WORLD COMPETITION DAY 2020

TOOLKIT ON

COMPETITION POLICY AND ACCESS TO HEALTHCARE

CUTS International, Geneva
and
CUTS Institute for Regulation & Competition

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Enhancing Knowledge, Strengthening Capacity

INTRODUCTION

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

This kit sheds some light on how to use the *ex ante* competition policy and then *ex post* competition law enforcement as tools to enhance access to healthcare, understanding that access to healthcare is largely dependent on its 'availability' and 'affordability'. It is all the more important and relevant in the wake of Covid-19 pandemic.

This kit contains slides on the following topics:

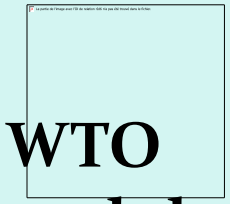
- **Regulation and Competition Policy**
- **Pro-competition Patent Laws**
- **Horizontal Agreements**
- **Vertical Arrangements**
- **Abuse of Dominance**
- **Pay for Delay**
- **M&As in Pharma Industry**
- **Frivolous Litigation**
- **Covid-19 Responses**

REGULATION AND COMPETITION POLICY

- Pharmaceutical sector is highly regulated. At least market approval regulation and price regulation needs to be optimal i.e. not more restrictive than needed. For instance the regulation of biosimilar (generic version of biological drugs) has been generally flagged as over-regulation, which creates barriers to generic competition.
- Price regulations of drugs where generic competition is available, will kill market contestability. Price regulation needs to be used as last resort in case of market failure.
- Doctors prescribing in brand name pose hurdles to competition. Though they may be doing so due to 'trust' on quality, a nexus with pharma cos. cannot be ruled out. Thus in order to engender confidence in doctors, it would be wise to invest in drug quality regulation, so that there is no trust deficit.
- A standard treatment guide would contribute to transparency by removing information asymmetries, and could reduce cost of healthcare. Hence better access to affordable healthcare.

PRO-COMPETITION PATENT LAWS

Generic competition in the pharmaceuticals markets is highly dependent on the domestic patent laws. For instance, the change in patent policy of India in 1970 is being attributed to the development of vibrant domestic industry and consequent high level of generic competition. The change recognised only process patents making it easy for reverse engineering of patented products. This led to enhanced access to drugs not only in India, but in the world.



In 2005, when the clause on product patents under the WTO TRIPs Agreement came into force, India fully incorporated the same along with its pro-competition provisions (TRIPs flexibilities) in its patents law in order to maintain generic competition. One of the key Indian patent law provision is S.3(d), which makes patentability criteria stricter to check 'evergreening' of patents. 'Evergreening' adversely affects generic competition.

EVERGREENING OF PATENTS – CASE LAWS

- **In 2006 the Indian Patent Authority rejected a patent application, by Novartis on Gleevec, based on S.3(d) of the Patents Act, 1970 stating that the drug was a modification of an existing substance 'imatinib' and therefore represented a case of 'evergreening'. The rejection was upheld by higher courts, including establishing the constitutionality of S.3(d). While Novartis' Gleevec was sold at USD 2666 per patient per month, its generic versions were available at USD 177 to 266 per patient per month.[1]**
- **In 2018, Menzis, an insurance company took AstraZeneca to a Dutch court, asserting that it abused its position in the market and maintained a high price of Seroquel through evergreening of its patents. A Dutch court had declared the patent invalid in June 2014. Menzis claimed € 4.1 million in damages from AstraZeneca for unlawfully maintaining a monopoly position in the market. The Dutch Court agreed.**

1. https://www.ip-watch.org/2018/05/20/five-years-indian-supreme-courts-novartis-verdict/
2. https://medicineslawandpolicy.org/2020/10/dutch-court-orders-astrazeneca-to-pay-damages-in-patent-evergreening-case/

HORIZONTAL AGREEMENTS

ISSUES

- Collusion to prevent the commercialisation or supply of affordable generic substitutes by adopting various means.
- Drug distributors associations exercising control over drug supplies, entry of distributors, ability of retailers and wholesalers to provide discounts, fixing trade margins.

RECOMMENDATIONS

- Keep monitoring drug associations and discourage certain practices such as mandatory requirement of the ‘No Objection Certificates’ before appointing any new stockists and distributors.
- Discourage the practice of fixing 'trade margins' by distributors associations.
- Leniency schemes should be advocated to bust the cartels present in the pharmaceutical supply chain.
- Annual compliance training programme to avoid the recurrence of anti-competitive behaviour.

CASE LAWS

- **All India Organization of Chemists and Druggists had been controlling trade margins of various manufacturing firms and also regulating their arrangements with stockists/distributors. It also formulated guidelines for the appointment of wholesalers, agents and distributors by the pharma companies. The Competition Commission of India observed that these practices limit and control the supply of drugs in the market and found them to be anti-competitive.[1]**

- **Participants in the bidding called by the national hospitals for a clinical laboratory test in several regions of Japan were found to be colluding and rigging the bids. The conspiracy to rig and allocate bids to predetermined winning bidders resulted in a substantial lessening of competition in the market place.[2]**

1. https://www.cci.gov.in/sites/default/files/302011_1.pdf
2. https://www.jftc.go.jp/en/pressreleases/yearly_2003/feb/individual_000405.html

VERTICAL AGREEMENTS

ISSUES

- Tying arrangement between hospitals and in-house pharmacies, where doctors are incentivised to prescribe drugs of specific brands available in in-house pharmacies. Doctors reject the diagnostic reports from the non-affiliated laboratories.
- Agreements such as exclusive supply or distribution, resale price maintenance, refusal to deal creating entry barriers, causing high trade margins and increase in retail prices of the products.

RECOMMENDATIONS

- In-house pharmacies and diagnostic services at hospitals should be for convenience and emergencies. Any agreements or nexus between the two should be made illegal.
- Doctors should be encouraged to prescribe generic medicines.
- Ensure that efficiency and consumer welfare as a result of vertical integration outweighs any adverse effect on competition.
- Parity clause should be reviewed on a case by case basis.

CASE LAWS

- **Pierre Fabre developed a 'selective distribution network' to market and distribute its products. The distributors were chosen on the basis of quality of the point of sale services. This put a *de facto* ban on the sale of the products through online medium. The French Competition Authority held that this agreement breached French and the European Competition Law.[1]**

- **Eisai Co. Ltd. was found to be indulging in unfair trade practices by directing its retailers to sell the Vitamin E products at the retail price as stipulated and not resell it to other sellers.[2]**

1. http://curia.europa.eu/juris/document/document.jsf;jsessionid=C77D0E5F9A740131F47F7F5DFBC70E8C?text=&docid=111223&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=1672779
2. https://www.lexology.com/library/detail.aspx?g=9515bb27-e04b-4799-856f-2ff0fc172f2b

ABUSE OF DOMINANCE

ISSUES

- Denial of market access to third party providers
- Excessive and unfair pricing of patented drugs
- Price discrimination
- Refusal to supply – seeking antimonopoly 'immunity' for intellectual property
- Discounts and offers to prevent pharmacies from obtaining supply from the generic manufacturer
- Abusing the dominant position by misleading pharmacists and physicians about the quality and safety of generic substitutes

RECOMMENDATIONS

- Licensing of patents to other companies
- Price regulation of certain essential medicines in case of market failure
- Recommending compulsory licensing in exceptional circumstances
- Strengthening of competition advocacy to address information asymmetry
- Competition assessment of healthcare sector

CASE LAWS

- **CD Pharma, a distributor of Labour inducing drug increased the pricing of the drug 2000% around the time of selling the drugs to Amgros I/S. The Danish Competition Council found that this was an abuse of dominant position as CD Pharma holds a dominant position having structural advantages in the form of an exclusive distribution agreement for Denmark with the manufacturer.[1]**

- **Chongqing Southwest Pharmaceutical was held by the Chinese competition authority (MOFCOM) to be abusive of its dominant position as it was a monopoly supplier of phenol API. It held 100% market shares and had the ability to control the prices, supply and other trading conditions. It was found to be indulging in exclusionary practices to eliminate competition.[2]**

1.https://www.internationallawoffice.com/Newsletters/Competition-Antitrust/Denmark/Gorrissen-Federspiel/Competition-Council-finds-that-CD-Pharma-abused-its-dominant-position
2. https://law.unimelb.edu.au/__data/assets/pdf_file/0004/2239618/China-Competition-Bulletin-Nov-Dec-2016.pdf

PAY FOR DELAY

ISSUES

- Patent holders might be abusing their dominant position if they enter into a number of pay for delay agreements with generics with the intention to further cement their market monopoly.
- Delay of entry of generics for a long time after patent expiration and keeping prices artificially high.
- This may be achieved by various types of agreement such as license, supply, distribution, joint marketing and production.

RECOMMENDATIONS

- Agencies to advocate for pro-competition patent laws.
- Evaluate the contracts' terms carefully to understand the implicit intention behind the agreement.
- Monitor potential buyouts by originator companies to establish monopolies for drugs in small markets and increase prices beyond reasonable levels and without proper justifications.
- Monitor settlement agreements between originator and generic firms.

CASE LAWS

- **Lundbeck developed and sold a popular antidepressant. After the expiration of its patent in 2002, it started entering into a number of agreements with the generic producers to not to enter the market for a specified period of time in exchange of monetary incentives. The European Commission imposed hefty fines on all the parties to such agreements.[1]**

- **Johnson and Johnson commercialised Fenatyl – a painkiller in USA in the 1960s and subsequently in other countries. The European Commission opened an investigation into the arrangement between Johnson and Novartis. It was found that the arrangement delayed the entry of a cheaper generic medicine for 17 months and kept the prices of the drug artificially high.[2]**

1. https://www.herbertsmithfreehills.com/latest-thinking/ecj-rules-for-the-first-time-on-%E2%80%9Cpay-for-delay%E2%80%9D-agreements
2. https://ec.europa.eu/commission/presscorner/detail/en/IP_13_1233

M&As IN PHARMA INDUSTRY

ISSUES

- Strategic mergers leading to monopolies or duopolies reduce competition, lead to price increase and loss of innovation.
- Gun-jumping.
- The non-compete clauses which usually form part of the Business Transfer Agreement of mergers and acquisitions (M&As), prohibits the seller from producing, researching or marketing any new drugs. This may also hamper innovation.

RECOMMENDATIONS

- Divestiture in products or pipeline research overlaping with the other party's product.
- Licensing out of products to prevent lessening of competition.
- Reducing the duration of the non-compete clause in the Business Transfer Agreement.
- Consider using 'significantly impedes effective competition test' devised by the EC, which goes beyond the ambit of dominance of firms and looks at the general adverse effect on competition caused by the merger.

CASE LAWS

- **Bristol-Myers Squibb proposed to acquire Celegne Corporation in a cash and stock deal valued at USD 74 Billion. The US FTC held that the acquisition would have a drastic impact on competition and create a monopoly. Celegne was made to divest Otelza to counteract the anti-competitive effects of the merger. The divestiture was valued at USD 13.4 Billion.[1]**

- **GlaxoSmithKline (GSK) and Novartis proposed to enter a multi-tier merger agreement. As Novartis and GSK were the only suppliers of branded nicotine patches in the Indian market, the merger would have lead to an increase in the prices and reduction in competition. When Novartis and GSK divested their nicotine patches to Dr. Reddy, CCI approved the meger.[2]**

1. https://news.bms.com/news/corporate-financial/2019/Bristol-Myers-Squibb-Completes-Acquisition-of-Celgene-Creating-a-Leading-Biopharma-Company/default.aspx
2. https://www.business-standard.com/content/b2b-pharma/dr-reddy-s-completes-acquisition-habitrol-from-novartis-114122200173_1.html

FRIVILOUS LITIGATION

ISSUES

- Litigation claims are filed with the mala-fide intentions to delay the entry of generics.
- Sham litigation by unlawfully enforcing patents in the medical product market.

RECOMMENDATIONS

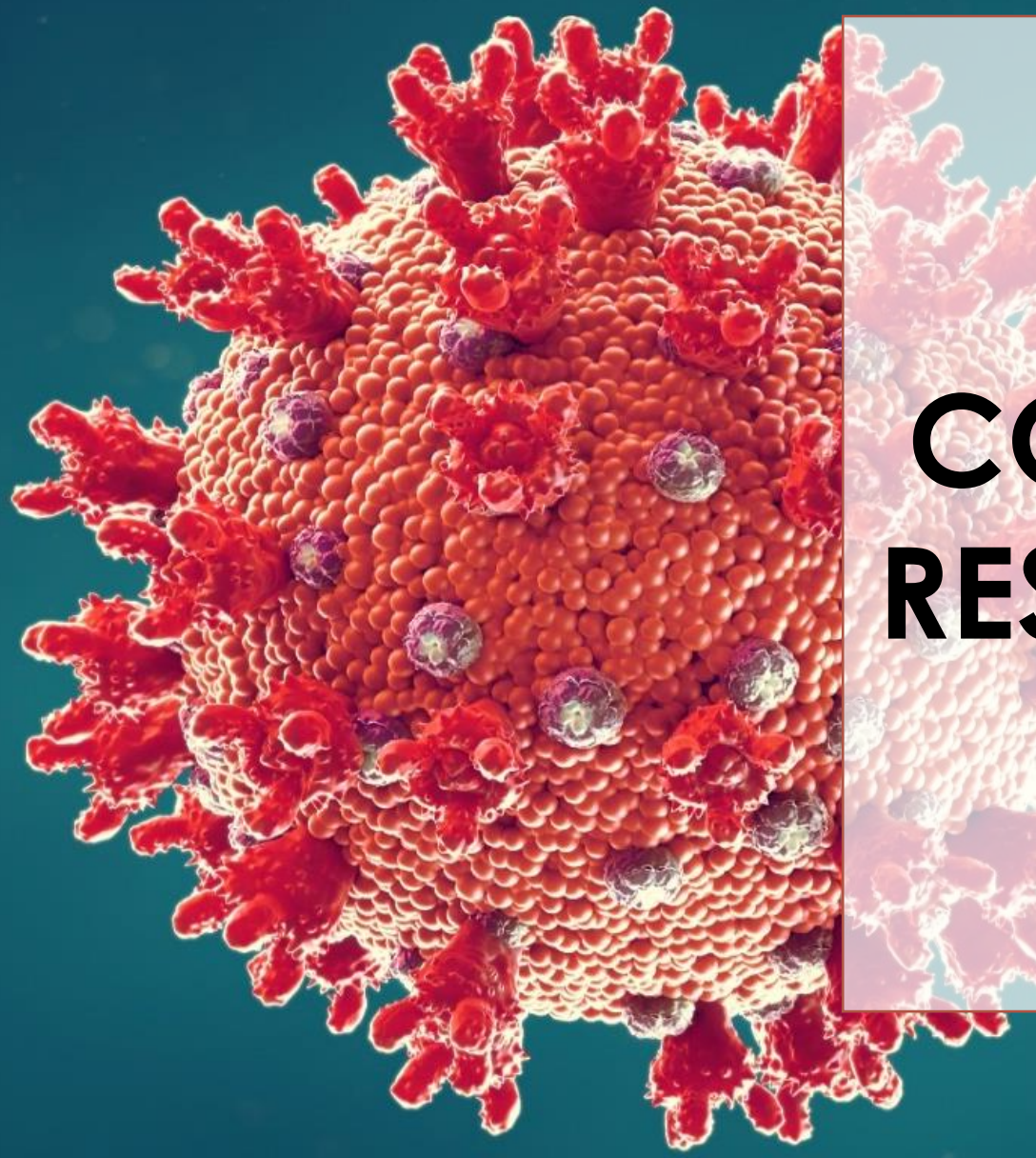
- Recognise that sham litigations could be a strategy to defeat competition and maintain monopoly.
- Heavy penalties should be imposed on the party which brings court action without merit and to harm the defending party.
- Note the two part objective and subjective test established in the Professional Real Estate Investors v. Columbia Pictures (1993), which includes proving that litigation is a sham, merely strips a litigant of antitrust immunity.

CASE LAWS

- **The US FTC filed a complaint stating that AbbVie and Besin lodged sham patent infringement cases against Teva and Perrigo to delay the entry of their product in the market. The Court held that the proceedings were vexatious since they had secured the relevant patent after amending their patent application which the attorneys for AbbVie were aware of.[1]**

- **Brazilian Association of Generic Medication filed a complaint against Eli Lilly on the allegations of sham litigation. The CADE held Eli Lily liable as the suits filed were not credible and had little chance of succeeding.[2]**

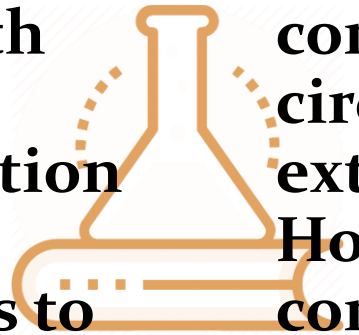
1. https://www.ftc.gov/enforcement/cases-proceedings/121-0028/abbvie-inc-et-al
2. https://tpguidelines.com/brazil-vs-eli-lilly-april-2018-carf-case-no-1302-002-725f/



COVID-19 RESPONSES

COMPETITION BODIES' RESPONSES (1)

Competition policy responses in the extraordinary situation are two-prong – one for smooth supply of essential items like healthcare and food items, and the other with respect to the recovery of the shattered economy. Competition agencies, in general, allowed collaborations between firms to ensure essential supplies, which hitherto could have been booked under respective laws. But acted or warned against those who took advantage of the situation.



The International Competition Network (ICN) advised that competition agencies may accommodate collaboration between competitors necessary to address the circumstances of the crisis to the extent that their laws permit. However, it also iterated that competition enforcement and policy efforts to promote and protect competition will be vital to manage the impacts of the crisis and create the best environment for economic recovery.

COMPETITION BODIES' RESPONSES (2)

The UK Competition and Markets Authority (CMA) laid down six conditions: (1) Coordinated action by businesses are temporary; (2) Measures are appropriate and necessary to ensure supply; (3) Measures are in the public interest; (4) Measures contribute to the wellbeing of consumers; (5) Measures deal with critical issues that arise as a result of the COVID-19 pandemic; and (6) Measures last no longer than necessary to deal with these critical issues.

The UNCTAD recommended five key actions: (1) Ensure a level playing field between competitors; (2) Temporarily allow cooperation arrangements to ensure the supply of affordable products; (3) Closely monitor markets to ensure availability of essential products; (4) Vigorously enforce competition law against businesses that take advantage of the crisis; and (5) Adapt competition procedures and deadlines to the circumstances created by the pandemic.

https://cuts-ccier.org/pdf/competition-enforcement-for-business-collaborations-during-covid-19.pdf

TRIPs WAIVER PROPOSAL

India and South Africa, vide Communication IP/C/W/669 in the WTO, have called for temporary waiver from the implementation, application and enforcement of IP protection on copyright, industrial design, patents and undisclosed information under the TRIPs Agreement for 'prevention, containment or treatment' of COVID-19.

The idea is that IPRs do not create barriers to timely access to affordable medical products or to scaling up R&D, manufacturing and supply of such products to combat COVID-19.

The proposal also flags difficulties that many countries, particularly those with insufficient or no manufacturing capacity, may face due to Article 31*bis*, which prescribes a cumbersome and lengthy process for the import and export of pharmaceutical products under compulsory license.

The proposal has received support from many countries – Egypt, Indonesia, Bangladesh, Honduras, Sri Lanka, Pakistan, Venezuela, Nepal, Nicaragua, Argentina, Tunisia, Mali, Mauritius, Mozambique, 43-member African Group and 36-member LDCs group.

While few like China, Turkey, Nigeria etc. are open to discussions, some members – the US, Switzerland, Japan, Norway, the UK, Canada, Australia, Brazil and the EU – are opposing the move.

Many civil society groups have extended support and so have intergovernmental bodies like WHO and UNAIDS. The issue is currently being discussed in the WTO TRIPs Council.

THANK YOU

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