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Frederick M. Abbott

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EDITORIAL

Let International Competition Negotiations Sleep a While Longer: Focus on Tools and Capacity

Frederick M. Abbott

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The idea of a multilateral agreement on competition law is essentially as old as multilateralism itself.[1] Among other efforts, Wolfgang Fikentscher and the Max Planck Institute in Munich developed a concrete set of proposals in the early 1990s,[2] and the WTO briefly took up the idea of multilateral norms as part of the Singapore Agenda.[3] My experience over the past several years working with the United

[1] *See* the Havana Charter for an International Trade Organization, UNCTAD efforts starting in the 1970s, the WTO Singapore Agenda, and so forth. Frederick M. Abbott, *Public Policy and Global Technological Integration: An Introduction* in Public Policy and Global Technological Integration, pp. 3–13, F. M. Abbott and D. Gerber, eds., Kluwer Law International, 1997, available at SSRN: https://ssrn.com/abstract=1989042 [Abbott & Gerber 1997] [also in Chicago-Kent Law Review, Vol. 72, p. 345, 1996–1997]; Frederick M. Abbott, *Are the Competition Rules in the WTO TRIPS Agreement Adequate?* Journal of International Economic Law, Vol. 7, No. 3, pp. 687–703, 2004, available at SSRN: https://ssrn.com/abstract=917108 [Abbott 2004]; Carlos M. Correa, *Intellectual property and competition – room to legislate under international law*, in UNDP, Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries, United Nations Development Program (ed. F. M. Abbott) (2014), available at SSRN: https://ssrn.com/abstract=2439416.

[2] Wolfgang Fikentscher, *The Draft International Antitrust Code (DIAC) in the Context of International Technological Integration – The Institutional and Jurisdictional Architecture*, 72 Chi.-Kent. L. Rev. 533 (1996), available at: http://scholarship.kentlaw.iit.edu/cklawreview/vol72/iss2/14, also in Abbott and Gerber 1997, at pp. 211–220 and Appendix 2.

[3] *See* paragraph 20 of the Singapore Ministerial Declaration, Singapore WTO Ministerial 1996: Ministerial Declaration WT/MIN(96)/DEC, 18 Dec. 1996, providing, *inter alia*:

"… we also agree to:

…

establish a working group to study issues raised by Members relating to the interaction between trade and competition policy, including anti-competitive practices, in order to identify any areas that may merit further consideration in the WTO framework."

F. M. Abbott (✉)
Edward Ball Eminent Scholar Professor of International Law, Florida State University College of Law, Tallahassee, USA
e-mail: fabbott@law.fsu.edu

Nations Development Program (UNDP) leads me to conclude that focus on the development of multilateral competition norms – as such – should remain dormant at least for the medium-term future.[4] Incorporation of competition rules in bilateral, regional and plurilateral agreements between low- and middle-income countries (LMICs) and high-income country (HICs) is premature and may be counterproductive. More productive enterprise involves improving the tools that competition authorities employ, while bolstering the capacity of competition authorities in LMICs to deploy them. Regional cooperation agreements directed toward pooling of resources may be useful in this regard.

UNDP is encouraging the use of competition law in LMICs to improve access and affordability of health products, primarily pharmaceuticals.[5] As an expert advisor to the program, I have assisted in organizing and participated in the conduct of capacity strengthening consultations in Asia, Africa and the Latin America bringing together competition authorities, health regulators and intellectual property office personnel directed toward collectively building capacity and assisting with the implementation of national strategies.[6] Based on discussions during these capacity strengthening consultations and other meetings, there is a broad consensus among the participating government representatives that high-prices for medicines are a serious problem that needs to be addressed.[7] The competition authorities are typically engaged in some type of ongoing study/investigation or enforcement process in the pharmaceutical sector.[8]

[4] The basic idea that LMICs are better served by avoiding negotiation of international competition norms is not new. *See, e.g.*, Abbott 2004.

[5] UNDP, Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries, United Nations Development Program (ed. F. M. Abbott) (2014), available at SSRN: https://ssrn.com/abstract=2439416.

[6] *See*, *e.g.*, PowerPoints by Frederick. M. Abbott at Access to Health Technologies, Patents and Prices: Capacity-building Consultation on the Use of Competition Law to Promote Affordable Access, ISAGS UNISUR-FioCruz-UNDP, Rio de Janeiro, Brazil, 5–7 Dec. 2017, http://frederickabbott.com/content/isags-unisur-fiocruz-undp-consultation-competition-and-access-health-technologies#overlay-context=recent_presentations [hereinafter "ISAGS UNISUR-FioCruz-UNDP 2017"].

[7] As a general matter, LMIC governments face substantially greater challenges in assuring affordable access to healthcare than HIC governments. This should not come as a surprise. Healthcare is a line item in the national budget, and resources available in LMICs are more constrained than in HICs. In consequence, whatever may be the access problems in the Netherlands or USA, they are almost certainly greater in a low or middle-income country. Certainly, some countries do more than others. The Chinese government, for example, is strongly committed to achieving universal access to health care and devotes substantial budgetary and personnel resources to achieving this goal. WHO, China Policies to Promote Local Production of Pharmaceutical Products and Protect Public Health, World Health Organization 2017 (prepared by F.M. Abbott), available at: http://www.who.int/phi/publications/china_policies_promote_local_production_pharm/en/. The Indian government provides a minimum of resources to its healthcare system. WHO, Indian Policies to Promote Local Production of Pharmaceutical Products and Protect Public Health, World Health Organization 2017 (prepared by F.M. Abbott), available at: http://www.who.int/phi/publications/indian_policies_promote_local_production_pharm/en/. But, regardless of the general government attitude toward the health of the local population, high-prices for pharmaceutical products hinder access to medicines and harm patient populations.

[8] *See*, *e.g.*, Frederick M. Abbott, PowerPoint: Competition litigation/prosecutions and sector-wide inquiries in healthcare and health technologies: Country experiences, at ISAGS UNISUR-FioCruz-UNDP 2017.

There are fairly common problems that LMIC competition authorities face that make enforcement more difficult. Without question, a substantial impediment to enforcement is a comparative lack of resources available or allocated to fund the activities of the competition authority. This lack of resources sometimes reflects a general budgetary situation within the relevant country. Sometimes the resource constraint reflects a decision about government priorities which do not necessarily entail strong competition law enforcement. In any case, we see situations where company-specific or sector inquiries are not undertaken because funding, including for staffing, is not available. This is an area where solutions may be "less controllable" as a matter of legal or policy choice than other areas. But, it is by no means the only obstacle.

1 Access to Evidence

In the competition law context, access to information is important across all aspects. The traditional means for securing prosecutable information is voluntary and compulsory production of evidence by the target or targets of investigation.[9] Without adequate evidence, there is a limited range of potential action by competition authorities. This is an area where the relatively "young" competition authorities in LMICs suffer in comparison to their HIC counterparts.[10] Many competition authorities lack the power to compel the production of evidence, even when an enterprise is identified as the target of an investigation. For competition authorities in a substantial number of LMICs the answer to the question "what powers do you have to gather evidence" is answered by "we can only ask for it". Sometimes if the initiation of a formal inquiry is approved by the head(s) of the competition authority, compulsory process can be initiated. But there may be substantial political constraints affecting a decision to open a formal investigation. In effect, only by bringing a case before a judicial authority can compulsory production of evidence be secured. This is putting the cart before the horse. Bringing the case before assembling and analyzing the evidence presents obvious difficulties.

Recommendation 1: Support should be given to competition authorities in LMICs for the purpose of supporting legislative and/or regulatory reforms that will enhance investigative authority, in particular the authority to compel the production of evidence based on the competition authority's mandate to enforce competition law. Safeguards may and should be employed as appropriate to protect confidential commercial information against disclosure.

[9] *See*, *e.g.* Frederick M. Abbott, PowerPoint: Evidence and Remedies in Competition Law Investigations, ISAGS UNISUR-FioCruz-UNDP 2017.

[10] *See* US Department of Justice Antitrust Division Manual, Fifth Edition, Last Updated August 2017, available at: https://www.justice.gov/atr/file/761166/download; ECN Working Group Cooperation, Issues and Due Process, Investigative Powers Report, 31 Oct. 2012. European Commission Report on powers of competition authorities, and DOJ enforcement manual, available at: http://ec.europa.eu/competition/ecn/investigative_powers_report_en.pdf.

2 Transparency of Prices and Other Information

There is today a lot of talk about "transparency" in relation to the pharmaceutical sector, such as in the context of evaluating R&D costs in relation to prices.[11] Such information may be important to enforcement actions involving excessive pricing if patented single-source pharmaceuticals are brought within the scope of excessive pricing investigations.[12]

More generally, in relation to the general theme of transparency, a major issue across competition authorities is lack of data regarding pricing. Here, widely adopted corporate strategies enter into play. Pharmaceutical companies routinely require that pharmaceutical procurers enter into agreements that obligate secrecy of pricing information, which are treated as a "trade secret". Procurement authorities and other purchasers are potentially subject to legal action for breach of trade secrecy obligations if they disclose prices. The common seller's "pitch" for this obligation is that "we are giving you a special deal, but we cannot do that if others will learn of it, because they will demand the same thing".

At the outset of a pharmaceutical sector inquiry, the competition authority will want to assess the prices being charged in the local market in comparison with prices charged in other markets.[13] As a consequence of pharmaceutical industry practice, comparison across markets becomes quite difficult. Because the price of a pharmaceutical ultimately charged to a patient or insurance provider is typically subject to markup through the distribution process, access to the end-user price of that product may be of limited use. It is not clear how often pharmaceutical companies attempt to enforce trade secrecy regarding price in terms of initiating actions before courts or administrative authorities. It could be that "civil disobedience" by those procuring medicines would be sufficient to address this problem. But, to be clear, it is a common theme of competition authorities in LMICs that they are unable to get pricing information because of contractual confidentiality restrictions.

Recommendation 2: LMICs should be encouraged to adopt legislation making it unlawful to establish an obligation precluding the disclosure of the prices paid for pharmaceutical products, whether through trade secret or other forms of protection.

Broader efforts to require transparency of information relating to costs, margins and prices in the pharmaceutical sector should be pursued.

[11] *See*, *e.g.*, Catherine Saez, *WHO Members Set to Debate Transparency of R&D Costs*, Intellectual Property Watch, Jan. 24 2018; Council of Europe Parliamentary Resolution regarding public health and the pharmaceutical sector, Eur. Parl. Doc., Resolution 2071, 30th Sitting (2015) ¶ 1.

[12] Frederick M. Abbott, Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health, UC Irvine Law Review, Volume 6, Issue 3, pp. 281–320, Dec. 2016, available at SSRN: https://ssrn.com/abstract=2719095.

[13] Anticompetitive abuses are prevalent with respect both to the originator and generic pharmaceutical sectors as evidenced, for example, in the ongoing antitrust action by the US States Attorney Generals against a substantial number of generic producers, In re: Generic Pharmaceuticals Pricing Antitrust Litigation, United States District Court, Eastern District of Pennsylvania, Lead Case: 16-AG-27240.

3 Imbalance in Lawyering Resources

Competition authorities in LMICs face the same imbalance in legal resources that affect LMIC officials in other areas of law enforcement. The idea of taking on a Novartis, Pfizer or GSK in a protracted legal battle is intimidating in the sense that "winning" will likely mean defending appeals to the highest court of the land, and the attendant expense associated with protracted litigation. Novartis, for example, is famous in the patent arena for pursuing cases without hope of victory "because it can".[14] Pfizer and GSK may be willing to settle with the US government because they know that they cannot wear down government litigators until they surrender.[15] That may not be true in the typical LMIC.

Imbalance in legal resources is a persistent problem in the international legal system and its ultimate implementation and enforcement of rules in domestic law. It is a problem that affects implementation and enforcement of patent rules generally, and it has become a growing problem regarding investor to state dispute settlement (ISDS) mechanisms, causing a number of governments to step back from ISDS commitments. The wide-spread nature of the problem does not mean that it should not be addressed in respect to implementation and enforcement of competition law to the extent feasible. Since government budgets in LMICs are generally constrained, one route to approach the problem is by pooling resources. This is not so easy since domestic procedures differ, as do substantive law and language. Nevertheless, a good deal of competition law involves securing basic evidence and economic analysis, and aspects such as these may be less subject to material variation. For example, a regional investigation of pharmaceutical prices, patent and/or exclusivity abuses, and related matters are probably good subject matter for cooperative evidence-gathering and analysis.

Recommendation 3: LMICs should be encouraged to invest in establishment of pooled legal resource centers or other cooperative arrangements for investigating, analyzing and prosecuting competition law actions. Such centers or other arrangements may be most practical at the regional level.

4 New International Rules are Likely Pursued for the Wrong Reasons

In the competition arena, for the 60 + years from failure of the Havana Charter until quite recently, multinational business interests (i.e. the rent seekers) strongly resisted negotiation of multilateral competition rules. Yet, during the past several

[14] *See*, *e.g.*, *Novartis v. Union of India*, In the High Court of Judicature at Madras Dated: 06.08.2007 The Hon'ble Mr. Justice R. Balasubramanian and The Hon'ble Mrs. Justice Prabha Sridevan W.P. Nos. 24759 and 24760 of 2006, in which Novartis argued for direct application of the TRIPS Agreement despite obvious constitutional impediment of India's "transformation" system of treaty implementation.

[15] *See*, *e.g.*, US Department of Justice, Office of Public Affairs, GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data, July 2, 2012, to "resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices …"; Gardiner Harris, *Pfizer Pays $2.3 Billion to Settle Marketing Case*, NY Times, Sept. 2, 2009.

years, chapters on competition have emerged in bilateral, regional and plurilateral trade and investment agreements (TIAs), with active support from groups like the US Chamber of Commerce. It should be evident that US-based multinational corporations have not suddenly developed a passion for having themselves more closely regulated. They are, instead, worried about the activities of competition authorities in emerging market countries like China and India that suddenly threaten their freedom to operate.[16]

When two HIC governments negotiate a TIA and address competition policy and law, it is likely that the national competition authorities of the respective governments will have a significant voice at the negotiating table, and will appreciate the issues at stake in terms of potential restrictions on authority. The EU Competition Directorate and the US Department of Justice/Federal Trade Commission are unlikely to allow themselves to be frozen out of important potential changes to their authority. In the Australia-United States FTA, by way of illustration, a substantial portion deals with matters of cooperation in investigations based on previous specific agreements on competition law enforcement.[17] Though such TIA competition chapters have the capacity to restrict freedom of action, texts designed to facilitate cross-border prosecution of competition actions, including enforcement of judgments, may be useful. Moreover, negotiators were careful to avoid subjecting significant competition provisions to dispute settlement under the agreement.[18]

When the context is broadened to TIAs between LMICs and HICs, because of the relatively nascent character of many LMIC competition authorities and their lack of relative power within the national government structure, risks are substantially heightened that rules restricting the freedom of action of national authorities will be unduly constraining. This is, of course, the history of TRIPS-plus rules constraining intellectual property-related flexibilities in FTAs. This is not an argument based on the premise that competition authorities in LMICs lack the sophistication to understand the risks of terms that constrain competition rules. Individual competition personnel in LMICs may have equal sophistication with their HIC counterparts. The problem is rather that they confront the same power imbalance that public health-sensitive IP LMIC negotiators have faced in FTA negotiations. They lack the power status of finance ministry within the national government and their interests are more likely to be conceded as part of a trade package, just as the interests of the health authorities have been conceded. Moreover, even seemingly benign constraints imposed in the early days of competition law implementation may have deleterious consequences.

[16] *See, e.g.,* US Chamber of Commerce, Competing Interests in China's Competition Law Enforcement: China's Anti-Monopoly Law Application and the Role of Industrial Policy (2014), available at: https://www.uschamber.com/sites/default/files/aml_final_090814_final_locked.pdf.

[17] *See* Australia-United States Free Trade Agreement, Chapter 14, Competition-Related Matters, *e.g.*, at Art. 14.2: Competition Law and Anticompetitive Business Conduct (done May 18, 2004), available at: https://ustr.gov/trade-agreements/free-trade-agreements/australian-fta/final-text.

[18] *See* Art. 14.11, Aus-US FTA.

In the TPP, where a number of LMIC governments were involved with HICs, the competition rules on their face are benign procedural or due process obligations.[19] No one can object in principle to "good governance". But, the stakeholders supporting these rules have not set out to champion individual rights. Instead, their objective is to create a legal environment where trade authorities can bring pressure to bear with respect to the adequacy of processes, a way of throwing a wrench into competition law enforcement actions.[20] This goal may not be so difficult to achieve in many LMICs because of the general constraints facing the competition authorities in these countries, which make prosecuting enforcement actions somewhat difficult without these additional complications.

Just as with the inter-competition authority agreements traditionally entered into between HIC authorities, the nascent interests of LMIC authorities are perhaps best served by intra-group rules facilitating cooperation on matters such as evidence-sharing, enforcement of judgments and other matters relating to making prosecution more efficient. Care should be exercised even with respect to seemingly benign rules regarding matters such as internal due process. Such rules can be taken advantage of by powerful corporate actors to inhibit investigations and prosecutions. Substantive rules are almost certainly better left for a later stage.

One final aspect should be mentioned. Based on a long history, competition doctrine in HICs is to some extent "calcified". Basic doctrinal shifts are very slow in coming. LMICs are positioned to serve as competition laboratories because domestic doctrine is evolving today. My own hope is that LMIC competition authorities will lead a push for enforcement against excessive pricing; recognizing that the UK Competition and Markets Authority (CMA) has already moved in this direction, and the EU Commission has taken some small steps. Efforts by USTR and other HIC trade negotiating authorities to prescribe competition norms is almost certain to be directed towards putting a break on the evolution of strengthened doctrine.

Recommendation 4: LMICs (and HICs) should resist efforts to introduce competition rules in international agreements that impose constraints on the discretion embodied within national competition systems. "Due process" should be left for national constitutional and judicial processes, within the general constraints imposed by international law. As discussed in Recommendation 3, regional negotiations aimed at improving the tools at the disposal of competition authorities, such as establishment of pooled legal resource centers and evidence-sharing should be pursued.

[19] *See, e.g.*, Chapter 16, Competition Policy, Art. 16.2: Procedural Fairness in Competition Law Enforcement, Transpacific Partnership Agreement, Consolidated TPP Text, available at: http://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/tpp-ptp/text-texte/final_agreement-accord_finale.aspx?lang=eng.

[20] In the TPP, the competition rules are not subject to enforcement pursuant to the dispute settlement chapter of the agreement. (*see* Art. 16.9: Non-Application of Dispute Settlement: "No Party shall have recourse to dispute settlement under Chapter 28 (Dispute Settlement) for any matter arising under this Chapter." While this certainly reduces the immediate threat, this is a first "beachhead" into the area, and should be anticipated to become stronger once the concept becomes embedded.

5 Conclusion

There is wide international consensus that competition rules play a valuable role in balancing public and private interest. Significant progress has been made in the development of competition law interests in LMICs. Nonetheless, competition authorities face substantial obstacles in investigating and prosecuting anticompetitive abuses. Improved investigatory tools are needed, as are budget resources. Cooperative regional arrangements are one approach that has potential. National reforms that give competition authorities stronger investigative powers, and to promote transparency, are important. In the meantime, subjecting these nascent authorities to additional constraints through rules in TIAs is unnecessary and likely to be counterproductive.

The concept of an integrated international competition rule and enforcement system has a natural appeal for those who believe that multilateral organizations can serve a valuable role in promoting shared values and broadly advancing public interests. History teaches caution. Governments negotiate and ultimately control multilateral governance, and governments, and particularly trade negotiators, are influenced by stakeholder interests. In the competition arena, until recently major multinational corporations strongly resisted the negotiation of multilateral rules because they enjoyed wide freedom to operate, particularly in LMICs. That has changed as freedom to operate has been increasingly curtailed. The pushback is a demand for rules to regulate competition authorities. This demand should be treated with great caution.

There may come a "golden age" when there is a sufficient balance between corporate and LMIC competition authority power that negotiation of substantive competition rules can be undertaken to further the public interest. We are not in that golden age.