Nicolas Charbit
Sébastien Gachot
Editors

Eleanor M. Fox

Antitrust Ambassador to the World

Liber Amicorum

Skaidrīte Ābrama, Berfu Akgün, Giuliano Amato, Donald I. Baker, Maciej Bernatt, Darryl Biggar, Tembinkosi Bonakele, Dennis M. Davis, Lisl J. Dunlop, Adrian Emch, Allan Fels, Harry First, Owen Fiss, Albert A. Foer, Michal S. Gal, Damien Gerard, David J. Gerber, Bulut Girgin, Gönenç Gürkaynak, Deborah Healey, Andrew Heimert, Alberto Heimler, Edward Iacobucci, Jonathan Klaaren, Assimakis P. Komninos, Ujjwal Kumar, Pradeep S. Mehta, Giorgio Monti, Wendy Ng, Sibusiso Radebe, Albie Sachs, Taimoon Stewart, Michael Trebilcock, Joseph Wilson, Koren W. Wong-Ervin, Wang Xiaoye

Concurrences
Antitrust Publications & Events

Competition Policy and Access to Healthcare

Pradeep S. Mehta and Ujjwal Kumar*
CUTS International

Abstract

This focuses on the role of competition policy and law in enhancing access to healthcare, understanding that access to healthcare is largely dependent on its "availability" and "affordability." In countries where the free or subsidized public health systems are not so robust, out-of-pocket expenditure has the potential to further push people below poverty line. The paper analyses the ex ante competition policy and then ex post competition law enforcement as tools to enhance access to healthcare.

---

* The authors work for CUTS International, a global policy think tank situated in India, US, Switzerland, Ghana, Kenya, Zambia, and Vietnam. Pradeep S Mehta is founder and Secretary General of CUTS, established in 1983. Mehta, a prolific writer, gifted speaker, and skilled trainer and organizer, has been a member of several national and international committees and other policymaking bodies. Mehta has been named as one of the 30 most famous columnists in India by a leading newspaper in India and has published/edited several books and papers on trade, investment, competition, and development. Ujjwal Kumar is policy analyst at CUTS and has been working on issues related competition, regulation, and intellectual property rights across sectors for more than 20 years.

I. Background

The coronavirus (COVID-19) pandemic has put healthcare as the top policy priority the world over. Public health interests prevailed over national economic interests when widescale lockdowns were announced that had severe adverse effects on economic activities, including loss of livelihood for millions. The global economic slowdown due to the pandemic is not only shrinking gross domestic products (GDPs) of economies of the world, but is also severely hitting international trade. It is believed that economies may further spiral down before showing signs of recovery. All these have resulted (or resulting) in pushing millions below the poverty line, dwarfing several gains from liberalization and globalization in the last three decades.

Like many other policy tools, competition policy also responded on the extraordinary situation created by the pandemic lockdown. Several articles and reports dealt with how competition policy reacted or how it should react.[1] This also include a discussion paper by Andrew Tyrie, chair of the UK Competition and Markets Authority (CMA).[2]

In general, competition policy (suggested) responses are two-pronged–one for smooth supply of essential items like healthcare and food items, and the other with respect to post-lockdown economic recovery. For the first, the most prominent approach has been to ensure that competition enforcement does not pose a hurdle for business cooperation necessary for the supply of essential items. However, for the second (i.e. to address economic recovery) the matter is complex, owing to the continued economic uncertainties due to emergency pandemic measures. Nonetheless the approach suggested in this regard, inter alia includes measures to curtail likely increase in market concentrations and to check policy-induced market distortions.

In sum, the post-pandemic policy interventions would need to address increased poverty while simultaneously ensuring economic recovery. Here a decade-old competition policy prescription by Eleanor Fox could be the guiding *mantra*. According to her, "If policy is to be friendly to economic development, it must look dire poverty in the eye: it must harness market forces to keep prices competitive; it must build a ladder of mobility from the lowest rung up, to enable mobility centered entrepreneurship and stimulate innovation."[3]

---

1 For instance, *see*, Frédéric Jenny, *Economic resilience, globalisation and market governance: Facing the COVID-19 test* (OECD, Apr. 2020); Udai S. Mehta & Sakhi Shah, *Competition Enforcement for Business Collaborations during COVID-19–A Global Perspective* (CUTS International Discussion Paper, July 2020), https://cuts-ccier.org/pdf/competition-enforcement-for-business-collaborations-during-covid-19.pdf.

2 Andrew Tyrie, *How Should Competition Policy React to Coronavirus?* (CMA Discussion Paper, 2020), www.ippr.org/files/2020-07/how-should-competition-policy-react-to-coronavirus-july20.pdf.

3 Pradeep S. Mehta & Taimoon Stewart, Should Competition Policy & Law be Blind to Equity? The Great Debate 96–97 (2013).

According to Fox, competition is in fact a market system with handful of sister systems and efforts, the success of each being a necessary condition for enabling the disempowered. This includes education, healthcare, infrastructure, job opportunities, and availability of capital for good ideas, all in a context of good governance, which must include the absence of pervasive corruption. The house of opportunity, participation, and ultimately growth is built one small brick at a time. The entire system, if it pulls together, can improve the lot of the half of the world that is living in poverty. All of the efforts together can help to close the gap.[4]

In this backdrop, this paper focuses on the role of competition policy and law in enhancing access to healthcare, understanding that access to healthcare is largely dependent on its availability and affordability. In countries where free or subsidized public health systems are not so robust, out-of-pocket expenditure has the potential to further push people below poverty line. This paper analyses the *ex ante* competition policy and *ex post* competition law enforcement as tools to enhance access to healthcare. The final section includes a conclusion and a few suggestions for policymakers and competition agencies around the world. In looking at the healthcare, the scope of this paper is largely confined to healthcare services and pharmaceuticals.

II. Competition Policy Approach

To keep markets competitive, competition law enforcement alone may not be sufficient. The first thing that is needed is an enabling policy environment that promotes competition in the market, including removing entry barriers, removing market distortions, and inducing ease of doing and running businesses.

1. Patent and competition policy

Competition in the pharmaceuticals market depends more on intellectual property (mainly patent) policy than on the enforcement of competition law. Access to medicines significantly increases when generic competition is present, which in turn is highly dependent on the kind of domestic patent law applicable.

For instance, change in patents law of India in 1970 are attributed to the development of domestic pharmaceutical industry and consequent high level of generic competition. It recognized process patents only and not product patents. This allowed Indian manufacturers to reverse-engineer patented pharmaceuticals and use a different process to manufacture the same at a much lower cost. This has significantly helped access to drugs not only for the poor population in India, where out-of-pocket healthcare expenditure is more prevalent, but also poor

4 OECD, *Global Forum on Competition–Competition and Poverty Reduction: Contribution from Ms. Eleanor Fox* (DAF/COMP/GF(2013)4, Feb. 14, 2013), at 2–3.

populations in many parts of the world. In addition, export of generic drugs from India significantly contributes to its economy. In fact, India has the largest generic pharmaceutical industry in the world.

In 2005, when the clause on product patents under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) of the World Trade Organizationcame into force, India fully incorporated the same along with its procompetition provisions (TRIPs flexibilities) in its patents law i.e. the Patents Act, 1970. This approach helped India maintain its level of generic competition to significant extent. Bangladesh has also developed a domestic manufacturing base with good level of generic competition using the mandated transition period for least developing countries (LDCs) under the TRIPs agreement.

One of the identified issues having adverse effect on competition in pharmaceutical market is "evergreening" of patents.[5] To overcome this menace, the Indian patents law has stricter patentability criteria to ensure the quality of patents.[6] The constitutionality of this unique provision has already been established by the Supreme Court of India in the famous *Gleevec* case, where the Court upheld the rejection of patents and observed that the substance sought to be patented was a modification of a known drug and there was no evidence of any enhanced therapeutic efficacy.[7] There is no ambiguity in the Indian law, which was postulated by one of these two authors.[8]

There are many flexibilities in the TRIPs agreement, such as compulsory license for domestic production as well as exports, Bolar exception, exhaustion of IPRs, data protection under article 39.3, etc., which if incorporated in domestic IP laws will have procompetition effects on the market. International instruments like the Doha Declaration on the TRIPs Agreement and Public Health, 2001 and the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, 2008 (GSPA-PHI) mandates countries to use such flexibilities to enhance access to medicines. However, there are bilateral, regional, or plurilateral trade agreements, particularly involving the USA, that tend to mitigate available TRIPs flexibilities. Developing countries and LDCs need to be careful in signing such TRIPs+ deals. Competition agencies can, accordingly, advocate this to their respective governments.

---

5 Evergreening of patents is a strategy to extend the life of patents by applying for secondary patents over related or derivative technologies, often for trivial changes to the invention.

6 According to section 3(d) of the Patents Act, 1970, "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant" are not inventions, and hence, are not patentable.

7 Novartis AG v. Union of India (Civil Appeal Nos. 2706-2716, 2013); https://docs.google.com/file/d/0Bxi2TzVXul5ZQ1BMeFNJbnV1Mkk/edit.

8 www.financialexpress.com/archive/there-is-no-ambiguity-in-indian-legislation/211334/.

2. Regulation and competition policy

The pharmaceutical sector is one of the most regulated sectors in most jurisdictions. Two of them *viz.*, market approval regulation and price regulation, need to be optimal–not more restrictive than needed. The regulation of biosimilar drugs (generic version of biological drugs) have been flagged as overregulation in most jurisdictions, which creates barriers on generic competition.[9] Similarly, price regulation of drugs is also included in the list where generic competition is available in large volume, which kills market contestability. Price regulation needs to be used as last resort in case of market failure.

Another hurdle is with respect to the prescription practices of doctors, who generally prescribe in the form of brand names. Their main argument for such practice is "trust" of quality, however, a nexus between prescribers and pharma companies also cannot be ruled out.[10] Therefore, in order to engender confidence of doctors in available generic substitutes, it would be wise to invest in regulation and make it trustworthy. Once doctors and consumers perceive available generics to be of same quality, it will have procompetition outcomes. Having standard treatment guides would also contribute to transparency by removing information asymmetries, and hence would be procompetitive.

Similarly, policymakers need to remove entry barriers for the establishment of new hospitals and medical colleges. These have high initial establishment costs and a long gestation period to break even, which discourages investors. If government policies can facilitate land requirements, import of medical equipment and devices, penetration of health insurance, etc., coupled with optimal regulation of medical education, it will significantly contribute to competition in healthcare market as well as accessibility.

III. Competition Enforcement

There are several anticompetitive practices in the healthcare and pharmaceutical sector that have been dealt with by competition agencies around the world. Following are some of such examples.

1. Pay-for-delay

Pay-for-delay (also called as reverse payment settlements) is a practice in the pharmaceutical industry whereby the originator firms compensate their generic counterparts for delaying the introduction of their generic versions in market.

---

9 *See*, *e.g.*, Amit Sengupta, Biological Drugs: Challenges to Access (2018).

10 *See*, *e.g.*, CUTS, Unholy Alliances in Healthcare–Collusive Behaviour in Healthcare and Impact on Consumers: Evidences from Assam & Chhattisgarh (2011), https://cuts-ccier.org/pdf/Research_Report-Unholy_Alliances_in_Healthcare_Services-COHED.pdf.

Generally, such deals are in form of patent dispute settlements in which generic manufacturers acknowledge the patent of the originator company and agree to refrain from marketing their generic versions. In return, generic firms are compensated by the originator firms. Such arrangements can be anticompetitive since they prevent generic competition that could bring the prices down significantly.

In 2013, in the *Lundbeck* case, the European Commission found the presence of a pay-for-delay arrangement and imposed fines on all the parties involved–€93.8 million on Lundbeck and a total of €52.2 million on the generics companies.[11] In 2016, the General Court upheld this decision.[12] In 2014, the Commission decided another pay-for-delay case and fined Servier and five other generic drug manufacturers with €427.7 million.[13] The US Supreme Court, in *FTC v. Actavis* (2013), has also held that a pay-for-delay agreement can face an antitrust challenge under rule of reason.[14]

2. Frivolous litigation

The pharmaceuticals sector is heavily regulated mainly to ensure "unavoidably unsafe products," which offer desired benefits but are not without risk. However, these regulations provide several windows giving rise to litigation, which sometimes could be frivolous with the intention to impose hurdles on generic competition.

In the case *Biocon v. Roche* (2016) before the Competition Commission of India (CCI), it was alleged that the Roche Group started indulging in frivolous litigation with the intention of preventing the entry of the generic version (biosimilar) of the biologic drug Trastuzumab. The CCI, finding a prima facie case of abuse of dominance, ordered an in-depth inquiry.[15]

In 2005, the European Commission had fined AstraZeneca €60 million for abusing its dominance, where it made misleading representations before patent offices and national courts of several European countries and had also taken steps to delay the marketing of generic versions, including by preventing parallel imports by exploiting loopholes in the legal system.[16] The Commission's decision was

---

11 Case AT.39226 Lundbeck (Commission decision C(2013) 3803), https://ec.europa.eu/competition/elojade/isef/case_details.cfm?proc_code=1_39226. *See also* Johan Van Acker & Dina Ansari, *The EU Commission imposes fines totaling up to €145 million on a Danish pharmaceutical group over pay-for-delay agreements (*Lundbeck*)*, E-Competitions June 2013, Art. N° 53996 (June 19, 2013) Concurrences+.

12 European Commission, Press Release, Antitrust: Commission welcomes General Court judgments upholding its Lundbeck decision in first pharma pay-for-delay case (MEMO/16/2994, Sept. 8, 2016), https://ec.europa.eu/commission/presscorner/detail/en/MEMO_16_2994.

13 European Commission, Press Release, Antitrust: Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine (IP.14.799, July 9, 2014), http://europa.eu/rapid/press-release_IP-14-799_en.htm.

14 FTC v. Actavis, Inc., 570 U.S. 136 (2013). *See also* Tim Frazer et al., *The US Supreme Court holds that "reverse payment" patent settlements between brand-name drug manufacturers and would-be generic competitors should be reviewed under the antitrust rule of reason (*Actavis*)*, E-Competitions June 2013, Art. N° 52994 (June 17, 2013) Concurrences+.

15 Biocon v. Roche (Case No. 68, 2016), www.cci.gov.in/sites/default/files/68%20of%202016_0.pdf.

16 Case AT.37507 Generics/Astra Zeneca https://ec.europa.eu/competition/elojade/isef/case_details.cfm?proc_code=1_37507.

later upheld by the General Court in 2010 and an appeal to the European Court of Justice was rejected in 2012.[17]

3. Cartels

Cartels are arrangements between competing firms designed to limit or eliminate competition between them, with the objective of maximizing their profits and without resulting in any objective countervailing benefits. In practice, this is generally done by fixing prices, limiting output, sharing markets, allocating customers or territories, bid-rigging or a combination of these. Cartels are harmful to consumers and society as a whole. Pharmaceuticals and healthcare sectors are also marred by such anticompetitive agreements, facing competition enforcement.

The Fiscalía Nacional Económica (FNE), Chile, filed a complaint in December 2008 against three retail pharmacies accusing them of concerted action resulting in increases in the prices of 206 drugs between December 2007 and March 2008. In April 2009, a settlement agreement was reached between FNE and Farmacias Ahumada, which agreed to pay a fine of USD 1 million. In January 2012, Tribunal for the Defense of Free Competition (TDLC) imposed a maximum applicable fine of approximately USD 20 million on each of the two remaining retail pharmacy chains. In September 2012, the Supreme Court upheld TDLC's decision, flagging that economic interest was placed before human dignity, life and individual health.[18]

In 2008, the Competition Commission of South Africa published a press release having prosecuted three pharmaceutical companies that were involved in bid-rigging and market allocation arrangements. One of the cartel members applied for leniency and cooperated with the Commission. In the same year, the Peruvian Competition Authority sanctioned certain suppliers of medical oxygen to Peru's public health system who were found to be in cartel. These suppliers had distributed the procurement bids geographically between 1999 and 2004.[19]

A primary study by CUTS International in 2011 had found the presence of collusive behavior and vertical relationships between doctors/hospitals and pharmacies/ diagnostic centers. An extremely high frequency of referrals combined with the prevalence of "cuts" for referring doctors was noted.[20]

---

17 Case T-321/05 AstraZeneca v. Eur. Comm'n, EU:T:2010:266; Case C-457/10 P AstraZeneca v. Eur. Comm'n, EU:C:2012:770.

18 UNCTAD, Intergovernmental Group of Experts on Competition Law and Policy: The impact of cartels on the poor (13th session, Geneva, July 8–12, 2013), https://unctad.org/meetings/en/SessionalDocuments/ciclpd24rev1_en.pdf.

19 *Id.*

20 *See*, *e.g.*, CUTS, *supra* note 10.

4. Vertical restraints

Vertical agreements (i.e. between undertakings operating at different levels of the production chain) are a common feature in the market as a substitute for vertical integration. Since vertical arrangements exert mixed effects on the competitive process, it has to be judged on the basis of the reasonableness of any restraint that they pose. Generally, vertical agreements include exclusive or selective distribution agreements, exclusive supply agreements and tying agreements. Such agreements may result in foreclosure of the market to competitors and elimination of interbrand competition.

The CCI has dealt with a number of cases where the pan-India and/or state-level chemist and druggists associations tried to control the appointment of stockists, sales of pharmaceutical products, and wholesale and retail margins. In most such cases the practices of mandating a "No Objection Certificate" (NOC) as a prerequisite for the appointment of stockists and also to refrain from fixing "trade margins" for retailers and wholesalers were involved.[21]

The CCI, in October 2018, published a policy note titled "Making Markets Work for Affordable Healthcare," wherein it made the following observation about trade associations:

> The cases before the Commission have shown that the entire supply chain of drugs is self-regulated by the trade associations who regulate entry by mandating a NOC prior to the appointment of stockists, control distribution by restricting/controlling the number of stockists and influence price by deciding the wholesale and retail margins of drugs. The Commission's past interventions have led to some positive outcomes and businesses and business associations have revised their policies and practices to bring them in alignment with the principles of competition.[22]

In 2011, the National Development and Reform Commission (NDRC), China found that two pharmaceutical companies (Shuntong and Huaxin) had signed exclusive distribution agreements with the only two domestic producers of active pharmaceutical ingredients, allowing them to control the supply of a key raw material for a commonly used compound in high blood pressure treatments. These agreements required the producers to obtain approval from both companies before selling the product to any other party, in order to eliminate competition. The NDRC fined these companies RMB 7 million (c. USD 1.1 million).[23]

---

21 *See*, *e.g.*, Rupin Chopra & Chanakya Sharma, CCI–Chemists and Druggists Associations Warned to Refrain from Indulging into Anti-Competitive Practices (2016), www.lexology.com/library/detail.aspx?g=eef58c14-38da-446f-ae71-cb592d51fd8b.

22 CCI, *Policy Note: Making Markets Work for Affordable Healthcare* 6 (Oct. 2018), www.cci.gov.in/sites/default/files/event%20document/POLICY_NOTE_0.pdf?download=1

23 James Quinney et al., NDRC imposes high fines on two pharmaceutical companies for antitrust infringements (2011), www.lexology.com/library/detail.aspx?g=dc6b7cf6-1923-48b5-8307-353a9d9024b9.

5. Excessive pricing

There are instances where unilateral conduct of companies has been found to result in excessive prices of drugs. The famous *Aspen* case in Italy is a good example. In 2016, the Italian Competition Authority (AGCM) fined the Aspen pharmaceutical group for abuse of dominance in form of excessive prices concerning some essential off-patent drugs. The price increase ranged between 300 to 1500%. The AGCM found both the lack of effective competition (Aspen was the only supplier in each of the relevant markets) and potential competition. Despite being off-patent, new generic producers lacked the incentive to enter in the market given the scarce volume of the market.[24]

6. Mergers and acquisitions (M&As)

There are instances where M&As can also pose competition concerns in one or more therapeutic segments. In such cases the general trend has been to put specific divestment conditionality for allowing such M&As.

Very recently (in 2020) the European Commission approved the acquisition of Pfizer's Consumer Health Business by GlaxoSmithKline (GSK). During the review it was found that the acquisition would reduce the competition in topical pain management products in countries like Austria, Germany, Ireland, Italy, and Netherlands. The products of GSK and Pfizer were broadly substitutable in the market for topical pain management. Therefore, the acquisition was allowed, subject to a condition for the global divestment of Pfizer's topical pain management business under the *ThermaCare* brand.[25]

In 2019, the US Federal Trade Commission (FTC) reviewed the merger of Bristol-Myers Squibb (BMS) and Celgene Corporation. The FTC observed that if this acquisition would take place, it would lessen competition in the relevant market and create a monopoly by eliminating any future competition between Celgene and BMS in development of drugs for treatment of psoriasis. Consequently, any new competitors in the market would face delays for drug development and obtaining marketing approval. The merger was allowed when Celgene consented to divested Otezla, a popular skin ailment drug, to Amgen, a California-based pharmaceutical company. This was the largest divestiture ever made in a merger enforcement matter, valued at USD 13.4 billion.[26]

---

24 OECD, Excessive Pricing in Pharmaceutical Markets–Note by Italy (DAF/COMP/WD(2018)106, Nov. 28, 2018). https://one.oecd.org/document/DAF/COMP/WD(2018)106/en/pdf.

25 European Commission, Press Release, Mergers: Commission approves GlaxoSmithKline's acquisition of Pfizer's Consumer Health Business, subject to conditions (IP/19/4030, July 10, 2019), https://ec.europa.eu/commission/presscorner/detail/sv/ip_19_4030.

26 Fed. Trade Comm'n, Press Release, FTC Requires Bristol-Myers Squibb Company and Celgene Corporation to Divest Psoriasis Drug Otezla as a Condition of Acquisition (Nov. 15, 2019), www.ftc.gov/news-events/press-releases/2019/11/ftc-requires-bristol-myers-squibb-company-celgene-corporation.

In 2015, the CCI approved the Sun Pharma and Ranbaxy merger only when the parties agreed to divest certain products to a third party.[27]

IV. Conclusion and Policy Suggestions

As far as access to healthcare is concerned, competition can play a significant role. In order to have a competitive market, both *ex ante* competition policy and *ex post* competition enforcement are important tools.

Looking at the patent policy through the lens of competition policy is very important for engendering generic competition in the pharmaceutical market, which significantly reduces the price of drugs and hence enhances accessibility. Therefore, incorporating TRIPs flexibilities into domestic laws is crucial. India can serve as an example in this regard. Competition agencies around the world can advocate the incorporation of TRIPs flexibilities and cautioning their governments against agreeing to TRIPs+ provisions in bilateral or regional agreements.

Similarly, removing regulatory and policy barriers for private sector entry into healthcare services assumes importance if governments are unable to provide free universal public healthcare. Optimal regulation, i.e. regulation that is not more restrictive that to achieve the desired objective, needs to be the mantra.

Furthermore, competition agencies need to prioritize enforcement in the healthcare space because it hits the poor the most. Market studies may also be conducted in the sector to understand modern nuances. Most importantly, agencies have to play a proactive role as far as advocacy is concerned.

The ensuing pandemic, where many countries, particularly developing countries and LDCs, have felt the need to strengthen their healthcare systems with a domestic base for pharmaceutical production, means that adhering to the competition policy approach would be very helpful.

27 CCI, Order in Combination Registration No. C-2014/05/170 of Dec. 5, 2014, www.cci.gov.in/sites/default/files/C-2014-05-170_0.pdf.

Nicolas Charbit
Sébastien Gachot
Editors

Eleanor M. Fox

Antitrust Ambassador to the World

Liber Amicorum

Pioneer, avant-garde, transformationalist - Eleanor M. Fox is regularly described in these terms by the manifold antitrust practitioners who have been influenced by her industry-shaping scholarly work. Over the course of an extraordinary career, she has helped establish a coherent set of competition law and policy principles designed to promote markets that work in favor of inclusivity, and to ensure economic development that reduces unequal access to markets. Her mold-breaking contributions to the tailored development of competition law in developing economies are acknowledged today across international forums that she helped create. This book honours Professor Fox's indelible mark on antitrust law and policy with contributions from her friends and colleagues around the world. The articles explore subjects such as the role of competition policy, its intersection with social policies, external pressures, and challenges for developing economies amongst others.

Concurrences
Antitrust Publications & Events

ISBN 978-1-939007-97-1
90000
9 781939 007971

230€ - 280$ - 200£