder-informed ethics for new technologies with high socio-economic and human rights impact] Project funded by the European Union's H2020 research and innovation programme under grant agreement No 741716, 18.

45 Read extensively D.C. Myrick, "The Impact of *Ordre Public* and Morality on the Regulation of Gene Editing Patents in the United States and the European Union", *WIPO and University of Turin* (2023) 49–56, available online at https://ssrn.com/abstract=4347343.

46 See e.g. A. Brown et al., *Contemporary Intellectual Property Law and Policy* (OUP, 5th edition 2019) p. 380.

47 Emphasis added.

The first meaning of public order in China, arguably the most basic one, pertains to the safety of the public. To exemplify what safety entails health-wise, this is an excerpt from a Chinese court case addressing multi-compound applications of the same molecule:

> The plaintiff claimed that the standards for the limit of a substance in different components are different, but did not tender any evidence to prove that it complies with the corresponding standards or norms. As the limit has been set in the hygienic norms, and the limit of this application exceeds the limit by more than twenty times, a person skilled in the art may reasonably [assume] that it is harmful to public health, but the plaintiff did not provide any safety test evidence to [dispel such an assumption]. Therefore, the implementation or use of this application will endanger the life, health, and safety of the public, and thus harm the public interest [...].[48]

Reading this case, one may conclude that Chinese courts understand patents' safety in essentially the same way as their Western counterparts do, but said conclusion would be grossly superficial. In fact, public order holds, for China, one further valence which is more typically regime-linked, authoritarian, conservative, and securitisation-aimed, primarily directed at regime stability, social conformity, and possibly even censorship or, more widely, chilling effects via overpolicing.[49] Through these distortionary lenses, applications that do not conform to *ordre public* are rejected not out of health (or more generally safety) concerns, but because they fail to contribute fruitfully towards the regime's survival cause and social-policing manifesto, not rarely disguised as "social harmony".[50] Sharing these objectives, Chinese scholars suggested that

48 Beijing Intellectual Property Court, Administrative Judgment, *Jing 73 Xing Chu* [2017] No. 2129, Chief Judge Zhao Ming, 27 September 2019. Interestingly, faced with a re-examination application grounded in "abandonment" claims under Article 33 of the Patent Law, the court went on to dismiss findings from scholarly literature, holding that 'the paper mentioned by the plaintiff in the court trial only belong[ed] to the scope of academic discussion, not laws and regulations, and [could not] be used as the basis for amendment [to the original patent application]'.

49 Read also R. Vecellio Segate, "The Distributive Surveillant Contract: Reforming "surveillance capitalism through taxation" into a legal teleology of global economic justice", *Talent Program PhD Thesis in International Law at the Department of Global Legal Studies* (*Faculty of Law*) *of the University of Macau* (2022), 287;724.

50 On "harmony" as a trope in Chinese discourses on security and civilization (and their international implications, not least for comparative sociolegal studies) see, among others, X. Wang et al., "Harmony as language policy in China: An Internet perspective", *Language*

medical institutions where neuroenhancement is offered should be monitored in observance of and alignment to the scoring principles of China's social credit system.[51] In these terms, IP regulation, too, would become a proxy for security rather than for health (or at least, security would work in addition thereto).

The just-mentioned considerations illuminate the second meaning of public order, which has to do with prevailing ethics and related customary struggles. As far as ethical principles are concerned, there is no clear-cut solution to enhancement patentability in China: it just depends on the circumstances. An official regulatory response is urgent, and I anticipate it would also be based on forecasted users' intentions; this is because if one scrutinises Chinese values, neuroenhancement is putatively both acceptable and unacceptable from an ethical standpoint, depending on its intended effects on individuals but particularly on society overall. To this end, one insight can be retrieved from the rejection of sex toys' patentability; judges expressed themselves as follows:

> The Court holds that social morality is a social norm based on the traditional culture of a country or region, and is generally accepted and recognized by the public of that country or region. The Court does not deny that since the reform and opening up, the acceptance or tolerance of the people in China towards such matters has changed greatly. However, the Court equally believes that at least in terms of the general psychology of the citizens of China at this stage, artificial sex organs or their substitutes for non-medical purposes are not yet to be deemed elegant. [...] This not only falls within the scope of the provisions of the Guidelines for Patent Examination in that it runs against social morality and therefore cannot be granted a patent right, but it also hits the bottom line of the tolerance or acceptance as shown in the current social psychology in China.[52]

In light of this reasoning, one may be tempted to conclude that neuroenhancers will obviously be ruled out by Chinese court and legislators from the perspective of morale; and yet, that is not necessarily the case. Sex toys have

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Policy 15 (2016) 299–321; L. Hagström and A.H.M. Nordin, "China's "Politics of Harmony" and the Quest for Soft Power in International Politics" (2020) 22(3) *International Studies Review* 507–525; W.A. Callahan, "Remembering the Future—Utopia, Empire, and Harmony in 21st-Century International Theory", *European Journal of International Relations* 10(4) (2005) 569–601.

51 Refer to Q. Sun, "The Legal Risk of Human Enhancement Technology and Its Regulation in China", *Open Journal of Social Sciences* 9(1) (2021) 39–53, 50.

52 Beijing Intellectual Property Court, Administrative Judgment, *Jing 73 Xing Chu* [2019] No. 11371, Chief Judge Li Bingqing, 28 June 2020.

been patentable and circulated in most jurisdictions for decades or centuries already, so that the Chinese court's verdict might lead one to assume that the moral threshold for patentable items to meet being so high, neuroenhancers would a fortiori miss out on it, but this would represent an unmistakably ethnocentric West-centred value-metric. To the contrary, each candidate to patentability shall be assessed in its own merits, and the appraising scale might differ from the Western one even remarkably, to such an extent that while sex toys are deemed unacceptable, certain forms of neuroenhancement—here, certain neuroenhancing substances—might be found acceptable should the matter be submitted before a court in the near future. In fact, it shall be noted that sex toys, specifically, feature as an exemplification of non-patentable items under paragraph 3(1)(2) of the China National Intellectual Property Administration (CNIPA) Patent Examination Guidelines.[53] No mention, however, is made therein about neuroenhancement or pharmaceutical drugs, although paragraph 3(1)(1) specifies that 'narcotics, sedatives, and stimulants *used for medical treatment*'[54] violate the law *when they are abused*.[55] An equally vague but apparently contradictory formulation is embodied in paragraph 3(1)(3), whereby

> if the invention-creation may cause public disruption *through abuse*, or if the invention-creation produces positive effects but presents certain defects, *like a medicine causing side effects* to the human body, the patent right shall *not* be refused on the ground of "public interests".[56]

In short, putting abuse aside, the vague and inconsistent formulation of these clauses, worsened by the dry reasoning provided in actual judgements, makes the matter an open-ended one, still.[57] Whenever mentioned substances are expected to be societally neutral or, better, to make one contribute more

53 These Guidelines are currently being updated as a follow-up to the newly amended Patent Law that entered into force on 1 June 2021. *Check* CNIPA's Draft Revised Patent Examination Guidelines (Draft for Solicitation of Comments) [专利审查指南修改草案（征求意见稿）] released on 3 August 2021.

54 Emphasis added.

55 Refer further to the "Narcotic Drugs and Psychotropic [or Psychoactive] Substances Management Act", Decree of the State Council of the People's Republic of China (Order No. 442), promulgated on and in effect as of 1 November 2005, English transnational available at https://doi.org/10.2753/CLG0009-4609450203.

56 Three emphases added.

57 The aforementioned Guidelines, and the Patent Law they comment upon, incorporate a variety of expressions which are usually translated into English as "public order", "public

proactively to society and everyone's wellbeing (assuming we know what that entails) by enhancing their solidaristic, altruistic, empathetic, generous, and even submissive traits, that would plausibly help counsels make a case for patentability.[58] At odds with such Confucianist take, whenever neuroenhancement is expected to make citizens cheat or to enhance their athletic, financial, creative, scientific, artistic, school performances artificially and merit-free, highlighting their selfishness and individualistic pursuits, its patentability will straightforwardly be negated. In particular, a Chinese law professor from the Research Center in Theoretical Law at Jilin University has recently rejected the ethical viability of enhancement for competing in sports, arguing that aid-free egalitarianism is what we should continue to strive for, instead.[59] News channels also emphasise the experience of young Chinese students who have reportedly taken enhancers to try to pass exams 'without effort, nor talent' but now 'regret the experience' and 'would act with more wisdom if just they could go back in time'.[60] All in all, in China and beyond, neuroenhancement should never become a proxy for the usual tenet of

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interest", and "social morality", though the distinction between "public" and "social" is not settled, and neither is that between "morality" and all other "interests". Significant scholarly work remains to be done in this area, but some guidance is provided in S. Chengyan [沈成燕], 'Research on the Judicial Application of the Public Interest Clause in Intellectual Property Law' 《知识产权法公共利益条款司法适用研究》(2019) Unpublished PhD Thesis in PRC Law at the Zhongnan University of Economics and Law [中南财经政法大学 士学位论文]. Helpfully, to grasp the scope of said legal expressions, she draws a number of comparisons with other Chinese statutes in IP (such as the Trademark Law and the Copyright Law) as well as with the PRC Constitution itself.

58 *Read further* Wang Kening, Wang Qian, and Yi Xianfei [王克宁，王前，易显飞], 'Emerging Human Enhancement Technologies from the Perspective of Traditional Chinese Humanism' 《中国传统人文主义视野中的新兴人类增强技术》(2021) 36(4) *Journal of Changsha University of Science and Technology* (Social Sciences Edition) 《长沙理工大学学报（社会科学版）》 29–35. And indeed, a few "innocuous" neuroenhancing compounds have already been authorised in China; *refer e.g. to* patent application CN:201410019232:A submitted on 16 January 2014, referred to a 'beverage for improving memory and enhancing intelligence'.

59 *Refer to* Zhu Zhen [朱振], 'Reflection on the Ethics and Jurisprudence of Human Body Augmentation: An Analysis of Human Body Augmentation in Sports as an Example—Chinese Legal Thought' [人体增强的伦理与法理反思——以体育运动中人体增强为例的分析 | 中法评 · 思想] (2022) 1 *China Law Review* [中国法律评论] 131–143, JLUXKJC2020304.

60 千禧一代的高考冒险：那些偷偷吃「聪明药」的学生 [The college entrance examination adventure of millennials: Those students who secretly take "smart medicine"] (2019) *The Paper*, https://www.thepaper.cn/newsDetail_forward_3523512; the liberal translation in the quotes is mine. In a similar vein, *check also* 兴奋剂助考考试也"兴奋"：细数考试兴奋剂"三宗罪" [Those who cheat in exams become also

neoliberal exploitation whereby 'qualitative *better* is frequently confused with the quantitative *more*';[61] rather, to regulate it, a two-fold preliminary question is worth asking: 'what exactly is being improved and why should that outcome be considered "better"?'.[62]

In legislative and administrative terms, scholarly attention should focus on the Guidelines being reviewed—and further reviews might be scheduled by Chinese authorities very close in time. As to cater for neuroenhancement innovations, would that document need to incorporate neuroenhancement-tailored provisions, or cited innovations could fit within the current definitions and categories? This is a tough take for regulators in China, all the more so as most substances might enucleate both potentially beneficial and potentially detrimental effects.

As examined, *on paper* (and drawing heavily on Confucius' teachings), China tends to be approving of enhancement only as long as the latter is expected to reduce rather than widen the divide between social classes, social atomisation, and the friction among different components of society. The endpoint, for China's thinkers, shall be about *group* dignity, sustainable *collective* development, and the "rights" of the Chinese people *as a civilisation* endowed with the wisdom of history. This would make it stand significantly far from the meaning and conditionalities Western jurisdictions (would) attach to neuroenhancement-related ethical problematics, whose emphasis is placed on individual safety, personal biological limits and needs, techno-privatised human rights, and inter-individual "fairness".

If one inspects China's posture more closely, though, its approach to ethics could be characterised as more pragmatic. Today, its departure point *in practice* seems to be that no regulation could effectively prevent Chinese citizens from aspiring to access pharmacological sources of efficiency and happiness

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"anxious": Count the "three deadly sins" of doping before exams] (2018) *Xinhuanet*, http://www.xinhuanet.com/politics/2018-06/29/c_1123055267.htm; Pang Wei and Qi Xin, 会上瘾的"聪明药" [Addictive "smart drugs"] (2019) *Beijing News*, https://baijiahao.baidu.com/s?id=1625942109933704350; 吃了就能变聪明的"神药"到底是什么药？ [What is the "magic medicine" that can make you smarter by taking it?] (2019) Xinhua News Agency, https://baijiahao.baidu.com/s?id=1636120876477899726; Zhang Xiao and Wu Yuanjing, 吃了"聪明药"高考考得好？专家：精神类药物不可滥用 [Did you do well in your college entrance examination after taking "smart medicines"? An expert explains that psychotropic drugs should not be abused] (2016) *CN Hubei*, http://news.cnhubei.com/xw/2016zt/2016hbgk/gkqwlgk/201605/t3632507.shtml.

61 B. Hofmann, "Limits to human enhancement: Nature, disease, therapy or betterment?", *BMC Medical Ethics* 18(56) (2017), available at https://doi.org/10.1186/s12910-017-0215-8, emphases in the original.

62 *Ibid.*, emphasis removed.

if they become aware of said drugs' potential (assuming there is any). This "inevitability argument" has even been featuring in several Chinese writings on neuroenhancement over the last few years, with one scholar going so far as to claim that while neuroenhancement can be currently regarded as morally unacceptable in China, its diffusion appears irreversible and will eventually normalise by law as well, so that a balance should be sought soon.[63]

The last observation I would like to submit on China for this part is that in either case, despite a quasi-monist approach to PIL, authoritative guidance from international treaties (and treaty bodies) will be sought by its patent officers to a lesser extent compared to officers in most jurisdictions. First, quite differently from EU MSs, China has not ratified several international human-rights treaties, including the International Covenant on Civil and Political Rights (ICCPR) —neither has the US, for that matter. Second, the Council of Europe's human-rights framework, whose court in Strasbourg frequently decides on property and freedom-of-expression disputes and to which all MSs are parties,[64] is for the latter to comply with, while standing as a loose-only (and virtually never considered) jurisprudential reference for Chinese adjudicators. Just like in any other field, judicial politics in IP matters is very telling about the overall regulatory environment.

Zooming out of China and any specific jurisdiction, I will now offer a few remarks on neuroenhancement-related morality and security issues in a more general fashion.

One frequently recalled question is whether patent offices should *de facto* conform to international human-rights law (IHRL) standards and domestic constitutional requirements,[65] including on property rights, 'human dignity, freedom, equality, non-discrimination, the rights to privacy, informed consent concerning medical acts, the right to enjoy the benefits of scientific progress, freedom of thought, conscience and religion, and freedom of opinion and expression'.[66] The recent Chilean constitutional momentum corroborates the topicality of framing neuroenhancement against the wider regulatory environment, especially on neurorights, with brain-altering substances and technologies being constitutionally deployed to the service of citizens and not

63 Refer to W. Liqing and W. Dan, "On the Ethical Problems and Legal Regulation of the Application of Neuro-Enhancing Drugs", *Chinese Health Administration* 10 (2018).

64 Read P. O'Callaghan and B. Shiner, "The Right to Freedom of Thought in the European Convention on Human Rights", *European Journal of Comparative Law and Governance* 8(1) (2021) 112–145.

65 For Europe, see Nordberg, *supra* note 9, 55.

66 *Ibid.,* 61–62.

vice versa.[67] A subordinate question is whether, for that purpose, patent offices should draw inspiration from major international human-rights treaties as well as bioethics-centred covenants including the Oviedo Convention, or even non-binding documents such as the World Medical Association (WMA) Helsinki and Taipei Declarations. They might even refer to the jurisprudence of supranational courts of regional and global *ratione loci* scope, and even to "general principles of law" as retrievable from domestic jurisdictions and effective under PIL.[68]

Relatedly, one could doubt the qualification of those who eventually get to decide on a substance's ethical compliance; more generally, is it really for public institutions' employees to decide? Granted, the patentability of neuroenhancers is an IP issue at first, but through patents it also becomes a of public-policy process more widely, which triggers the question of how to avert the triumph of a "paternalistic State" and its hyper-recourse to preventative regulation grounded in the precautionary principle. This is, indeed, a pivotal dilemma: 'legal rules should reflect general ethical principles and common morality principles of society, but should not curtail individual choices where they pose no direct harm to others'.[69] Put differently, we shall avoid to 'medicalize mood states and personality traits',[70] or to create a society of factual automatons where the State supremely presides over one's choices pedantically and patronisingly in order to suppress extreme emotions away

67 Read extensively M.I. Cornejo-Plaza and C. Saracini, "On pharmacological neuroenhancement as part of the new neurorights' pioneering legislation in Chile: A perspective", *Frontiers in Psychology* 14(1177720) (2023) 2.

68 "General principles" are those that can be extrapolated from a representative majority of municipal laws (domestic legal orders). Check e.g. X. Shao, "What We Talk about When We Talk about General Principles of Law", *Chinese Journal of International Law* 20(2) (2021) 219–255; I. Saunders, *General Principles as a Source of International Law: Art 38(1)(c) of the Statute of the International Court of Justice* (Bloomsbury, 2021); L. Pineschi (ed), *General Principles of Law: The Role of the Judiciary* (Springer, 2015).

69 Nordberg, *supra* note 9, 66.

70 *Ibid.*, 80. It is important to note here that medicalisation per se, with the emphasis it places on the poor and the marginalised, is a positive phenomenon and a powerful trigger for more genuine and suffering-tailored rights discourses. See generally C. Konnoth, "Medicalization and the New Civil Rights", *Stanford Law Review* (2020) 72(5) 1165–1267; E. Parens, "On Good and Bad Forms of Medicalization", *Bioethics* (2013) 27(1) 28–35. The object of my criticism is its neoliberal misappropriation for non-medical "status displaying" and big-pharma profiteering. On this misuse, read further M. Bury, "The Medicalization of Society: On the transformation of Human Conditions into Treatable Disorders—by Conrad, P.", *Sociology of Health & Illness* 31(1) (2009) 147–148; J. Busfield, "The concept of medicalisation reassessed", *Sociology of Health & Illness* 39(5) (2017) 759–774; E. Kaczmarek, "Promoting diseases to promote drugs: The role of the pharmaceutical industry in fostering good and

from society. A neuroenhanced society was defined *inter alia* as "bionic",[71] but I suspect that an overpoliced society is equally to be refuted. In other words, we shall not over-restrict the behavioral normalcy spectrum: doing so would ultimately benefit capitalist modes of production and consumption rather than embracing the cause of human happiness, harmonious development, and peaceful coexistence, and it might even be misappropriated for surveillance, military, or paramilitary purposes, including human experimentation programs pursued by secret-service agencies.[72] 'Human fighters are seen as the weakest link in increasingly machine-centered warfare, and therefore [...] they need to be enhanced':[73] the sharper and more codified the contrast between "the normal" and "the enhanced", the stricter enhancement requirements will be enforced, eventually neoliberalising the very essence of human nature and choice-taking in pursuance of mostly privatised and often oligarchic military-corporate interests. Others disagree, opining that refraining from codifying the difference between normalcy and enhancement, and/or omitting to enforce it in the name of "individual responsibilisation", would be compatible with the general retraction of the State as a responsible (as opposed to farcically

bad medicalization", *British Journal of Clinical Pharmacology* 88(1) (2022) 34–39. In other words, one may understand "medicalisation" as either the expanding scope of medical assistance to those in need, through deeper study of and care for their suffering, or as the overreliance on medical pursuits and devices to treat conditions which would better be addressed through societal policing and structural changes to the way we live, die, and relate to each other. The second form of medicalisation seems short-sighted, while the first shall always be welcomed and incentivised.

71 Refer to A.F. Maturo, "Medicalization: Current Concept and Future Directions in a Bionic Society", *Mens Sana Monographs* 10(1) (2012) 122–133.

72 Refer generally to H. Goodley, "Pharmacological performance enhancement and the military: Exploring an ethical and legal framework for "supersoldiers"", *Chatham House International Security Programme Research Papers* (2020); C.L. McCain, "Looking at Levels of Medicalization in the Institutional Narrative of Substance Use Disorders in the Military", (2015) Unpublished MA Thesis in Sociology at the University of South Florida; P.A. Taraska, "How can the use of human enhancement (HE) technologies in the military be ethically assessed?" (2017) Unpublished PhD Thesis in Liberal Arts at Duquesne University; Spencer Ackerman, 2015. "CIA torture appears to have broken spy agency rule on human experimentation." *The Guardian*, available at https://www.theguardian.com/us-news/2015/jun/15/cia-torture-human-experimentation-doctors; W.J. Aceves, "Interrogation or experimentation? Assessing non-consensual human experimentation during the war on terror", *Duke Journal of Comparative & International Law* 29(1) (2018) 41–102, 63.

73 M. Coeckelbergh, "Cyborg Humanity and the Technologies of Human Enhancement", in: A.F. Beavers (ed.) *Philosophy: Technology* (Macmillan, 2017) pp. 141–160, 152.

responsibilising) agent which underpins much of what is wrong with deregulated, unfettered capitalism.[74]

Besides the "who", the "how" is understudied as well: methodologically speaking, based on the collection of what evidence will patent offices set moral standards for patentability purposes?[75] What is the applicable "standard of proof"—if one wants to borrow this terminology from more established legal fields? What documents and figures, and whose opinions and (big) data, will they take into account to establish whether a submitted substance conforms to a normative culture—that is, to draw the boundaries of acceptability for such a culture? And in the absence of conclusive scientific evidence, what sort of probabilistic reasoning are they going to rely upon? This issue will prove just as momentous in distinguishing between enhancement and medication: '[w]hether an invention pertains to the medical field is often more a matter of convention than objective technical distinction',[76] thus in this case, too, who is entrusted to have the final say, and why, are two topical and pertinent questions. Furthermore, it is worth pondering whether patent offices somehow end up apportioning enhancement's risks and benefits across fractions of society, themselves unwittingly abiding by the usual logics of capitalism whereby those who are privileged will obtain more and those who are not will keep having less and less—not solely in monetary terms, but health-wise just as much. And because of their weak (or hopefully absent) political mandate, patent offices plausibly tend to be conservative rather than taking on responsibility for any bold steps in a progressive direction.[77]

At this juncture, the sempiternal problem of law, which endlessly endeavours to catch up with societal changes which happen too rapidly for it to digest, also creeps in. Evaluations may depend on changing public sensibility to and appreciation of a given practice, which might witness fluctuations in accommodation and repulsion. These are unavoidable cultural cycles which depend on the evolving values and composition of the citizenry; hence, what "public" should regulators select for the sake of identifying and verifying the perimeter of such changes, and at what point in time? Additionally, how to dispel selection bias—not to mention confirmation bias, sampling bias, and other cognitive or measurement biases displayed by institutional representatives? Considerations on whether a certain invention would be

74 Read e.g. D. Rabet, "The Political Economy of Neurolaw: Can Neurolaw Destabilize the Neoliberal Discourse About Human Behavior?", in: M. de Leeuw and S. van Wichelen (eds.) *Personhood in the Age of Biolegality: Brave New Law* (Palgrave, 2020) pp. 39–54, 50.

75 See also Nordberg, *supra* note 9, 72.

76 Nordberg, *supra* note 10, 21.

77 See also Nordberg, *supra* note 9, 66.

deemed so abhorrent by the public as to be considered contrary to the *ordre public* are definitely not extraneous to the EPO Board of Appeal's case-law,[78] so that again, in this case the relevant question becomes: what is the reference public? Does it overlap with the general population or the psychiatric one? And, for instance, who is going to compose the latter? Is the latter "reliable" and "generalisable" for evidentiary purposes? But is "reliability" even relevant a criterion in this context? These (and other) questions are vital because, for example, the general population might weigh benefits and drawbacks differently from (actual or potential, self- or hetero-declared) psychiatric patients—and their doctors and caregivers—by characterising as "obscene" or "repugnant" substances whose effects patients would find rather helpful. 'To some degree, there will likely never be a bright line distinction, and there will always be a visceral response to many areas of human enhancement technologies, even those that might seem to some as therapeutic'.[79] Inferring from technological appliances and cosmetic surgery, think e.g. of

> the issue of determining whether a body modification is a purely aesthetical procedure or whether, for legal purposes, it can be considered a treatment of conditions such as gender identity disorders, body dysmorphic disorder, bulimia, anorexia nervosa, body integrity identity disorder[,] or xenomelia.[80]

Along related lines, should democratic populations be tested and surveyed differently from autocratic ones? Namely, is it really meaningful for the patent office of an autocratic system to make polls and commission expert dossiers which would probably return the same viewpoint of state institutions presiding over such jurisdiction?

In addition to the "who" and "how" questions, it is equally important to assess whether decisions on ethics might be reviewed, and if so, whom by, which also encompasses an investigation of the politics underpinning such review. Will judges review patent-office decisions? What will their background and status be? If traditional courts are tasked with this role, institutional differences between jurisdictions such as the EU and the PRC would stand out loudly. By way of exemplification, insufficient guarantees of separation of powers and courts independence in China have long been fuelling concerns as IPRs have

78 See e.g. *ibid*., 72.

79 D. Greenbaum and L.Y. Cabrera, "ELSI in Human Enhancement: What Distinguishes It from Therapy?", *Frontiers in Genetics* 11(618) (2020) 1–3, 2.

80 Nordberg, *supra* note 10, 22.

been indeed strategised, as introduced above, as a proxy for regime stability and security beyond their medical and entrepreneurial significance. Most of the technically most demanding cases are appealed before the Supreme People's Court, whose decision-making is—just like for the top court of most jurisdictions—highly politicised; nevertheless, it is worth noticing that China's patent bodies are routinely sued before Chinese courts (differently from virtually all other state administrations).

On a more sophisticated level, it is also necessary to isolate the actual object of ethical evaluation. To exemplify, in Europe, 'under the morality clause[,] what should be evaluated is the moral conformity of the exploitation of the invention and not the ethical valuation of the form of commercial exploitation of the patent'.[81] Variations of the same principle are applied in China and the US as well, but the distinction presents aspects of obscurity. When it comes to a molecule, the principle would equate to requiring that the recourse to it per se (i.e., its effects *in the absolute*) conforms to public morals, and not just its marketed application as either neuroenhancement or psychiatric treatment—or even off-label medication. But is this interpretation any meaningful in the pharmaceutical domain? It seems to be a clear-cut assessment which admits of no functional discernments or exceptions: if a substance yields, say, five effects, out of which one only is societally dangerous from a moral standpoint, that substance would not be patentable for the other four uses, either. Nor technological embodiments of the substance do matter. What is a *molecule per se* in moral terms? For the time being, this nonsensical barrier almost never is an impediment in practice, but neuroenhancement might revive practitioners' interest in these obsolete and often forgotten tenets.

Of course, while resonating beyond the IP sphere, ethical evaluations performed by patent offices do not preclude the commercialisation of an invention per se, but only its exclusive economic exploitation in the form of patent entitlements.[82] In fact, a patent's 'function is not to grant authorization to introduce a product on the market or to certify quality, nor is it an ethical endorsement of a given technology';[83] this reinforces the preposition that patent law is not the right forum for debating ethical issues concerning psychiatry and enhancement, nor to prevent access to treatment and/or enhancement. In other words, if I am analysing patent law here it is just because, at the time of writing, it seems one of the fields of law which most concretely engage with the "psychiatry versus enhancement"-conundrum.

81 Nordberg, *supra* note 9, 74.

82 See *ibid.*, 66–67.

83 *Ibid.*, 67.

My choice is in no way meant at supporting the idea that patent law is also the most appropriate discipline to inspect such conundrum, and besides legal specialties, these matters should be addressed not regulatorily but legislatively (starting from the constitutional level), possibly with a regional or—even more appropriately—global reach, and supported by a precise political mandate attuned with the citizenry.[84] Upon political direction by citizens, they should be handled by medical expert bodies, possibly integrated with socio-legal and statistics expertise, but definitely not confined to IP bureaucrats' decision-making. No matter their deficiencies, United Nations (UN) agencies should serve in the proper capacity, too.

Sitting well beyond the patent prism, this is more the competence of regional/global health governance than of IPRs per se. Indeed, not only is the fact that patent offices rule on morality not confined to IP: it is not confined to the claimants, either, nor exhausted into a particular society; it shall be placed in context, and its broader impact assessed. In a sense, these rulings can be assimilated to judgements on social rights, which are being regarded with increased interest by scholars for their broader societal implications, besides the specific parties and field of application; those implications are usually defined as social-right judgements' "distributive" or—most recently—"relational" effects—a variation of what economists would define as "externalities". Said rulings influence (or to an extent, even *determine*) who can factually access certain rights, how such rights will be received by and enforced onto communities, and the way the latter will be preserved or disrupted as a result. Relevantly for this paper's purposes, when it comes to the right to health, scholars have argued that case-law from e.g. Brazil and South Africa demonstrates that winning a court case is just the starting point of a journey towards the enjoyment of said right that depends on the different social-balancing considerations delivered by the court together with the mere upholding of one's right. In South Africa, constitutionally guaranteed rights are declaratory in nature: the court is not going to impose their speedy satisfaction, let alone the procedures or protocols through which satisfaction should be realised. Contrariwise, in Brazil, courts use to read

> right-to-health provisions as protecting individually enforceable rights and, where [they find] a violation, grant[] the claimant immediate, individualised relief in the form of the medical treatment that is being sought. […] By interpreting the right to health as an individually enforceable right and granting claimants immediate, individualised relief

84 See also *ibid.*, 68.

> in the form of medical treatments, the [Supreme Federal Tribunal] has presented itself to citizens as an alternative source of those treatments. It has signalled to holders of the right that if (or more likely, when) their government refuses to provide them with a medical treatment that they need, they can turn to the court to obtain it.[85]

This is not necessarily progressive though: litigation is expensive; as a consequence, an alternative reading would ascribe lower standards of equality to Brazilian courts when compared to e.g. their South African counterparts. That is because in South Africa, balancing exercises with state budget apply to everyone, while in Brazil defendants often obtain medical treatment irrespective of costs, but a sort of self-selection of defendants applies insofar as only those who are wealthy enough to afford lawyers for year-long litigation will be granted healthcare through judicial proxy.[86] At any rate, the passage just quoted refers to constitutional-level judgements issued by constitutional-level courts, but the tenet that one can infer therefrom is of salience for almost any judicial or meta-judicial ruling on social rights: their impact extends beyond the parties, and redistributes legal entitlements across segments of population—usually along wealth divides.

Why is this relevant to patent offices? When they deny or grant a patent on morality grounds, they encourage or discourage corporations from pursuing business models and production lines related to certain substances, and they do so by proceeding so far as to interpreting the will of national communities on dilemmas of moral value. True, as I mentioned *supra*, denying a patent does not equate to denying marketisation, but it still impacts the latter to a remarkable extent, while also delivering a value-laden message which resonates beyond the IP arena up to influencing policymakers and thus (geo)political storytelling. Refusing a patent may broaden access to the substance concerned (because its production would not be monopolised by corporations, and medical professionals would be less restricted in prescribing it, particularly across the "Global South"), but it may also long-term restrict such an access because no corporation would be interested in producing and/or distributing it anymore in the market where the patent application was or would have been lodged—not to mention research and development (R&D) on new drugs and some *seriously needed* clinical improvements on existing ones. In fact, several

85 D.A. Vitale, "The relational impact of social rights judgments: A trust-based analysis", *Legal Studies* 42(3) (2022) 1–17, 8.

86 See *ibid.*, 9.

'pharmaceutical companies closed their respective laboratories and rather invested in other fields because of the lack of successes of newly developed compounds resulting in high business risks regarding the introduction of new medications'.[87] As long as policy does not incentivise them to behave otherwise, big pharma will continue to profit out of countless farcical *non-needed* "improvements" on existing substances rather than financing efforts to discover or synthetise new ones 'to find solutions to long unanswered questions'.[88]

On top of all these considerations, one shall never downplay the globalised politics of comity, i.e. the extent to which patent agents, attorneys, health administrations, drug regulators, and so forth form "invisible colleges" which directly or indirectly, purposively or accidentally, sooner or later "socialise" trends and legal reasonings on the international or regional circuit. What this implies in practice is that if the patent office in a "leading" IP jurisdiction rules a certain substance is unpatentable on immorality grounds, other patent offices in "satellite" jurisdictions will likely follow suit, often ideologically, by "socialising" legal reasoning from the centre to the periphery; exceptions to this model do exist, but they remain indeed exceptions. Definitory issues on health products and practices have frequently traversed judicial and quasi-judicial bodies, not exclusively at the constitutional level,[89] originating profound societal repercussions. This is not yet current in neuroenhancement due to the field's relative novelty, so that the implications above are mere hypotheticals for the time being, but there is good reason to assert that wider social-right consequences of decisions at the intersection between neuroenhancing and psychiatric substances will play a major role in healthcare policing over the coming decades.

As a side note, one shall observe that such socialisation bears positive effects as well, not secondarily by discouraging parallel trade in pharmaceuticals. In competition law, parallel trade is defined as the purchasing of products in one jurisdiction to then resell them in other jurisdictions for regulatory (i.e. it cannot be produced there) or economic (i.e. pricing differentiation) reasons, mostly without being authorised to operate that way by the IP owner related to such products.[90] Coherent patent stances mean that lesser incentive exists

87 Schleim and Quednow, *supra* note 1, 1–7, 2.

88 N.A. Thomas, "Secondary Considerations in Nonobviousness Analysis: The Use of Objective Indicia Following *KSR v. Teleflex*", *New York University Law Review* 86(6) (2011) 2070–2111, 2102.

89 Refer e.g. to Vitale, *supra* 85, 14.

90 Check e.g. M.K. Kyle, "Parallel Trade in Pharmaceuticals: Firm Responses and Competition Policy", *International Antitrust Law & Policy: Fordham Competition Law* 13 (2009) 339–358, 339.

for corporations to resell (both online and offline) pharmaceutical products in jurisdictions other than the one(s) granting the patent; they would opt for reselling, for instance, in order to (re)establish a presence in those markets where the previously patented drug has meanwhile expired (or so is its original producer's exclusivity) and risks being replaced by its generic/unlicensed counterparts, and where patent-linkage cannot be pursued.[91] Disincentivising these behaviors—or, more accurately, the need to resort to them—helps reduce the circulation of counterfeited or repackaged products and, most relevantly for our purposes here, helps ensure that a drug sold as patented enhancement in one jurisdiction is not traded in other jurisdictions as non-patented neuropsychiatric substance, or that it is not compulsorily licenced[92] in other jurisdictions for non-intended purposes. In other words, it increases regulatory standardisation trade-wise as well, in compliance with the TRIPS Agreement.[93]

5 Trends in (neuro)Psychiatric Pharmacology

In an effort to reprioritise the human as a *functional indivisible entity*, which is no discount to acknowledging the metaphysical dimension of humans which somehow captures something "higher" than a merely deterministic brain,[94] mental health is increasingly recognised as an essential component of medical

91 For instance, patent-linkage was introduced only extremely recently in Chinese patent law and related judicial-administrative measures. Check e.g. Mark Allen Cohen [柯恒], 'Take Me Out to the Law Game: China's Patent Linkage Doubleheader' (2021) *China IPR*, https://chinaipr.com/2021/07/05/take-me-out-to-the-law-game-chinas-patent-linkage-doubleheader/; B.M. Wexler, M. Zhou, and M. Sperling, 'Takeaways from Recent Implementation of China's Patent Linkage System' (2021) Paul Hastings LLP, https://www.paulhastings.com/insights/client-alerts/takeaways-from-recent-implementation-of-chinas-patent-linkage-system. For some historical background on the legislative process leading to patent linkage in China, refer to B.P. Liu, "Fighting Poison with Poison? The Chinese Experience with Pharmaceutical Patent Linkage", *John Marshall Review of Intellectual Property Law* 11(3) (2012) 623–672.

92 On compulsory licensing in the pharmaceutical industry in public-international-law terms, refer e.g. to J.H. Reichman, "Compulsory licensing of patented pharmaceutical inventions: Evaluating the options", *Journal of Law and Medical Ethics* 37(2) (2009) 247–263; M.A. Bagley, "The Morality of Compulsory Licensing as an Access to Medicines Tool", *Minnesota Law Review* 102(6) (2018) 2463–2495.

93 Read also J. Chen et al., "TRIPS-plus and access to medicines in China", *Journal of Public Health Policy* 34(2) (2013) 226–238.

94 Read also M. Coeckelbergh, "Human development or human enhancement? A methodological reflection on capabilities and the evaluation of information technologies", *Ethics and Information Technology* 13(1) (2011) 81–92, 87.

practice and patients' life, and as a catalyst for or preventive factor against physical illness. It is now accepted, in the jurisprudence of patent bodies as well, that curing one's mind is tantamount to treating one's body: the classic *mens sana in corpore sano* adagio is finding experimental support in neuroscientific studies across all cultures, with the signalling pathways and neural plasticity making it science being gradually declassified. And yet, many implications stemming from this simple statement continue to cause controversy in daily dealings with bureaucracy and one's rights, triggering profound consequences *inter alia* in the legal sphere.

The obsolescence of legal understandings of the human as an all-comprehensively functioning entity comes as no surprise, and draws heavily on shortcomings in the medical science first and foremost. Suffice it to observe *how artificially* distinctions are made between the domains of psychiatry and neurology, with millions of patients falling in between and being rotated from one specialist to another with little clue on what their problem might be. I am referring to multiple disorders which bear both a psychiatric and a neurologic component, first among them the so-called "functional neuropsychiatric disorder" (FND) and rare, unknown, contested, underdiagnosed, or misdiagnosed diseases like chronic fatigue syndrome, fibromyalgia, and further chronic-pain conditions. Alarmingly enough, about one third of the referrals to neurologists end up receiving no diagnosis (and/or no treatment) due to the presence of partly psychogenic neurological symptoms which are wholly or mostly inexplainable through traditional neurological investigation,[95] and that previous medical doctrine would have listed in the psychiatric spectrum under the label of "hysteria" or even dismissed as feigning, malingering, or expressive of Munchausen's syndrome. In fact, functional disorders are a relatively common cause of distress and disability: they account for the second-most common cross-age cause for seeking a neurologist, after migraine but before sleep disorders and degenerative diseases.[96]

Aside from FNDs and other specific disorders, the compenetration of symptoms and diagnoses once categorised as either "mental" or "physical"

95 See J. Stone et al., "Functional symptoms and signs in neurology: Assessment and diagnosis", *Journal of Neurology, Neurosurgery & Psychiatry* 76(1) (2005) 2–12, 2; J. Stone et al., "Symptoms "unexplained by organic disease" in 1144 new neurology out-patients: How often does the diagnosis change at follow-up?", *Brain: A Journal of Neurology* 132(10) (2009) 2878–2888. *See further* L. DoVal Herbert et al., "When neurologists diagnose functional neurological disorder, why don't they code for it?", *CNS Spectrums* 26(6) (2021) 664–674.

96 Check e.g. A.D. Fobian and L. Elliott, "A review of functional neurological symptom disorder etiology and the integrated etiological summary model", *Journal of Psychiatry*

is gaining momentum, up to voicing a true wake-up call for policymakers, medical schools, hospitals' leadership, and health professionals worldwide.

> Scientists now understand, for example, that stress—a psychological factor—can predispose people to Alzheimer's disease and that inflammation—a physical factor—may give rise to depression. In addition, traditional neurological diseases such as epilepsy and stroke are often associated with mood and behavioral disturbances.[97]

Exemplifications are indeed countless, but to mention just one more of them, one of the latest clinical findings in somatised (or somatoform) anxiety-depression research concerns the immune system triggering or exacerbating anxiety physical symptoms via dysfunctional regulation of molecule IL-17 in the brain tissue.[98] This also explains why, in managing psychiatric conditions both legislatively or in the executive domain, technical committees should feature neurologists, too, depending on what their academic background is and how they have been trained clinically.

Coherently, a recent case has been made in literature for the reunification of these two disciplines into what is currently known as "neuropsychiatry"—and, consequently, "neuropsychopharmacology". I call it a *re*unification because their separation is indeed a relatively recent phenomenon, with neurologists and psychiatrists having undergone the same medical training and shared joint careers along most part of the history of modern medicine. Their later divergent paths symbolise the limits (and perils) of today's hyperspecialisation, and is being questioned on more and more grounds as neuroscientific knowledge advances.[99] There are of course organic neurological disfunctions as well as behavioral abnormalities which can still be classically explained and

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& Neuroscience 44(1) (2019) 8–18, 8; K. Bennett et al., "A practical review of functional neurological disorder (FND) for the general physician", *Clinical Medicine Journal* 21(1) (2021) 28–36, 28. In other studies, functional disorders are ranked third, after headache and seizure/epilepsy; refer e.g. to F. Biggin, "Variation in waiting times by diagnostic category: An observational study of 1,951 referrals to a neurology outpatient clinic", *BMJ Neurology Open* 3(1) (2021) 1–8, 3–4; 6.

97 D. Kwon, "Decoding a Disorder at the Interface of Mind and Brain: A mysterious condition once dismissed as hysteria is challenging the divide between neurology and psychiatry", *Scientific American* (2020); https://www.scientificamerican.com/article/decoding-a-disorder-at-the-interface-of-mind-and-brain/.

98 See K. Alves de Lima et al., "Meningeal γδ T cells regulate anxiety-like behavior via IL-17a signaling in neurons", *Nature Immunology* 21(11) (2020) 1421–1429.

99 Other authoritative physicians believe that the two professional domains could be split along the lines of our brain's plasticity: disorders triggered by those components

traditionally addressed, respectively, by neurologists and psychiatrists in a separate fashion, but the wildly underexplored functional universe in between is—and must rebecome—the domain of both specialists, inseverably. Pain management and attention/memory deficits could stand as two obvious examples of necessary interfaces, but as argued, references could be indeed countless. To further remark the extent of current medical cluelessness on these subjects, one can note that 'prescription drugs [are being] used in individuals without a related diagnosable ICD (International Classification of Diseases) or DSM-5 (Diagnostic and Statistical Manual of Mental Disorders 5) defined condition'.[100]

Implanted technologies and non-invasive brain-computer interfaces have gradually stepped in as well,[101] not least in China,[102] including in a do-it-yourself formula.[103] For instance, it was suggested that transcranial direct current stimulation improves subjects' ability to learn by enhancing their visual memory and ability to process symbols.[104] Unsophisticatedly enough, some scholars claim—or report—that brain implants will replace pharmacological treatment in the near future,[105] but I must partly disagree, in that while I concur that this might be the case for certain disorders such as depression and terminal diseases such as Parkinson or Alzheimer, other medical conditions will probably benefit only slightly from such devices. Furthermore, these are extremely complex disorders that, triggered by emotional and behavioral states, show both some disfunction in the electric impulse communication

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whose physiology is immutable (in the course of a lifetime) should be referred to a neurologist, while the psychiatrist should deal with those functions which rely on our brain being plastic and thus normally able to "rewire itself" to adapt to social normalcy in the aftermath of traumatic events or transition periods. Read e.g. V. Andreoli "The complexity of psychiatric nosography and the "simplicity" of molecular genetics", *Journal of Psychiatric Research* 26(4) (1992) 279–284, 282.

100 Daubner et al., *supra* note 7, 2.

101 See generally K.S. Gaudry et al., "Projections and the Potential Societal Impact of the Future of Neurotechnologies", *Frontiers in Neuroscience* 15(1) (2021) 1–8.; H. Maslen et al., "The regulation of cognitive enhancement devices: Extending the medical model", *Journal of Law and the Biosciences* 1(1) (2014) 68–93.

102 At the time of writing, several patent applications for transcranial stimulation systems were under substantial review with China's Patent Office; refer e.g. to application number CN:201880033691:A, submitted on 18 May 2018, number of public announcement CN110662576A as published in CNIPA's website.

103 See generally A. Vexler, "Do-it-yourself and direct-to-consumer neurostimulation", in: I. Bárd and E. Hildt (eds.) *Ethical Dimensions of Commercial and DIY Neurotechnologies* (Elsivier, 2020) pp. 127–156.

104 Refer to Kolber, *supra* note 33, 313.

105 Refer e.g. to Nordberg, *supra* note 9, 79.

and an altered biochemical balance: deep-brain-stimulation and transcranial-magnetic-stimulation techniques can surely assist with the electric component, but will do nothing for the biochemical one. Hence, integrated implant-drug treatment will probably pave the way ahead, particularly in that enormous grey area that sits right in between neurology and psychiatry, and in situations such as drug withdrawal or discontinuation, but also intermittent resistance to drugs and drug-resistant relapse.[106]

What I have elaborated upon so far are the interfaces between neurology and *psychiatry*, but clinical *psychology* plays a pivotal role as well. Faced with patients with psychiatric conditions, physicians tend to address the problem pharmacologically in order to alleviate the physical symptoms or temporarily restore the pre-condition physiological state of the individual concerned—particularly their molecular balance brain-wise. This approach clearly demarcates a watershed between psychiatrists and psychologists, but this is not to say that the two disciplines themselves are mutually exclusive. Quite the opposite holds true:[107] even in the most several cases, behavioral therapy is often advised as a corollary to the intake of medicines, and the World Health Organisation (WHO) itself has spared no efforts in conveying a concept of health as a state of overall wellbeing. In fact, a 'need exists to develop common physical, psychological, and socioeconomic measures of brain health according

106 See also B. Habelt et al., "A Multimodal Neuroprosthetic Interface to Record, Modulate and Classify Electrophysiological Biomarkers Relevant to Neuropsychiatric Disorders", *Frontiers in Bioengineering and Biotechnology* (2021) 9, https://doi.org/10.3389/fbioe.2021.770274; D. Carlson et al., "Dynamically-timed stimulation of corticolimbic circuitry activates a stress-compensatory pathway", *Biological Psychiatry* 82(12) (2017) 904–913; UC Berkeley. 2019. "Wireless 'Pacemaker For the Brain' Could Offer New Treatment For Neurological Disorders". NeuroscienceNews. Retrieved January 2, 2019; 'A pacemaker-like device to treat neuropsychiatric disorders: Neural closed loop actuator for synchronizing phase (nCLASP)' (2018) https://otc.duke.edu/technologies/neural-closed-loop-actuator-for-synchronizing-phase-nclasp/; V. Kremen et al., "Integrating Brain Implants With Local and Distributed Computing Devices: A Next Generation Epilepsy Management System", *IEEE Journal of Translational Engineering in Health and Medicine* (2018) 6, https://dx.doi.org/10.1109%2FJTEHM.2018.2869398; H. Joo et al., "Soft implantable drug delivery device integrated wirelessly with wearable devices to treat fatal seizures", *Science Advances* 7(1) (2021) https://doi.org/10.1126/sciadv.abd4639; P.E. Holtzheimer and H.S. Mayberg, "Deep Brain Stimulation for Psychiatric Disorders", *Annual Review of Neuroscience* 34 (2011) 289–307; J. Sarris et al., "Adjunctive Nutraceuticals for Depression: A Systematic Review and Meta-Analyses", *American Journal of Psychiatry* 173 (2016) 575–587.

107 See also Nordberg, *supra* note 9, 65–66.

to age, sex, and ethnicity, and other relevant characteristics, and to learn how brain health could be enhanced'.[108]

Just like most disorders are accompanied by psychopathological symptoms, there is also a non-negligible socio-emotional component to wellbeing, and it might play out in neuroenhancement policing as well. In our neoliberal societies of performance, where empty star-systems abound, relationships are marketized, and everyone is incessantly assessed according to digitised corporate metrics, some forms of neuroenhancement (such as, indeed, assumingly affordable neuroenhancing pills) could be (in the very near future) factually coerced onto individuals—perhaps disguised as "safety requirements"[109]—in order for them to sustain labour exploitation and "keep going" productively and proficiently with their private lives. Even the few who would refuse to take it initially, would feel eventually compelled to do so in order to escape exclusion, retaliation, dismissal, marginalisation, economic loss, relational detriment, professional downgrading, direct or indirect harassment, and further manifestations of discriminatory, offensive, or even degrading treatment.[110] What this entails is that in such a scenario, a substance which should ordinarily be considered "neuroenhancement" turns out being also therapeutical in an emotional sense, meaning that it prevents the sense of rejection and unaccomplishment that too often accompanies underperformance in our metric- and ranking-based societies. In these instances, therefore, neuroenhancing substances would become a proxy for emotional fitting and thus relative wellbeing (though within a distortive, perhaps even dystopian system), positioning themselves closer to "treatment" than to enhancement per se.

Allegations that forcing neuroenhancers consumption onto individuals (e.g. workers) for competition purposes may induce anxiety disorders,[111] and that parents push their children into said consumption to increase their

108 V. Hachinski et al., "A new definition of brain health", *The Lancet: Neurology* 20(5) (2021) 335–336, https://doi.org/10.1016/S1474-4422(21)00102-2.

109 Read e.g. Nordberg, *supra* note 9, 84; see also R. Vecellio Segate and A. Daly, "Encoding the Enforcement of Safety Standards into Smart Robots to Harness Their Computing Sophistication and Collaborative Potential: A Legal Risk Assessment for European Union Policymakers", European Journal of Risk Regulation (2023) 28, https://doi.org/10.1017/err.2023.72.

110 Check also B.J. Sahakian et al., "The impact of neuroscience on society: Cognitive enhancement in neuropsychiatric disorders and in healthy people", *Philosophical Transactions of the Royal Society of London: Series B, Biological Sciences* 370(1677) (2015); F. Pasquale, "Cognition-Enhancing Drugs: Can We Say No?", *Bulletin of Science Technology & Society* 30(1) (2010) 9–13.

111 Refer to Italian National Bioethics Committee, *supra* note 11, 51–52.

own status and wealth back,[112] are persuasive, but the problem in this case is only superficially about the intake of neuroenhancers. More perniciously, it involves the result-oriented society we live in, its hecticness, performativity, surveillance, insecurity, scientism, hyper-rationalisation, chaotic time-shrinking, coupled with its endless, exhausting, overwhelming, and deregulated demands. In this unhealthy context, if there were no neuroenhancers to take, individuals would still be coerced into cynically and ruthlessly competing with each other both because of our nature as humans and to survive in the neoliberal economic structure underpinning our modern modes of living together. Strategies would turn from pharmacological to other domains, but retain inter-subjective competition as their core thread. What this implicates is that even *not* taking neuroenhancers could cause anxiety disorders related to underperformance: we should probably avoid normalising neuroenhancers to the extent that everyone feels compelled to use them and the bar is raised for everyone, but at the same time, possibly counterintuitively, it may be in the weakest people's interest to "enhance" themselves if they feel they would be left behind otherwise. The reader will appreciate that there are always two sides to these arguments, which is why it is generally appreciable if public regulators take one step back and those who believe to have reasons to avail themselves of neuroenhancers are allowed to do so, as long as it is reasonably demonstrable that this does not endanger public safety or violate fundamental rights of others. Neuroenhancers intake will not *originate* hypercompetitive behaviours: it is merely an expression thereof—one of the unfortunate many; and a symptom of broader societal malaise that strategises pharmacological products as competitive advantages.

In sum, no doubt exists that had we possessed advanced-enough instruments, the pathways of emotion and cognition could be somewhat distinguished physiologically *while complementing each other functionally* and eventually agency-wise as well. Indeed,

> ethical questions in human bioenhancement are only fully intelligible at the level of persons imbued with feelings, thoughts, intentions, desires, values, and abilities, embedded within a particular social context, rather than at the level of pharmacological modulation of particular cognitive or affective capacities which, though conceptually distinguishable, in the embodied context of moral agency are profoundly intertwined. [… S]ince no scientific investigation will reveal "the mind" as an object of empirical study, once one moves from the conceptual to the physical, the putative

112 Refer to O'Connor and Nagel, *supra* note 13, 5.

> distinctions made when talking at the level of the former are inadequate when attempting to map them on to the latter.[113]

Nevertheless, what I am arguing here is that if one tries to distinguish psychiatric treatment from neuroenhancement even on purely physiological grounds for legal (namely IP) purposes, such endeavour will mostly prove frustrating, unscientific, and unreliable. Reality is that even in a supposedly more basic physical sense, we know very little as yet about what "treatment" should entail in these areas of medicine, and a huge percentage of patients are treatment-resistant, still.

To make everything even more tangled, responses are far more diverse and personalised in this area than in virtually any other branches of medicine. It is not just about the general trend of "personalised medicine" that values patients' self-awareness; rather, it stands as a truly specific feature of this medical sub-field. Although *commonly accepted* diagnostic parameters and indicators do exist, such responses might even be culturally mediated (which only adds further layers of complexity) and depend on one's experience and self-reflectivity. No (or too rudimental) objective diagnostic instrument and exam being available, lacking theories that can be empirically tested through scientific methods, and despite the more and more prominent role of psychiatrists' experience in diagnosis, patients' own experiential, subjective self-assessments are still central to both diagnosis and treatment. The effects of antipsychotic medications and other drugs in this realm can only rarely be observed objectively, or the full spectrum of effects will anyway be returned incomplete, so that psychiatrists find themselves bound to rely on patients' own impressions at least in part. It is a matter of dialogue, trust, and trying to trace a "before" and an "after" the problem as accurately as possible; think e.g. of somatisation/conversion disorders and how their *physical* symptoms either they can be observed but not clinically explained through objective exams, or they cannot be observed at all *but patients do genuinely feel them* and become very much frustrated when doctors—not to mention family members, friends, and colleagues—have a hard time believing them.

To sum up, all available evidence points to the unserviceability of confining mental illness to mere socially construed phenomena: while what is considered "normal" or "sane" does change with time and the rubric of mental illness has been indeed abused by several autocratic regimes over history for political

113 G. Pavarini et al., "Smarter Than Thou, Holier Than Thou: The Dynamic Interplay Between Cognitive and Moral Enhancement", *Frontiers in Pharmacology* 9 (2018) 1;9.

reasons,[114] the suffering of psychiatric patients is real. In most cases there must be a precise biochemical disfunction underpinning it; regrettably, our brain-mind complex seems not adamant to disclose the overwhelming majority of its secrets, hence we are not (yet) able to track mentioned disfunctions down or measure them objectively through standardised exams. And in the few cases when we are able to diagnose them objectively, we lack the proper means to treat their biochemical roots as effectively and individually as we would hope.

Capitalising on what we have learnt in this part, let me now dissect and debunk the separation between neuro treatment and enhancement.

6 (Neuro)psychiatric Treatment or Neuroenhancement?

Besides the immorality/unsafety ground to reject the granting of patents, several IP offices worldwide decline to afford patentability to therapeutical *methods* (not to be confused with therapeutical substances per se, such as medical drugs). This is not true for all major IP offices (the US Supreme Court has recently upheld the non-patentability of two diagnostic tools and methodologies,[115] but its holding was based on law of nature or abstract idea,[116] and not on the non-patentability of all therapeutical methods)[117], but it does

114 Refer e.g. to R. van Voren, "Political Abuse of Psychiatry—An Historical Overview", *Schizophrenia Bulletin* (2010) 36(1) 33–35; R.J. Bonnie, "Political Abuse of Psychiatry in the Soviet Union and in China: Complexities and Controversies", *Journal of the American Academy of Psychiatry and the Law* 30(1) (2002) 136–144; A. Schacht, "Power in psychiatry: Soviet peer and lay hierarchies in the context of political abuse of psychiatry", *History of Psychiatry* 33(1) (2022) 21–33; R. Van Voren, "Abuse of Psychiatry for Political Purposes in the USSR: A Case-Study and Personal Account of the Efforts to Bring Them to an End", in: H. Helmchen and N. Sartorius (eds.), *Ethics in Psychiatry: European Contributions* (Springer 2010) 489–507; J.P. Tobin, "Political abuse of psychiatry in authoritarian systems", *Irish Journal of Psychological Medicine* 30(2) (2013) 97–102; C. Heath-Kelly, "Cold War Psychiatry, Extremism, and Expertise: The "Special Committee on the Political Abuse of Psychiatry"", *International Political Sociology* 16(1) (2021); M. Gregg Bloche, "Law, Theory, and Politics: The Dilemma of Soviet Psychiatry", *Yale Journal of International Law* 11(2) (1986) 297–361.

115 See A.K. Rai, "Biomedical Patents at the Supreme Court: A Path Forward", *Stanford Law Review Online* 66 (2013) 111–116, available at: https://www.stanfordlawreview.org/online/biomedical-patents-at-the-supreme-court/.

116 See also R.C. Dreyfuss, J. Nielsen, and D. Nicol, "Patenting nature: A comparative perspective", *Journal of Law and the Biosciences* 5(3) (2018) 550–589.

117 And indeed, the USPTO has recently granted a patent (US11318277B2) for a "[m]ethod and apparatus for neuroenhancement to enhance emotional response" which, based on the description, is evidently to be intended (also) as a therapeutical device.

apply to most of them,[118] for instance the Chinese and European ones. Indeed, Article 25 of the PRC's Patent Law expresses such an exception to patentability; in Europe, too, Article 53(c) EPC contains an exception from patentability for methods for treatment and diagnostic methods. The underlying rationale of Article 53(c) is to avoid hampering access to needed therapeutical methods and protecting physicians' freedom,[119] but it perilously entrusts patent offices with interpretative tasks which exceed the scope of both their skills and mandate.[120] Nordberg notes that under the

> interpretation of the EPO Boards of Appeal, any intervention destined to cure, alleviate, remove or lessen symptoms of, and prevent or reduce the possibility of contracting any disorder or malfunction is considered to be therapy. *The EPO jurisprudence is less clear as far as mental and behavioural disorders are concerned*.[121]

And yet, she stops short of inspecting this matter further. Hence, I am going to perform that task here, but from a different angle: innovativeness.[122] Needless to say, this embodies the pillar of any patent system, as featured in e.g. China's Patent Law under Article 22.

In fact, when it comes to seeking to patent a drug, rejection based on the method-for-treatment ground is almost irrelevant per se: whereas cases where patent applications are lodged to patent new uses (therapeutic methods) of already patented drugs are relatively rare or accommodated as purpose-limited

118 Refer further to O. Mitnovetski and D. Nicol, "Are patents for methods of medical treatment contrary to the *ordre public* and morality or "generally inconvenient"?", *Journal of Medical Ethics* 30 (2004) 470–475; S. Soni and P. Devarapalli, "Patenting Therapeutic Methods: Statutes and Strategies", *Journal of Commercial Biotechnology* 24(2) (2018) 54–58; L.G. Abinader and J.L. Contreras, "The Patentability of Genetic Therapies: CAR-T and Medical Treatment Exclusions Around the World", *American University International Law Review* 34(4) (2019) 705–762; M.H. Davis, "Excluding Patentability of Therapeutic Methods, Including Methods Using Pharmaceuticals, for the Treatment of Humans Under Trade Related Aspects of Intellectual Property Rights Article 27(3)(A)", *Hofstra Law Review* 43(1) (2014) 185–205.

119 Refer to Nordberg, *supra* note 10, 24.

120 Refer generally to S. Sterckx and J. Cockbain, *Exclusions from Patentability: How Far Has the European Patent Office Eroded Boundaries?* (Cambridge University Press, 2012) pp. 135–171.

121 Nordberg, *supra* note 9, 87, emphasis added.

122 This is often referred to as "non-obviousness" compared to the "prior art", according to "those with common knowledge in the relevant field"; I will also use the term "inventiveness" interchangeably. For the two main theories of justification for relying on non-obviousness as a patentability metric, refer to L.G. Pedraza-Fariña and R. Whalen, "A Network Theory of Patentability", *The University of Chicago Law Review* 87(1) (2020) 63–144, 67–73.

claims, what matters instead is classifying a substance as medical drug or enhancement *for the sake of assessing its innovativeness*. I will return to inventiveness in the next section, as the present section is exclusively dedicated to attempting a classification of medical drugs versus neuroenhancement, but just to introduce the problem, suppose you have a molecule which differs exceedingly slightly from another molecule already patented by your competitor. Borderline cases of this sort are all too common in pharmaceuticals and the life sciences more generally, and usually decided along quasi-subjective "plausibility thresholds",[123] or even power politics, lobbying, and revolving doors—although quantifying their impact scientifically is hardly possible. Why would distinguishing between medical drugs and enhancement matter in these borderline cases? One hypothesis I would suggest is that when there is no rigorous scientific criterion by which to conclude that a molecule is "more innovative than not" or the reverse, the teleological narrative it is accompanied by may concur to shaping the outcome of patent granting. That is because if the very similar molecule by your competitor was patented as a medical drug but you seek to patent yours as enhancement, chances are that this purpose-phrased argument makes a stronger case for patentability and shift the case to your favour. This is a supposition that I am going to justify further in the forthcoming section, but the first step is to elaborate on the rationales which may underpin a substance's attribution as "neuroenhancement" or "medical drug".

As a tangential remark, my focus on this matter is not meant to testify my endorsement of its enduring importance: in fact, especially with an outlook on the next decades, I do *not* deem this distinction meaningful in the 21st century; contrariwise, I advocate for its remodulation or suppression, and this article will hopefully clarify why. Truth is, however, that patent law is not prone to be radically rethought any time soon, so that it is transitionally noteworthy to allocate current developments in either box: medical drug (most relevantly here, neuropsychiatric treatment) or enhancement (most relevantly here, pharmaceutical neuroenhancement).

For the discussion to take off, it seems wise to recall that enhancement, by definition, applies to the human body, including our brain in a physical sense but excluding our mind per se;[124] we can find ways to enhance any physical

123 Refer also to A. Clarke, "Is *Dasatinib* Dead?—An Incredible Change to the Plausibility Threshold", *Gill Jennings & Every LLP* (2021), https://www.gje.com/is-dasatinib-dead-an-incredible-change-to-the-plausibility-threshold/.

124 Despite centuries of controversy and hypotheses, the relationship between what is popularly identified as "brain" and "mind" remains one of the most fascinating and insidious neuroscientific problems of all times, and it has indeed represented the subject of intense scholarly scrutiny over the last half a century. Not only clinicians, neuroscientists, and cognitive psychologists, but philosophers, too, stepped in with

component of our body, but when it comes to enhancing our degree of consciousness, emotional intelligence, and spirituality in a metaphysical sense, solutions are unlikely to be delivered in the foreseeable future. What this means is that when one examines techno-scientific enhancement on our nervous system and more specifically on our brain understood in a physical sense, the medical counterpart of it is psychiatric treatment rather than psychological remedies (such as group or individual "cognitive behavioral therapy"). As far as

"classical" pieces *such as* P. Smith Churchland, "A Perspective on Mind-Brain Research", *The Journal of Philosophy* 77(4) (1980) 185–207. The debate mostly revolves around the supposedly dualistic nature of mentioned relationship, or around which party should claim agency, dominance, "emergence", "production", "assembly", or primacy over or from the other, and so forth. I have neither the competence nor the aspiration to contribute to this debate here. I will confine myself to noting that because our knowledge base of the physiology of our brain does not (yet?) account for the complexity of our behaviours, responses, thoughts, emotions, self-perception, and instincts, a discussion on the interfaces between those and the "brain as such" does have merit. The nomenclature is wide, ranging from "brain and consciousness" to "brain and subjectivity" and indeed "brain and mind"; it is a specification of the somewhat wider "mind-body problem", but it differs slightly from another debate, the lawyering one on "reason and emotion" (refer to R. Vecellio Segate, "Navigating Lawyering in the Age of Neuroscience: Why Lawyers Can No Longer Do Without Emotions (Nor Could They Ever)", *Nordic Journal of Human Rights* 40(1) (2022) 268–283), wherein the focus is rather on physiology versus effect complexity: however one puts it, it is all about the brain as an organ or (again, the brain?) as the site where our gestures and thoughts seem to somehow take shape. Out of dizzyingly exhaustive and interdisciplinary research on the subject, *refer for instance to* E.T. Rolls, "On the Relation between the Mind and the Brain: A Neuroscience Perspective", *Philosophia Scientiae* 17(2) (2013) 31–70; S.L. Satel and S.O. Lilienfeld, *Brainwashed: The Seductive Appeal of Mindless Neuroscience* (Basic Books, 2015); M. Bertolero and D.S. Bassett, "How the Mind Emerges from the Brain's Complex Networks", *Scientific American* (2019), available at: https://www.scientificamerican.com/article/how-the-mind-emerges-from-the-brains-complex-networks/; S. Grossberg, *Conscious Mind, Resonant Brain: How Each Brain Makes a Mind* (OUP 2021); C.E.V. Mahy et al., "How and where: Theory-of-mind in the brain", *Developmental Cognitive Neuroscience* 9(1) (2015) 68–81; S.A. Greenfield, "Mind, brain and consciousness", *The British Journal of Psychiatry* 181(2) (2002) 91–93; E.T. Rolls, "A Neuroscience Levels of Explanation Approach to the Mind and the Brain", *Frontiers in Computational Neuroscience* 15 (2021) 649679; E.V.C. Friedrich et al., "Mind over brain, brain over mind: Cognitive causes and consequences of controlling brain activity", *Frontiers in Human Neuroscience* 8(348) (2014); J. Jamieson Carswell Smart, "The Mind/Brain Identity Theory", in: E.N. Zalta and U. Nodelman (eds.), *The Stanford Encyclopedia of Philosophy* (Stanford University, 2022); E.M. Gordon et al., "A somato-cognitive action network alternates with effector regions in motor cortex", *Nature* 617(4) (2023) 351–359; L. Feldman Barrett, *How Emotions are Made: The Secret Life of the Brain* (Macmillan, 2017); R.M. Sapolsky, *Determined: Life Without Free Will* (Penguin, 2023); J.M. Schwartz and S. Begley, *The Mind and the Brain: Neuroplasticity and the Power of Mental Force* (Harper, 2003); R,M. Shiffrin et al., "The brain produces mind by modeling", *PNAS: Proceedings of the US National Academy of Sciences* 117(47) (2020) 29299–29301; L. Feldman Barrett, "The Future of Psychology:

our brain is concerned, pharmaceutical neuroenhancement basically translates into neuroactive substances, such as the molecules in a pill. The medical side of it currently falls in the realm of psychiatry—or, as argued *supra*, in that of neuropsychiatry, which encompasses neurological expertise as well. Needless to say, interfaces with psychology are still worth mentioning, and indeed 'the medical and scientific community is not unanimous in defining frontiers between medical conditions, personal taste and inclination or personality traits'.[125] However, I will consider psychological aspects only as long as they are or could be curable in a physical sense through (neuro)psychiatric—or at least combined (neuro)psychiatric-psychological—intervention.

What substances am I referring to? Drawing on a most recent scientific literature review,[126] these are mainly purines, methylxanthines, phenylethylamines, modafinil, nootropics, antidepressants (such as selective serotonin reuptake inhibitors), but also benzodiazepines, β-adrenoceptor antagonists, acetylcholinesterase inhibitors, and cannabis. Others may soon join the list, of course, and indeed several new substances are being clinically trialled as I write. Most of these substances are popularly known as either abuse drugs[127] or treatments for anxiety-depression disorders, sleep disorders, neurodegeneration, narcolepsy, schizophrenia, bipolar/cyclothymic and multiple personality disorders, and dementia, but they can in fact be recruited as neuroenhancers and general psychostimulants as well—just like caffeine/theine, nicotine, and alcohol, but more powerfully (and carrying far more disturbing side-effects).[128] From a medical standpoint, the predominant pharmacodynamic target structures of these substances comprise the noradrenergic/dopaminergic, orexin, and cholinergic receptor/transporter systems, as well as adenosine, serotonin, and glutamate receptors. Indeed,

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Connecting Mind to Brain", *Perspectives on Psychological Science* 4(4) (2009) 326–339. The peer-reviewed journals *Brain and Behavior* and *Neuropsychoanalysis* are also an excellent reference sources on the matter.

125 Nordberg, supra note 9, 66.

126 Read Daubner et al., *supra* note 7, 8–19.

127 That of "abuse" is a non-scientific and often misleading term, which is why the 11th revision of the WHO International Classification of Diseases and Related Health Problems for Mortality and Morbidity Statistics (ICD-11), released in January 2022, rather employs the "harmful patterns of use"-formula. This is meaningful as it more explicitly shifts the focus from the substance per se to the way it is used.

128 Refer further to A.G. Franke and K. Lieb, "Pharmacological Neuroenhancement: Substances and Epidemiology", in: E. Hildt and A.G. Franke (eds.), *Cognitive Enhancement: An Interdisciplinary Perspective* (Springer, 2013) pp. 17–28; D. Repantis, "Psychopharmacological Neuroenhancement: Evidence on Safety and Efficacy", in: E. Hildt and A.G. Franke (eds.), *Cognitive Enhancement: An Interdisciplinary Perspective* (Springer 2013) pp. 29–38.

> [w]hile pharmacological enhancers are typically designed to affect or mimic certain neurotransmitters, also neural signaling molecules themselves such as adrenaline, GABA [receptors], glucocorticoids, ovarian hormones, and different neuropeptides have been suggested as cognitive enhancers.[129]

Having clarified what the substances at stake are (or might be, also depending on the applicable jurisdiction), the tougher task is to attempt a distinction between *their employment as* either enhancement or medication. What criterion should be adopted to operate such a distinction? Prior to attempting any answer, it should be disclaimed that a patent application might well incorporate both medical and neuroenhancing purposes. That was the case in the example that follows before the US Patent and Trademark Office:

> In one aspect of the invention, the medicament is for use in preventing or treating nerve cell death or damage. In one aspect of the invention, the medicament is for use in neuroprotection. In one aspect of the invention, the medicament is for use in regeneration of nerve cells. […] In one aspect, the medicament is for use in preventing or treating a neurological or a psychiatric disease. In one aspect of the invention, the medicament is for use in preventing or treating a disease selected from the group consisting of a neurological disease, a preferentially neurodegenerative disorder […]. Another goal of [the] present invention is the use of the compounds […], and pharmaceutically acceptable salts and prodrugs thereof, as neuroenhancing drugs[,] or the[ir] use for manufacturing neuroenhancing drugs. Neuroenhancing drugs include those that improve learning and memory, attention, mood, communicative skills[,] and sexual performance. Examples of neuroenhancing drugs are those that target long-term synaptic potentiation (LTP) or long-term depression (LTD), modulation of calcium channels, or the cAMP response element-binding (CREB) protein. […] Particular examples of neuroenhancing drugs are phosphodiesterase inhibitors like rolipram; donepezil;

129 M. Dresler et al., "Hacking the Brain: Dimensions of Cognitive Enhancement", *ACS Chemical Neuroscience* 10 (2019) 1137–1148, 1139. For a dissertation on the reasons why neurotransmitters are considered key to the pathogenesis of neuropsychiatric disorders (but whose "retuning" or "rebalancing" might well also serve neuroenhancing purposes), *see* B.E. Leonard, "Neurotransmission and Mechanisms of Drug Action", in: P.M. Haddad and D.J. Nutt (eds) *Seminars in Clinical Pharmacology* (Cambridge University Press, 2020) pp. 69–123.

> agonists of the NMDA glutamate receptor like D-cycloserine; ampakines; modafinil; methylphenidate.[130]

This double nature, however, does not and cannot mean that the two purposes are interchangeable, nor is it the same as to say that the two ordinarily feature together in the same application, or that the divergent narratives an applicant may craft around the two purposes have no bearing on lodging a successful application (and/or on defending it in post-grant litigation, where applicable).

Is the distinction all about permanent effect, with enhancement supposedly producing lasting—up to being transmissible reproductively, from a phenotype to a genotype expression—change? In this event, if one considers 'the brain as a dynamically adapting interface between the changing environment and the biological self',[131] what about physiological accommodation (not necessarily in its negative connotation as "addiction")? Should it not be considered a form of "permanence" as well? In addressing permanence, one shall decide whether to consider a substance's application or its effects. Arguably, the first applies to technological appliances which might permanently be installed into or interact with our non-enhanced bodies, but effects are more relevant when talking about substances, and they might last even after the intake. And yet, when psychiatric treatment cures a patient in a more or less definitive fashion and they feel better long-term, that does not imply any difference with neuroenhancement, therefore permanence does not sound like a valid distinctive criterion. One might stretch the concept very far by debating whether the meaning of "permanence" would invest the intervention's intergenerational transmissibility; of course, this is primarily a concern with gene editing as a form of enhancement, but the effects of substances are not completely immune from reproductive transmissibility (think e.g. of pregnant women whose dietary and medical intakes may cause alterations in the foetuses, who would later in life reproduce and possibly transmit some of those altered traits, even through phenotypical accommodation). Alternatively, is it the underlying condition motivating the substance's use (as opposed to the latter's effect) that has to be "permanent"? This inspection sounds theoretically fascinating, but it, too, would feature no useful or scientifically definable demarcation.

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130 Submission by P. Villoslada and A. Messeguer, Publication No US2012/0052094A1, dated 1 March 2012 [Agonists of Neurotrophin Receptors and Their Use as Medicament], paras. 0017;0132–0133.

131 B.L. Ganzel, P.A. Morris, and E. Wethington, "Allostasis and the human brain: Integrating models of stress from the social and life sciences", *Psychology Review* 117(1) (2010) 134–174, 134.

Once permanence is discarded, the next candidates are intentionality and/or predictability. I am not sure which one between the two would carry more predictable outcomes for the individuals concerned and humanity as a whole, but in either case, the gap between intent and result might prove remarkable; this is problematic as while intentions, to an extent, might be policed pre-emptively, actual outcomes cannot be addressed by policy or law, if not retrospectively. In fact, while these substances can be tested on reasonably large pools of humans and their effects generally discerned, individual variability in this field is peculiarly frustrating: for any specific person, a substance might be more of a treatment than about enhancement (and vice versa). This is not to mention that psychiatric treatment *applied to already* (*but not necessarily cognitively*) *enhanced humans* might bear unprecedented and unpredictable effects, both positive and (arguably most often) negative. Even in the few cases where a substance's effects on neuropsychiatric populations are fully understood, expecting any enhancing outcome on healthy subjects is fallacious reasoning,[132] and the effects on already enhanced humans would be even more obscure. On a more general take, pharmaceutical sciences are becoming so complex that virtually no one is possibly able to forecast all possible effects of a product apart from their developers (and not even), so that patent offices must accept this unfortunate limitation and acknowledge that the right to contend scientific arguments does not fall squarely into their hands.[133] While it is a longstanding truth of pharmaceutical R&D that the precise mechanism of action and/or all possible physiological effects of a particular drug are often unknown to developers (not to mention sellers and prescribing physicians) themselves, complexity and "obscurity" are arguably on the rise due to the combined effect of *inter alia* AI drug discovery and development, unfettered competition from once-"developing" countries (now "frontier" or even "emerging" manufacturing and service markets for pharmaceutical and para-pharmaceutical products), and neurodiversity-phrased claims, along with more demanding societal expectations on immediacy and efficacy for a spectrum of users which had never (overtly) been as wide, exigent, and diverse. Wisely, the EPO has already dismissed the (expected) intention of the user as a ground for appreciation in patentability decisions; however, it did so by distinguishing 'between methods bearing an additional therapeutic effect clearly distinguished from the claimed non-therapeutic use, and methods in which the claimed non-therapeutic use is inevitably and inextricably linked to

132 See also Schleim and Quednow, *supra* note 1, 20 3.

133 Read further S.B. Seymore, "Patently Impossible", *Vanderbilt Law Review* 64(5) (2011) 1491–1544, 1518–1523.

a therapeutic effect'.[134] While I join the EPO in admitting that user intention is a slippery-slope metric by which to appraise patentability, I submit that the EPO's reasoning behind this non-acceptance, i.e. the just-quoted distinction, is meaningless or unfeasible when trying to distinguishing between psychiatric treatment and neuroenhancement: virtually all of them would fall in the second category identified by EPO. Rather, I deem (unsupervised) user intention to be a risky ground because it might fluctuate over time (especially within the psychiatric population), but even more compellingly due to the unpredictability of these substances' effect spectrum.

What if the distinction was about users' focus, i.e. the intensity of their objectives? A moderately safe substance may be taken out of a precise intended outcome, or more casually to try and see what its effects are and whether one will feel or perform better after intake. This premise is, however, problematic:

> [w]hat matters for ethics is not so much what the technology does to our brains, minds, or bodies but rather what it enables us to do, how it impacts [...] capabilities we have as humans [...] living in a particular societal, cultural, and technological context.[135]

This means that neuroenhancement, and not only psychiatric treatment, *should* bear intended outcomes as an *ex ante* qualifying element.

Might the distinction have to do with individual versus societal benefits? After all, psychiatrically treating mentally ill patients is beneficial for the wider society as well. Notwithstanding this, also enhancement carries societal benefits when rather than making us compete more, it makes us more humane, euphoric, solidaristic, etc., or e.g. if it prevents serious defect at birth and reduces the chance of future illness, thus optimising care and reducing pain without burdening welfare systems. In fact, '[h]uman enhancement does not need to be only about high-technological interventions for a selected group of individuals; rather, it should be a continuous project aiming to include everyone and maximize the public benefit'.[136] Here, a point of controversy is that this approach brings the problem back to a neoliberal logic (and lexicon) of "maximisation" which tends to assume that everyone agrees on what the ultimate objectives pursued through public policing should be; in practice, though, both what is to be maximised and what can be neglected stem from

134 Nordberg, *supra* note 10, 24.

135 Coeckelbergh, *supra* note 94, 81–82, two emphases removed.

136 L.Y. Cabrera, "Reframing Human Enhancement: A Population Health Perspective", *Frontiers in Sociology* 2(4) (2017) 1.

élite-driven bottom-down preferences propagandised among and enforced onto all others—often in a patronising manner—for "their best". I subscribe to the advice of those who warn against atomising the access to and use of neuroenhancement, but at the same time it is essential to reckon that public objectives are non-rarely misappropriated by oligarchic configurations of plutocratic corporate-state power which do not necessarily coincide with any common consensual stance—nor even with majority consensus.

One more potential distinction involves the need for prescription and/or supervision and, relatedly, the strength of these substances' effects depending on consumption modes and habits. And yet, when applied to certain vulnerable segments of society and exceeding a given dosage, all substances display contraindications and induce high risks for individuals and societies alike. Would it be truly feasible for the line to be drawn in relation to any substance's intake dosage or intended users? The deficiency in answering in the positive would lie with evidence that most substances have different effects on different people (due to concurrent treatment and/or depending on their personal/family medical history, or even along ethnical, racial, genderised lines) more than they have upon different dosages per se. Classifying a substance as treatment or enhancement based on its dosage seems insufficient across a considerable number of scenarios. Answering in the positive would also make one wonder what authority would be entrusted with enforcing those limits on dosage and intended addressees. By all means, this would turn to a problem of product and professional liability instead of patent law.[137]

Because none of the aforementioned distinctions alone is satisfactory, distinguishing between medication and enhancement might rather be a functional matter of restoration and re-setting (the former) versus advancement/improvement (the latter). This, too, turns out to be an unfortunate circle whereby distinguishing between restorative and enhancing effects is anything but straightforward. Not only is this problematic across all neuroenhancing solutions, but it reads particularly problematic vis-à-vis pharmacological neuroenhancement, as the classification would swing not simply in accordance with the evolution of the relevant technology/science (which holds plausibly true for all forms of neuroenhancement), but depending on significant degrees of individual variability, too. What for one represents thorough "wellbeing" or "wellness", for another might barely feel bearable as a state of bottom-line non-illness; somewhat, this makes sense by scientific accounts of human diversity, as we all live by different thresholds for pain tolerance, discomfort, pleasure,

137 Under e.g. US law, refer to J. Husgen, "Product Liability Suits Involving Drug or Device Manufacturers and Physicians: The Learned Intermediary Doctrine and the Physician's

sensorial accuracy, etc., as well as by uneven appreciations of what "therapy" is and should be all about. In the neuropsychiatric field, these thresholds are also sensitive to age as a marker of functional decay which is, however, to an extent physiological, so that a substance which would reverse or delay such physiological (as opposed to pathological) decay could stand in either camp as enhancement or treatment, depending on one's standpoint. Indeed, scholars have proposed 'a definition of brain health in adults as a state of complete physical, mental, and social wellbeing *through the continuous development and exercise* of the brain'.[138]

In any case, psychiatric disorders are not so much about fixed thresholds and objective quantitative parameters, as they are about a "before" (normalcy) and an "after" (clinical condition) *relative to the patient*, whereby the "after" is identified as inconvenient by the patient and plausibly corresponds to some alteration in their brain's chemistry which we are currently unable to track down and measure scientifically. Variability (i.e. non-generalisability) is further contentious in clinical neurosciences in that it entails causality and replicability issues in turn: if individuals' responses to a given substance are *this* variable, one consequence is that studies performed on a certain cohort are not only hardly generalisable (which means statistics have low applicability value to concrete cases), but also aleatory, correlational, and hardly replicable, as too many variables would need to be taken into account in selecting subjects for a causality-confirming comparable cohort. This also makes it unviable for a patent office to apply analogical reasoning from the (known) effects of a substance to another when they are supposed to treat

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Duty to Warn", *Missouri Medicine* 111(6) (2014) 478–481; J.E. Grant, "The "Misuse" Defense in Drug Products Liability Cases", *Pace Law Review* 8(3) (1988) 535–570; S. Garber, "Economic Effects of Product Liability and Other Litigation Involving the Safety and Effectiveness of Pharmaceuticals" (RAND, Institute for Civil Justice, 2013) https://www.rand.org/content/dam/rand/pubs/monographs/MG1200/MG1259/RAND_MG1259.sum.pdf; J.C. Vivian, "Federal Preemption of States' Drug Product Liability Laws DOA: FDA Labeling Regulations Are Floors, Not Ceilings", *U.S. Pharmacist* (2009), https://www.uspharmacist.com/article/federal-preemption-of-states-drug-product-liability-laws-doa; L. Noah, "This Is Your Products Liability Restatement on Drugs", *Brooklyn Law Review* 74(3) (2009) 839–926; K.J. Stoffelmayr, "Products Liability and "Off-Label" Uses of Prescription Drugs", *University of Chicago Law Review* 63(1) (1996) 275–306; T.J. Philipson, E. Sun, and D. Goldman, "The Effects of Product Liability Exemption in the Presence of the FDA", in: D.P. Kessler (ed.), *Regulation vs. Litigation: Perspectives from Economics and Law* (University of Chicago Press, 2010) pp. 137–163; A. Bernstein, "(Almost) No Bad Drugs: Near-Total Products Liability Immunity for Pharmaceuticals Explained", *Washington and Lee Law Review* 77(1) (2020) 3–96.

138 Hachinski et al., *supra* note 108, emphasis added.

the same disorder or enhance a "similar" cognitive ability. All the more so in this field: 'neuroenhancement epidemiological follow-up studies are difficult to set up'.[139] On the whole, variability entails that as odd as it might read from a regulatory and medical perspective, most beneficial and collateral effects of neuroactive drugs (especially in the long run, and when addiction intervenes) are only discovered once enough subjects/patients have gotten to try them, because no feasible clinical trial would ever offer a sufficiently representative testing sample beforehand.

Let me now amend the question slightly. Rather than pondering on what criterion marks the distinction between medication and enhancement, I will elaborate on what conditions need to be in place for any distinction—whatever its grounding criterion—to be redefined over time in line with changing medical discoveries, theories, and approaches (which might simply overlap with accommodation in medical practice). As an example, it was noted that '[s]timulant drugs such as methylphenidate and mixed amphetamine salts[,] commonly used to treat attention deficit hyperactivity disorder [(ADHD),] may also enhance attention in healthy subjects'[140]—and to that end they are massively (and lawfully) used by German and UK students for instance,[141] also as a result of peer-pressure.[142] These drugs are used by non-patients with either enhancing or recreational purposes also in countries such as the Netherlands, Ireland, Switzerland, and the US, although—defying pessimistic predictions by many—prevalence statistics have remained relatively stable.[143] By any account, the dual-use nature of stimulant drugs is of limited help in delineating boundaries, as medical practice has recently witnessed a spike in ADHD diagnoses, and the curve seems in its ascending part still, so that many subjects once considered within the normality spectrum would be now

139 National Consultative Ethics Committee for Health and Life Sciences (France), Opinion No. 122 on 'The Use of Biomedical Techniques for "Neuroenhancement" in Healthy Individuals: Ethical Issues', 12 December 2013, https://www.ccne-ethique.fr/sites/default/files/publications/ccne.avis_ndeg122eng.pdf, 10.

140 Nordberg, *supra* note 9, 82.

141 Read for instance S. Sattler and C. Wiegel, "Cognitive Test Anxiety and Cognitive Enhancement: The Influence of Students' Worries on Their Use of Performance-Enhancing Drugs", *Substance Use & Misuse* 48(3) (2013) 220–232; I. Singh, I. Bárd, and J. Jackson, "Robust Resilience and Substantial Interest: A Survey of Pharmacological Cognitive Enhancement among University Students in the UK and Ireland", *PLOS One* 9(10) (2014).

142 See e.g. I. Bárd et al., "Bottom Up Ethics: Neuroenhancement in Education and Employment", *Neuroethics* 11(3) (2018) 309–322, 311.

143 See Schleim and Quednow, *supra* note 1, 4.

diagnosed with at least mild ADHD.[144] This holds true for other psychiatric disorders as just as alarmingly, whose increased diagnosis owes to complex sociological and lifestyle explanations, but also to aging and autorecovery pessimism.[145] Compared to previous generations, we also probably tend to hold ourselves to higher standards of health checking and as-perfect-as-possible wellbeing,[146] whether out of a genuine sense of personal urgence, or because society requires us to top our best performance in the workplace as well as family life in order to stay afloat and not be mechanically replaced in the unforgiving professional and relational markets respectively.[147]

Moreover, with regards to amphetamine-based treatments for ADHD, it was stressed that for pharmaceutical trials to stand less prone to bias, longer-term studies are warranted, in order to capture potential side-effects which short-term studies often ignore or downplay.[148]

Besides any rhetoric in the field, no question exists that the distinction between medication and enhancement is a dynamic rather than a settled one, susceptible to change over both individual traits and doctrinal findings—and even cultural revolutions. Once the unavoidability of these changes is taken for granted, the follow-up question concerns the typologies of changes which one should reasonably expect and accept in this domain. Are they doctrine-driven, technology-enabled, or both? One example from the US is due here. That of patents granted to psychiatric drugs is a relatively recent history tracing back to the second half of the XX century; while most patents were initially released for anxiety treatments, medical classification of anxiety "sophisticised" to the point that "anxiety" was split into several disorders,[149] including generalised anxiety disorder but also subsets of depressive, maniacal, and dissociative ones. This illustrates the difficulties in keeping with slogans and definitory exercises that easily become obsolete, and points to the inconvenience of granting or

144 See further I. Singh et al., "Globalization and Cognitive Enhancement: Emerging Social and Ethical Challenges for ADHD Clinicians", *Current Psychiatry Reports*15(9) (2013).

145 Read further H. Häfner, "Are mental disorders increasing over time?", *Psychopathology* 18(2) (1985) 66–81; Daubner et al., *supra* note 7, 4.

146 See e.g. *ibid*., 16.

147 Check also M.J. Sandel, "The Case Against Perfection: What's wrong with designer children, bionic athletes, and genetic engineering", *The Atlantic* (2004), https://www.theatlantic.com/magazine/archive/2004/04/the-case-against-perfection/302927/; D. Masci, "Human Enhancement: The Scientific and Ethical Dimensions of Striving for Perfection" (2016) Pew Research Center, https://www.pewresearch.org/science/2016/07/26/human-enhancement-the-scientific-and-ethical-dimensions-of-striving-for-perfection/.

148 Refer e.g. to Schleim and Quednow, *supra* note 1, 3.

149 Read further at ktMINE 2019, *supra* note 31.

refusing patents due to a substance's *current* use alone. What is more, modes of feeling and relating may change as well, shifting our conception of what is "standard", normal", or even "healthy" and "sane".[150] For instance, it might 'be questioned whether an enhanced being, [e.g.] a being with infrared vision, telepathic abilities[,] or with [their] brain directly connected to a network of computers, would deviate sufficiently in [their] interaction with the environment and society to be considered non-human',[151] or whether such a "human" would ever need psychiatric rehabilitation at all. Phrased otherwise, psychiatry might even become selectively obsolete, that is, unnecessary for some of the new "humans" populating our (by then hybrid) societies while still sought after by the "old" ones.

If doctrine or practice remodulates the connotation of a substance, it would be essential to have a mechanism in place for patent offices to apply patent law retroactively upon consulting with health agencies and other regulatory authorities. In the US, patent offices can revoke patents already issued with relative ease, while in China—and one might say "civil law" jurisdictions more generally—a post-grant patent invalidation procedure does feature in the Patent Law but is triggered more cautiously, in observance of the non-retroactivity principle. The rationale of non-retroactivity lies with protecting investments and ensuring regulatory predictability, although it might not be the most convenient hurdle to face in this politically and medically sensitive area of law. Neither can patent legislation be retuned prospectively: it is non-flexible before scientific change, meaning that the duration of any patent greatly exceeds potential advances in medical science,[152] including reclassification of a substance as "treatment" or "enhancement" based on new beneficial effects or side-effects being discovered. This should prompt a revision of patent codes aimed at either reducing the patent duration or providing mechanisms for science-based reassessments of patents *ex post* as needed; and in any case, it should urge to consider forecasts on the near/mid-term future when deciding on whether a patent should be granted. At present, patent applicants are only being advised

> to be circumspect with respect to positions taken that may potentially later be contradicted in data submitted to the [relevant drug regulatory authority], such as by data being gathered during preclinical or clinical

150 Refer to Nordberg, *supra* note 9, 60.

151 *Ibid.*, 63.

152 See also Nordberg, *supra* note 10, 25.

> studies that are ongoing or in the future at the time the patent application is filed[,][153]

while when it comes to prospected neuroenhancing uses, a system of cyclic re-examination would be worth considering.

On a different note, '[e]vidence suggests that off-label prescriptions for neuroenhancement and prescription drug misuse are gradually increasing in both adult and pediatric populations'.[154] From an IP policy perspective, it would be advisable to contribute towards countering this phenomenon through the issuance of clear guidance on how neuroenhancement should be reported in patent applications. Once again, the assumed or actual watershed between enhancement and treatment, particularly the psychiatric one, becomes of the essence, and explanatory frameworks in the patent field might bear repercussions on long-standing shortcomings in public safety and health policing.

One inquiry which is left for further research may investigate what the nature of psychiatric-treatment needs for posthumans will be, if any at all. Indeed, when appraising substances and uses here as either psychiatric-therapeutical or enhancing, I have assumed the current *Homo sapiens* as the starting point, but the transhuman (at times called *homo chimaera*) might express their own psychiatric needs, which should be evaluated in their own right once the qualification of "transhuman" has become clearer.

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153 S. Arora et al., "The Interplay between FDA and Patent Law: Infusing Organizational Knowledge for Medical Device Companies", *William Mitchell Law Review* 39(4) (2013) 1176–1206, 1193.

154 W.D. Graf et al., "Pediatric neuroenhancement Ethical, legal, social, and neurodevelopmental implications", *Neurology* 80(13) (2013) 1251–1260, 1251. And indeed, psychotropic therapy is often marketised and sold off-label as neuroenhancement; see H. Siipi, "Is Neuroenhancement Unnatural, and Does It Morally Matter?", in: J. Giordano (ed.), *Neurotechnology: Premises, Potential, and Problems* (CRC Press, 2012) pp. 199–212, 199; I. Singh and K. Kelleher, "The Case for Clinical Management of Neuroenhancement in Young People", in: A. Chatterjee and M.J. Farah (eds.) *Neuroethics in Practice: Medicine, Mind, and Society* (Oxford University Press, 2013) pp. 16–34, 26–28; E.A. Moore, *The Amphetamine Debate: The Use of Adderall, Ritalin and Related Drugs for Behavior Modification, Neuroenhancement and Anti-Aging Purposes* (McFarland, 2011) p. 202; R. ter Meulen, A. Mohammed, and W. Hall, *Rethinking Cognitive Enhancement* (Oxford University Press, 2017), 63; R.M. Julien, C.D. Advokat, and J.E. Comaty, *A Primer of Drug Action* (Worth, 2010) p. 417; S.G. Hofmann, E.A. Mundy, and J. Curtiss, "Neuroenhancement of Exposure Therapy in Anxiety Disorders", *AIMS Neuroscience* 2(3) (2015) 123–138, 130.

7 A Selected Survey of Practical Implications

As introduced in the previous section, the degree of inventiveness is a topical problem in pharmaceutics as most patents being sought for new drugs appear to be fundamentally based on previous drugs as already known treatments, and improve on them only marginally—this becomes, in fact, a form of "patent evergreening" or "product hopping".[155] This case does not exactly correspond to the so-called "second medical-use claim", also available in China,[156] whereby a patent is sought for a newly discovered application of an already patented substance originally approved to treat another disorder[157]—second-use patents with no appreciable alteration of the product are granted upon presumption that the remarketisation of the relevant substance will entail significant costs for clinical trials, approval bureaucracy, and investments for internationalisation.[158] Conversely, the borderline situation I am describing here does encompass minor changes in the substance concerned. Suppose you have synthetised a molecule 0.000001% different from your direct competitors' antianxiety one and you wish to patent it as an antidepressant: this difference in narrative might matter in the eyes of examiners for leaning towards patentability rather than rejection, as well as for dispelling subsequent objections that the claims on which the patent was based were

155 Refer extensively to F. Papadopoulou, *Evergreening Patent Exclusivity in Pharmaceutical Products: Supplementary Protection Certificates, Orphan Drugs, Paediatric Extensions and ATMPs* (Bloomsbury, 2021). Check further K.T. Richards, K.J. Hickey, and E.H. Ward, "Drug Pricing and Pharmaceutical Patenting Practices", U.S. Congressional Research Service (2020) R46221, https://sgp.fas.org/crs/misc/R46221.pdf; M. Balasegaram, M. Childs, and J. Arkinstall, "The Fight for Global Access to Essential Health Commodities", in: G.W. Brown, G. Yamey, and S. Wamala (eds.), *The Handbook of Global Health Policy* (Wiley, 2014) pp. 245–266, 258.

156 X. Chen and H. Liu, "Clarifying the patentability of medical use inventions in China", *AWA Point* (2020), https://awapoint.com/clarifying-the-patentability-of-medical-use-inventions-in-china/.

157 With all probability, the most celebre Chinese case in this respect is that concerning Viagra; refer e.g. to Y. Liu, "The Tale of Viagra Patents: Comparative Studies of the Global Challenges in China and Other Countries", *Journal of Intellectual Property Rights* 18(6) (2013) 523–533.

158 See further M. Bhagwat et al., "Second Medical Use Patenting: A Review of Practices Across Different Jurisdictions", *Journal of Intellectual Property Rights* 21(4) (2016) 260–264; P. England, "Infringement of second medical use patents in Europe and the Unified Patent Court", *Journal of Intellectual Property Law & Practice* 11(6) (2016) 426–434; O. Butriy, "The interpretation of second medical use claims and the indirect nature of their infringement", *Journal of Intellectual Property Law & Practice* 13(1) (2018) 61–67; I. Agranat and H. Marom, "In Defense of Secondary Pharmaceutical Patents in Drug Discovery and

inherently anticipated by other applications. By analogy, this result will be reached even more probably if a molecule which is patented as psychiatric treatment (for whatever disorder) is then modified by an inappreciably slight margin but rephrased as enhancement—in this case, the two molecules not being both addressed to the medical arena, you would not even risk to satisfy the therapeutical-method exception to patentability. In other words, in those borderline scenarios, where patent offices have no clue on how to proceed, i.e. no solid scientific evidence or definitive legal means to resolve the dispute without being unfair to one of the parties, applicants' narrative will plausibly help shape the outcome of their decisions, despite "purpose" being only slightly relevant in this field and boundaries between medication and enhancement being at best contested. This represents one more reason to reiterate that when it comes to intervening on the electrochemical balance in our brains, more granularly distinguishing between medicine and enhancement would be fundamental IP-wise; this is why I have devoted to this issue the second research question of the present article.

Second, appreciating the implications of the distinction between enhancement and medical drugs, i.e. the "non-therapeutic use of *X* for purpose *Y*",[159] arguably helps *not* falling into the therapeutical-method exception. Suppose a non-patented neuroenhancement is being marketed; a corporation might try to take the producer over and patent such product as a drug, possibly altering the underpinning molecule to a negligible extent. That would become a borderline case: either the drug is deemed innovative and patentable

Development", *ACS Medical Chemistry Letters* 11(2) (2020) 91–98; B.N. Sampat and K.C. Shadlen, "Secondary Pharmaceutical Patenting: A Global Perspective", National Bureau of Economic Research, Working Paper No. 23114 (2017), https://www.nber.org/system/files/working_papers/w23114/w23114.pdf; M. Aboy et al., "Mapping the European patent landscape for medical uses of known products", *Nature Biotechnology* 39(11) (2021) 1336–1343; M. Zigann, "Infringement of Swiss-Type Second Medical Use Patent Claims in Germany: Recent Developments in Case Law", *Washington Journal of Law, Technology & Arts* 12(3) (2017) 245–251; Kluwer Patent blogger, "Importance of second medical use protection is growing", *Kluwer Patent Blog* (2021). http://patentblog.kluweriplaw.com/2021/05/22/importance-of-second-medical-use-protection-is-growing/.

159 This patentability technique is called "purpose-limited product claim" in Europe and other jurisdictions, including China's Hong Kong Special Administrative Region; on the latter, refer to Friedmann, "Paint Medical Patents Green or Improve Efficacy", *Intellectual Property Watch* (2017). Check also M. Montgomery and S. Kirsch, "What to consider when drafting patent applications to maximise the potential for use claims", *Carpmaels & Ransford LLP* (2021) https://www.carpmaels.com/therapeutic-vs-non-therapeutic-use-at-the-epo/; M. Stott, "Protecting non-therapeutic methods at the EPO", *Mathys & Squire* (2021), https://www.mathys-squire.com/insights-and-events/news/protecting-non-therapeutic-methods-at-the-epo/.

by the patent office thanks to its marginal improvement on its enhancing counterpart, or, most probably, the office would outline its insufficient degree of inventiveness, finding that the company is trying to patent a therapeutical method (i.e. a "new" way to treat patients with substances that already exist) and that the substance therefore falls within exception to patentability as unoriginal and undeserving of exclusivity protection. This reasoning would work dissimilarly to the one recounted above: here, a difference in narrative about the same substance does *not* help patent the product, while it was decisive for succeeding in the first scenario. Hereby, the importance of appreciating definitions and storytelling, and their limits, is reiterated.

From a public-policy standpoint, yet another potential consequence may concretise. When a molecule first engineered for use as psychiatric treatment is in fact patented as—or can only be offered patentability as long as it is phrased as—neuroenhancement, those who might have genuinely needed it as treatment will be deprived of public benefits such as controlled price for such drugs or reimbursement of the cost thereof under health-welfare schemes. Furthermore, whereas a molecule marketed as neuroenhancement might not experience the same delays as its potential therapeutical counterpart (which would undergo stricter trials), it might face subsequence retraction from the market due to value-based contentions and redefined public attitudes towards enhancing drugs.

Additional implications intersect indeed with the morality dilemma. For instance, rejecting patentability on immorality grounds promises to impact socio-political discourses as well, and might even end up precluding private channels of patented medication in the event public services refuse to prescribe a certain substance whose non-patented equivalent exists in the public domain. As for neuroenhancing molecules which might border psychiatric treatments, non-patentability might impact access to mental healthcare for those borderline individuals who are not (yet) officially psychiatric patients and thus cannot be prescribed a certain substance, and find themselves unable to access its "neuroenhancing" equivalent, either, because no corporation would marketise it without exploiting it as a patent.

A disclaimer is due. All listed implications are, in my view, of pertinence and significance, but should not neglect the often unsophisticated (and always very much politicised) reality on the ground, which depends on a myriad factors, most of which fall outside the design of a jurisdiction's patent system per se. Take China, for example: in such an online-intensive jurisdiction, regulatory and IP efforts to operate due distinctions might turn out unserviceable or tangential because dark markets, cryptomarkets, and e-commerce platforms would frustrate them from scratch. There, frequently smuggled from abroad

through cross-border trafficking in the dark economy, but also thanks to domestic illicit production,[160] consumers can find most substances and obtain them oversight-free, without prescription, at relatively low price, conveniently delivered anywhere, and in relative anonymity. They may further access them while holding a valid prescription, to then (re)use them for treating another disorder; or, in fact, to (re)utilise them as enhancers. Despite the commitments undertaken by China across numerous negotiating tables including, most recently, with the US bilaterally under the "Phase One" Agreement,[161] these commercial runarounds are becoming commonplace as online marketplaces and interconnected digital-app ecosystems thrive.[162] Resultantly, if China (or similar e-commerce-intensive jurisdictions, assuming—without conceding—there is any at the moment) deems a substance more problematic than not, in no way it will be able to prevent *literally everyone* from accessing it sooner or later. The only option it is left with is to ban it completely, followed by enforcement action coordinated by health agencies rather than (or prior to) patent offices.

8 Conclusions

Controversies on the implications of human enhancement, namely in biomedical law, have been unfolding for more than half a century. Most recently, regulation and legal scholars have been discussing the influence of IP rights, most notably patents, on enhancement intake, focusing on Western jurisdictions and most prominently on the US and the EU. They outlined two main interfaces between patents and enhancement. First, patent offices deny patentability to innovations which stand against the public order, understood through security but also value-laden paradigms: does enhancement represent a threat for the overall stability and safety of society? Second, patent offices reject applications for therapeutical methods: when is enhancement also a therapeutical method? Legal scholarship, particularly by Nordberg, had already explored these issues in general terms, mostly from a European

160 See also J. Cunliffe et al., "Nonmedical prescription psychiatric drug use and the darknet: A cryptomarket analysis", *International Journal of Drug Policy* 73 (2019) 263–272, 269.

161 Article 1.18(2)(a).

162 Refer e.g. to W. Xiaoxiao, H. Xinya, and W. Hang, 2021. "失控的网上药店：精神药品违法售卖，处方药无需处方 [Out-of-control online pharmacies: Illegal sales of psychotropic drugs, prescription drugs without a prescription]." *The Paper*, https://www.thepaper.cn/newsDetail_forward_11697812; 2010. "处方药"利他林"网站打折卖？[Is prescription drug "Ritalin" being discounted online?]." *Sina News*, https://news.sina.com.cn/o/2010-06-05/145917615035s.shtml.

perspective. Yet, elaborating on mentioned research, the present paper has dug deeper into a specific class of enhancers: pharmaceutical neuroenhancers, whose complexity resides in molecules potentially functioning as both neuropsychiatric treatment (for patients) and enhancers for non-patients' cognitive functions. Therewith, this work sought to advance the debate on enhancement patentability in two directions: *ratione loci*, by scrutinising China's stances on enhancement's safety and morality; and *ratione materiae*, by illuminating the porous boundaries between treatment and enhancement in the controversial yet fascinating domain of neuropsychiatry. It has disputed patent offices' *de facto* regulatory role in defining and policing citizens' access to neuroenhancing substances through illegitimate and clinically dubious narratives of innovativeness and morale as embedded in IP regulations, decisions, and procedures.

Admittedly, the question whether patent systems impair or foster innovation and research is still open to controversy,[163] and as far as neuroenhancement *and* neuropsychiatric drugs are concerned, relevant case-law is confined to just a few patent cases as yet; nonetheless, I am confident that the present investigation has embodied threads and tendencies whose necessary acquaintance with will become obvious in the near future. It will prove even more compelling in China, where although the disproportionate number of patents granted per year might be indicative of a system which is not yet finely tuned, "securitised" IP protection is high on the political agenda (and frequently features in President Xi's speeches),[164] with courts at all levels having embarked on a long journey of doctrinal and procedural modernisation. With psychiatric disorders being on the rise (both epidemiologically and due to prompter diagnosis) and the pharmacological responses thereto having become so pervasive (if often controversial) and sophisticated, biomedical dilemmas will come to the fore more and more often and inform problems of patentability as well. Hence, legal doctrine should be prepared to accommodate the rapid onset of these phenomena, and anticipate their potential developments whenever doable. There appears to be no need for a cardinal overhaul of patent doctrines as yet, but steady progress in neuroenhancement research and application urges policymakers to update and readjust relevant clauses related to morality, innovativeness, and therapy, with particular care for the regulation of neuropsychiatric medications' patentability and medical praxis.

163 Refer e.g. to H.L. Williams, "How do patents affect research investments?", *Annual Review of Economics* 9 (2017) 441–469.

164 Read further R. Vecellio Segate, "Litigating trade secrets in China: An imminent pivot to cybersecurity?", *Journal of Intellectual Property Law & Practice* 15(8) (2020) 649–659, 658.

From whatever angle one scrutinises these issues, patent offices are *not* the appropriate *forum iuris* to handle them; thus, I call upon legislators to step in—not only domestically, but globally as well, also generalising from the Chinese and Western experiences among others—and design (or readjust) supranational techno-political institutions of scope. The COVID-19 pandemic has dramatically exposed the inadequacy of global health policing—or even the substantial lack thereof; and yet, only a global agreement on what "pharmacological neuroenhancement" stands for could offer long-lasting perspectives on the problems outlined in the present work.

Whereas it offered no conclusive overarching solution, and opened more interrogatives than it answered, this article aimed at unearthing all the complexity surrounding definitory exercises in the neuroenhancement debate, particularly where it borders the exceedingly controversial and *permanently shifting* (an oxymoron!) boundaries of psychiatric treatment. Coherently, I firmly join the Italian National Bioethics Committee, among others around the world, in its call to establish international collaborations in order to fund study programs dedicated at catalysing research on the short- and long-term effects of neuroenhancement,[165] especially—I would add—into the fragmented interstices between psychiatry and neurology.

Although keeping the current distinction seems unmeaningful, I do not believe that denying or granting patentability to both neuropsychiatric treatment and neuroenhancing pills altogether would resemble a desirable outcome. Instead, the entire regulatory process of granting and revoking patents in this field should be radically reconsidered against a broader systemic perspective, for example by granting reduced-duration patents (e.g. in cases where therapeutical and non-therapeutical applications of a molecule are indistinguishable or inextricably interlinked) and by strengthening the link between person-centredness and professional supervision in post-patenting commercialisation. Whereas it is true that an individual misidentifying their point of restoration and normalcy may be in itself an indicator of their psychiatric condition, it stands as equally true (for liberals, at least) that in the overwhelming majority of cases, *supervised* and competent adults should be left free to decide what substances to intake and under what conditions,[166] that is, they should be those who eventually get to decide after receiving non-binding advice in the form of guidelines and expert opinions. Put differently, assumptions should tend to reside in favour and not against self-assessment, even though for this approach to work well, demographically sensitive

165 Refer to Italian National Bioethics Committee, *supra* note 11, 61.

166 Read also F.R. Trabucco, "Neurorights between ethical and legal implications", *Cuadernos de Derecho Transnacional* 15(1) (2023) 750–757, 755.

expert-information channels should be significantly strengthened, and their quality assured. As societies grow more complex and humans learn to be more exigent on their rights and freedoms, policy flexibility probably represents the necessary evil to cater for medicine's unstoppably expanding scope. On the one hand, it is the subject, being it a patient or a healthy individual, who plausibly knows themselves deeper and should ultimately preside over their health choices, which include both treatment and enhancement and the whole osmotic universe in between. Patent offices have neither the tools nor the expertise to rule out any such substance as "immoral", and a substance does not become therapeutical just because it is administered by a medical practitioner, therefore I generally support over-the-counter dispensation and disagree that neuroenhancers 'should always and only be prescribed by specialists in the sector with specific skills in neuropharmacology'.[167] Making recourse to patent offices' *regulatory* function in the medical realm does not read like a wise option: it might not lead to fine-tuned societal outcomes policy-wise.

On the other hand, and to conclude, it seems only fair to restate that corporations should never be placed in the condition of exploiting this wildly huge market in disregard of people's *informed* decision-making process, e.g. by selling drugs off-label,[168] acquiescing to parallel trade, or (subliminally) advertising enhancement as treatment (and vice versa).[169] Health professionals

167 Italian National Bioethics Committee 2014, cit., 61.

168 For a less negative view on normalising off-label prescription and marketisation of psychotropic substances, refer to S. Khanra and B. Das, "Off-label Psychotropics Use: Isn't it Now an Inevitable and a "Norm" in Psychiatry?", *Indian Journal of Psychological Medicine* 40(4) (2018) 390–391. For a description of how common the phenomenon is, refer to P.L. O'Brien, N. Cummings, and T.L. Mark, "Off-Label Prescribing of Psychotropic Medication, 2005–2013: An Examination of Potential Influences", *Psychiatric Services* (2017) 68(6) 549–558; A. Vijay, J.E. Becker, and J.S. Ross, "Patterns and predictors of off-label prescription of psychiatric drugs", *PLOS One* (2018), https://doi.org/10.1371/journal.pone.0198363; D.G. Larriviere, "Ethical Perspectives in Neurology: Prescriptions to Help Healthy Patients Focus", *Continuum Lifelong Learning Neurology* 16(4) (2010) 165–169; S. Sattler, "Cognitive enhancement in children by using prescription drugs", in: T. Burns and F. Gottschalk (eds.), *Education in the Digital Age: Healthy and Happy Children* (OECD Publishing, 2020) 113–130; U. Müller-Sedgwick and J.A. Sedgwick-Müller, "Drugs to Treat Attention Deficit Hyperactivity Disorder (ADHD)", in: P.M. Haddad and D.J. Nutt (eds.), *Seminars in Clinical Pharmacology* (Cambridge University Press, 2020) 392–432, 421. For liability considerations around this phenomenon, refer to R.C. Ausnesst, ""There's Danger Here, Cherie!": Liability for the Promotion and Marketing of Drugs and Medical Devices for Off-Label Uses", *Brooklyn Law Review* 73(4) (2008) 1253–1326.

169 And indeed, '[n]on-propositional advertising content may lead viewers to hold beliefs that are inconsistent with the explicit claims made in DTCA [direct-to-consumer advertising of prescription pharmaceuticals]'—P. Biegler and P. Vargas, "Feeling Is

should provide as informative and comprehensive information as possible, and supervise the use of these substances within their remit, i.e. neuropsychiatric populations. Patents, in turn, should not help corporations harvest undue gains and profit from the unfettered influence they can exercise on consumers—especially the most fragile and/or naïve among them. Refraining from denying patentability on obsolete, aprioristic, and dichotomically abstract grounds (i.e. moral versus immoral, safe versus unsafe, medical versus recreational, therapeutical versus enhancing, exogenous versus endogenous, adaptation versus resistance, adjustment versus inconformity, etc.), while simultaneously strengthening access to medical professionals for genuinely informed decisions, as well as regulatory oversight over subliminal advertising and off-label marketisation,[170] seems to me a viable compromise between all main

Believing: Evaluative Conditioning and the Ethics of Pharmaceutical Advertising", *Journal of Bioethical Inquiry* 13(2) (2016) 271–279, 278. General regulation on the matter does exist, including in East Asia; in Japan, for instance, 'no person should advertise the name, manufacturing process, efficacy, effects or performance of pharmaceuticals or medical devices, or regenerative medicine products that have not yet been certified pursuant to Article 68 of the Act on Pharmaceuticals and Medical Devices'—H. Fukushima et al., "In brief: Prohibited and controlled advertising in Japan", *Lexology* (2023), https://www.lexology.com/library/detail.aspx?g=17692342-7f2d-4670-9ba0-512f5dc54cc6. However, as this article has hopefully persuasively argued, the boundaries between "treatment" and "enhancement" in the neuropsychiatric domain can be so porous that drawing legally enforceable boundaries through unspecific legislation might remain largely ineffective. In other words, "the science" is so contested here that general legislation (untailored for the specific challenges in this field) can be too easily circumvented.

170 Studies have demonstrated that the marketisation of pharmaceuticals is heavily influenced by multisensorial marketing strategies and pricing communication tactics, that due to their potential health implications for consumers have long been strictly regulated by eg the EU and, to a lesser extent, the US—refer to C. Spence, "The multisensory design of pharmaceuticals and their packaging", *Food Quality and Preference* 91 (2021) 104200; S. Silverglate, "Subliminal Perception and the First Amendment: Yelling Fire in a Crowded Mind?", *University of Miami Law Review* 44(5) (1990) 1243-1281, 1264. Subliminal marketing is arguably even more pernicious, and will prove increasingly so as AI advances; it thus calls for similar or higher degrees of regulatory oversight—read also G. Orzan et al., "Neuromarketing techniques in pharmaceutical drugs advertising: A discussion and agenda for future research", *Journal of Medicine and Life* 5(4) (2012) 428-432. Even the most futuristic scenarios seem proximate to stand at our doorsteps; to exemplify, scholars have already hypothesised that 'sleep data collected voluntarily or involuntarily could conceivably be sold to companies selling sleep aids or other pharmaceuticals', in what appears to be the latest frontier of subliminal messaging—D. Marlan, "The Nightmare of Dream Advertising", *William & Mary Law Review* 65 (forthcoming 2024) (pp 135–137 of the preview available at https://ssrn.com/abstract=4361477). In truth, the concern here is not merely with the *commercial* impact of subliminal advertising, but with their influence *on emotions* even more: even if one assumes that this type of advertising is not commercially effective

interests at stake and a balanced, depoliticised, unideological, hopefully long-sighted way forward.

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Cited laws, court cases, and policies are up-to-date as of the time of research. The most remarkable development since then has been the establishment of the Unified Patent Court in Europe; future research is warranted to account for potential case-law and/or doctrinal developments under such new patent system.

but highly influential from an emotional standpoint "only"—check e.g. R. Strand and M. Kaiser, "Report on Ethical Issues Raised by Emerging Sciences and Technologies, written for the Council of Europe's Committee on Bioethics", *Report for the Council of Europe Committee on Bioethics* (2015) 20—the fact that it increases targets' satisfaction with the advertised products means that if the latter are made recourse to as enhancers, the intaker will have their efficacy hopes reinforced and confirmed. Studies in psychiatry and cognition preliminarily suggest that sham subliminal presentation of information might yield changes in pharmaceuticals' expected performance, which can thus be subjected to subliminal manipulation—check A. Winkler and C. Hermann, "Placebo- and Nocebo-Effects in Cognitive Neuroenhancement: When Expectation Shapes Perception", *Frontiers in Psychiatry* 10 (2019) 498. Lastly, the subliminal itself can function as enhancement, especially towards stimulating "prosocial behavior", adaptation, and value alignment, and thus working as public nudging; read e.g. M. Elgendi et al., "Subliminal Priming—State of the Art and Future Perspectives", *Behavioral Sciences* 8(6) (2018) 54; M. Froufe and C. Schwartz, "Subliminal Messages for Increasing Self-Esteem: Placebo Effect", *The Spanish Journal of Psychology* 4(1) (2001) 19–25. More generally, on the interfaces between enhancement and surreptitiously "brain-intruding" subliminal techniques, *see also* R.J. Neuwirth, *The EU Artificial Intelligence Act: Regulating Subliminal AI Systems* (Routledge, 2023) pp. 4–5; 27; R.J. Neuwirth, "Prohibited artificial intelligence practices in the proposed EU artificial intelligence act (AIA)", 48 Computer Law & Security Review (2023) 105798.