Implementing Competition Policy to Enhance Public Health in Developing Countries

Gelişmekte Olan Ülkelerde Halk Sağlığını Geliştirmek İçin Rekabet Hukuku Politikası

Atilla Kasap*

Abstract

Patents must be made available in all fields of technology. However, this makes the supply of affordable medicines to the public a challenging duty for developing countries in the post-Agreement On Trade-Related Aspects of Intellectual Property Rights (TRIPS) era. This is because patent owners—the majority of them are pharmaceutical companies—may freely determine the price of medicines thanks to patents on these medicines to compensate for their investment. However, these patent owners have the potential to violate competition rules. Competition law is one of the TRIPS flexibilities, yet developing countries have not effectively exercised it. One of the important reasons is that developing countries have generally established legal regimes regulating competition only in the very recent past. This Article proposes that developing countries must build their own competition policies to address access to medicines. To do this, this Article argues that the international community should provide technical assistance to developing countries via programmes devised by the World Trade Organization (WTO) Council.

Keywords: access to medicines, patents, intellectual property rights, competition law, TRIPS

*Doktor, Ondokuz Mayıs Üniversitesi Medeni Hukuk Ana Bilim Dalı, ORCID: 0000-0002-8130-9776, atilla.kasap@omu.edu.tr.

Öz

Patentler teknolojinin her alanındaki buluşlara verilmelidir. Ancak bu durum Ticaretle Bağlantılı Fikri Mülkiyet Hakları Sözleşmesinin (TRIPS) kabulünden sonraki dönemde gelişmekte olan ülkeler için halka uygun fiyatlı ilaç tedarikini zorlu bir görev haline getirmiştir. Zira ilaçlar üzerindeki patentler sayesinde büyük çoğunluğu ilaç şirketleri olan patent sahipleri yapmış oldukları yatırımı kompanse edebilmek için ilaç fiyatını serbestçe belirlemektedirler. İşte bu gibi patent sahiplerinin rekabet hukukunun alanına giren ihlallerde bulunması söz konusu olabilmektedir. Rekabet hukuku TRIPS'in sağladığı esnekliklerden biri olmasına rağmen gelişmekte olan ülkeler tarafından etkin bir şekilde kullanılamamaktadır. Bunun bir önemli sebebi ise gelişmekte olan ülkelerin genellikle rekabet hukukuna ilişkin yasal düzenlemeleri yakın geçmişte yapmalarıdır. Bu makalede gelişmekte olan ülkelerin ilaçlara erişimi kolaylaştırmak için kendi rekabet hukuku politikalarını oluşturmaları önerilmektedir. Bunu yapmak için ise gelişmekte olan ülkelere Dünya Ticaret Örgütü gibi uluslararası kuruluşlar tarafından tasarlanan programlar aracılığıyla teknik yardım sağlanması tavsiye edilmektedir.

Anahtar Kelimeler: ilaçlara erişim, patentler, fikri mülkiyet hakları, rekabet hukuku, TRIPS

I. INTRODUCTION

In the post-TRIPS[1] era, patents must be made available in all fields of technology, making the supply of affordable medicines to the public a challenging duty for developing countries. The potential of competition law, as one of TRIPS flexibilities,[2] has not been effectively exercised by developing countries. This is also related to the fact that European Commission (EC) has recently paid attention to anti-competitive practices in pharmaceutical sector, and the Court of Justice of the European Union (CJEU) started to hear the pioneering cases related to such practices' effect, *e.g.* reverse payment agreements, in previous years. Unilateral strategies such as patent clusters, product hopping, and defensive patenting can delay the entry of generic versions but have as yet not been discussed in detail by the EU and the US Courts. Such practices and strategies can create significant barriers to access affordable medicines and innovation. This issue becomes critical as we witness the effects of COVID-19 that are continuing worldwide, especially regarding access to vaccines.[3] Utilising competition policy and monitoring the pharmaceutical sector is crucial for developing countries if the potential benefits to society are to be realised. This Article uses South Africa as a case study because of its recent case law on competition law and patents and its pioneering role in raising international awareness of the means of establishing an effective competition policy against the abuse of intellectual property rights (IPRs).[4]

II. TRIPS FLEXIBILITIES RELATED TO COMPETITION LAW

TRIPS sets out principles that can be used to design a legal framework to address the tension between IPRs and competition law.[5] Art. 8(1) TRIPS is particularly relevant as it permits Members to formulate or amend their laws and regulations to preserve *public health*. Art. 8(2)

[1] Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS 299, 33 ILM 1197 (hereinafter TRIPS).

[2] Shirin Sayed, 'Incorporation of Competition-related TRIPS Flexibilities in the Domestic Law: A Case Study of India' (2020) (23)2 J World Intellect Prop. 2, 3 ('[T]he remedies within the competition law can be treated as flexibility available within the TRIPS Agreement to address abuse of patent rights.'); WTO, *Intellectual Property and the Public Interest: Promoting Public Health Through Competition Law And Policy Communication From China And South Africa* (25 May 2018) IP/C/W/643 ('Competition law is one of the least discussed flexibilities within the WTO's TRIPS Agreement.').

[3] See UNDP, 'Using Competition Law to Promote Access to Health Technologies: A Supplement to the Guidebook for Low- and Middle Income Countries' (2022), 15-27.

[4] See WTO, *Intellectual Property And The Public Interest: Promoting Public Health Through Competition Law And Policy Communication From South Africa* (1 February 2019) IP/C/W/651.

[5] Jonathan Berger, 'Advancing Public Health by Other Means: Using Competition Policy' in Pedro Roffe *et al, Negotiating Health: Intellectual Property and Access to Medicines* (Earthscan, 2006), 183.

further states that measures can be taken to preclude *abuse* of IPRs or *practices* that would unfairly constrain trade or have a debilitating effect on the international transfer of technology. These principles can be utilised by developing countries to establish a competition regime that would promote the development of a local pharmaceutical industry that could supply affordable and accessible medicines as the language of the provision is sufficient to prohibit the exercise of any IPRs that might have an adverse effect on trade and technology transfer.[6] The Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines explicitly states that:

> Competition policies are important levers that governments can employ to ensure that health technology markets operate competitively and that the public benefits from low prices and innovation. Should governments pay closer attention to competition law, it could serve as an important policy tool for closing access to health technologies.[7]

On the other hand, Fox cautions that were there excessive take up of such a strategy, the impact on a Member of TRIPS would be such that the US would likely react and attempt to limit this practice on the grounds that protection of IPRs is guaranteed by TRIPS.[8] That said, developed countries might not necessarily try to prevent these moves, since any country intending to deploy competition policy under Art. 8(2) provisions as a means to protect public health must still respect the principles of *necessity, appropriateness* and *compliance* with TRIPS.

One significant flexibility, offered under Art. 31 of TRIPS, is the right of a government to grant a compulsory licence to a third party to exploit a patented invention without the patent owner's consent.[9] Pursuant to Art. 31(k), if a compulsory licence is issued against anti-competitive practices following either a judicial or administrative process of review, the two requirements ordinarily specified do not apply to the country in question. First, the proposed user does not need to acquire the patent holder's authorisation on acceptable commercial

[6] ibid 185.
[7] UNGA, 'The Report of the United Nations Secretary-General's High Level Panel on Access to Medicines' (2016), 24.
[8] Fox EM, 'Trade, Competition, and Intellectual Property--TRIPS and Its Antitrust Counterparts' (1996) 29(3) V and J Transnat'l L 481, 492.
[9] UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, (Cambridge University Press, 2005), 461.

terms and conditions, and these efforts need not be resulted in a successful agreement within a reasonable period, which is otherwise required by para(b). Second, the compulsory license is not necessarily aimed at predominantly for the supply of the domestic market, which otherwise significantly restricts countries' ability to import products from other countries pursuant to para(f).

III. EXAMPLES OF ANTI-COMPETITIVE PRACTICES AND ABUSES BY THE PHARMACEUTICAL INDUSTRY IN DEVELOPED COUNTRIES

A. REVERSE PAYMENT AGREEMENTS

Reverse payment agreements are a generally lawful means to resolve patent disputes and are beneficial for dispute settlement mechanisms in accordance with public policy considerations. However, anti-competitive concerns would be raised where such agreements include clauses that limit competition, establish price-fixing or share information related to products and prices.[10] In the US, these agreements mostly take place according to procedures set out in the Hatch-Waxman Act[11] between the originator pharmaceutical company that brings a lawsuit for patent infringement, and the generic company that counterclaims the patent's invalidity and enforceability.[12] Pharmaceutical companies argue that they are legitimate since they fall within the scope of patent protection, also knowns as the 'scope of patent' approach.[13] The FTC, on the other hand, applied the 'quick look' approach, which considers such agreements to be *presumptively* illegitimate.[14] The Supreme Court in *FTC v Actavis* rejected both approaches and held that reverse payment settlements can occasionally breach antitrust law and are not exempted from antitrust investigation even though the scope of the patentee's exclusionary rights encompasses the agreement's anticompetitive effects.[15] The Court established a 'rule of reason' test for the lower courts, whereby the anticompetitive effects are analysed by considering the following features of an agreement: (1) its size; (2) its scale in connection with the payor's expected litigation costs; (3) its independence from other services

[10] Hovenkamp H and Janis MD and Lemley MA, 'Anticompetitive Settlement of Intellectual Property Disputes.' (2003) 87(6) Minn L Rev 1719.

[11] It is officially known as The Drug Price Competition and Patent Term Restoration Act of 1984.

[12] Congressional Research Service Report for Congress, 'The Hatch-Waxman Act: Legislative Changes in the 108th Congress Affecting Pharmaceutical Patents' (2004) Order Code: RL32377, 13.

[13] Olga Gurgula, 'US Supreme Court decision on reverse payment agreements: new era in patent litigation settlements- *FTC v Actavis, Inc.*, 570 US (2013)' (2013) 3(4) QMJIP 325.

[14] ibid.

[15] FTC v Actavis, Inc., 570 U.S. 136 (2013).

which it would justify payment, and; (4) the absence or lack of any other persuasive justification.[16] This approach led to a significant decline in the number of anti-competitive agreements after the *FTC v Actavis* judgment.[17]

In the EU, reverse payment agreements may be concluded both at the court stage but also out of court.[18] In *Lundbeck*, the General Court, for the first time in legal history, held that reverse payment agreements agreed by Lundbeck and generic companies in return for lump sum restricted competition *by object* had wiped out competition coming from the generic companies without any convincing justification.[19] The Court went on to say that this constituted an infringement of Art. 101 of the Treaty on the Functioning of the European Union (TFEU), which prohibits any agreement that restricts, distorts, or prevents competition by its object or effect[20] on the ground that although the Commission was incompetent to decide the scope of a patent, this does not preclude it from taking action when the scope of the patent is necessary to rule out Art. 101 and 102 violations.[21] Compared to the US, the EU has adopted therefore a stricter approach, and this has resulted in a significant decrease in the number of patent settlements since the sector inquiry was completed.[22]

Sir Robin Jacob harshly criticizes the EU's policy towards patent settlement agreements as being unrealistic and uncommercial on three main grounds: (1) the agreement is binding only for the generic company that signed it; (2) there is a danger of precluding genuine settlement agreements and; (3) these agreements do not severely affect the potential market of the drug by simply reaching one generic company.[23]However, the sector inquiry of 2009 revealed that originator companies also aim to *prevent other generic companies' entry* by reverse payment

[16] ibid 159.

[17] FTC Press Release, 'FTC Report on drug Patent Settlements Shows Potential Pay-for-Delay Deals Decreased Substantially in the First Year Since Supreme Court's Actavis Decision' (13 January 2016) <https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf> accessed 11 April 208.

[18] Duncan Matthews and Olga Gurgula, 'Patent strategies and competition law in the pharmaceutical sector: implications for access to medicines' (2016) 38(11) E.I.P.R 662, 664.

[19] Case T-472/3, H.Lundbeck A/S and Lundbeck Ltd v European Commission, [2016] 5 CMLR 18.

[20] Consolidated version of the Treaty on the Functioning of the European Union (2012) OJ C326/47.

[21] Lundbeck v European Commission (n 19). See also, European Commission COMP/39612 Servier-Perindopril (9 July 2014) (In *Servier*, unlike *Lundbeck*, the Commission also discussed the breach of Art.102 of TFEU since Servier's aim in promoting vying technologies was to eliminate competition.)

[22] European Commission, '6th Report on the Monitoring of Patent Settlements (period: January-December 2014).'

[23] Sir Robin Jacob, 'Competition Authorities Support Grasshoppers: Competition Law as a Threat to Innovation', (2013) 9(2) CPI Spring 15, 18-20.

agreements when they realise that they have a weak case or are unlikely to acquire interim injunctions.[24] Moreover, although other generic companies are free to challenge the originator companies, the first thing they ponder in considering legal action is the anticipated cost of litigation, whereas the majority of originator companies first analyse their position in the case.[25] Furthermore, such agreements might occur in the involvement of more than one generic company, e.g. Lundbeck and Servier agreed with a few geographically and potentially strategic generic manufacturers, four and five respectively.[26] Therefore, in this environment, it is not realistic to expect bona fide settlements to be concluded between originator companies and generic companies.

B. PATENT CLUSTERS, PRODUCT HOPPING AND DEFENSIVE PATENTING

Pharmaceutical companies might engage in unilateral strategies to maintain their monopoly and delay the market entry of generic companies. Patent clusters involve filing patent applications that encompass any feature of a product that could conceivably be financially significant, i.e. processes, formulations, extra pharmaceutical elements or other indications.[27] It is a key strategy for firms to adopt to maximize patent protection on their commercial products. These patent applications might be divided into one or more narrower applications either by the patentee itself or at the patent office's request.[28] The denser the patent cluster, the more it will potentially delay generic entry.[29] This is because generic companies are aware that they are likely to confront a few valid patents as soon as production begins, resulting in unacceptable compliance costs to ensure that any valid patents in the cluster are not infringed.[30]

Sir Jacob argues that patent thickets occur in sectors characterised by intense innovation and rapid technological development, noting how Edison protected himself via clusters under such

[24] European Commission, 'Pharmaceutical Sector Inquiry: Final Report' (8 July 2009), 263 <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> accessed 11 April 2018.

[25] ibid 266.

[26] Lundbeck v European Commission (n 19) 983-4, Servier-Perindopril (n 21).

[27] The EC Pharmaceutical Inquiry (n 24) 189.

[28] European Commission, 'Communication from the Commission: Executive Summary of the Pharmaceutical Sector Inquiry Report' (2008), 11 <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf> accessed 12 April 2018.

[29] UNCTAD, 'The Role of competition in the pharmaceutical sector and its benefits for consumers' (2015), para.21 <http://unctad.org/meetings/en/SessionalDocuments/tdrbpconf8d3_en.pdf> accessed 12 April 2018.

[30] ibid.

conditions over a century ago.[31] However, Matthews and Gurgula offer the example of Abbot's two current, combination HIV medicines—Norvir (containing ritonavir, approved in 1996) and Kaletra (lopinavir/ritonavir, approved in 2000)—which are protected by a total of 108 separate patents.[32] This dense patent cluster is likely to delay competition from generic companies until at least 2028. One study shows that lopinovir and ritonavir are already being produced by generic companies in India.[33] Moreover, Amin and Kesselheim contend that the inventiveness of some of the secondary patents of lopinovir/ritonavir are doubtful.[34]

Product hopping, also knowns as product switching, occurs when branded manufacturers introduce a new formulation of a patented medicine that is about to lose patent protection. Originator companies guide doctors and pharmacists to switch demand over to the novel formulation of the drug, newly patented. At the same time, doctors are discouraged from prescribing the older version of the drug, inhibited generic competition.[35] A US court found that product hopping by an originator company without a lawful commercial justification is a breach of antitrust law if customers are forced to use the new product.[36] Accordingly, the Court of Justice of the European Union held that by conducting such strategy without justification, dominant undertakings cannot misuse regulatory procedures to preclude or impede the entry of competitors to the market, thereby the conduct constituted an abuse of dominant position pursuant to Art. 102 of TFEU.[37]

Defensive patenting a strategy whereby a firm purchases or otherwise acquires patents or patent rights as a means to prevent acquisition by a competitor, and are typically stockpiled in important markets.[38] The firm's objective is to take compounds of interest to competitors out of circulation rather than to pursue royalties or sales.[39] Matthews and Gurgula argue that if patents are deployed to prevent competitors from improving medicines, competition

[31] Jacob (n 23) 18.
[32] Matthews and Gurgula (n 18) 665-6.
[33] Tahir Amin and Aaron S. Kesselheim, 'Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades' (2012) 31(10) Health Affairs 2286, 2292.
[34] ibid 2291.
[35] UNCTAD (n 29) para.23.
[36] New York ex rel. Schneiderman v Actavis PLC, 787 F.3d 638 (2015)
[37] Case C-457/10P, AstraZeneca AB v European Commission, [2013] 4 CMLR 7.
[38] The EC Pharmaceutical Inquiry (n 24) 386.
[39] ibid.

authorities should intervene since the overarching rationale for patents is to reward the inventor rather than retard competition.[40]

IV. *HAZEL TAU v OTHERS*: THE SOUTH AFRICAN EXAMPLE

South Africa introduced a new competition law in 1998 (the Act).[41] Non-governmental organizations (NGOs) took advantage of competition law to challenge pharmaceutical companies' pricing policy in South African market. For instance, NGOs and individuals took complaints about two large pharmaceutical companies, GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI), to South Africa's Competition Commission in 2002, arguing they had infringed the Act by charging excessive prices. The complainants argued that even accounting for research and development costs, license fees and the need for a reasonable return on innovation investment, the prices charged by the pharma companies were still excessive and unreasonable.[42] After the investigation, which took one year, the Competition Commission found that GSK and BI had engaged not only in excessive pricing, but also two additional infringements: refusal to allow access to an essential facility and undertaking exclusionary acts.[43] In 2013, GSK and BI decided to settle and undertook to: (1) extend voluntary licenses to the private sector; (2) grant three more voluntary licenses; (3) allow the licensees to export contract products manufactured under the license to sub-Saharan African countries, and; (4) demand a royalty rate of no more than 5 per cent (30 per cent in the case of GSK).[44] The license was later granted to eight generic manufacturers.[45] The competition investigation ensured a relatively inexpensive and sustainable supply of ARVs in South Africa, with significant payoffs in terms of public health.[46] Berger argues that *Hazel Tau v Others* shows how competition policy can be effectively deployed in developing countries.[47]

---

[40] Matthews and Gurgula (n 18) 666.

[41] The Competition Act, Act No. 89, 1998.

[42] The Price of Life: Hazel Tau and Others vs GlaxoSmithKline and Boehringer Ingelheim: A Report on the excessive pricing complaint to South Africa's Competition Commission, (2003), 35.

[43] 'Competition Commission finds pharmaceutical firms in contravention of the Competition Act' (16 October 2003) <http://www.cptech.org/ip/health/sa/cc10162003.html> accessed 13 April 2018.

[44] 'Competition Commission concludes an agreement with pharmaceutical firms' CPTech (10 December 2003) <http://www.cptech.org/ip/health/sa/cc12102003.html> accessed 12 April 2018.

[45] Tenu Avafia *et al.*, 'The Ability of Select Sub-Saharan African Countries to Utilise TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries' (2006) TRALAC Working Paper, 25.

[46] Berger (n 5) 199.

[47] ibid 199-200. See also Heinz Klug, 'Access to Medicines and the Transformation of the South African State: Exploring the Interactions of Legal and Policy Changes in Health, Intellectual Property, Trade, and Competition Law in the Context of South Africa's HIV/AIDS Pandemic' (2012) 37(2) L.& Soc. Inquiry 297, 310-11.

V. CONCLUSION

Little attention has been paid to the of use competition law instruments in addressing access to medicines in developing countries. This is because developing countries have generally established legal regimes regulating competition only in the very recent past. Matthews and Gurgula argue that competition law is a key instrument to achieve a balance between encouraging innovation via IPR protection and protecting consumer welfare via competitive markets. They argue that the effective implementation of competition law—so that legal precedent is established and guidelines are clarified so that pharmaceutical firms can adopt stable long-term market strategies—can significantly lower prices and boost access.[48] One of the essential advantages of using a competition law is that there is currently no multilateral agreement on competition law, which provides significant policy space for developing countries regarding competition law policy.[49]

Developed countries have taken note of the methods pharmaceutical firms use to abuse IPRs to enhance competitive advantage at the expense of the public interest and effective measures have been taken to prevent these approaches from being used to extend market monopolies or prevent generic company entry. Developing countries must learn these lessons and build their own competition policies to achieve the same outcomes under the provisions of the TRIPS regime. However, developing countries cannot establish the competition policy regimes necessary to enforce such an approach without technical assistance from the donor community. Technical support could be provided by programmes devised by the WTO Council.

[48] Duncan Matthews and Olga Gurgula (n 18) 662-3. See also B.N. Pandey and Prabhat Kumar Saha, Competition Flexibilities In The Trips Agreement: Implications For Technology Transfer And Consumer Welfare (2015) 57(1) J Indian L Inst 92, 108 ('[T]he anti-competitive provisions in the TRIPS are the first significant leap for developing country members of WTO. These provisions establish a legal framework for WTO members with a substantial discretion to customize their domestic competition law to deal with anti-competitive practises in technology transfer agreements.').

[49] Sayed (n 2) 5.

BIBLIOGRAPHY

Table of Cases

European Cases

Case C-457/10P, AstraZeneca AB v European Commission, [2013] 4 CMLR 7.

Case T-472/3, H.Lundbeck A/S and Lundbeck Ltd v European Commission, [2016] 5 CMLR 18

European Commission COMP/39612 Servier-Perindopril (9 July 2014) (not reported)

Other Cases

FTC v Actavis, Inc., 570 U.S. 136 (2013)

New York ex rel. Schneiderman v Actavis PLC, 787 F.3d 638 (2015)

Table of Legislations

Treaties and Conventions

Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS 299, 33 ILM 1197

Consolidate version of the Treaty on the Functioning of the European Union (2012) OJ C326/47

EU Legislation

Commission Regulation (EC) No: 316/2014 of 28 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements, OJEU L 93/17

Other Jurisdictions

The Competition Act, Act No. 89, 1998 (South Africa)

The Drug Price Competition and Patent Term Restoration Act of 1984. (The US)

Books

The Price of Life: Hazel Tau and Others vs GlaxoSmithKline and Boehringer Ingelheim: A Report on the excessive pricing complaint to South Africa's Competition Commission,(2003*).*

Jonathan Berger, 'Advancing Public Health by Other Means: Using Competition Policy' in Pedro Roffe *et al, Negotiating Health: Intellectual Property and Access to Medicines* (Earthscan, 2006).

UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, (Cambridge University Press, 2005).

Journal Articles

Pandey BN and Saha PK, Competition Flexibilities In The Trips Agreement: Implications For Technology Transfer And Consumer Welfare (2015) 57(1) J Indian L Inst 92.

Matthews D and Gurgula O, 'Patent strategies and competition law in the pharmaceutical sector: implications for access to medicines' (2016) 38(11) E.I.P.R 662-3.

Fox EM, 'Trade, Competition, and Intellectual Property--TRIPS and Its Antitrust Counterparts.' (1996) 29(3) Vand J Transnat'l L 481.

Klug H., 'Access to Medicines and the Transformation of the South African State: Exploring the Interactions of Legal and Policy Changes in Health, Intellectual Property, Trade, and Competition Law in the Context of South Africa's HIV/AIDS Pandemic' (2012) 37(2) L.& Soc. Inquiry 297.

Hovenkamp H and Janis MD and Lemley MA, 'Anticompetitive Settlement of Intellectual Property Disputes.' (2003) 87(6) Minn L Rev 1719.

Gurgula O, 'US Supreme Court decision on reverse payment agreements: new era in patent litigation settlements- *FTC v Actavis, Inc.*, 570 US (2013)' (2013) 3(4) QMJIP 325

Sayed S, 'Incorporation of Competition-related TRIPS Flexibilities in the Domestic Law: A Case Study of India' (2020) (23)2 J World Intellect Prop. 2.

Jacob SR, 'Competition Authorities Support Grasshoppers: Competition Law as a Threat to Innovation', (2013) 9(2) CPI Spring 15.

Amin T and Kesselheim AS, 'Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended For Decades' (2012) 31(10) Health Affairs 2286.

Other Printed Sources

Congressional Research Service Report for Congress, 'The Hatch-Waxman Act: Legislative Changes in the 108th Congress Affecting Pharmaceutical Patents' (2004) Order Code: RL32377.

European Commission, '6th Report on the Monitoring of Patent Settlements (period: January-December 2014)'

European Commission, 'Communication from the Commission: Executive Summary of the Pharmaceutical Sector Inquiry Report' (2008), <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf>

European Commission, 'Pharmaceutical Sector Inquiry: Final Report' (8 July 2009) <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf>

Avafia T. *et al.*, 'The Ability of Select Sub-Saharan African Countries to Utilise TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries' (2006) TRALAC Working Paper.

UNCTAD, 'The Role of competition in the pharmaceutical sector and its benefits for consumers' (2015) <http://unctad.org/meetings/en/SessionalDocuments/tdrbpconf8d3_en.pdf>.

UNDP, 'Using Competition Law to Promote Access to Health Technologies: A Supplement to the Guidebook for Low- and Middle Income Countries' (2022).

UNGA, 'The Report of the United Nations Secretary-General's High Level Panel on Access to Medicines' (2016).

WTO, *Intellectual Property and the Public Interest: Promoting Public Health Through Competition Law And Policy Communication From China And South Africa* (25 May 2018) IP/C/W/643.

WTO, Intellectual Property And The Public Interest: Promoting Public Health Through Competition Law And Policy Communication From South Africa (1 February 2019) IP/C/W/651.

Website and Blogs

'Competition Commission concludes an agreement with pharmaceutical firms' CPTech (10 December 2003) <http://www.cptech.org/ip/health/sa/cc12102003.html>

'Competition Commission finds pharmaceutical firms in contravention of the Competition Act' (16 October 2003) <http://www.cptech.org/ip/health/sa/cc10162003.html>

FTC Press Release, 'FTC Report on drug Patent Settlements Shows Potential Pay-for-Delay Deals Decreased Substantially in the First Year Since Supreme Court's Actavis Decision' (13 January 2016) <https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf> accessed 11 April 208.