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Trading Pharma Goods the WTO Legal Framework

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Response

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ABSTRACT

Trading of pharma goods has attracted widespread global attention in the wake of the COVID-19 pandemic. The Agreement on Trade in Pharmaceutical Products ("Pharma Agreement")–a sectoral agreement between a handful of WTO members–was concluded in 1994 and aimed to eliminate duties on various pharmaceutical products.

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Nevertheless, this is all that the Pharma Agreement does: it eliminates duties and does not touch upon the regulatory aspects relating to marketing of pharmaceutical goods. WTO members remain sovereign to decide on this score, but must observe the WTO Licensing Agreement as well as nondiscrimination. Thus, while the intensity of regulatory intervention is a function of a WTO member's risk aversion, members still have to ensure that their intervention does not counteract the assumed obligation aiming, roughly, to address protectionism.

I. THE ISSUE

In their thoughtful piece, Thomas Bollyky and Aaron Kesselheim advance an argument aimed to solve the persistent shortages in generic drugs in the United States.[1] We want to take one step back and provide a complementary argument regarding the consistency of this and similar policies with the rules of the World Trade Organization ("WTO"). We want to demonstrate why, wisely, the WTO regime has limited scope and does not prejudge the level of risk aversion that individual WTO members can endogenously define. The heterogeneity of its membership is in and of itself a good reason to adopt this attitude. This does not mean that WTO members cannot engage in trading of pharmaceutical ("pharma") goods with other like-minded players without being obliged to open up trade in pharma goods on a membership-wide basis. We explain why, even though case law on discrimination (an amorphous term, which is the legalese for protectionism) leaves a lot to be desired, there are solid arguments supporting this view.

In the following sections, we explain the Pharma Agreement, the natural place to kick-start our discussion. What we aim to do is to show the limits of the agreement and explain why it does not prejudge the level of risk aversion that individual members can unilaterally define. Then, in Section III, we move to our "plat de resistance," and explain why agreements with like-minded players are not only plausible (from an economics perspective), but also legally possible under the existing multilateral regime. Section IV discusses the role of the WTO in dealing with measures that impose restrictions on the export of pharma goods. The form of this role could be important in determining countries'

1. *See generally* Thomas J. Bollyky & Aaron S. Kesselheim, *Reputation and Authority: The FDA and the Fight over U.S. Prescription Drug Importation*, 73 VAND. L. REV. 1331, 1339 (2020) ("[S]uggesting a pathway for importing already-approved foreign versions of U.S. medications without patent protection or other forms of exclusivity…" as a way of preventing and reducing "the duration of off-patent drug shortages and price hikes.").

access to pharma goods such as personal protective equipment (PPE) kits, masks and vaccines (critical goods when faced with a pandemic) and more broadly, their fight against the COVID-19 pandemic. Section V concludes this response.

II. THE PHARMA AGREEMENT

A few weeks before the historic Marrakesh agreement signaling the advent of the WTO was signed, a few of the contracting parties of the General Agreement on Tariffs and Trade (GATT) signed the Pharma Agreement.[2] This agreement did not make any headlines. And yet, it accomplished no small feat: it eliminated duties on various pharma goods, and it did so on a most-favored nation ("MFN") basis, even though only a few WTO members negotiated it. Thus, while nonparticipants could still impose duties on goods covered by the Pharma agreement, they could profit from duty-free access in the markets of the signatories.

A. The Nature of the Agreement

The Pharma Agreement is termed in the WTO vernacular as a "sectoral" agreement, since it concerns one sector only. This is neither the only agreement of the sort, nor is it the exclusive privilege of the Uruguay Round. Other sectoral agreements exist, and sometimes they are self-standing (e.g., Civil Aviation Agreement),[3] whereas on other occasions, the results of sectoral negotiations were embodied in the schedules of concessions (e.g., beer, chemicals). Sectoral agreements were signed already in the Kennedy and Tokyo Rounds as well.[4]

2. 1994 Agreement on Trade in Pharmaceutical Products, Mar. 25, 1994, GATT L/7430 [hereinafter Pharma Agreement]. The original negotiators of the Agreement were Australia, Austria, Canada, Czech Republic, European Communities, Finland, Japan, Norway, Slovak Republic, Sweden, Switzerland, and the United States. Australia removed itself from the final Agreement later. *See* Communication from Australia, *Trade in Pharmaceutical Products: Record of Discussion*, June 30, 1994, GATT L/7430/Add.3. The current participants to the Pharma Agreement are Canada, the European Union, Japan, Macao (China), Norway, Switzerland, the United Kingdom and the United States.

3. Agreement on Trade in Civil Aircraft, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 4(a), 1186 U.N.S.T. 15511, 1869 U.S.N.T. 4508, https://www.wto.org/english/docs_e/legal_e/air-79_e.htm.

4. World Trade Organization, Sector Specific Discussions and Negotiations on Goods in the GATT and WTO, WTO Doc. TN/MA/S/13 at 5–7 (Jan. 24, 2005).

B. The Scope of the Agreement

The Pharma agreement concerns goods in the Harmonized System ("HS") chapter 30, a few items classified in scattered HS headings, as well as pharmaceutical active ingredients and chemical compounds used by the pharma industry. These are described in four annexes to the agreement, sometimes by their name, and sometimes in combination with an HS heading.[5]

Signatories agreed to eliminate tariffs and all other duties and charges (that is, all border protection of fiscal nature) with respect to the items covered on an MFN basis. But this is all they agreed to do.

III. TRADING PHARMA

Trade of pharma goods is of course not simply a question of tariff protection. Regulators, for good reasons, might wish to restrict trade in two respects: by imposing standards that imports must observe (since pharma are "sensitive" goods), and/or by restricting the agents who might lawfully commercialize pharma goods.[6]

Since the WTO is overwhelmingly a negative integration contract,[7] WTO members can decide on their level of risk aversion. Considering that some pharma goods could be abused, WTO members might restrict sales of such pharma goods by qualified agents only. Furthermore, and more to the point, WTO members might not trust production and marketing processes elsewhere. The U.S. Food and Drug Authority ("FDA") prides itself for embodying the "gold standard" in this area.[8] Assume an extreme case, where a WTO member, say the United States, consistently aims to approach, to the maximum extent possible, the "zero risk" scenario. Well then, in this case, only a few products will be allowed in its market. If, for example, there are two flu shots, one with a sixty-five to seventy percent efficacy (immunization) rate, and one with at least an eighty five percent efficacy rate, the

5. See Pharma Agreement, supra note 2, ¶ 1.

6. *See* E. Wesley, F. Peterson, Mechel Peggi & Guy Henry, *Quality Restrictions as Barriers to Trade: The Case of European Community Regulations on the Use of Hormones*, 13 W. J. AGRIC. ECONS. 82 (1998) (discussing how quality controls have been used in the European Union to enforce the hormones legislation).

7. The only common policy that WTO members agreed to is protection of intellectual property rights, as embodied in the Agreement on Trade-Related Aspects of Intellectual Property Rights. WTO disciplines, either absolute (like necessity) or relative (like nondiscrimination or consistency) aim to question the means employed to achieve an objective unilaterally defined by the regulating state, but never the objective itself. WTO members remain free to set their regulatory objectives endogenously, with no guidance from WTO headquarters.

8. Michelle Meadows, *Promoting Safe and Effective Drugs for 100 years,* FDA CONSUMER MAG. (2006).

United States has a nonjusticiable right to privilege only the latter. In that case, by virtue of the obligations assumed under the WTO, the United States will be obliged to open its doors to any flu shot, irrespective of its origin, that achieves the higher efficacy rate. To this effect, the United States is of course, legitimized to perform inspections and verifications (conformity assessment) to ensure that this has been the case. When preparing and performing these procedures, it will have to observe its obligations under various WTO agreements.[9] This is how it all unfolds.

A. Who Should Engage in Trading Pharma?

Some WTO members have notified schemes, where they restrict sales of goods aiming to protect public health through licensed-only vendors.[10] They have done so for various reasons, ranging from dual use of some goods to potential consumption externalities stemming from using drugs without adequate explanation regarding their proper use. It is qualified vendors (pharmacists) who are entrusted with the sale of similar goods.

There is no bright line between automatic and nonautomatic licensing in the WTO: the former is not precisely circumscribed, and the latter is understood as the default category. A few questions have been legitimately raised regarding the presence of conditions in the realm of automatic licensing, and how their presence might blur the frontier between automatic- and nonautomatic licensing.[11] The absence of case law makes it quite hard to distinguish one from the other.

It is quite remarkable that case law in the WTO has consistently established a hierarchy between a Uruguay Round Annex 1A agreement and the GATT: when confronted with claims under both, it would always initiate its analysis from the former, and revert to the latter only when necessary, and in practice very rarely so.[12] But the Import Licensing Agreement is an exception.[13] Panels have preferred to

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9. *See, e.g.*, Agreement on Technical Barriers to Trade art. 5–7, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1868 U.S.N.T. 120 [hereinafter TBT Agreement].

10. *See* PETROS C. MAVROIDIS, THE REGULATION OF INTERNATIONAL TRADE: THE WTO AGREEMENTS ON TRADE IN GOODS 15–16 (2016) (offering examples of such schemes focused on public health, such as the Korean import licensing scheme).

11. *See* MAVROIDIS, supra note 10, at 11.

12. *See* Appellate Body Report, *European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, ¶¶ 80–81 WTO Doc. WT/DS135/AB/R (adopted April 5, 2001) [hereinafter *EC–Asbestos*]. *See also* Appellate Body Report, *European Communities – Trade Description of Sardines*, ¶ 7.15, WTO Doc. WT/DS231/AB/R (adpted Oct. 23, 2002).

13. Appellate Body Report, *Argentina – Measures Affecting the Importation of Goods*, ¶ 6.448, WTO Doc. WT/DS438/444/445 (adopted Jan. 15, 2015).

review the well-founded of claims within the four corners of the GATT, without entering into the realm of the disciplines embedded in the Import Licensing Agreement.[14]

As mentioned, this has not stopped WTO members from restricting sales of pharma goods through some channels only.

B. Whose Pharma Do You Trust?

"Trust, but verify," is a phrase associated with U.S. President Reagan in his dealings with Soviet Union, the then fading superpower In a similar vein, WTO members retain the right to verify that imports exhibit the product characteristics indicated, for example, in their labels. They might want to engage in similar practices particularly in the realm of pharma trade, where meeting the product characteristics makes all the difference when it comes to measuring their effectiveness.

Inspection and verification are legitimate instruments irrespective of whether there is a harmonized or diversified process of production. We can distinguish between the following possibilities, at least in principle:

A. Home and Foreign produce pharma goods following their divergent regulatory paths;
B. Home and Foreign have harmonized their production processes;
C. Home and Foreign produce, as in (A), but have concluded a mutual recognition agreement ("MRA"), whereby they recognize each other's standard as equivalent to their own;
D. Home and Foreign, besides (C), have also concluded an MRA whereby they recognize each other's conformity assessment procedures as equivalent to their own.

(D) is of course the most trade-facilitating avenue. All that the pharma producers in Home and Foreign have to do, to be in a position to export to the other country, is to certify at home that their product conforms to the national production standard. They have, thus, concluded two recognition agreements: one recognizing each other's production standard, and a different one recognizing each other's conformity assessment procedures. The latter are referred to in literature as MRA+, and were an integral part and parcel of the now defunct

14. *See, e.g.*, *id.* at ¶¶ 6.361, 6.505, 6.511, 6.517, 6.523, 6.529, 6.535, 6.540, 6.543; Panel Report, *Indonesia – Importation of Horticultural Products, Animals and Animal Products*, ¶¶ 7.352–7.353, WTO Doc. WT/DS477/R (adopted Nov 22, 2017).

Transatlantic Trade and Investment Partnership ("TTIP") initiative, between the European Union and the United States.[15]

Compared to (D), all the other options represent an increase in transaction costs. They all share one feature: Home (or Foreign) will be verifying whether the goods imported meet the standard, even when they trust each other's standard, as in (C). This means that, upon exportation, there is uncertainty as to transaction costs. Indeed, the extreme point is that there is looming uncertainty as to whether there will be trade at all, since Home (Foreign) might find that the imported good falls short of their regulatory requirements, and order that it is shipped back to the country of origin. (D) provides the necessary certainty as to transaction costs and guarantees that gains from trade will be realized.[16]

Finally, (C) and (D) allow for gains from innovation to be collected. They create certainty as to transaction costs as does (B), but they also provide Home and Foreign with the incentive to compete in the production of goods, with respect to their respective regulatory regimes.

But of course, (B), (C), and (D) could concern only a subset of the WTO membership. How can this square with MFN, the quintessential element, indeed, the foundational stone of the WTO edifice? We turn to this question next. Before doing so though, let us briefly address (B). (B) could be either bilateral or multilateral. The latter is comprehensively addressed in the WTO Agreement on Technical Barriers to Trade ("TBT Agreement"), and Agreement on Sanitary and Phytosanitary Measures ("SPS Agreement").[17] Suffice to state that, to the extent an international standard can serve the regulatory objective of a WTO member, resort to it is compulsory. In case of deviation, the complainant will have to demonstrate that the regulating member did not observe necessity, or nondiscrimination. In the case of measures coming under the aegis of the SPS Agreement, WTO members need to ensure that the measures comply with the obligations to ensure consistency by basing their measures on scientific risk assessment, or, in its absence, by

15. *See* MAVROIDIS, *supra* note 10, at 431. *See also* Thomas J. Bollyky & Anu Bradford, *Getting to Yes to Transatlantic Trade*, FOREIGN AFFS. (July 10, 2013), https://www.foreignaffairs.com/articles/united-states/2013-07-10/getting-yes-transatlantic-trade [https://perma.cc/V2UL-5LQE].

16. Trade agreements are, of course, the means to combat uncertainty. For a recent reiteration of this intuition, see Nuno Limão & Giovanni Maggi, *Uncertainty and Trade Agreements*, 7 AM. ECON. J.: MICROECONOMICS 1 (2015).

17. *See* TBT Agreement, *supra* note 9, at art. 2.4, 2.5, 2.6; Agreement on the Application of Sanitary and Phytosanitary Measures art. 3, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 493.

observing the statutory requirements for lawful adoption of precautionary measures.

The legal test for bilateral harmonization is akin to the following discussion, as the only point to debate is to what extent bilateral harmonization observes or circumvents the cardinal obligation assumed under the WTO, namely, MFN.

i. Recognition and Nondiscrimination

Is recognition akin to conditional MFN? The latter concept has been in the radar screen of U.S. trade policy for many years, as Douglas Irwin explains in his unparalleled volume on this subject.[18]

Case law had not managed to provide an unambiguous response until recently, when in *EC-Seal Products*, the Appellate Body seems to have closed the door to whatever doubts had remained. In this report, the now extinct Appellate Body ruled that distinctions unrelated to origin are lawful, if they do not negatively affect competitive conditions for like products.[19] The key is the term "like product," and in *EC-Asbestos*, the same Appellate Body had endorsed the "reasonable consumer test": two goods are like products if a reasonable consumer would treat them as such.[20] In this latter case, a reasonable consumer would never privilege, in the Appellate Body's view, a health-impairing over a health-protecting good. Note that the degree of impairment, and the relative price of the two classes of goods, were not criteria for determining likeness in this decision.

The combined effect of these two reports should lead us to conclude that, in principle, conditions relating to meeting a certain health objective do not violate the MFN obligation. What could violate MFN is only serving one sauce for the goose, and another for the gander: if two pharma goods originating in two different countries both meet the standard, then both should be allowed in the market.

How does all this work with MRAs?

Recall, there are two salient elements in case law, and they must be cumulatively satisfied:

A. Conditions for granting an advantage must be unrelated to the origin of the goods involved; and

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18. *See* DOUGLAS A. IRWIN, CLASHING OVER COMMERCE: A HISTORY OF US TRADE POLICY 365 (2017).

19. Panel Report, *European Communities – Measures Prohibiting the Importation and Marketing of Seal Products*, ¶¶ 5.90, 5.93, WTO Doc. WT/DS401/5 (adopted March 15, 2011) [hereinafter *EC–Seal Products*].

20. *EC–Asbestos*, *supra* note 12, at ¶ 122.

B. They should not affect competitive conditions across like goods.

We now know that "like goods" will not be judged as such by uninformed, but by reasonable, consumers.[21]

Is a recognition agreement, say between the United States and Canada, regarding pharma goods, irrespective of whether we are dealing with generic or branded drugs, an advantage related to the origin of pharma goods? It seems that this is the question that needs to be addressed.

There should be no doubt that a recognition agreement is a trade advantage. An MRA absolves participants from a procedural step that is necessary (but might be insufficient) to access a foreign market.

Why would the United States enter into a recognition agreement with Canada, and not another WTO member? What is so special about Canada?

For starters, recognition is based on a rough notion of equivalence, a relative notion par excellence. The benchmark is provided by the regulatory framework of the recognizing state. A very risk averse nation will recognize as equal another risk averse nation, whereas a risk neutral nation will not be that picky. Homogeneity across players holds the key in predicting the dyads where recognition will occur. Juan Marchetti and Petros Mavroidis established a list of criteria (ranging from per capita income to quality/type of legal regime), which they used as proxies for homogeneity across players.[22] They then examined recognition agreements concluded in the realm of services trade: the higher the number of tabs a dyad was kicking, the likelier it became to sign a recognition agreement.

Second, recognition agreements are forward-looking instruments. It is not past experience that inspires them. It is confidence going forward. This means that what matters is not just past performance. It is the trust that, in the future as well, a certain level of performance will be attained. [23] It is trust about outcomes, based on

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21. It is irrelevant whether we agree or not with the findings in *EC–Asbestos*. *EC–Asbestos*, *supra* note 12, at ¶ 122. The purpose of our exercise is to discuss legality from the perspective of WTO law as it now stands, e.g., as contemplated through case law (in the absence of authoritative interpretations in this respect, as per Article IX of the Agreement Establishing the WTO), and not as how the law ought to have been understood.

22. Juan A. Marchetti & Petros C. Mavroidis, *I Now Recognize You (and Only You) as Equal: An Anatomy of (Mutual) Recognition Agreements in the GATS*, *in* REGULATING TRADE IN SERVICES IN THE EU AND THE WTO: TRUST, DISTRUST AND ECONOMIC INTEGRATION 415–443 (Ioannis Lianos & Okeoghene Odudu eds., 2012).

23. See the excellent analysis of Paola Sapienza, Anna Toldra-Simats & Luigi Zingales, *Understanding Trust*, 123 ECON. J. 1313 (2013), on this score.

trust on future conduct pursued, and the conviction that the observed conduct will continue to obtain in future times as well.

Under the circumstances therefore, choosing Canada looks like a rational choice for the United States. The density of regulatory intertwining between the two countries is quite remarkable, and the Council of Regulatory Cooperation, a forum where regulatory concerns are being discussed by the two partners before laws are even enacted, is the hallmark of this relationship.[24]

But all recognition agreements must, of course, observe MFN. So an eventual MRA (and/or MRA+) between the United States and Canada must also observe MFN. This is so, since Canada definitely receives a trade advantage, as described above, by signing an MRA with the United States (and vice versa).

Indeed in *US-Shrimp*, the Appellate Body held that offering the opportunity even to sign an agreement to some but not to all WTO membership constituted a violation of the requirement for evenhandedness (another way for nondiscrimination).[25] If offering the opportunity to sign an agreement suffices to find a violation of nondiscrimination, all the more so the actual signing of a contractual arrangement.

Indeed, the term "advantage" has been interpreted broadly under WTO case law[26] This is, of course, consistent with the standard of review adopted in similar cases: to protect not actual trade outcomes, but competitive conditions.

We stated above that a number of MRAs have been signed by various WTO members. The WTO itself encourages the signing of recognition agreements (see for example, Article 6 of the TBT Agreement).[27] No one has challenged the consistency of similar agreements with the WTO so far. We cannot state with any certainty whether this is because they are all WTO-consistent. What is clear though is that complainants have the burden of production of proof, and they face a formidable burden of persuasion as well. We explain this in the following section.

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24. MAVROIDIS, *supra* note 10, at 386.

25. Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, ¶ 171-17, WTO Doc. WT/DS58/AB/R (adopted Oct. 12, 1998); Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products,* art. 21.5 – Malaysia, ¶ 122,

26. *See, e.g.*, Appellate Body Report, *Canada – Certain Measures Affecting the Automotive Industry*, ¶ 84, WTO Doc. WT/DS139/AB/R, WT/DS142/AB/R (adopted May 5, 2000).

27. TBT Agreement, *supra* note 9, at art. 6.

ii. Nondiscriminatory Recognition: Untested in WTO Case Law

Assume a third country challenges the MRA between Canada and the United States, and requests its extension to it. It is clear that the complainant has the burden of production of proof.[28] The complainant will have to make a prima facie case that the advantage granted to Canada (or the United States) must be extended to it automatically and unconditionally.

The term "unconditionally," appearing in Article I of the GATT (MFN), emerges as the key term.[29] Case law has been far from clear and internally coherent on this score. In *EC-Seal Products*, the Appellate Body held that distinctions unrelated to origin are legal, if they do not negatively affect competitive conditions for like products.[30] Are two drugs, tested differently, marketed differently, the conformity of which has been assessed in different ways, like products?

We submit that, even in the worst-case scenario, i.e., even if complainant manages to prevail in its claim under Article I of GATT, it will not prevail overall. This is so because of the chapeau of Article XX of GATT (General Exceptions) to which Canada (or the United States) will seek justification.[31] According to the chapeau, evenhandedness (nondiscrimination) must be obtained, between countries where the same conditions prevail. How many countries look like Canada? How many countries can claim that they have enjoyed the same intensity and quality of regulatory cooperation with the United States? And recall, recognition is a forward-looking instrument. Complainants will have to rebut evidence provided by Canada (or the United States) to the effect that their preexisting cooperation was the main reason why they could trust each other's future regulatory practices.

The burden of persuasion is thus quite high and is in and of itself, a deterrent factor against frivolous legal challenges.

Additionally, of course, there must be awareness that rational actors would not engage in repeat interaction (the natural consequence of signing MRAs and MRAs+) for protectionist reasons. Why would any nation inflict on itself a recurring cost, deviating from more efficient sources of supply? At best (from the complainant's perspective) recognition agreements are signed on mixed motives. Rationally, the complainant should anticipate a deferential standard of review by

28. Panel Report, *United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India* 14, WTO Doc. WT/DS33/R (adopted Jan. 6, 1997).

29. General Agreement on Tariffs and Trade, art. I:1, Oct. 30, 1947, 55 U.N.T.S. 194 [hereinafter GATT].

30. *EC–Seal Products*, *supra* note 19, at ¶¶ 5.9, 5.93.

31. GATT, *supra* note 29, at art. XX.

judges, who might find it a quixotic test to distinguish wheat from chaff in similar scenarios.

The better arguments, thus, are in favor of staying away from litigating, unless it is for the most egregious cases. As stated above though, empirical accounts like that offered by Marchetti and Mavroidis suggest that recognition agreements are routinely signed by homogeneous players, as it should be expected to happen.[32]

IV. DISCRIMINATORY EXPORT QUOTAS ON PHARMA GOODS

The recent appointment of Dr. N'gozi Iwuela Okoji as the Director General of the WTO has sparked new interest on this issue because of her prior involvement in this issue through Global Alliance for Vaccines and Immunizations ("GAVI"). The problem in a nutshell is this. Import and export quotas are banned by the GATT Article XI, which can be imposed only upon demonstration of good cause, and assuming that impositions of quotas observe nondiscrimination.[33] But, whereas the GATT included detailed disciplines regarding the (nondiscriminatory) treatment of import quotas, there is nothing in terms of statutory language explaining what nondiscriminatory export quotas should amount to. In part, this is due to the intellectual difficulty in designing nondiscriminatory export quotas, a point already illustrated by Henrick Horn and Mavroidis.[34] It is also due to the absence of practice when the GATT was being negotiated.

Against this background, those who cannot produce vaccines, can hope that they will be spared from export restrictions. And they received some help from COVAX, an initiative put together by the World Health Organization, Coalition for Epidemic Preparedness Innovation, and GAVI, which distributed vaccines to Ghana first, and eventually to others as well.[35] The new WTO Director General, who had until recently been the Chairperson of GAVI, seems keen to see a role for the WTO in COVAX, if we judge by her nomination speech.[36] But what would that role be? In Horn and Mavroidis's line of thinking, the

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32. *See* Marchetti & Mavroidis, *supra* note 22.

33. GATT, *supra* note 29, at art. XI.

34. Henrik Horn & Petros Mavroidis, *Guest Post: What's Sauce for the Goose is not Sauce for the Gander? On Discriminatory Export Quotas for Vaccines*, INT'L ECON. L. & POL'Y BLOG (Feb, 27, 2021), https://ielp.worldtradelaw.net/2021/02/guest-post-whats-sauce-for-the-goose-is-not-sauce-for-the-gander-on-discriminatory-export-quotas-for.html.

35. *COVAX Vaccine-sharing Scheme Delivers First Doses to Ghana*, BBC (Feb. 24 2021), https://www.bbc.co.uk/news/world-africa-56180161.

36. *DG Okonjo-Iweala: WTO Can Deliver Results if Members "Accept We Can Do Things Differently"*, WORLD TRADE ORGANIZATION (March 1 2021), https://www.wto.org/english/news_e/spno_e/spno1_e.htm (full text of the speech).

GATT will either have to be observed, and thus outlaw all discriminatory export quotas of medicine, like, for example, those practices by the European Union,[37] or be "completed" by adding provisions to address the issue of nondiscriminatory export quotas in a detailed manner.[38] The latter has the merit that it will preempt unwarranted judicial discretion, which could occur if WTO judges are left on their own, in the current state of affairs, with no guidance as to what nondiscrimination is. Should they, for example, be inspired by the discipline in Articles I/III GATT, or by that in the chapeau of Article XX of GATT? The latter makes room for countries in dissimilar position (e.g., those in need to import vaccines, and those in no similar need), whereas the former does not. Of course, as it has been the case with the Pharma Agreement that we discuss in this paper, nothing stops the membership from entering into an ambitious negotiation to address the COVID-19 pandemic (and similar future occurrences, which, we are told by scientists risk seeing the light of day in the future) head on. In this case, the WTO will have to adopt a realistic approach. The multilateral legislative function is moribund, and some might see a similar negotiation as a proper forum for incongruous quid pro quos. The trading community should reflect on the merits of a plurilateral approach, as originally advocated by Bernard Hoekman and Mavroidis.[39]

V. CONCLUSION

In more than one way, trading of pharma goods is a precursor, a harbinger indeed of things to come. In a world where tariff protection has become irrelevant, markets are being segmented by regulatory barriers. Even though some tariffs in some markets in some countries still exist, the overall impact of tariffs on world trade has been, by any reasonable benchmark, in freefall during the last years. The occasional tariff hikes, like the ones we have experienced recently in the Sino-American trade war, are transitional.

Regulatory barriers can be erected at any time by any WTO member. The very purpose of the GATT (and of the WTO) was not to bring about an instrument for deregulation. The purpose of the GATT/WTO is to combat discrimination (legalese for protectionism). Nondiscrimination concerns the application, not the innate nature of

37. Commission Implementing Regulation (EU) 2021/111, 2021 O.J. (L 311) (making the exportation of certain products subject to the production of an export authorization).

38. Horn & Mavroidis, supra note 34.

39. Bernard M. Hoekman & Petros C. Mavroidis, *WTO 'à la carte' or 'menu du jour'? Assessing the Case for* More *Plurilateral Agreements*, 26 EUR. J. INT'L L. 319, 342 (2015).

regulatory interventions. For good reasons, the GATT/WTO is a negative integration regime, hence, it is unrealistic to believe that a deeper form of integration is feasible on a membership-wide basis.

Deeper integration is, on the other hand, necessary for market access to happen. Indeed, nondiscrimination is an empty shell for a country which cannot meet the higher regulatory standards of its preferred export market. But deeper integration, especially in the form of recognition, requires more than a willingness to integrate. Unlike (international) harmonization, there is no common agent, where policies are negotiated and concluded. In a harmonized context, the outcome is owned by all participants. In a recognition context Home cannot influence the shaping of policies in Foreign. It places its trust in the manner in which Foreign's regulatory process will work in the years to come.

One can thus easily understand why similar schemes cannot be WTO-wide. Sapir noted correctly, in our view, that the rise in free trade areas ("FTAs") coincides with tariffs worldwide being at an all-time low.[40] Their content, as reported in dozens of accounts, is eminently regulatory. And FTAs very often include recognition in one form or the other.

One way to look at FTAs is as expression of variable geometry. This is precisely what recognition agreements are all about. There is trade regionalization, albeit at a lower scale. And unlike FTAs, MFN must be observed. Variable geometry is the only realistic way forward in a world where trade is segmented by nontariff barriers, which, unlike tariffs, usually pursue a regulatory objective (and market segmentation is often the collateral damage). Hoekman and Mavroidis have argued that this is probably the most appropriate means for WTO to keep its relevance.[41] Unlike FTAs, plurilateral agreements, for example, keep the umbilical cord to the WTO intact. This is particularly true in the case of recognition agreements, which, anyway, must observe MFN.

40. André Sapir, *The Political Economy of EC Regionalism*, 42 Eur. Econ. Rev. 717, 727 (1998).

41. Hoekman & Mavroidis, *supra* note 39, at 342.