Essays

Direct-to-Consumer Neurotechnologies Under the Framework of WTO Agreements

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ABSTRACT: The emerging possibility of incorporating neurotechnologies into products and services that are directly accessible on the market offers new avenues of research. To the best of our knowledge, this article is the first attempt to investigate how the rules of the multilateral trading system can help regulators respond to the challenges posed by these new products and services in the global markets. The study discusses whether the rules of the WTO allow governments to block potentially harmful DTC neurodevices from accessing their internal market; suggests that the rules for standardization and technology transfer may play a positive role in this context; proposes a potential role of the WTO institutional framework in the governance of neurotechnologies.

KEYWORDS: Direct-to-consumer neurotechnologies; WTO; trade restrictions; standardization; transfer of technology

1. Introduction

The last two decades have witnessed an unprecedented leap in the growth of frontier technologies that can be considered to be disruptive, in the sense that their generalized use by private individuals may affect how our society is currently shaped.

According to the United Nations Conference on Trade and Development (UNCTAD), the market value of these technologies – encompassing Artificial Intelligence (AI), the Internet of Things (IoT), big data, nanotechnology and gene editing – will increase from $1.5 trillion in 2020 to $9.5 trillion by 2030.[1] The report also claims that "only a handful of countries supply frontier technologies and almost all of them

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[1] UNCTAD, *Technology and Innovation Report 2023. Opening green windows Technological opportunities for a low-carbon world*, New York, 2023, 12.

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are developed economies".[2] Market analyses of neurotechnological devices have predicted a growth in the specific sector from $10.9 billion in 2021 to $ 35.5 billion in 2030.[3]

The above projection by UNCTAD regarding the growth of frontier technologies may be concerning, in the light of the fact that neurotechnologies[4] that have long been applied for medical diagnosis and the treatment of diseases and health conditions, have lately emerged as the driver for the development of an innovative set of direct-to-consumer (DTC) products and services[5] for various aims, including well-being, education, employment and workers management, and leisure and marketing.

Non-invasive technologies like electroencephalography (EEG) provide access (read) and monitor neural data when used in wearable brain-computer-interfaces (BCI), while transcranial magnetic stimulation (TMS) and transcranial direct current stimulation (tDCS) can affect the functionality of specific areas of the brain, such that the products based on them are conceptually situated on the boundary between the medical and the non-medical fields. Nonetheless, there is a tendency among manufacturers to classify DTC neuro devices in the latter category, and to advertise them as enhancing 'focus' or concentration, rather than being capable of treatment, to avoid the stricter regulatory regime to which medical devices are subject.[6]

The 'intended medical purpose' of a device is, indeed, the condition for the applicability in the European Union of Regulation no. 2017/745 (Medical Devices Regulation - MDR), which prescribes a regime of a combination of specific requirements and measures of control for medical devices that become increasingly stringent depending on the potential risks posed by the products.[7] It is noteworthy that also a software may also be considered to be a medical device under the MDR.

At least in the EU, consumers' protection is implemented through a series of rules that may be applicable to specific cases. For devices that are not qualified as 'medical' by the manufacturer, the exacting regime of the MDR is expressly extended to types of equipment "intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify

[2] *Ibidem*, 14.

[3] See the Global Forecast of Global Market Inside of May 2022: www.qminsights.com/industry-analysis/neuro-tech-devices-market?qclid=Cj0KCQjw5f2lBhCkARIsAHeTvli-NEPvI2olMT-KbXyNnVlYNPInBeSz-IN51Twcw_56LvCYNNEiTu8aAn4ZEALw_wcB.

[4] The OECD has defined neurotechnologies as "devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural system of natural persons": OECD, *Recommendation of the Council on Responsible Innovation in Neurotechnology*, OECD/LEGAL/0457, 2022, 6.

[5] The term 'product' in this article refers not only to hardware (physical goods) but also to systems comprising software/digital platforms and apps used to provide services based on neurotechnologies.

[6] A. Wexler, P.B. Reiner, *Oversight of Direct-to-Consumer Neurotechnologies*, in *Science*, 363(6424), 2019, 234-235, www.science.org/doi/10.1126/science.aav0223.

[7] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, http://data.europa.eu/eli/reg/2017/745/oj. The MDR allows access to the internal market only to devices that are compliant with the general safety and performance requirements, and with specific technical standards. For low-risk devices, it is the responsibility of the manufacturer to assess compliance through a declaration of conformity and to affix the CE (European Conformity) mark on them, while a certification of conformity released by a Notified Body is required for potentially dangerous goods. On the application of the MDR to neurodevices see: P. Mariani, *Patient or Consumer? The EU's Regulatory Framework on Medical Devices and Neurotechnologies*, forthcoming.

neuronal activity in the brain".[8] The 'common specifications' released by the European Commission in December 2022 require manufacturers of such devices to carry out a risk management process to «analyse, eliminate or reduce as far as possible» risks related to hazards or harms specific to devices intended for neurostimulation.[9] The list in Annex VII, Section 3.3 of the Regulation expressly includes, among these, psychological risks (a); short-term, medium-term and long-term cognitive side-effects (c); long-term side-effect changes of the brain functioning (e). It is noteworthy that the introductory part of the Regulation reminds that the MDR "requires a product without a medical purpose listed in Annex XVI to that Regulation, when used under the conditions and for the purposes intended, to present no risks at all or present a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons" (Whereas (7)).

The application of the rigorous regime of the MDR is affirmed by the doctrine also for 'scanning' BCIs that are "used for communicative purposes or other assistive goals, by disabled persons".[10] In the latter case, the applicability of the MDR is deduced from the fact that, while the relevant devices are not among those that are excluded from the scope of the regulation in Section 6 of Article 1, scanning BCIs perform a 'broad medical function', being "instruments by which a state of 'disability' or an 'injury', which causes the communicative deficit (or which undermines other autonomous activity like moving), is 'alleviated' or 'compensated'".[11]

Devices with neurotechnologies embedded into them that are beyond the scope of the MDR are not exempted from respecting other, possibly relevant, EU laws either. Specifically, devices using low voltage electrical equipment (such as BCIs) cannot be offered in the internal market unless they comply with the Directive no. 2014/35/EU.[12] Moreover, for neurodevices using AI, the requirements provided for under the draft EU AI Act, once adopted, will need to be satisfied along with other relevant rules.[13]

[8] Under the combined provisions of Article 1, Section 2, Article 9, and Annex XVI of the MDR "existing harmonised standards for analogous devices with a medical purpose, based on similar technology" must be taken into account in the regulation of these products.

[9] Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, *OJ* L 311, 2.12.2022, 60.

[10] See F.G. PIZZETTI, *Brain-Computer Interfaces and the Protection of the Fundamental Rights of the Vulnerable Persons*, in A. D'ALOIA, M.C. ERRIGO (eds.), *Neuroscience and Law*, Switzerland, 2020, 291 ff, https://doi.org/10.1007/978-3-030-38840-9_15.

[11] *Ibidem*, 304. According to Pizzetti, even if the scope of the devices is not correlated with "diagnosis, monitoring or treatment" of a pathology, we are far removed from the case of those "sports goods which enable the functioning of certain organs in the human body to be measured without any medical use", with respect to which the European Court of Justice said—in *C- 219/11, Brain Products GmbH*—that requiring a certification procedure would be without any justification.

[12] Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (recast), available at: http://data.europa.eu/eli/dir/2014/35/oj.

[13] Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52021PC0206. The coordination of the forthcoming AI Regulation

Furthermore, if no specific legislation is applicable, the circulation of any devices on the EU market requires compliance with the so-called General Product Safety Regulation (GPSR). The new version of the GPSR comes into force in December 2024, and pays close attention to the regulation of products with new technologies embedded into them that may pose unknown risks.[14]

To strengthen the protections provided under this fragmentary legal framework against the risks associated with neurotechnologies, the extension of the MDR regime to all neurodevices (independently of their medical purposes) has been proposed, although with some perplexity.[15] In any case, access for DTC neurodevices to the EU market is subject to surveillance procedures that are more demanding than those in the United States, where tDCS devices may escape regulation by the Food and Drug Administration (FDA) by being marketed as intended for wellness purposes.[16]

Advances in neurotechnologies are currently being authoritatively questioned from a legal perspective mainly owing to their possible impact on human rights, to determine whether the current framework for human rights, both at the global and regional levels, provides adequate protections against these new risks, or if additional rights need to be incorporated to this end.[17]

The emerging possibility of the incorporation of neurotechnologies into products and services intended for consumers that are directly accessible on the market offers new avenues of research. One of them focuses on the governance of the neurodata that are captured by such technologies, possibly without the knowledge of the individuals to whom they belong.[18]

A still unexplored avenue of research involves assessing the readiness of the multilateral trading system, administered by the World Trade Organization (WTO), to address the challenges posed by these new products and services to the global markets.

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with the MDR will be particularly important in the context of neurodevices: see the insightful analysis by S. PALMIERI, P. WALRAET, T. GOFFIN, *Inevitable Influences: AI-Based Medical Devices at the Intersection of Medical Devices Regulation and the Proposal for AI Regulation*, in *European Journal of Health Law* 28, 2021, 341-358.

[14] Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC, http://data.europa.eu/eli/reg/2023/988/oj.

[15] In her insightful analysis of the application of the MDR to products with embedded neurotechnologies, Paola Mariani doubts that this would be enough to afford adequate protection to the mental integrity and privacy of the individual using the device: see P. MARIANI, *op. cit*.

[16] See A. WEXLER, P.B. REINER, *op. cit.*, 235.

[17] See the seminal article by M. IENCA, R. ANDORNO, *Towards New Human Rights in the Age of Neuroscience and neurotechnology*, in *Life Sciences, Society and Policy*, 13: (1), 2017, 1-28 and more recently J. GENSER , S. HERMANN, R. YUSTE, *International Human Rights Protection Gaps in the Age of Neurotechnology*, Neurorights Foundation, 2022, available at: https://static1.squarespace.com/static/60e5c0c4c4f37276f4d458cf/t/6275130256dd5e2e11d4bd1b/1651839747023/Neurorights+Foundation+PUBLIC+Analysis+5.6.22.pdf; R. ANDORNO, *Why human rights are crucial in responding to the challenges posed by neurotechnologies* in *Risks and challenges of neurotechnologies for human rights*, Unesco-Università Milano-Bicocca, Paris, 2023, 29-31 and M. SOSA NAVARRO, S. DURA BERNAL, *Human Rights Systems of Protection Against Risks Deriving from Neurotechnologies that Alter Brain Activity*, in *Drexler Law Journal, 15:(4),* 2023, 893-942.

[18] M. IENCA, J.J. FINS, R.J. JOX, F. JOTTERAND, S. VOENEKY, R. ANDORNO, T. BALL, C. CASTELLUCCIA, R. CHAVARRIAGA, H. CHNEIWEISS, A. FERRETTI, O. FRIEDRICH, S. HURST, G. MERKEL, F. MOLNÁR-GÁBOR, J.M. RICKLI, J. SCHEIBNER, E. VAYENA, R. YUSTE, P. KELLMEYER, *Towards a Governance Framework for Brain Data*, in *Neuroethics*, 15(2), 2022, 20. https://doi.org/10.1007/s12152-022-09498-8.

While the theoretical foundations of the international economic order to which the WTO system belongs are identified as economic liberalism, they have been 'adjusted' to grant States some policy space, such that it is more accurate speak of regulated trade rather than free trade.
A set of tools are available to members of the WTO to address the needs of their citizens, businesses and society at large. In this study, we investigate whether some of these tools can be instrumental in tackling the issues created by the arrival of products embedded with neurotechnologies on the market. In Sections 2 and 3 we discuss whether WTO rules allow governments to adopt restrictive trade measures to block DTC neurodevices from accessing their internal markets in case they are deemed potentially harmful. Leaving aside this national defence perspective, in Sections 4-6 we delve into the capacity of the rules of international trade to play a positive role in regulating these a, innovative technological products. This involves examining the positive effect of the promotion of standardization at the level of the WTO on streamlining the global trading of neurotechnological products due to their compliance with a host of internationally agreed requirements. We then argue that the WTO system can make another positive contribution to the emerging market for neurotechnological devices through its rules on the transfer of technologies. We conclude by proposing a role for the institutional framework of the WTO in the governance of neurotechnologies.

2. Fencing internal markets against potentially harmful DTC neurotechnologies

By adopting a mindset grounded in the system of international trade that is coherent with the legal provisions that justify the adoption of trade restrictive measures to preserve the prevailing interests of WTO members,[19] the challenges of neurotechnological products can be understood through a risk-based taxonomy that identifies three categories of risks posed by them: health risks; hazards related to 'public morals' or 'public order', and national security-related hazards.

2.1. Risks deriving from products potentially harming human health

Studies on the household use of neurowearable devices (headbands) with transcranial direct current stimulation (tDCS) have reported the occurrence of adverse effects, such as, for example, headaches and skin rashes or bruises and psychological harm.[20] These collateral effects have been mainly reported to be mild, but the fact that such devices have only recently been introduced on the market beyond the medical context suggests an attitude of caution, as the effects of their prolonged use on health, brain development, and personality remain unknown.

[19] In the WTO legal order, such provisions assume the form of general exceptions that allow for the waiving of the fundamental principles of trade liberalization: Article XX of the General Agreement on Tariffs and Trade (GATT), and Article XIV in the General Agreement on Trade in Services (GATS). For a concise, yet incisive, overview of the rules of the multilateral trading system, see: P. VAN DEN BOSSCHE, D. PREVOST, *Essentials of WTO Law*, Cambridge, 2021.

[20] A. WEXLER, P.B. REINER, *op. cit.*, 234; N. MINIELLY, V. HRINCU, J. ILLES, *A view on incidental findings and adverse events associated with neurowearables in the consumer marketplace*, in I. BÁRD, E. HILDT (Eds), *Developments* in *Neuroethics and Bioethics. Ethical Dimensions of Commercial and DIY Neurotechnologis*, 2020, 267-276.

Under the rules of the multilateral trading system, the free flow of goods can be legitimately denied owing to health-related reasons. Such restrictions can be implemented under different rules, each of which is designed to respond to the specific needs of a State.

A cornerstone of the multilateral trading system is the principle recognising the *freedom of each member of the WTO to choose the level of protection of health within its boundaries.* Although it has not been affirmed with the same strength in different WTO agreements, this principle is horizontally effective, such that it is clear that the distribution of DTC neurotechnological goods on the market can be prohibited due to health concerns. Moreover, it can be argued both on normative and systemic grounds that the precautionary principle is applicable within WTO law, because of which a cautious approach to the issue would be covered. While it is expressly mentioned only in Article 5.7 of the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), which sets out the basic rules for food safety as well as the standards of animal and plant health, a systemic interpretation of WTO agreements in the light of the WTO declaration on public health of 2001 allows for the general extension of the principle to protect people's health from risks that may arise within the purview of the Organization.

However, the decision to keep neurowearables out of the domestic market would need to comply with the general WTO rules, primary among which is that of non-discrimination based on the country of origin of a product.

According to WTO law, claims of discrimination in favour of domestic products[21] can even be brought comparing products that are significantly different from one another: wearables intended to enhance focus/concentration and drugs with similar prescription.

In such a case, the health risks associated with the product may be deemed relevant to the determination of 'likeness' to the extent that they have an impact – so, *if they have an impact* – on the competitive relationship between the products. For example, the fact that consumers tend to prefer to buy drugs/pills instead of neurostimulation devices owing to health concerns can lead to the determination that such pills and devices cannot be considered 'like products', with the consequence that different terms of trade may be legally applied to them.[22]

In light of how neurotechnology markets are taking shape, that is – considering that, while the US has the lead in the market for neuro-devices, EU start-ups are emerging especially in the market of software/digital platforms and apps[23] – we can hypothesize a claim brought by the US against the EU. Let us suppose that the US alleges discrimination by the EU under Article III.4 of the General Agreement on Tariffs and Trade (GATT) – the provision prohibiting countries from favouring domestic over imported products – on the grounds that DTC neurodevices to treat depression and technological platforms and apps for the same purpose compete with each other on the market. Thus, a European measure banning the former from its market while allowing the latter would amount to discrimination.

[21] The non-discriminatory treatment of foreign goods of different national origins is also granted under the Most Favored Nation (MFN) clause, in Article I of the General Agreement on Tariff and Trade.

[22] *United States-Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406, *Report of the Appellate Body*, paras. 118, 119.

[23] See G. VELASCO, T. DURÁN ET AL., *Where is European Brain Innovation Happening? The role of tech-based start-ups*, Madrid, 2021. The report is available at: *www.humanbrainproject.eu/en/collaborate-hbp/innovation-industry/market-analysis-and-technology-roadmaps/*.

However, this hypothetical seems unrealistic as the two parties are currently collaborating on technological innovation.[24]

The right of WTO members to decide the level of protections to impose on products for health-related reasons within their geographical boundaries can go so far as to justify even clear violations of WTO rules prescribing non-discrimination (GATT Articles I and III), or those prohibiting restrictions/restrictive technical regulations (GATT Article XI,[25] and the Agreement on Technical Barriers to Trade – TBT). This means that restrictive measures hindering the international trade of neurowearables can be allowed if they are deemed 'necessary to protect human (…) life or health' (GATT Article XX(b)). However, any such measure will have to comply with the requirement of necessity as interpreted by the dispute settlement bodies of the WTO,[26] and will need to be applied in such a manner to avoid discrimination and undue restriction on international trade.[27]

Moreover, under the TBT agreement, any stringent technical regulations of neurotechnological products (for example, labelling requirements) will appear to be justified if it is adopted to fulfil a legitimate objective, such as the protection of human health or safety (TBT Article 2.2).[28]

2.2. WTO tools for tackling risks to 'public morals'

Health risks are only one – and apparently not the more serious – of the dangers arising from direct-to-consumer neurowearables. While neurostimulation devices raise the most significant health concerns, even the mere acquisition of neural data from healthy individuals can raise quite delicate ethical issues.[29] Public moral concerns involve the risk of hacking of neural data (violation of privacy rights),

[24] See, *infra*, note 48 and corresponding text.

[25] The article prohibits the adoption of trade-restrictive measures (bans and quantitative restrictions). Although even an outright ban on the import of neurodevices from abroad can be enacted and justified – see, *infra*, Sections 2.1, 2.2, and 2.3 – it seems more likely that future laws on neurodevices will apply equally to domestic and imported goods, thus falling out of the scope of Article XI. Such laws would fall, instead, under the rules providing for non-discriminatory treatment (GATT Article I and Article III).

[26] The 'necessity' of a measure is related to the importance of the non-trade value that the State aims to protect through its implementation. According to WTO jurisprudence, human life and health are valued as 'vital' interests. Still, to be justifiable, a measure aimed at their protection needs to contribute significantly to the aim pursued, and cannot be too restrictive on international trade flows. For an analysis of the WTO jurisprudence on the health exception of GATT Article XX(b), see E. BARONCINI, UE, *Covid-19 e commercio internazionale: una nuova governance sugli* healthcare products, in *Il diritto dell'Unione Europea*, 3, 2020, 539, 554 ss.

[27] On these conditions, provided for under the introductory paragraph of Article XX of the GATT (the so-called '*chapeau*'), see, among others, L. BARTELS, *The chapeau of the general exceptions in the WTO GATT and GATS agreements: a reconstruction*, in *American Journal of International Law*, 109(1), 2015, 95-125.

[28] Under the TBT agreement as well, the regulation cannot be more trade restrictive than necessary, and should take account of the risks of non-fulfilment.

[29] For example, we can discuss whether permitting the free introduction of a neurodevice that allows employers to control the brain activity of their employees on the market is compliant with our moral values of dignity and respect for the personal sphere of each individual. Alternatively, we can raise the same question for devices that can enhance the learning skills of children but are accessible, due to price-policy, only by wealthier layers of the population, thus introducing a further element of social inequality.

In the first example the end use of the products can be deemed unacceptable for a population that highly values the dignity of workers and the respect for a sphere of personal privacy; in the latter case the 'sense of good and ba' of the population may endorse the use of enhancing technology that is limited to the system of public education (State funded), and is subject to the State's guarantee against any possible bias and inequality.

the possible abuse of technologies (for instance, in employment relationships, for political ends, and in justice/criminal settings), and the hazards linked to the use of technologies to enhance human capabilities (in the military field or in a way conducive to increasing inequality between people).

The agreement regulating the international trade of goods contains an exception that justifies measures to restrict trade for moral reasons (GATT, Article XX:1(a)), while a mirroring article in the agreement on the liberalization of trade in services (GATS) lends the same effect to motives grounded in the need to preserve public morals and public order motives (GATS, Article XIV(a). The presence of exceptions in both agreements may be of particular interest in the context of neurodevices, because the case of a service relating to a specific good or one supplied in conjunction with a good can easily be envisaged.[30]

The content of the so-called 'moral exception' is not explained in either of the above-mentioned agreements, and the blurred boundaries of the concept of public morals can be a precious instrument for regulating innovative technological products, such as neurowearables for both reading/recording neural data and conditioning/enhancing brain functions. Elaborating on the notion of 'public morals' in the context of the GATS Agreement, WTO jurisprudence makes clear that "the term 'public morals' denotes standards of right and wrong conduct maintained by or on behalf of a community or nation".[31]

Such policy objectives, as guaranteeing the respect for human dignity in the employment relationships and avoiding social inequalities in education, may both be covered by the above exception. Protecting citizens from the hacking and misuse of their neural data can instead be considered to be adequate to satisfy the standard in footnote 5 to Article XIV(a) of the GATS, which provides that the public order exception in the GATS may be invoked "where a genuine and sufficiently serious threat is posed to one of the fundamental interests of society". This allows member countries to ban services aimed at providing such contents to private or public entities and individuals. The recommendations on neuroethics released by the OECD and UNESCO can serve as a guide for identifying such threats and values.[32]

To sum up, the 'public morals' exception may come to play a relevant role in the near future, consenting to frame the distribution of neurotechnological devices and services on the global markets in a manner that reflects the different cultural identities of the members of the multilateral trading system. For example, under this exception, European countries would be allowed to restrict market access to foreign devices that do not comply with their high standards for the protection of personal data; the

[30] The goods/services dilemma with respect to goods with embedded AI (conceptually valid for neurotechnologies as well), and the connected problem whereby services supplied through related apps might fall under the duties due for the hardware has been raised by P. KRUMMENACHER , *International Trade and Artificial Intelligence: Is Trade Policy Ready for Chat GPT?,* in *IISD Trade and Sustainability Review*, 3(2), 2023, available at www.iisd.org/articles/iisd-trade-sustainability-review-volume-3-issue-2-april-2023. The WTO has, however, affirmed that a given trade measure may need to be scrutinized under both the GATT and the GATS: see AB Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas*, WT/DS27/AB/R (adopted Sept. 25, 1997, para. 221).

[31] Appellate Body Report 7 April 2005, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, WT/DS285, para. 296.

[32] See: OECD, *Recommendation of the Council on Responsible Innovation in Neurotechnology*, OECD/LEGAL/0457, OECD, 2022; UNESCO, *Report of the International Bioethics Committee (IBC) on the Ethical Issues of Neurotechnology*, SHS/BIO/IBC-28/2021/3 Rev., Paris, 15 December 2021.

U.S. would be allowed to block apps and services for public control/social scoring acceptable in Oriental cultures and effectively implemented in China.[33]

2.3. Possible restrictions on the international trade of products with embedded neurotechnologies for reasons of national security

It can be argued that products with embedded non-invasive neuro technologies could pose severe threats to national security if accessed by criminal and terrorist organizations or used by enemy countries in military/defence-related contexts. Consider, for example, the possibility of external entities (criminal groups/ foreign countries) accessing and collecting the neural data of the citizens of the target country in an abusive way or using augmentation technologies to increase their own military and defense systems.[34] To prevent such public hazards, WTO law allows a member to resort to "any action which it considers necessary for the protection of its essential security interests".[35]

Precisely to explore the opportunity to resort to this exception, the Bureau of Industry and Security of the US Department of Commerce published an 'advance notice of proposed rulemaking' in November 2018, seeking public comment on the inclusion of BCI technology in a list of emerging technologies that are essential to US national security, so that effective export control could be implemented on them[36].

Although they are likely WTO compliant (the justifying rule in this case would be the exception provided in Article XXI of the GATT), measures of export/import restrictions will prove to be both detrimental and ineffective. As highlighted by some of the comments sent to the above-cited US agency, excessively strict export controls on BCI technology can hinder research in the US, and can divert future research and development programs, and even investments by private companies, to other technologically advanced countries in Europe, Asia and the Americas.[37]

[33] See, *supra*, note 29.

[34] A study on the possible applications of brain computer interface (BCI) technology in the military field, calling for a strategy "for the United States and the Air Force to lead in research, design, manufacturing, employment, exploitation, security and counterproliferation of this technology" was published by Lieutenant Colonel Brian E. Moore over ten years ago: see B.E. MOORE, *The Brain Computer Interface Future: Time For a Strategy*, Air War College Air University Maxwell AFB United States, accessible at https://apps.dtic.mil/sti/citations/tr/AD1018886.

[35] Under the national security exception of GATT Article XXI (b), which expressly covers any action necessary for the protection of the members essential security interests (ii) relating to the traffic in arms or "in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment." This last sentence cannot be interpreted as encompassing all dual-use goods, but should apply only to products that can be of particular significance in the context of military activities or national security: see, in this sense, M. BUCCARELLA, A. LIGUSTRO, *The World Trade Organization (WTO) condemns Trump's tariffs on steel and aluminum, but Biden condemns the WTO* in *DPCE online*, 1, 2023, 1529, 1534.

[36] Department of Commerce Bureau of Industry and Security, *Request of Comments Concerning the Imposition of Export Controls on Certain Brain-Computer Interface (BCI) Emerging Technology*, in *Federal Register*, 86(204), Tuesday, 2021, 59070-59073.

[37] *Ibidem*, 59071-59072.

From a more general perspective, such actions would injure those who could benefit from further advancements in neurotechnologies in the medical context. This consideration applies equally to import restrictions allegedly adopted for the same national security reasons, as they can hinder the use of such devices for medical research and treatment in the domestic market.[38]

Having expressed skepticism about the effectiveness of limiting the international flow of neurotechnologies in preventing abuses of neurodevices and related technologies for military-national security concerns, it must be added that the deference to the decision of the State in rightfully invoking the security exception gives WTO members large discretion to resort to trade-restrictive measures on grounds of national security.[39] Only a broad recognition of the principle of transparency in the use of neurotechnologies in the military context by governments – not to be expected in this period of thickening geopolitical concerns – can be a game-changer on this issue.

3. The role of IPRs protection

Another venue offered by the WTO system to tackle concerns about health, morals, and public order arising from neurotechnology products is that of resorting to the flexibilities provided for by the agreement on the trade-related aspects of intellectual property rights (TRIPS), such as the exclusion from patentability or the compulsory licensing mechanism. More precisely, while all inventions, including those in the medical and pharmaceutical fields, must be granted patent protection under WTO rules, States reserve the right to exclude from patentability "inventions whose commercial exploitation could be contrary to public order or morality, or could endanger human […] health" (TRIPS Article 27.2). Patentability can also be excluded for "diagnostic, therapeutic and surgical methods for the treatment of humans or animals […]" (TRIPS Art. 27.3).

The generalization of patent protection under the TRIPS Agreement and its effects on public health have been broadly debated since the mid-1990s, when the TRIPS Agreement was signed. This debate intertwines with our topic without covering it completely. DTC neurotechnology products have spread from medicine to the wellness/leisure/educational fields, and raise concerns that could be faced either with a ban on them or, on the contrary, with a policy of public funding to grant the entire population equal access to neurotechnologies.

[38] In the European Union such restrictive measures can be adopted for neurotechnologies that qualify as 'dual-use items', i.e., "items, including software and technology which can be used for both civil and military purpose", under Regulation (EU) 2021/821 of the European Parliament and of the Council, that sets up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items, *OJ* L 206, 11.6.2021, 1.

[39] Until recently, the selfsame justiciability of Article XXI(b) was debated, with the result of an almost unlimited freedom of States in determining the existence of the conditions that could justify the violations of commitments taken under the WTO agreements. A stark change has been determined by the decision in the *case Russia – Measures Concerning Traffic in Transit* (*Russia – Traffic in Transit*), WT/DS512/R, 26 April 2019, para. 7.56. In the report of Panel (unappealed), the justiciability of the provision is grounded in the principle of good faith, that prevents Members of the WTO from using the security exceptions in Article XXI to circumvent their obligations to liberalize trade. On this significant shift in the case law of the Organization see: G. MAROTTI, A. ADINOLFI, *WTO Security Exceptions: A Landmark Panel Report in Times of Crisis, in Questions of International Law* (*QIL*), 2020, 1-3; S. LAPA, *The WTO Panel Report in Russia – Traffic in Transit: Cutting the Gordian Knot of the GATT Security Exception?*, in *QIL*, 2020, 5.

It can at least be doubted that the exclusion of neurotechnological products from patentability might be appropriate: It is in the interest of the social community not to renounce the transparency of the information ensuing from the duty of the patent applicant to unveil the project of their invention, in the context of breakthrough technologies, with such a wide range of possible applications.
On the contrary, the recourse to the compulsory licensing system provided for under Articles 31 and 31 bis[40] of the agreement may be relevant to the neurotechnological field: the possibility to use – under strict requirements – a patent of a neurotechnological product or process without the authorization of the right holder might consent to give access to a device which is proving to have a game-changing effect on the interpersonal relationships in society to the generality of the population for reasons of equality and distributive justice.[41]

4. Fostering a States-led standardization of neurotechnological products

Having surveyed how the WTO system allows its members to restrict the access for neurotechnological devices to their domestic markets due to concerns regarding public interest, we need to assess whether the rules regulating international trade can have a role in the governance of neurotechnological innovation.
From this perspective, the *multilateral character of the WTO,* which is profoundly embedded in its institutional structure and its aims, together with its support for the values of international cooperation and sustainable development, can offer interesting opportunities for addressing the issues related to the market dimension of neurotechnologies in a multilateral setting.
At least three fields in which the multilateral trading system can play a positive role can be envisaged. To start with, the present section discusses regulatory harmonization and international standardization and affirms that WTO law offers a framework favouring a harmonized approach to regulating commercial neurotechnologies, that can be highly beneficial in this initial developmental phase of the market.
With the declining relevance of tariff-related barriers in trade policy, the surge of regulatory protectionism has been portrayed as the worst form of domestic protection of the economy.[42] This is true when internal regulation is undertaken with the sole aim of affording protection for national production. However, it must be remembered that the WTO respects the policy-related choices of national regulators.

[40] With regard to the second provision, only for neurodevices or processes for medical use, in force of an extensive/analogical construction of the norm, whose aim is consenting the access to pharmaceutical products in developing and least developing countries.
[41] In suggesting a possible role of the compulsory licensing mechanism to provide more affordable "needed and valuable neurotechnologies in developing countries", Brindley and Giordano ground their arguments in the "duty of assistance" towards developing countries, so that their peoples can live "worthwhile lives" as proposed by John Rawls: see T. BRINDLEY, J. GIORDANO, *International Standards for Intellectual Property Protection of Neuroscience and Neurotechnology: Neuroethical Legal and Social (NELS) Considerations in Light of Globalization,* in *Stanford Journal of Law, Science & Policy*, VII, 2014, 33-49, 44.
[42] J.H.B. PAUWELYN, A.T. GUZMAN, J.A. HILLMAN, *International Trade Law*, New York, 2016, 285.

Although trade restrictive in their effects, technical regulations can be used "to pursue a legitimate objective",[43] and as such should be considered for the adoption of rules that limit the use of new and disruptive technologies to conform to the public interest, and to the main values shared within the national community.[44]

The EU has always been keen on making use of this policy space. For example, it adopted one of the strictest-ever regulations on chemical products in 2007, that forced the countries exporting to its internal market to conform to its requirements in order to gain access.[45] Even the General Data Protection Regulation (GDPR) has compelled foreign subjects – researchers, companies and public bodies – who want to collect and treat data coming from the EU, to comply with the level of data protection chosen in the EU.

A similar scheme is currently being developed for AI, but with a noticeable difference. The EU is not relying solely on its power as a global rule setter,[46] but is consulting like-minded countries with a view to harmonize reciprocal approaches and vouching for the respect for fundamental values (in this case, the trustworthiness and human-centred nature of AI).[47] Such collaboration is ongoing with the US under the ambit of the Trade and Technology Council (TTC) established in June 2021, and is being negotiated with Japan, the Republic of Korea and Singapore under the framework of new bilateral Digital Partnerships.[48]

[43] See *supra,* Section 2.

[44] The TBT agreement covers three types of measures: *technical regulations* – which lay down the main characteristics of products or their related process and production methods; *standards* – which differ from the foregoing mainly owing to their non mandatory nature; and *conformity assessment procedures*. All are defined in Annex 1.1 to agreement.

[45] On the thrust effect towards harmonization exerted by the Registration, Evaluation, Authorization and Restriction of Chemicals – REACH Regulation on third countries, see: R. QUICK, *Regulatory Cooperation-A Subject of Bilateral Trade Negotiations or Even for the WTO?*, in *Journal of World Trade*, 42(3), 2008, 391-406, 394-395.

[46] On the different forms that regulatory influence can take – from the enactment of hard legislation with requirements conditional on getting market access, to the drawing of regulatory cooperation chapters in preferential trade agreements or simply setting the agenda in international conferences – see A.R. YOUNG, *The European Union as a Global Regulator? Context and Comparison,* in *Journal of European Public Policy*, 22(9), 2015, 1233-1252, http://dx.doi.org/10.1080/13501763.2015.1046902.

[47] In its amendments to the AI Act of June 14, 2023 (P9_TA(2023)0236), the European Parliament supports international regulatory cooperation strongly enough to invite the Commission to negotiate, with "countries which are on a comparable level of technical development and have compatible approach concerning AI and conformity assessment", mutual recognition agreements for documents produced by competent bodies of assessment to certify compliance with the requirements of the regulation: see the new Recital 65a to the Commission proposal, available at www.europarl.europa.eu/doceo/document/TA-9-2023-0236_EN.html.

[48] See the *Communication of the European Commission: An EU Strategy on Standardisation Setting global standards in Support of a Resilient, Green and digital EU Single Market*, on February 2, 2022, COM (2022) 31 final, 8. The EU-US collaboration on AI within the TTC has already resulted in a common EU-U.S. Terminology and Taxonomy for Artificial Intelligence, a document touching on concepts that are also important for the regulation of neurotechnologies (e.g. deep learning, machine learning, and differential privacy). Available at: https://digital-strategy.ec.europa.eu/en/library/eu-us-terminology-and-taxonomy-artificial-intelligence.

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The WTO system can offer the opportunity for such consultation on regulating disruptive technologies, which can be embedded into marketable products, at the multilateral level, within an already institutionalized international committee (the Committee on Technical Barriers to Trade – TBT Committee) composed of representatives of all the 164 members of the Organization.[49]

The clear gain in transparency obtained by embracing the above procedure appears particularly relevant if the draft measures to be presented, and possibly discussed in the frame of 'specific trade concerns' lead to the marketing of products, such as those based of neurotechnologies, that can powerfully shape the way in which people live, and can impact their health, wellbeing, work, and leisure.

While international fora for discussing the regulatory harmonization of medical devices already exist and are thriving,[50] the capacity of DTC neuro-devices to be horizontally relevant in significantly differentiated areas of the market adds value to the availability of such a broad venue for international debate.

A further argument in favour of pursuing regulatory harmonization at the intergovernmental level is linked to the need for legislators not to renounce their normative prerogatives in the ethically sensitive domain of neurotechnologies in favour of private institutions or businesses. Although it may seem too early to standardize BCIs, private standardization bodies are already working on this issue. The Institute of Electrical and Electronics Engineers Standard Association (IEEE SA) is set to release four standards on human augmentation: those on taxonomy and definitions, privacy and security, identity, and the methodologies and processes for ethical considerations.[51] The development of 'foundational standards' related to BCIs was undertaken in 2022 by the Joint Technical Committee for information technology, a consensus-based and voluntary international standards group established by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).[52] Once approved, these international standards will become the model for national regulatory measures that, by using them 'as a basis', would be presumed to be WTO legitimate under TBT Article 2.5.[53] The rationale of the provision is firstly to disincentivize regulatory protectionism and ease international trade. Standardization is also a means to fine-tune the quality and security of the goods and services.

In the context of neurotechnologies, however, the need to protect public interest and human rights demands that foundational decisions on how to integrate this technology into our society be made by

[49] On the structure, functions and possible enhancement of the role of the Committee from the perspective of the WTO reform, see: WTO, OECD, *Facilitating trade through regulatory cooperation*. The case of the WTO's TBT/SPS Agreements and Committees, 2019, 32 ff: https://www.wto.org/english/res_e/publications_e/tbtsps19_e.htm.

[50] Regulatory collaboration has proved successful for medical devices within the framework of the Global Harmonization Task Force (GHTF), which has been replaced by the International Medical Device Regulator Forum (IMDRF): www.imdrf.org/.

[51] https://standards.ieee.org/ieee/2049.4/10214/.

[52] The ISO/IEC AWI 8663 standard will provide definitions of terms commonly used in the field of Brain-computer Interface (BCI), including related neuroscience concepts such as coding and decoding, and feedback and stimulation: www.iso.org/standard/83268.html.

[53] The WTO jurisprudence has made it clear that the obligation to 'use as a basis' international standards in TBT Article 2.4 is fulfilled when there is no contradiction between such standards and the enacted measure: see *Appellate Body Report*, EC-Sardines (2002), para. 249.

democratically elected policymakers.[54] This demand can be satisfied by exploiting the potential of the TBT Committee as a forum for the multilateral discussions on regulatory options in the field of neurotechnological innovation.[55]

5. Transfer of technology and technology assistance as means to address the distributive justice issue

Another positive contribution that the legal order of the WTO can play in harnessing some of the risks related to the dissemination of DTC neurodevices can come from the implementation of the mechanism for the transfer of technology provided by the TRIPS Agreement and is instrumental for avoiding the dystopian segregation between an enhanced developed world and an unenhanced developing world.[56]

Non-invasive neurotechnologies, like TMS, tDCS, and neurofeedback can, in fact, be used to enhance personal capabilities related to learning (including language learning), memory, complex problem solving and mood.[57] Devices based on such technologies can arouse developers' interest in products intended for the highly profitable markets of developed countries, and this can widen the gap between developed economies and the so-called Global South. Citizens of the former will have available means of personal enhancement that will widen the already large gap between developed and developing countries in access to wellness and advanced education and in the national human resources development. It has been correctly affirmed that cognitive enhancement has "the potential to exacerbate socioeconomic disparities within and between countries".[58]

The risk posed by unequal access to technology has dual dimensions: for the individual and the endowment of their rights[59] and for society at large. The second facet of the issue (linked to the geopolitical aim to provide aid for the economic and sustainable development of the so-called third world)

[54] The need to limit the influence of businesses within the European Standardization Organization has been the driver of the recent modification of Regulation 1025/2012 of the European Parliament and of the Council of October 25, 2012 on European standardization: see Regulation (EU) 2022/2480 of the European Parliament and of the Council of 14 December 2022, http://data.europa.eu/eli/reg/2022/2480/oj.

[55] On the part of the EU, this approach would also be consistent with the view that the WTO reform will need to address the increased importance of regulatory issues compared with that of tariffs: www.europarl.europa.eu/factsheets/en/sheet/161/the-european-union-and-the-world-trade-organization.

[56] The risk of an 'enhancement divide' is acknowledged in the *Report of the International Bioethics Committee of UNESCO (IBC) on the Ethical Issues of Neurotechnology*, SHS/BIO/IBC-28/2021/3 Rev., Paris, 15 December 2021, para. 90.

[57] R. HAMILTON, S. MESSING, A. CHATTERJEE, *Rethinking the thinking cap: ethics of neural enhancement using noninvasive brain stimulation,* in *Neurology* 76, 2011, 187-193.

[58] M.J. FARAH, *Neuroethics*: *The Ethical, Legal, and Societal Impact of Neuroscience,* in *The Annual Review of Psychology* 63, 2012, 571-591.

[59] For example, the right not to be discriminated against in the access to higher education or in competing in the job market, or, for people with disabilities, the right to access and use neurotechnologies that can enable them to live independently and participate in social life, under Article 4 of the UN Convention on the Rights of Person with Disabilities (CRPD). Interestingly, as Marcello Ienca points out – in the Report on Common Human Rights Challenges Raised by Different Applications of Neurotechnologies in the Biomedical Field, which was commissioned by the Committee on Bioethics of the Council of Europe, 2021, 63 – the existence of a similar right of

can be addressed by promoting the advancement of knowledge and research in neurotechnologies under the TRIPS framework for the transfer of technology.[60]

To realize the TRIPS objective to "contribute to the promotion of technological innovation and to the transfer and dissemination of technology […] in a manner conducive to social and economic welfare",[61] Article 66.2 of the agreement mandates that "developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base".[62]

Since 2003, the implementation of this provision has been strengthened by the requirement that developed countries report annually on the implementation of their obligation under Article 66.2.[63] Among the initiatives listed in the 2021 report by the United States, we find, for example, the National Institute of Health *Mobile Health's programme* for exploring the potential for the development, validation, implementation, scaling-up, and commercialization of mobile health technologies. This covers a five year span, and encourages participation by the private sector.[64]

This mechanism is mandatory only for the least developed countries, and remains underexploited. Still, it provides an initial tool that can be used to address the inequality of the Global South in accessing all disruptive technologies, including neurotechnologies. In 2003 the mechanism was strengthened by the commitment by the members "to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector".[65] Moreover, it is supplemented with the technical assistance that WTO members, especially developing countries, can request in the preparation of technical regulations and standardization under Article 11 of the TBT.

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healthy people to access neurotechnological devices for the enhancement of their capabilities has not been recognized by the doctrine. In this regard, it is suggested that further studies investigate the relational, and non-absolute, nature of such a right, to be inferred from the level of technological development of the social community to which the subject belongs.

[60] The idea that reaching this aim requires filling up the gap in human capabilities between the developed and developing worlds, and that the responsibility to act lies with the States, which should use "a net of international treaties and other agreements" to this end, is expressed by Martha Nussbaum in *Creating Capabilities. The Human Development Approach*, Cambridge (Mass.), London, 2011, chapter 6. Delving deeper into the relationship between the capabilities approach and technology, Oosterlaken affirms that embedding technology into social local nets can lead to steadier development: see I. OOSTERLAKEN, *Technology and Human Development*, London-New York, 2015, 78 ff. These views strengthen the conviction of the significant potential of technology transfer in the fight against North/Global South inequalities.

[61] See Article 7 of the TRIPS Agreement.

[62] On the importance of the transfer of technologies and skills to reduce the inequality gap among countries, see: J. MAYER, *Globalization, technology transfer and skill accumulation in low-income countries*, in J. MAYER, S.M. MURSHED, *Globalization, Marginalization & Development*, 2002, 62–79, available at: https://search-ebscohost-com.unimib.idm.oclc.org/login.aspx?direct=true&db=bth&AN=17443199&site=ehost-live.

[63] J. WATAL, L. CAMINERO, *Least-Developed Countries, Transfer of Technology and the TRIPS Agreement*, Staff Working Paper ERSD-2018-01, WTO, 22 February 2018.

[64] *Report on the Implementation of Article 66.2 of the TRIPS Agreement of the United States of America*, 16 September 2021, P/C/R/TTI/USA/2, 35, accessible at the following link: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/CRTTI/USA2.pdf&Open=True.

[65] Annex to the Agreement on Trade-Related Aspects of Intellectual Property Rights, para. 6.

Although it needs to be triggered at the request of the interested country (especially 'developing country members') the kind of assistance provided for under this provision falls short of being an actual 'transfer of technology'. In fact, if a developing country requests it, a developed member "shall grant them technical assistance on mutually agreed terms and conditions regarding the steps that should be taken by their producers if they wish to have access to systems for conformity assessment operated by governmental or non-governmental bodies within the territory of the member receiving the request" (TBT Article 11.5).
If applied at their full potential, these legal tools can contribute to driving the technological advancement of developing countries and can make it less likely for a rise in medical and non-medical neurotechnological devices for human augmentation to broaden the gap between the societies of industrialized countries and those of the Global South.

6. Conclusions

Our inquiry into the contributions of the legal order of the WTO to the regulation and governance of the international trade of neurodevices allow us some final considerations.
A first possible role of the multilateral trading rules considered here is that of consenting governments to limit access to neurodevices to their domestic markets for reasons of safety, the protection of public morals and national security. We have briefly surveyed the trade-restrictive tools that WTO members can resort to for these purposes, from the refusal to acknowledge a likeness between drugs and brain-stimulation devices for mood modulation, to a vast array of exceptions to the commitments to trade liberalization that bind States under the GATT, GATS and TBT. The option to resort to the precautionary principle, and to make use of some of the flexibilities of the TRIPS Agreement to protect human health have also been suggested.
Particular attention has been devoted to illustrating the positive outcomes of the thorough use of the rules and procedures of the TBT to foster international regulatory harmonization and standardization, in order to develop a common approach to products that are ready for the market, and to exploit the frameworks for the transfer of technology and technical assistance to overcome the risks of a neurotechnological biopower[66] gap between developed countries and the Global South.
The WTO system is structurally open to intergovernmental and interagency collaboration. It offers an institutional framework for States to attain a high level of transparency and a global forum for striking a balance between the different and sometimes diverging public interests at stake in regulating international trade.[67]
The challenges of trading neurotechnological products can be fruitfully discussed within the Organization, especially in the TRIPS Council and the TBT Committee,[68] as well as under the framework of the trilateral cooperation on public health, trade and intellectual property, started in 2009 between the

[66] The expression was coined by T. BRINDLEY, J. GIORDANO, *op. cit.*, 37.
[67] *Treaty Establishing the World Trade Organization*, Marrakesh, April 15, 1994, Article III, paras. 2 and 5.
[68] The conviction that WTO committees and working groups are the correct setting for discussing the regulation of AI at global level, in order to overcome the different regional approaches that are also emerging within industrialized countries (for example in the protection of personal data) is expressed by P. KRUMMENACHER, *op. cit*.

World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the WTO.[69]

This initial collaboration on *trade-related aspects of neurotechnologies* can lead to the development of an international tool on the issue, and can help comprehensively regulate these technologies through a complex of international, regional and national instruments of different kinds (soft law or mandatory). They should take advantage of the support of the scientific community, which is already collaborating in the International Brain Initiative, and international organizations like the OECD, UNESCO,[70] and the Council of Europe[71] to develop a composite framework under which the relevant ethical challenges can be adequately addressed.[72]

The proposal to strengthen the role of the WTO, as a forum where its 164 member countries can discuss trade relationships in light of major changes undergoing in our society – from technological innovation to climate change – within a diversified and consolidated diplomatic infrastructure, and try to reach a consensus at the multilateral or even plurilateral level, also provides hope for a new dimension of an Organization whose role has been weakened in recent years, but that can still make an outstanding contribution to the peaceful course of international relations.[73]

[69] It is significant that at the eight Joint technical Symposium since the beginning of the trilateral collaboration the Director general of the WTO affirmed the centrality of trade in promoting the accessibility and affordability of cutting edge medical technologies, while the WHO Director general expressly mentioned among these technologies: 'wireless brain sensors', and 'artificial intelligence (AI) and machine learning': see WHO, WIPO, WTO *Joint Technical Symposium on Cutting-Edge Health Technologies: Opportunities and Challenges*, 31 October 2019, at www.wto.org/english/tratop_e/trips_e/wipobrien2019_e.pdf.

[70] In the United Nations system, the Human Rights Council has recently stepped in and has called for a study on how human rights opportunities, challenges and gaps arising from neurotechnology can be addressed: see www.ohchr.org/en/calls-for-input/2023/call-inputs-study-human-rights-council-advisory-committee-neurotechnology-and.

[71] The significant contribution that international organizations may provide through the adoption of non-binding rules, such as guidelines, codes, and/or principles of conduct, has been claimed by P. ACCONCI, *International Organizations and their Approaches to Neuroscience and Neurotechnology*, in *Risks and Challenges of Neurotechnologies for Human Rights*, Unesco-Università Milano-Bicocca, *cit*, 45-47.

[72] To this end, the establishment of a "broad international committee designed to meet regularly and assess neurotechnology developments with the aim of providing ethical guidance" has been recommended by S. GOERING, E. KLEIN ET AL., *Recommendations for Responsible Development and Applications of Neurotechnologies*, in *Neuroethics*, 14(365), 2021, 365-386, 380.

[73] On the crisis of the WTO see: G. SACERDOTI, *Multilateralism and the WTO in the Post COVID-19 World*, in *Italian Yearbook of International Law*, 29, 2019, 3-12.