

# Research Synthesis: Competition Law

*v. 1.0 researched and written by Catherine Saez, edited by Suerie Moon, last updated March 2019*

## Introduction

The literature on the application of competition law to the pharmaceutical sector is rich\*. Over 100 countries have enacted competition laws, compared to 159 countries that have intellectual property (IP) laws in place (Raju 2014). A wide range of pharmaceutical industry behaviors may fall under the remit of competition law, from innovation to pricing-related actions, as detailed further below. The use of competition law varies widely across countries, and its relationship particularly to IP law can be complex. We use the terms "competition" and "anti-trust" law interchangeably in this review.

## Search terms

Medicine/pharmaceutical and antitrust, competition law, parallel importation, pay-for-delay, patent pool, innovation

## Synthesis of the literature

### Types of potentially anti-competitive behavior in the pharmaceutical sector

A number of pharmaceutical company activities may be characterized as anti-competitive. Abbott et al (2014) have described these as either horizontal or vertical: Horizontal anti-competitive activities involve direct competitors, and include price-fixing, pay for delay, output restraints, and allocation of geographic territories.

Vertical anti-competitive activities involve firms at different parts of the value chain, and could include resale price maintenance, collusion between pharmaceutical companies and pharmacy benefit managers (PBMs) with market dominant positions (Yoo, 2018), and exclusive grantback requirements in patent licences (Abbott et al., 2014).

A number of remedial actions can be sought to address anti-competitive behavior, which can be initiated by public authorities or private parties (Abbott et al., 2014). Remedial actions can include settlements, injunctions, technology remedies (such as compulsory licenses), damages, criminal penalties, and limits on mergers and acquisitions (Abbott et al., 2014; WTO, WHO, WIPO, 2012).

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## Mergers and Collusion

Competition law has traditionally focused on preventing collusion (e.g. price-fixing) among competitors and scrutinizing proposed mergers to ensure an adequate degree of competition in the market, both of which are relevant to the pharmaceutical market (Arnaudo, 2017; WTO, WHO, WIPO, 2012). Mergers may not only hinder price competition but also impede innovation. Haucan and Stiebale found that after a merger, patenting and R&D expenditures declined in the merged entity and among non-merging rivals (Haucan & Stiebale, 2016). One of the areas of antitrust concern for R&D intensive pharmaceutical firms arises when two merging parties have potentially competing drug candidates in their R&D pipelines, as the merger could result in suppressing one of the research paths (Grabowski & Kyle, 2008).

## Excessive pricing

Competition law has rarely been used to mitigate "excessive" or "unfair" prices of pharmaceutical products (Abbott, 2016). High prices are a particular risk for products under monopoly, such as drugs and biologics under patent and/or regulatory market exclusivity, or generics without competitors. (Abbott, 2016).

Abbott et al. have argued that competition law is the least discussed flexibility of the World Trade Organization Agreement on Trade-Related Intellectual Property Rights (TRIPS) and is an untapped policy tool (Abbott et al., 2014; WTO, WHO, WIPO, 2012). Countries' competition authorities take varying approaches to excessive pricing. In Australia, Mexico, and the US, for example, competition laws do not cover excessive pricing by monopolies. In contrast, the South African Competition Commission has succeeded in securing several settlements based on allegations of excessive pricing of medicines (Abbott, 2016) (see Hazel Tau case, below).

Excessive pricing also falls within the remit of competition law in Europe, as established by the seminal 1978 *United Brands Co. v. Commission of the European Communities* case at the European Court of Justice (ECJ) (FitzPatrick, 1979; Jenny, 2016). The ECJ developed three approaches to determining whether a price was excessive: by comparing the price to computed costs of production, to other prices of the dominant firm, and to prices of other firms offering similar products (Motta & de Streel, 2003). The *United Brands* case has become a benchmark for determining excessive prices in medicines (Hou, 2011). For example, the Italian competition authority applied the ECJ test to determine whether the prices charged by pharmaceutical firm Aspen were excessive (Caro de Sousa, 2018).

Views differ significantly on what constitutes an excessive and/or unfair price (Jenny, 2016). One of the difficulties in determining excessive pricing is the lack of data on the cost of researching and developing originator pharmaceutical products, which is "deliberately shrouded in mystery" (Abbott, 2016). Abbott has argued that it would be necessary to require the originator industry to provide concrete data regarding the cost of R&D on individual drugs in order to make an assessment.

## Competition Law and Intellectual Property

The question of the appropriate relationship between intellectual property (IP) law and competition law has been much debated. Competition legislation may provide that the rules of competition shall apply to the exercise of IP rights, and the legislation may extend the definition of IP rights to know-how and certain unregistered businesses processes (UNCTAD, 2016).

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The most widely discussed form of horizontal IP-related potentially anti-competitive behavior is when patent-holders buyout generic patent challenges. An analogous practice is known as “pay for delay” (also known as reverse payment settlements) in which a dominant market player (such as a monopoly patent-holding company) pays a generic firm to delay entering the market and competing after patent-expiry (Hemphill, 2009). Not all countries take the same approach to regulating “pay for delay,” however. For example, in India there has been debate over whether pay for delay falls under the authority of the competition or patent authorities, though Chawla and Verma (2018) argue for the former. Raju (2014) has argued that both enforcing authorities should have a role in policy making, particularly in developing countries.

Patent pools can also be the focus of competition authorities. In particular, the accumulation of technologies within one pool strengthens its position in a given technology market and the pool can become a dominant market player (Odrobina, 2014). Anti-competitive concerns are greater when pools are closed, as the pool can hinder technological advancement and innovation by preventing the sale of patents or blocking access to a given technology (Odrobina, 2014). The European Commission considers that pool agreements do not infringe on competition laws if “their activities are confined to standard patent packages, pool members can freely grant licences for the use of their own patents to non-members, and pools do not have exclusive licence rights, thus enabling their members to develop alternative technologies outside the pool’s structure” (Odrobina, 2014).

An additional IP-related concern is the filing of new patent applications for minor modifications to existing health technologies, which can impede the potential entry of generics (Abbott and al., 2014). A joint WTO/WHO/WIPO report notes that some companies establish strategies to extend patent protection for originator drugs and to prevent market entry by generic competitors after patent expiry (WTO, WHO, WIPO, 2012)

Abbott et al. (2014) also argued that TRIPS Article 31(k) provides for the use of compulsory licences to remedy anti-competitive practice (Abbott et al., 2014). Alternately, competition law can be considered in lieu of compulsory licences, which have been challenging to implement, for mandating competition in a monopolistic medicines market. Matthews and Gurgula (2016) have argued that a decision by a competition authority to do so may establish a useful legal precedent and push companies to take those guidelines into consideration in their pricing strategies, and/or to engage in voluntary licensing.

Parallel importation, which depends on a country’s IP exhaustion regime, may also be considered an important enabler of competition. Treacy and Watson-Doig point out that the European Commission “has consistently found pharmaceutical companies to have infringed competition law by preventing parallel trade” within the EU (2016).

### Specific competition cases concerning pharmaceuticals

A number of important competition cases have been brought in the pharmaceutical sector. In 2002, the Treatment Access Campaign (TAC) lodged a complaint with the South African Competition Commission regarding the excessive pricing of three HIV medicines (AZT, lamivudine, and nevirapine) manufactured by GlaxoSmithKline and Boehringer Ingelheim (the Hazel Tau case). In 2003 the Commission found evidence that supported Tau’s allegations resulting in the matter being referred to the Competition Tribunal. The companies subsequently

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settled and provided licenses for competitors to supply lower-cost generics to South Africa and other countries in Sub Saharan Africa (Mdletshe, 2016).

AbbVie was found to have abused its monopoly in 2018 by a Federal District Court judge in Pennsylvania, who ruled in favour of the US Federal Trade Commission (FTC) and granted a civil award of US\$448 million. The same judge also found AbbVie to have engaged in sham patent litigation against generic firms Perrigo and Teva in 2017, when the firm sought to prevent the generics from early entry into the market for testosterone gel (Abbott, 2018). According to a WIPO study (2012), “A possible tentative definition for sham litigation on a strictly economic perspective is predatory or fraudulent litigation with anticompetitive effect, i.e., the improper use of the courts and other government adjudicative or granting processes against rivals to achieve anticompetitive ends (Institute for Applied Economic Research, 2012).”

In the EU, competition authorities have adopted several infringement decisions related to unfair pricing in the pharmaceutical sector since 2000, all pertaining to medicines that had already lost their market exclusivity. For example, in April 2001, the United Kingdom competition authority found that Napp Pharmaceuticals abused its dominant position by charging excessively high prices for morphine (Caro de Sousa, 2018). In 2005 the European Commission fined AstraZeneca €60 million for misusing its patent system and the procedures for marketing pharmaceuticals to block or delay market entry for generic competitors to its ulcer drug omeprazole (Baier, 2011; Caro de Sousa, 2018). In September 2016, the Italian competition authority found that Aspen abused its dominant position by imposing unfair prices for four off-patent anti-cancer medicines (melphalan, chlorambucil, mercaptopurine and thioguanine). Aspen's price increases ranged from 300% to 1500% without any economic justification for the price levels imposed, according to Caro de Sousa (2018). The first-level appeals court fully upheld the decision in June 2017; a further appeal against that judgment is still pending (Caro de Sousa, 2018). In 2016, the UK competition authority found that Pfizer and the distributor Flynn had each abused their dominant positions by charging unfair prices for phenytoin sodium capsules, an anti-epilepsy medicine manufactured by Pfizer (Caro de Sousa, 2018). The UK Competition and Markets Authority imposed a £84 million fine for abusing a dominant position, and Flynn a further £5.2 million. However, in June 2018, the Competition Appeal Tribunal partially upheld and partially reversed and remanded the decision (Abbott, 2018). According to Abbott, the Competition Appeal Tribunal decision is problematic because it creates unwarranted hurdles to findings of excessive pricing in the UK.

In January 2018, the Danish national competition authority found that CD Pharma (a pharmaceutical distributor) abused its dominant position in Denmark by charging Amgros (a wholesale buyer for public hospitals) unfair prices for oxytocin after a price increase of 2000%. An appeal against the decision is pending. Additional investigations by the European Commission and national competition authorities were ongoing as of 2018 (Caro de Sousa, 2018).

## **Critiques and proponents of competition law in the pharmaceutical market**

There is robust debate regarding the extent to which competition law should be used to regulate pharmaceutical markets. Some have argued against intervention by competition authorities, due to the risk of long-term anti-competitive implications if there is a chilling effect on new entrants. Such intervention could also generate uncertainty for dominant firms concerning the terms under which they can compete (Caro de Sousa, 2018). If companies anticipate that a competition authority can cap their prices, it has been argued, their incentive

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to invest and innovate would diminish (Motta & de Streel, 2003). Further, competition authorities may not be well-equipped for regulating medicines prices (Hou, 2011). For pharmaceuticals, Grabowski and Kyle (2008) have argued that competition authorities should focus any potential intervention on late-stage drug candidates and finished products rather than earlier stage R&D for which barriers to entry and costs are relatively low.

Although competition authorities in a number of countries have intervened against excessive prices by dominant firms, conditions under which high prices can be considered to be violations of competition law are "neither abundant nor very clear" and a number of economists and legal scholars have said that competition authorities should refrain from enforcing such provisions, save for some exceptional cases (Jenny, 2016).

Some further argue that high prices cannot last in the long term and suggest that high prices may constitute market signals which will attract entry, so the market will correct itself (Hou, 2011). Doubts remain, however on the time frame of this self-correction, and on the possibility to overcome high barriers to entry (Jenny, 2016).

While some warn against over-intervention, others have advocated for wider use of competition law. Matthews and Gurgula (2016) argue that competition authorities have not adequately addressed practices to delay generic entry nor to address "life-cycle management"/"evergreening" practices such as patent thickets, secondary patenting, and defensive patenting, which can considerably delay generic entry and innovation.

## Challenges in using competition law in the pharmaceutical market

For many developing countries, competition law is a relatively novel area and authorities may have limited resources and experience with it. Nyak (2014) has argued that technical assistance, provided by multilateral agencies, foreign governments, and civil society could alleviate the lack of capacity. Regional cooperation agreements focused on pooling resources may also be useful (Abbott, 2018).

Jenny has found that a number of developing countries that are following the EU approach to excessive pricing have a low level of enforcement, mainly for lack of means to assess whether prices are excessive or unfair (2016). Indeed, as noted above, in all countries the establishment of excessive prices is complex, in part due to the difficulty of assessing the relevant costs. National competition authorities in LMICs need stronger investigative powers, in particular the authority to compel the production of evidence, and LMICs should be encouraged to adopt legislation banning obligations precluding the disclosure of the price paid for pharmaceutical products, whether through trade secrets or other forms of protection (Abbott, 2018a). Furthermore, competition authorities may not have deep knowledge of the sector being investigated (Motta & de Streel, 2003). Caro de Sousa has argued that an important tool to be used by competition authorities may therefore be market studies, which might help competition agencies better understand market developments and tailor the most appropriate response. Market studies could be coupled with advocacy for the adoption of appropriate regulation, or the adoption of initiatives launched in cooperation with sectoral regulators (Caro de Sousa, 2018).

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## Emerging Issues

Biosimilars: It remains to be seen whether and how competition law may be applied to biologics and biosimilars (Carrier & Minniti, 2017). In the US, biosimilars are not governed by the Hatch-Waxman Act but by the Biologics Price Competition and Innovation Act (Carrier & Minniti, 2017). Heled (2018) has argued that companies such as Johnson & Johnson and Roche are abusing their dominant positions in the markets for biologics infliximab and trastuzumab, respectively, to block market entry by competitors. Johnson & Johnson has been accused of requiring exclusionary contracts with both health insurers and healthcare providers in the US to drive the competing biosimilars out of the market. Roche is accused of lowering the price of trastuzumab below cost to drive a competitor in Russia out of the market. Biologics may also be subject to patent thickets and other evergreening strategies, just as small molecule drugs. However, courts have not yet recognized these practices in biologics markets as anti-competitive, and enforcement has not been undertaken (Heled, 2018).

## International competition agreements

Abbott has argued that the incorporation of competition rules in bilateral, regional, and plurilateral agreements between LMICs and high-income countries is premature and may be counterproductive. Matthews and Gurgula (2016) have pointed out that in the absence of an international agreement on competition law, developing countries have the freedom to develop policies and objectives tailored to their specific needs, which they should retain.

## Research gaps

- The extent and manner in which competition law has been applied to pharmaceuticals in developing country contexts.
- Data for determining whether a price is excessive.

## Cited papers with abstracts

Abbott, Frederick M., Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health (January 19, 2016). UC Irvine Law Review, Volume 6, Issue 3, pp. 281-320, Dec. 2016; FSU College of Law, Public Law Research Paper No. 787; FSU College of Law, Law, Business & Economics Paper No. 16-4. <https://ssrn.com/abstract=2719095>

Abstract: Public health budgets and individual patients around the world struggle with high prices for pharmaceutical products. Difficulties are not limited to low income countries. Prices for newly introduced therapies to treat hepatitis C, cancer, joint disease and other medical conditions have entered the stratosphere. In the United States, state pharmaceutical acquisition budgets are at the breaking point -- or have passed it -- and treatment is effectively rationed. Competition/antitrust law has rarely been used to address "excessive pricing" of pharmaceutical products. This is a worldwide phenomenon. In the United States, the federal courts have refused to apply excessive pricing as an antitrust doctrine, either with respect to pharmaceutical products or more generally. Courts in some other countries have been more receptive to considering the doctrine, but application in specific cases has been sporadic, including with respect to pharmaceuticals. This remains a paradox of sorts. Competition law

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experts acknowledge that one of the principal objectives of competition policy is to protect consumers against the charging of excessive prices. The currently preferred alternative is to address the “structural problems” that allow the charging of excessive prices. That is, “fixing the market” so that the underlying defect by which excessive prices are enabled is remedied. There is a fundamental problem with the “fixing the market” approach when addressing products protected by legislatively authorized market exclusivity mechanisms such as patents and regulatory marketing exclusivity. That is, mechanical aspects of the market are not broken in the conventional antitrust sense. Rather, the market has been designed without adequate control mechanisms or “limiters” that act to constrain exploitive behavior. Political institutions, such as legislatures, that might step in are constrained by political economy (e.g., lobbying), and do not respond as they should. Competition law and policy should develop robust doctrine to address excessive pricing in markets lacking adequate control mechanisms. This article will focus specifically on the pharmaceutical sector because of its unique structure and social importance. This focus is not intended to exclude the possibility that development of excessive pricing doctrine would be useful in other contexts. This article is divided into two parts. The first addresses competition policy and why it is appropriate to develop the doctrine of excessive pricing to address distortions in the pharmaceutical sector. The second addresses the technical aspect of how courts or administrative authorities may determine when prices are excessive, and potential remedies. The policy prescription of this article is twofold: first, the United States should incorporate excessive pricing doctrine in its antitrust arsenal, and; second, other countries should maintain the status quo with respect to multilateral competition rules that allow them flexibility to develop and refine doctrine, including excessive pricing doctrine, that is best suited to their circumstances and interests.

Link: <https://ssrn.com/abstract=2719095>

Abbott, F. (2018). Let International Competition Negotiations Sleep a While Longer: Focus on Tools and Capacity. *IIC - International Review of Intellectual Property and Competition Law*, March 2018, Volume 49, Issue 3, pp 259–266, <https://doi.org/10.1007/s40319-018-0683-5>

Abstract not available

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

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intellectual property office personnel directed toward collectively building capacity and assisting with the implementation of national strategies. 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. The competition authorities are typically engaged in some type of ongoing study/investigation or enforcement process in the pharmaceutical sector. 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 global 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.

Link: <https://doi.org/10.1007/s40319-018-0683-5>

Abbott, Frederick (2018, July 3). Excessive Pricing And Sham Patent Litigation: The Pfizer And AbbVie Decisions. Intellectual Property Watch. Retrieved from <http://www.ip-watch.org/2018/07/03/excessive-pricing-sham-patent-litigation-pfizer-abbvie-decisions/>

Abstract not available

Introduction: Competition law is a critical tool in seeking to maintain some semblance of reasonable pricing in the pharmaceutical market. It is particularly important as legislators around the world appear extremely hesitant to address pharmaceutical pricing in meaningful ways, regrettably influenced by well-funded lobbying. Two recent competition law decisions discussed below illustrate the importance of and challenges to regulating the pharmaceutical sector. In the first, the UK Competition Appeal Tribunal (CAT) partially upheld and partially reversed and remanded (pending briefing) a decision by the Competition and Markets Authority (CMA) fining Pfizer and Flynn close to £90 million for abuse of dominant position in the excessive pricing of an anti-epilepsy drug. The CAT decision is problematic because it creates unnecessary and unwarranted hurdles to findings of excessive pricing in the UK. In the second decision, the US Federal Trade Commission succeeds in proving that AbbVie engaged in abuse of monopoly power by engaging in sham patent litigation against two generic producers in order to delay market entry of competitive products. The Federal District Court found that AbbVie’s patent lawyers by “clear and convincing” evidence had knowingly pursued patent infringement claims without chance of success for no other purpose than to delay market entry.

Link: <http://www.ip-watch.org/2018/07/03/excessive-pricing-sham-patent-litigation-pfizer-abbvie-decisions/>

Abbott, F., Flynn, S., Correa, C., Berger, J., & Nyak, N. (2014, May). Using Competition Law to Promote Access to Health Technologies: A guidebook for low-and middle-income countries. United Nations Development Programme. <http://www.undp.org/content/dam/undp/library/HIV-AIDS/Governance%20of%20HIV%20Responses/UNDP->

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Using%20Competition%20Law%20to%20Promote%20Access%20to%20Medicine-05-14-2014.pdf

Abstract not available

Foreword (Excerpt) Competition law is one of the least discussed flexibilities within the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. There remains great untapped opportunity for countries to achieve price reductions for health technologies by instituting competition law and policy frameworks and complimenting them with strong enforcement mechanisms. The need for greater use of competition law was highlighted by the Global Commission on HIV and the Law, an independent body of eminent persons tasked with interrogating the relationship between human rights, law and public health in the context of HIV. The Commission recommended that "countries must proactively use other areas of law and policy, such as competition law, price control policy and procurement law which can help increase access to pharmaceutical products."

Link: <http://www.undp.org/content/dam/undp/library/HIV-AIDS/Governance%20of%20HIV%20Responses/UNDP-Using%20Competition%20Law%20to%20Promote%20Access%20to%20Medicine-05-14-2014.pdf>

Arnaudo, L. (2017). Patents, Intellectual Property, Price Control and Competition Law in Access to Medicines: A Concept Note. [https://papers.ssrn.com/sol3/Delivery.cfm/SSRN\\_ID3090919\\_code1243582.pdf?abstractid=3090919&mirid=1&type=2](https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID3090919_code1243582.pdf?abstractid=3090919&mirid=1&type=2)

Abstract not available

Introduction: Affordability of medical essentials (essential drugs and medical devices) is a truly global issue, a matter of concerns for national states and international organizations. In order to curb possible pricing misconducts, many legal systems are vigorously enforcing antitrust rules: in fact, in the last few years a growing amount of undertakings' conducts related to illicit agreements (with direct effects on drug pricing) and unilateral unfair pricing has been prosecuted by major competition authorities. Such enforcement proved to be instrumental in achieving a more effective access to medical essentials and guarantee affordable products' prices; however, antitrust can only support ex post, case-by-case interventions. Ex ante general regulation has to be addressed, also in view of consequent positive interactions with specific legal instruments, e.g. competition protection rules. Proper regulation must be developed in order to establish a «legitimacy framework» for pricing strategies: provided the need to fine-tune with the pharmaceutical industry's features, such as possibly significant R&D costs, reference models could be borrowed by already existing regulations of public utilities, i.e. lines of business carried on by for-profit companies that, subject to special governmental provisions and agencies, fulfill fundamental necessities of the public at large. As regards innovation, while its drivers should be duly protected, also by means of IPRs, related economic interests must be harmonized with the need to guarantee access to products and services. After all, when dealing with medical essentials, such harmonization is required in order to fulfill fundamental human rights, starting from the same right to life. Having recognized medical essentials to be public

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utilities, together with the need to conveniently protect innovation, a shared better understanding of costs structures and economic dynamics is the basic precondition for efficient regulation. As a consequence, industrial and commercial actors have to face disclosure obligations: higher information symmetries, to be secured by means of open-access data repositories of comparable prices, will also enhance more equilibrated bargaining processes among sellers and purchasers, e.g. in the field of public procurement. In more detail, acceptable types and levels of costs, as well as types and rates of return along a proper time-window for exploiting market exclusivities, must be identified on a uniform basis: this in order to establish the legitimate pricing framework envisaged here above so, public/no profit contributions to R&D of medical essentials must be duly valorized when final results will be distributed on a commercial basis. Consensus must be reached on the main assumptions, analytical and operational elements to be taken into account when dealing with the pricing of medical essentials, in view of developing effective regulations. In fact, even when considering agencies having direct powers to set drugs' prices on a national basis, no uniform rules can currently be found on the same tenets for assessing and administering the fair levels of such prices. The existing situation is of great advantage, from a strategic viewpoint, for (global) companies when required to bargain their products' prices with (local) authorities: from a public interest viewpoint, this engenders unsustainable disadvantages for healthcare systems. To begin with, authoritative guidelines on pricing analysis and capping might be highly useful. International organizations are already making commendable efforts along this direction (see, for instance, the WHO Guideline on Country Pharmaceutical Pricing Policies): their results must be further detailed, bolstered and made effective at administrative levels, in view of reaching a homogeneous approach for impairing the strategic advantage held by for-profit actors vis-à-vis fragmented non-profit counterparts. A global issue needs a global response, with local outcomes.

Link:

[https://papers.ssrn.com/sol3/Delivery.cfm/SSRN\\_ID3090919\\_code1243582.pdf?abstractid=3090919&mirid=1&type=2](https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID3090919_code1243582.pdf?abstractid=3090919&mirid=1&type=2)

Baier, S. (2011). The European Commission's Closer Look on the Pharmaceutical Sector - New Development on the Interface between IP and Antitrust Law. 7 Asian Bus Law. 33. <https://heinonline.org/HOL/LandingPage?handle=hein.journals/asbulaw7&div=5&id=&page=>

Abstract: A recent investigation of the EU's pharmaceutical market carried out by the European Commission has been shedding new light on the question of abuse of a dominant position pursuant to Article 102 TFEU 1 by holding, acquisition or exploitation of IP rights. This so-called "sector inquiry" identified practices and strategies which "originator companies" exert on a large in order to target competitors, and found that such behavior results in significantly higher costs for buyers and competitors, in delay in the entry of generic medicine as well in as the access to innovative medicine, and in obstruction of innovation. This article investigates recent antitrust proceedings by the Commission and the decision practice of the European Courts - within and beyond the pharmaceutical sector - and argues that the practices revealed by the sector inquiry can be predominantly assumed to lack objective justification, lead to foreclosure of competitors and therefore constitute infringements of Article 102 TFEU. Towards the end, the article shows that the Commission's proactive policy in IP-related antitrust matters and its sensitivity to issues of abusive acquisition of intellectual property and abuse of public procedures by misleading representations establish a new quality in the application of European antitrust law, and serve

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as a guideline how to draw the line between IP protection, lawful business strategies and anticompetitive behavior under EU law.

Link:

<https://heinonline.org/HOL/LandingPage?handle=hein.journals/asbulaw7&div=5&id=&page=>

Caro de Sousa, P. (2018, November). Excessive Prices in Pharmaceutical Markets. OECD Competition Division. [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP\(2018\)12&docLanguage=En](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP(2018)12&docLanguage=En)

Abstract: There are strong arguments for not intervening against exploitative excessive pricing conducts, which have led to the development of stringent enforcement screens for the bringing of such cases. However, recent years have seen significant calls for intervention against high prices for pharmaceutical products, and there have been a number of competition enforcement cases regarding exploitative excessive pricing in this sector. These cases meet the criteria set out in the enforcement screens regarding excessive pricing. At the same time, the conditions that justify bringing such cases in the first place seem to be relatively common in the pharmaceutical sector. This raises questions regarding what is the best response to high prices in this sector, and particularly whether there are alternatives to bringing exploitative excessive pricing cases. The application of competition law against high prices in the pharmaceutical sector requires a deep understanding of market dynamics and sectoral regulation, and of the various regulatory responses that may be deployed to address high prices. As such, it may be appropriate to explore various avenues for intervention, if possible in cooperation with the applicable sector regulator.

Link: [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP\(2018\)12&docLanguage=En](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP(2018)12&docLanguage=En)

Carrier, M., & Minniti, C. (2017). Biologics: The New Antitrust Frontier. University of Illinois Law Review. [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2982190](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2982190).

Abstract: The pharmaceutical industry lies at the intersection of patent law, antitrust law, federal and state regulations, and complex markets. For the past several decades, courts and commentators have analyzed issues presented by brand-name and generic drug companies in the “small molecule” setting. But just as they have begun to comprehend the multiple moving parts, a new frontier has arisen involving large molecules known as “biologics.” Biologics differ from small-molecule drugs along multiple axes. They are more expensive, costing hundreds of millions of dollars to develop. They cannot be precisely replicated, followed by “biosimilars” rather than generics. They are governed not by the Hatch-Waxman Act but by the Biologics Price Competition and Innovation Act. And they present a blank slate on which issues of innovation and competition will be hammered out in the decades to come. Given that biologics promise revolutionary advances like treatments for previously incurable diseases and cancer regimens offering substantial benefits over chemotherapy, the stakes could not be higher. The small-molecule setting has been replete with collusive behavior such as “reverse payment” agreements by which brands and generics settle patent litigation and unilateral conduct by which brands modify their drugs to block generics, file frivolous government petitions, manipulate the regulatory regime, and deny materials generics need to enter the market. How likely are these (or other) forms of conduct to appear in the biologics industry? And if these

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behaviors occur, how should antitrust law respond? This Article addresses these questions, offering an antitrust framework for the conduct most likely to arise. In particular, it concludes that in the biologics setting, “citizen petitions,” the disparagement of biosimilars, and collusion between biologics and biosimilars will be more frequent and that “product hopping” and reverse-payment settlements will be less typical. The Article also recommends antitrust analysis similar to what courts have applied in the small- molecule setting and modestly more deferential for citizen petitions. Antitrust finds itself at a unique and crucial moment: poised at the precipice of a new industry but able to draw on decades of case law in an analogous setting that has addressed issues of competition and innovation. It is far from obvious how much courts can—or should—take from that setting. This Article assists in this task by determining which antitrust principles and doctrines should be exported to the biologics setting while appreciating the differences that counsel against such extrapolation. Given the importance of life- saving cancer treatments and an impending \$400 billion market, there is no time to waste.

Link: [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2982190](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2982190)

Chawala, T., & Verma, R. (2018). Pay for Delay Agreements: Antitrust Watch Intensifies. *Journal of National Law University*, 5(1), 22–39. <https://doi.org/10.1177/2277401718787952>

Abstract: The pharmaceutical sector has constantly endeavoured to balance its dual objectives of promoting state-of-art innovation and achieving affordable healthcare for all. The contrasting aims are also germane to the inevitable conflict between the competition law and the patent law with respect to this sector. Reverse payment settlement is one such concept that lies at the cross-section of these two legislations and strangely offers an uncanny mechanism where extreme partisans (i.e., innovator and generics) become comrades, thereby prodding genuine concerns and exposing legal vulnerabilities of such agreements. Against this backdrop, this article seeks to examine the growing undercurrent re reverse payment settlement agreements from a competition law perspective. In an attempt to harmonize the conflicting policy objectives, it will study the interplay between patent law and competition law by placing reliance on the approach followed by other jurisdictions. Further, this article will also assess whether reverse payment settlement agreements fall within the statutory construct of the Competition Act, 2002 and whether the Competition Commission of India (“CCI”) can assert its jurisdiction over such agreements. An attempt is also made to outline the approach which the CCI could adopt, bearing in mind the importance of ensuring exclusivity as an incentive for innovation.

Link: <https://doi.org/10.1177/2277401718787952>

FitzPatrick, M. H. (1979). *United Brands Company v. Commission of the European Communities: Window to Price Discrimination Law in the European Economic Community*. *Northwestern Journal of International Law & Business*, 1(1).  
<https://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1055&context=njil>  
b

Abstract not available

Introduction (Excerpt): Enterprises operating within the European Economic Community’have long faced the difficult task of ascertaining whether they are subject to the price discrimination restrictions of the Treaty of Rome.<sup>2</sup> The difficulty stems from the ambiguity present in the Treaty

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provisions and is exacerbated by the lack of authoritative interpretation of their restrictions.<sup>3</sup> However, a recent opinion of the European Communities' Court of Justice,<sup>4</sup> *United Brands Co. v. Commission of the European Communities*,<sup>5</sup> has brought the contours of the price discrimination prohibition into sharper focus. Although a year has passed since the opinion was handed down, the Court's decision in *United Brands* re-mains the fundamental interpretation of price discrimination law under the Rome Treaty. Despite some ambiguity, the Court's explanation clarified many of the issues raised in a price discrimination charge.

Link:

<https://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1055&context=njilb>

Grabowski, H., & Kyle, M. K. (2008). Mergers and alliances in pharmaceuticals effects on innovation and R&D productivity. In *The economics of corporate governance and mergers* (p. 262). Edward Elgar Publishing. <https://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/7374/Mergers-Kyle.pdf?sequence=1>

Abstract not available

Introduction (Excerpt): The pharmaceutical industry provides a good laboratory to investigate the effects of mergers and alliances on innovation and R&D productivity. Over the past few decades, the industry has been characterized both by significant consolidation of large pharma firms as well as the vertical disintegration of the R&D process. The latter is associated with significant entry into the discovery and development process by early stage biopharmaceutical firms. Since the early 1990s, an evolving marketplace for new technologies through licensing agreements and joint ventures has emerged, accompanied by the growth of contract research organizations that specialize in implementing clinical trials for new drug candidates. To put some of these changes in historical perspective, it is useful to chronicle some of the key dynamic forces affecting the pharmaceutical industry since the early 1980s. While the 1980s were a period of rising prices and profits for the industry, many challenging developments also occurred for the vertically integrated, multinational drug industry. These developments included rising R&D costs (DiMasi et al., 1991; 2003), the expiration of patents on major commercial products, and the beginning of intensive price competition from generics. The passage of the Waxman–Hatch Act in 1984 was a key legislative change that allowed generics to enter the market by demonstrating bioequivalence (that is without the need to do clinical tests of safety and efficacy) (Grabowski, 2007). These dynamic forces intensified in the 1990s with the rise of buyer-side market power in the form of managed care organizations and pharmacy benefit managers in the US, and increasingly stringent price controls in other major world markets. Market and political pressures have caused declining growth in sales and profits that have been particularly evident on an industry-wide basis since the mid-1990s.

Link: <https://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/7374/Mergers-Kyle.pdf?sequence=1>

Haucan, J., & Stiebale, J. (2016). *How Mergers Affect Innovation: Theory and Evidence from the Pharmaceutical Industry*. Düsseldorf Institute for Competition Economics. Retrieved from <https://www.econstor.eu/bitstream/10419/130193/1/856561223.pdf>

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**Abstract:** This paper analyses how horizontal mergers affect innovation activities of the merged entity and its non-merging competitors. We develop an oligopoly model with heterogeneous firms to derive empirically testable implications. Our model predicts that a merger is more likely to be profitable in an innovation intensive industry. For a high degree of firm heterogeneity, a merger reduces innovation of both the merged entity and non-merging competitors in an industry with high R&D intensity. Using data on horizontal mergers among pharmaceutical firms in Europe, we find that our empirical results are consistent with many predictions of the theoretical model. Our main result is that after a merger, patenting and R&D of the merged entity and its non-merging rivals declines substantially. The effects are concentrated in markets with high innovation intensity and a high degree of firm heterogeneity. The results are robust towards alternative specifications, using an instrumental variable strategy, and applying a propensity score matching estimator.

Link: <https://www.econstor.eu/bitstream/10419/130193/1/856561223.pdf>

Heled, Y. (2018). Follow-on Biologics Are Set Up To Fail. Georgia State University College of Law. [https://papers.ssrn.com/sol3/Delivery.cfm/SSRN\\_ID3113543\\_code327943.pdf?abstractid=2982190&mirid=1](https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID3113543_code327943.pdf?abstractid=2982190&mirid=1)

**Abstract:** In their article, “Biologics: The New Antitrust Frontier,” Michael Carrier and Carl Minniti provide a comprehensive review of the various kinds of antitrust violations that beleague pharmaceutical markets in the United States. Carrier & Minniti examine the applicability of these anticompetitive behaviors to biopharmaceutical (a.k.a. biologics) markets, and in doing so alert regulators and courts to such potential antitrust violations in the emerging area of follow-on biologics. Carrier & Minniti’s article also provides recommendations for limiting anticompetitive behavior in biologics markets that will, no doubt, serve as a valuable guide for regulators, judges, and practitioners. Yet, Carrier & Minniti’s article appears to share in an optimism about the prospects of such markets: that if we just policed them properly, competition could be guaranteed and, with it, prices would drop significantly. Such optimism is unwarranted. The legislative and regulatory efforts to instill competition into biologics markets have been fraught, from their outset, with persistent and mostly successful counter-efforts by the brand-name pharmaceutical industry (“Industry”) to make follow-on biologics a limited and contained regulatory and commercial phenomenon. To that end, the Industry — with its lobbying spearheads, BIO and PhRMA — and its many allies in Congress, state legislatures, and state and federal administrations, have been waging war to maintain existing and erect new regulatory obstacles to the development, approval, and marketing of follow-on biologics. The Industry’s success in undercutting the emergence of truly competitive follow-on biologics markets thus far rests on four pillars: (1) an Industry-favorable, obstructed pathway for the approval of follow-on biologics; (2) acceptance and upholding of the view that regulatory filings submitted to the FDA are proprietary and confidential; (3) state laws making onerous the substitution of biologics with follow-on versions thereof; and (4) efforts to block any and all specific attempts to make, gain approval for, and sell follow-on biologics. Of these four pillars, the area of antitrust law (and, thus, Carrier & Minniti’s article) addresses mostly the fourth. Yet, the emergence of competitively robust follow-on biologics markets requires dismantling more than one pillar. Until then, efforts to open biologics markets to competition will continue to be no more than a rearguard battle over the approval and marketing of a small number of follow-on versions of a mere handful of original products with limited substitutability. The price, as always, will be borne by payors, patients, and ultimately, the public. In this comment, I discuss each of the four pillars supporting

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the Industry's success in inhibiting the development, approval, and marketing of follow-on biologics. I show that unlike the story of the Hatch-Waxman Act, that of the Biologics Price Competition and Innovation Act (BPCIA) does not and probably will not have a happy ending; that if the goal is to significantly lower biologics' prices, then the paradigm of approval of follow-on biologics in the United States would need to change.

Link:

[https://papers.ssrn.com/sol3/Delivery.cfm/SSRN\\_ID3113543\\_code327943.pdf?abstractid=2982190&mirid=1](https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID3113543_code327943.pdf?abstractid=2982190&mirid=1)

Hemphill, C. S. (2009). Ann Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition. *Columbia Law Review*, 109(4).  
<https://heinonline.org/HOL/LandingPage?handle=hein.journals/clr109&div=22&id=&page=>

This Article examines the “aggregation deficit” in antitrust: the pervasive lack of information, essential to choosing an optimal antitrust rule, about the frequency and costliness of anticompetitive activity. By synthesizing available information, the present analysis helps close the information gap for an important, unresolved issue in U.S. antitrust policy: patent settlements between brand-name drug makers and their generic rivals. The analysis draws upon a new dataset of 143 such settlements. Due to the factual complexity of individual brand-generic settlements, important trends and arrangements become apparent only when multiple cases are examined collectively. This aggregate approach provides valuable information that can be used to set enforcement priorities, select a substantive liability standard, and identify the proper decision maker. The analysis uncovers an evolution in the means-including a variety of complex side deals-by which a brand-name firm can pay a generic firm to delay entry. The Article proposes two solutions for such anticompetitive behavior, one doctrinal and one institutional: a presumption of (illegal) payment where a side deal is reached contemporaneously with delayed entry, and an expanded role for agencies, to gather and synthesize nonpublic information regarding settlements, and potentially to engage in substantive rulemaking. The aggregate approach also reveals the shortcomings of antitrust enforcement where, as here, firms can exploit regulatory complexity to disguise collusive activity.

Link: <https://heinonline.org/HOL/LandingPage?handle=hein.journals/clr109&div=22&id=&page=>

Hou, L. (2011). Excessive Prices within EU Competition Law. *European Competition Journal*, 7(1).  
<http://cclp.sjtu.edu.cn/userfiles/1/files/20123933418628.pdf>

Abstract not available

Introduction: Due to the different views in economics the prohibition of excessive prices is among the most controversial subjects within EU competition law. This article aims to shed some light on this concept. In the following, it first identifies the exceptional circumstances that may justify antitrust actions against excessive pricing. Subsequently, an empirical research is undertaken on the two-step analytical framework established by United Brands: first, analysing whether the profit margin is excessive; if affirmative, then assessing whether the price is unfair in itself or compared with others. In particular, it focuses on the three uncertainties within that framework: (i) determining an excessive profit margin, (ii) examining whether a price is abusive in itself, and (iii) demonstrating an abusive price based on benchmarks.

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Institute for Applied Economic Research. (2012). Study on the Anti-Competitive Enforcement of Intellectual Property (IP) Rights: Sham Litigation. World Intellectual Property Organization. Retrieved from [https://www.wipo.int/edocs/mdocs/mdocs/en/cdip\\_9/cdip\\_9\\_inf\\_6\\_rev.pdf](https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_9/cdip_9_inf_6_rev.pdf)

Executive Summary (Excerpt - Abstract not available) The objective of this study was to trace a worldwide frame of the current state of the anticompetitive use of the judicial process to enforce intellectual property rights, also known as Sham Litigation. Sham litigation has been object of controversy, as it connects the exercise of allegedly legitimate rights to the idea of abuse of its uses, meaning (in economic terms) a strategic use with the objective of harming or excluding a rival from the market. A possible tentative definition for sham litigation on a strictly economic perspective is predatory or fraudulent litigation with anticompetitive effect, i.e., the improper use of the courts and other government adjudicative or granting processes against rivals to achieve anticompetitive ends. The Study suggests that the anticompetitive use of judicial actions to unduly protect intellectual property might be considered one type of non-price predation strategies.

Link: <http://ccpl.sjtu.edu.cn/userfiles/1/files/20123933418628.pdf>

Jenny, F. (2016, December). Abuse of Dominance by Firms Charging Excessive or Unfair Prices: An Assessment. ESSEC Business School. Retrieved from [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2880382](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2880382)

Competition authorities throughout the world are under pressure to use their enforcement powers to control excessive or unfair prices. In some countries, like the United States, competition authorities have clearly indicated that the antitrust laws were not meant to curb monopolistic prices. In other countries, like the European Union, excessive prices have occasionally been considered to be violations of the competition law. A vigorous debate among economists has taken place on what the definition of excessive prices could be and whether the control of excessive prices by competition authorities would in fact promote or discourage competition. This paper reviews this debate and considers alternative courses of action that competition authorities could consider in case of high prices.

Link: [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2880382](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2880382)

KD, R. (2014). Interface between Competition law and Intellectual Property Rights: A Comparative Study of the US, EU, and India. *Intel Prop Rights*, 2(3):115. <https://www.omicsonline.org/open-access/interface-between-competition-law-and-intellectual-property-rights-a-comparative-study-of-the-us-eu-and-india-ipr.1000115.php?aid=26445>

Abstract: It is generally viewed that Intellectual property protection and competition law are odds with each other. Is there really any tussle between intellectual property protection and competition law? Intellectual property law creates and protects monopoly power and the other seeks to exclude it. IP exclusion provisions are included in the Indian Competition Act, 2002 in Section 3(5). This is to provide enforcement to intellectual property rights. But protection of intellectual property rights are not per se violates any competition provisions. The objective of

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competition law is to prohibit anti-competitive practices and the objective of both the stream is wealth maximization in any economy. Intellectual property protection is necessary to foster innovation and choices of products in the market. It infuses efficiency in the market and increases consumer welfare. India is in the nascent state of its administration of competition laws. There are sizable number of cases came before the Indian competition authorities (CCI) and Indian courts. Cases against Microsoft India and abuse of dominant case against Ericsson filed by an Indian company named Micromax is only the beginning of the interface cases on intellectual property and competition law. There is no sufficient case laws and jurisprudence is available in India in guiding the Indian authorities and courts on the interface between intellectual property and competition. It is necessary to make an analysis of the jurisprudence in the US and EU. First part of this paper deals with the US Antitrust Act, 1890 and analysis of a number of cases dealt by the US courts. The EU Regulations and cases are clearer on issues of intellectual property and competition law. Indian jurisprudence is not clear so far and few cases are dealt by the CCI and Indian courts. The study concludes that Indian authorities should learn from other jurisdictions and the jurisprudence will act as guideline for Indian authorities.

Link:<https://www.omicsonline.org/open-access/interface-between-competition-law-and-intellectual-property-rights-a-comparative-study-of-the-us-eu-and-india-ipr.1000115.php?aid=26445>

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Abstract: Competition policy is an under-utilised tool. Policy coherence between the IP system and competition must be strengthened in order to promote innovation and access to health technologies. Article 8(2) of the TRIPS Agreement provides flexibilities for governments to adopt competition law measures to prevent abuse of intellectual property rights, including IP rights related to the life sciences, namely the pharmaceutical industry and the biotechnology sector. Post-TRIPS, some countries have implemented competition laws but in practice are not using these effectively. This is particularly striking in the pharmaceutical sector, where abuses of intellectual property rights, such as reverse payment agreements and strategic patenting, risk allowing pharmaceutical companies to extend their market monopoly by blocking the entry of both generic and innovative medicines and, as a result, stifling competition and harming consumers. Nevertheless, these practices lack adequate attention by competition authorities. Such anti-competitive practices create particular challenges for the developing world as they can lead to significant barriers to innovation and access. Used effectively, competition policy can be in the best interests of society. It is conducive to freedom of choice and lower prices while, potentially, also serving as an important driver for innovation and access.

Link:  
[https://papers.ssrn.com/sol3/Delivery.cfm/SSRN\\_ID2869273\\_code1175289.pdf?abstractid=2779014&mirid=1&type=2](https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID2869273_code1175289.pdf?abstractid=2779014&mirid=1&type=2)

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TAC's oral submission to the Competition Commission's Inquiry into the Private Healthcare Sector delivered on 17 February by TAC Deputy Chairperson

Abstract not available

Link: <https://tac.org.za/news/tacs-submission-to-the-private-healthcare-market-inquiry/>

Motta, M., & de Streel, A. (2003). Exploitative and Exclusionary Excessive Prices in the EU Law. Hart

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Link: [https://www.researchgate.net/profile/Alexandre\\_Streel/publication/251745586\\_Exploitative\\_and\\_Exclusionary\\_Excessive\\_Prices\\_in\\_EU\\_Law/links/5516f9220cf2f7d80a39e27d/Exploitative-and-Exclusionary-Excessive-Prices-in-EU-Law.pdf?origin=publication\\_detail](https://www.researchgate.net/profile/Alexandre_Streel/publication/251745586_Exploitative_and_Exclusionary_Excessive_Prices_in_EU_Law/links/5516f9220cf2f7d80a39e27d/Exploitative-and-Exclusionary-Excessive-Prices-in-EU-Law.pdf?origin=publication_detail)

Abstract not available

Introduction (Excerpt): Article 82 of the EC Treaty provides for a condemnation of excessive prices. However, the general concept of 'excessive price' may cover two very different realities. An excessive price may be an exploitative abuse, i.e. direct exploitation of market power. In this case, the dominant firm charges a high price to its customers (being end-users or undertakings with which the dominant firm does not compete). Alternatively, an excessive price may be an exclusionary abuse, aiming to strengthen or maintain the market power of the dominant firm by putting rivals at disadvantage. In this case, the dominant firm in one market, say upstream, sets the price of the input so high that the margin between wholesale and retail prices is insufficient for an efficient firm to profitably operate in the downstream market. These two types of excessive prices are based on different legal and economic principles, hence are analysed separately in this paper. This paper aims to study the current case law of both types of excessive prices, and on the basis of economic theories and legal reasoning, propose policy recommendations for the antitrust authorities and the Courts. This review is timely for several reasons.

Link: [https://www.researchgate.net/profile/Alexandre\\_Streel/publication/251745586\\_Exploitative\\_and\\_Exclusionary\\_Excessive\\_Prices\\_in\\_EU\\_Law/links/5516f9220cf2f7d80a39e27d/Exploitative-and-Exclusionary-Excessive-Prices-in-EU-Law.pdf?origin=publication\\_detail](https://www.researchgate.net/profile/Alexandre_Streel/publication/251745586_Exploitative_and_Exclusionary_Excessive_Prices_in_EU_Law/links/5516f9220cf2f7d80a39e27d/Exploitative-and-Exclusionary-Excessive-Prices-in-EU-Law.pdf?origin=publication_detail)

Nyak, N. (2014). Using Competition Law to Promote Access to Health Technologies: A guidebook for low-and middle-income countries. Retrieved from <http://www.undp.org/content/dam/undp/library/HIV-AIDS/Governance%20of%20HIV%20Responses/UNDP-Using%20Competition%20Law%20to%20Promote%20Access%20to%20Medicine-05-14-2014.pdf>

Abstract not available

Foreword (Excerpt): Competition law is one of the least discussed flexibilities within the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. There remains great untapped opportunity for countries to achieve price reductions

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for health technologies by instituting competition law and policy frameworks and complimenting them with strong enforcement mechanisms. The need for greater use of competition law was highlighted by the Global Commission on HIV and the Law, an independent body of eminent persons tasked with interrogating the relationship between human rights, law and public health in the context of HIV. The Commission recommended that “countries must proactively use other areas of law and policy, such as competition law, price control policy and procurement law which can help increase access to pharmaceutical products.”

Link: <http://www.undp.org/content/dam/undp/library/HIV-AIDS/Governance%20of%20HIV%20Responses/UNDP-Using%20Competition%20Law%20to%20Promote%20Access%20to%20Medicine-05-14-2014.pdf>

Odrobina A., Patent pools in light of European Union competition law, „Ekonomia i Prawo. Economics and Law.“, Polszakiewicz B., Boehlke J. (ed.), Vol. 13, No. 4/2014, pp. 523-532. DOI:<http://dx.doi.org/10.12775/EiP.2014.037>.

The functioning of patent pools leads to specific benefits in the transfer of technologies, and it accelerates technological advancement and provides easy access to technologies. Therefore, one could expect that the European Union (EU) – an organization which attempts to gain competitive advantage of its economy on the basis of knowledge and technology – should support patent pools. However, due to the possibility of anti-competitive practices, the functioning of patent pools is subject to EU legislation and competition laws. In this context patent pools pose a challenge in the area of reconciling the process of supporting technological advancement with the protection of fair competition. The paper presents an analysis of EU regulations in the area of patent pools. The author assesses the pro- and anti-competitive effects of activities carried out by patent pools. The further part of the paper discusses an evolution of the EU’s approach to such organizations, presenting specific patent pool laws in the context of technology transfer agreements. Finally, the author presents some specific problems and future changes related to EU competition laws with respect to patent pools. Keywords: legal patent pools, EU antitrust, technology transfer agreements.

Link: <http://dx.doi.org/10.12775/EiP.2014.037>.

Treacy, P., & Watson-Doig, N. (2016). What is Parallel Trade and How Does it Affect Pharma. KNect365 Law. <https://knect365.com/complaw-blog/article/073ed81f-0d17-4c0e-a819-38ff60332dec/what-is-parallel-trade-and-how-does-it-affect-pharma>

Abstract not available

Introduction: We’ve heard a lot about the single market recently. Following 24 June, it’s now a commonly known fact, and not just the preserve of EU lawyers, that the creation and maintenance of the EU single market is central to the EU project – and that applies in the field of competition law as well as everything else. As Thomas Kramler from DG Comp recently put it: “The priorities of EU competition policy cannot be decoupled from the broader EU policy goals such as the establishment of an internal market (see Protocol 27 to the TFEU).” To put it a bit more snappily, the EU single market means that there should be no unnecessary barriers to

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products, including pharmaceuticals, being traded freely between EU/EEA Member States. For governments, this means that they must not put in place tariff barriers to trade (e.g. custom duties) or non-tariff barriers to trade (e.g. unnecessary regulatory requirements). For companies, this means that they should not create barriers to parallel trade between EU countries whether through the agreements they conclude or, for dominant companies, by their unilateral conduct.

Link: <https://knect365.com/complaw-blog/article/073ed81f-0d17-4c0e-a819-38ff60332dec/what-is-parallel-trade-and-how-does-it-affect-pharma>

UNCTAD. (2016, October). Examining the interface between the objectives of competition policy and intellectual property. United Nations Conference on Trade and Development. [https://unctad.org/meetings/en/SessionalDocuments/ciclpd36\\_en.pdf](https://unctad.org/meetings/en/SessionalDocuments/ciclpd36_en.pdf)

Abstract not available

Executive Summary: The main objective of intellectual property is to encourage innovation and provide incentives for innovation by granting temporary protection to inventors. The objective of competition policy is to promote economic efficiency and ensure that markets function effectively for the benefit of consumers by correcting market failures. The ultimate goal of both intellectual property and competition policy is to enhance economic growth and consumer welfare. However, the exercise of intellectual property rights under certain circumstances may raise competition-related concerns. Therefore, innovation and the protection of competition in the market require a balanced approach. The present note considers the relationship between intellectual property rights and competition; elaborates on business practices in the exercise of intellectual property rights that create competition-related concerns, and addresses ways of dealing with anti-competitive practices related to intellectual property rights.

Link: [https://unctad.org/meetings/en/SessionalDocuments/ciclpd36\\_en.pdf](https://unctad.org/meetings/en/SessionalDocuments/ciclpd36_en.pdf)

WTO, WHO, WIPO. (2012). Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade. WHO, WTO, WIPO. [https://www.wipo.int/edocs/pubdocs/en/global\\_challenges/628/wipo\\_pub\\_628.pdf](https://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf)

Abstract not available

Presentation: Today's health policy-makers need a clear understanding both of the innovation processes that lead to new technologies and of the ways in which these technologies are disseminated in health systems. The study "Promoting Access to Medical Technologies and Innovation" seeks to reinforce the understanding of the interplay between the distinct policy domains of health, trade and IP, and of how they affect medical innovation and access to medical technologies. It captures a broad range of experience and data in dealing with the interplay between IP, trade rules and the dynamics of access to, and innovation in, medical technologies. A collaborative effort by WHO, WIPO and WTO, this study draws together the three Secretariats' respective areas of expertise. It is intended to inform ongoing technical cooperation activities undertaken by the three organizations and to support policy discussions. Based on many years of field experience in technical cooperation, the study has been prepared to serve the needs of policy-makers who seek a comprehensive presentation of the full range of issues, as well as

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lawmakers, government officials, delegates to international organizations, non-governmental organizations and researchers.

Link: [https://www.wipo.int/edocs/pubdocs/en/global\\_challenges/628/wipo\\_pub\\_628.pdf](https://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf)

Yoo, K. (2018). Interaction of Human Rights Law and Competition Law: The Right Access to Medicines and Consumer Welfare in the Pharmaceutical Sector. (Forthcoming) Vermont Law Review, 43.

[https://papers.ssrn.com/sol3/Delivery.cfm/SSRN\\_ID3250392\\_code2329374.pdf?abstractid=3250392&mirid=1](https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID3250392_code2329374.pdf?abstractid=3250392&mirid=1)

Abstract: Access to essential medicines as public goods arguably forms integral part of fundamental human rights. The current pharmaceutical industry faces serious challenges to access to medicines that result from anticompetitive business activities and structural shortcomings. Competition and human rights policies, though historically and theoretically following divergent paths, still have vigorously interacted with each other partly sharing policy goals one way or another. While such interaction occurs throughout a wide range of industries, those two policies commonly seek to safeguard and promote economic interests of consumers in the pharmaceutical industry. The right to access to medicines has a normative point of contact with consumer welfare in the competition context inasmuch as both right and welfare can receive sustainable protection particularly when the pharmaceutical industry effectively functions in a way to ensure the public equal and full access to lower-cost and higher-quality medicines.

Link:

[https://papers.ssrn.com/sol3/Delivery.cfm/SSRN\\_ID3250392\\_code2329374.pdf?abstractid=3250392&mirid=1](https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID3250392_code2329374.pdf?abstractid=3250392&mirid=1)

*\* For the purposes of this review, we have established three categories to describe the state of the literature: thin, considerable, and rich.*

- *Thin: There are relatively few papers and/or there are not many recent papers and/or there are clear gaps*
- *Considerable: There are several papers and/or there are a handful of recent papers and/or there are some clear gaps*
- *Rich: There is a wealth of papers on the topic and/or papers continue to be published that address this issue area and/or there are less obvious gaps*

*Scope: While many of these issues can touch a variety of sectors, this review focuses on medicines. The term medicines is used to cover the category of health technologies, including drugs, biologics (including vaccines), and diagnostic devices.*

*Disclaimer: The research syntheses aim to provide a concise, comprehensive overview of the current state of research on a specific topic. They seek to cover the main studies in the academic and grey literature, but are not systematic reviews capturing all published studies on a topic. As with any research synthesis, they also reflect the judgments of the researchers. The length and detail vary by topic. Each synthesis will undergo open peer review, and be updated periodically*

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## KNOWLEDGE PORTAL on innovation and access to medicines

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*based on feedback received on important missing studies and/or new research. Selected topics focus on national and international-level policies, while recognizing that other determinants of access operate at sub-national level. Work is ongoing on additional topics. We welcome suggestions on the current syntheses and/or on new topics to cover.*

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