

**Submission to the UN High-Level Panel on  
Access to Medicines:**

*The importance of competition law in facilitating  
access to medicines*

**Professor Duncan Matthews**

Chair in Intellectual Property Law, Queen Mary University of London

**Olga Gurgula**

Research Associate, Queen Mary University of London

**2016**

# Contents

<i>Executive summary</i> .....	2
<i>Recommendations</i> .....	3
<b>1. Competition law and access to medicines</b> .....	4
<b>1.1. General overview</b> .....	4
<b>1.2. Advantages of Competition Law</b> .....	5
1.2.1. <i>Expeditious measures to facilitate access to medicines</i> .....	5
1.2.2. <i>Providing transparency and legal clarity</i> .....	6
1.2.3. <i>The Hazel Tau case: using competition law to facilitate access to medicines</i> .....	6
<b>2. Anti-competitive practices in the pharmaceutical industry</b> .....	7
<b>2.1. Anti-competitive practices</b> .....	8
2.1.1. <i>Anti-competitive agreements: Reverse payment agreements</i> .....	8
2.1.2. <i>Anti-competitive unilateral strategies</i> .....	10
(a) <i>Patent thickets</i> .....	10
(b) <i>Product switching</i> .....	11
(c) <i>Defensive patenting</i> .....	11
2.1.3. <i>Competition law rules and abuses of IP by pharmaceutical companies</i> .....	12
<b>Conclusions</b> .....	12

## *Executive summary*

Competition policy is an under-utilised tool. Policy coherence between the IP system and competition must be strengthened in order to promote to the full extent 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. Even when competition authorities are active, many anti-competitive practices lack adequate attention. This is particularly striking in the pharmaceutical sector, where reverse payment agreements, for instance, are heavily litigated in the United States but have become the focus of attention in the European Union only more recently. Other business practices of pharmaceutical companies delay generic entry but competition authorities do not deal with this behaviour at all.

One example of potentially anti-competitive behaviour is strategic patenting, or as pharmaceutical companies call it, the life-cycle management practices in the form of patent thickets, secondary patenting (also known as evergreening) and defensive patenting. These practices delay considerably generic entry and innovative medicines and, despite being highlighted by the European Commission in its Pharmaceutical Sector Inquiry in 2009 and more recently in the Trilateral Study of the WHO, WIPO and WTO in 2012, in reality competition authorities have failed to deal with such practices thus far.

Anti-competitive practices create particular challenges for the developing world, given that they allow pharmaceutical patent owners to extend patent monopolies and, when considered together with provisions on data and market exclusivity, can lead to significant barriers to innovation and access. It is imperative therefore that the full range of policy tools is utilised in favour of access to medicines. Strengthening policy coherence between the IP system and competition must be central to achieving the aims and objectives of the High-Level Panel. 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.

## ***Recommendations***

### **1. *Utilisation of TRIPS flexibilities***

Countries have the right to utilise to the full flexibilities available in the TRIPS Agreement to ensure access to medicines. Article 8(2) of the TRIPS Agreement provides flexibilities for WTO Members to adopt competition law measures to prevent abuse of intellectual property rights. Existing or future trade and investment treaties must not undermine the utilisation of these flexibilities.

### **2. *A binding international agreement setting minimum standards of competition law enforcement***

A new international harmonised competition law system that sets the standards of minimum level of protection is essential to ensure properly functioning market economies. In this regard, it will be crucial to balance interests of developing countries and developed countries, since not all will have reached an advanced stage of economic development with a fully functioning, mature, competition law system in place. The existence of flexibilities in any future international harmonised competition law instrument must include in-built flexibilities similar to those enshrined in the TRIPS Agreement.

### **3. *Best practices and model laws on the competition law enforcement***

Best practices and model laws can assist considerably the consolidation of competition law enforcement internationally. They are important policy tools for the dissemination of knowledge and building capacity of a competition law enforcement in developing and developed countries alike, taking into account differences in the level of economic and social development of different users, as well as their policy objectives. International organisations should assist in the preparation of a toolkit of best practices and model laws to consolidate competition law enforcement globally.

### **4. *Fact-finding missions on the application of competition law in the pharmaceutical sector***

Practical steps should be taken to initiate fact-finding missions by international organisations to provide information on the current status of competition law, its application in the pharmaceutical sector and its impact on access to medicines. Such fact-finding missions should include analysis of the decisions taken by competition authorities and judicial bodies in different jurisdictions with respect to anti-competitive practices in the pharmaceutical industry. The resultant evidence would contribute considerably to the development of common rules and doctrines applicable in this field.

### **5. *Design and delivery of analytical tools to identify potentially abusive practices in the pharmaceutical sector***

Further initiatives should be undertaken to assist competition authorities in ascertain lawful and unlawful patenting practices. These initiatives would include the design and delivery of analytical tools that can be used by competition authorities seeking to identify potentially abusive practices in the pharmaceutical sector.

### **6. *Technical assistance and capacity building***

Greater recourse to technical assistance can assist in building capacity in the competition law field and contribute to the delivery of more effective policies on potentially abusive practices in the pharmaceutical sector in support of access to medicines.

## 1. Competition law and access to medicines

Article 8(1) of the TRIPS Agreement provides that: ‘Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.’

Article 8(2) of the TRIPS Agreement adds that: ‘Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.’

The TRIPS Agreement therefore explicitly permits WTO Members to employ specific measures in order to protect public health and nutrition, and to promote the public interest. In addition the TRIPS Agreement provides flexibilities for WTO Members to adopt measures to prevent abuse of intellectual property rights.

The most widely discussed provision available in the TRIPS Agreement to facilitate access to medicines is compulsory licencing under Article 31, which allows a WTO Member to authorise use of the subject matter of a patent without the consent of the right holder. In practice, compulsory licensing is not commonly utilised by WTO Members due to its complex procedures, lack of technical capacity and bilateral pressure.<sup>1</sup>

An alternative to compulsory licensing and, this submission argues, a more effective tool to protect public health and enhance access to medicines is by controlling abuses of intellectual property rights through competition law *per se*. Competition law is under-utilised but, when used effectively, can be an efficient mechanism in facilitating access to medicines. This is because courts and competition authorities are able to use competition law in order to balance the promotion of innovation via protection of intellectual property rights on the one hand, and protection of consumer welfare through competitive markets and lower prices by means of competition law on the other.

### 1.1. General overview

Governments have historically attempted to regulate competitive markets for goods and services, condemning monopolies and protecting trade and consumers. The United States Sherman Act of 1890 and the Clayton Act of 1914 proscribe unlawful mergers and business practices, including anti-competitive agreements and unilateral abuses. US antitrust law on restraint of trade had a major influence on the development of competition law in other countries. In the European Union anti-competitive practices are addressed, *inter alia*, in Articles 101 and 102 of the Treaty on the Functioning of the European Union. Yet despite the long tradition of competition law provisions in the US and EU, for the majority of developing countries competition law remains relatively new, implemented within the last 25 years.

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<sup>1</sup> Duncan Matthews, ‘TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements’ (2005) 11 European Intellectual Property Review 421.

Unlike the binding minimum standards of intellectual property protection and enforcement enshrined in the TRIPS Agreement, there is no equivalent international legal instrument for competition law that would provide such minimum standards of protection. The absence of an international agreement on competition law has both advantages and disadvantages. On the one hand, as trade becomes increasingly global it also becomes particularly difficult for international companies to meet the differing requirements of competition law in foreign jurisdictions because of the variation in its application and interpretation, as well as the difficulties with extraterritorial enforcement. On the other hand, the absence of international standards provides flexibilities to the developing countries in their drafting, interpretation and enforcement. In the absence of an international agreement on competition law, developing countries are free to define their own policy objectives.

## ***1.2. Advantages of Competition Law***

### *1.2.1. Expeditious measures to facilitate access to medicines*

When utilising in-built flexibilities in the TRIPS Agreement to facilitate access to medicines, competition law can assist in ensuring expeditious measures, particularly in instances where the issuance of compulsory licences is envisaged. Article 31 establishes specific procedures that need to be followed before a compulsory licence can be issued but this can be cumbersome and time-consuming.<sup>2</sup> However, unlike other provisions in Article 31 of the TRIPS Agreement, paragraph (k) provides that WTO Members are not obliged to apply the conditions set forth in paragraph (b) to the effect that prior to such use, the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time, and paragraph (f) to the effect that any such use shall be authorised predominantly for the supply of the domestic market of the Member authorizing such use, where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. Article 31(k) further provides that the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases, and that competition authorities shall have the authority to refuse termination of authorisation if and when the conditions which led to such authorisation are likely to recur.<sup>3</sup>

Compulsory licences that are granted on the basis of competition law enforcement are specifically exempted from the requirement of prior negotiation before the grant of a licence. This decreases the time required to be spent negotiating with an IP owner and is potentially an important policy tool to facilitate access to medicines.

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<sup>2</sup> Duncan Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' (2004) 7(1) *Journal of International Economic Law* 73.

<sup>3</sup> See also WTO, WIPO, WHO, 'Promoting Access to Medical Technologies and Innovation: Intersection between public health, intellectual property and trade' (2012) 76 <[https://www.wto.org/english/res\\_e/publications\\_e/who-wipo-wto\\_2013\\_e.htm](https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2013_e.htm)> accessed 10 May 2016.

### 1.2.2. Providing transparency and legal clarity

Compulsory licencing is a complex procedure and may trigger an adverse reaction on the part of the patent owner, as well as raising the risk of bilateral trade pressure as a means of retaliation against the grant of a compulsory licence. Often a fear of such retaliation may force a country to abstain from such a policy approach. On the other hand, a decision of a competition authority may establish a useful legal precedent as a benchmark of policy application and guidelines for pharmaceutical companies that should be taken into account in their business strategies, as well as being used as a basis of a penalty imposed on a company that fails to follow such a precedent. This facilitates transparency and clarity in the application of the law and its approach to specific practices, including those that involve utilisation of intellectual property rights. As such, competition law can provide an effective alternative to compulsory licensing, in doing so creating precedents that will inform subsequent proceedings and incentives for firms to engage in voluntary licensing.

### 1.2.3. The Hazel Tau case: using competition law to facilitate access to medicines

One of the clearest examples of how competition law can facilitate access to medicine in a developing country context by prohibiting abuses of intellectual property rights is the *Hazel Tau* case in South Africa.<sup>4</sup> The case arose when, in September 2002, 11 complainants of whom five were people living with HIV/AIDS (joined in February 2003 by a further two new complainants), brought an action against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI). The complainants alleged that the two companies were acting in violation of competition law by charging excessive prices for their ARV medicines and because of this they were directly responsible for the premature, predictable and avoidable loss of life, including of people living with HIV/AIDS.<sup>5</sup>

On 16 October 2003 the Competition Commission's investigation revealed that GSK and BI had contravened the Competition Act of 1998 by refusing to license their patents on ARVs to generic manufacturers in return for a reasonable royalty.<sup>6</sup> More specifically, GSK and BI were found to have abused their dominant positions in their respective ARV markets by engaging in restrictive practices consisting of: first, denying a competitor access to an essential facility; second, excessive pricing; and, third, engaging in an exclusionary act. According to the Commission, GSK and BI were using their exclusive patent rights to deny appropriate licences to other manufacturers, whilst simultaneously keeping their own prices high. The Commission referred the matter to the Competition Tribunal and asked it to make an order authorising any person to be able to exploit the patents to market generic medicines or fixed dose combinations that require the patents, on return for the payment of a reasonable royalty. The Commission also recommended a penalty of 10 per cent of the annual turnover of GSK

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<sup>4</sup> Hazel Tau et al. v. GlaxoSmithKline, Boehringer Ingelheim, et al. & Aids Healthcare Foundation et al v. GlaxoSmithKline, Boehringer Ingelheim, et al. Case Numbers: 2002sep226 & 2002jan357. See also Duncan Matthews, *Intellectual Property, Human Rights and Development: The Role of NGOs and Social Movements* (Edward Elgar 2011) 102-108.

<sup>5</sup> See Avafia, Tenu, Berger, Jonathan and Hartzenberg, Trudy, '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) 12 TRALAC Working Paper, Stellenbosch, South Africa: US Printers, 37; Berger, Jonathan, 'Advancing Public Health by Others Means: Using Competition Policy' in Pedro Roffe, Geoff Tansey and David Vivas-Eugui (eds.), *Negotiating Health: Intellectual Property and Access to Medicines* (London and Sterling, VA: Earthscan 2006) 197.

<sup>6</sup> Competition Commission Press Release, 'Competition Commission finds pharmaceutical firms in contravention of the Competition Act' (16 October 2003).

and BI's sale of ARVs in South Africa for each year that they were found to have violated the Act.<sup>7</sup>

On 10 December 2003, the Competition Commission announced that it had concluded a settlement agreement with GSK which resulted in the grant of non-exclusive royalty-free voluntary licences and that it was in discussions with BI, also regarding a settlement agreement. At the time the complaint was lodged, both GSK and BI had already granted licences to South African pharmaceutical company Aspen Pharmacare, but the terms and conditions had been found by the Competition Commission to be unacceptable.<sup>8</sup> Under the terms of the settlement agreement with GSK, the company undertook to: extend the voluntary licence granted previously to Aspen Pharmacare in respect of the public sector to include the private sector; grant up to three more voluntary licences on terms no less favourable than those granted to Aspen Pharmacare, based on reasonable criteria which include registration with the Medicines Control Council and the meeting of safety and efficacy obligations; permit the licensees to export the relevant ARV drugs to sub-Saharan African countries; where the licensee did not have the manufacturing capacity in South Africa, GSK would permit the importation of the drugs for distribution in South Africa; permit the licensees to combine the relevant ARV with other antiretroviral medicines; and charge royalties of no more than 5 per cent of the net sales of the relevant ARVs.<sup>9</sup>

By the end of 2004, GSK and BI had licensed to five and three generic manufacturers respectively.<sup>10</sup> This resulted in significantly lower prices and improved sustainability of supply for the pharmaceutical products involved.<sup>11</sup>

## **2. Anti-competitive practices in the pharmaceutical industry**

One of the most effective ways to extend market exclusivity for pharmaceutical products is through strategic patenting and patent settlement agreements with generic competitors. In 2009, the European Commission Pharmaceutical Sector Inquiry concluded that such practices considerably delay or even block generic competition.<sup>12</sup>

These anti-competitive practices may be divided into two groups: (a) anti-competitive agreements, including pay-for-delay agreements between originators and generic competitors and (b) anti-competitive unilateral strategies including patenting practices and abuse of regulatory procedures by pharmaceutical companies or providing misleading information to state authorities. Such conduct

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<sup>7</sup> 'Commission Questions Conduct of Anti-retroviral Companies' (2003) 14 Competition News 1 <<http://www.compcom.co.za/wp-content/uploads/2014/09/Dec-03-Newsletter.pdf>> accessed 10 May 2016.

<sup>8</sup> Both GSK and BI had granted licences to South African generic drug company Aspen Pharmacare to manufacture and sell these patented ARVs in return for royalty payments that were in some cases as high as 40 per cent. In the case of GSK, sales by Aspen Pharmacare were permitted only to the South African public sector. See Berger (n 5) 199; Matthews (n 4) 103.

<sup>9</sup> 'Competition Commission concludes an agreement with pharmaceutical firms' (2003) CPTEch <<http://www.cptech.org/ip/health/sa/cc12102003.html>> accessed 10 May 2016.

<sup>10</sup> Avafia et al. (n 5) 32.

<sup>11</sup> Berger (n 5) 199.

<sup>12</sup> European Commission, 'Pharmaceutical Sector Inquiry: Final Report' (8 July 2009) (Pharmaceutical Sector Inquiry) <[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf)> accessed 10 May 2016.



allows pharmaceutical companies to extend market exclusivity beyond the initial patent monopoly and prevent entry of generic medicines to the market. The proliferation of such practices calls into question the effectiveness of intellectual property law enforcement mechanisms and highlights the relevance of competition law enforcement in this context.<sup>13</sup>

## 2.1. *Anti-competitive practices*

### 2.1.1. *Anti-competitive agreements: Reverse payment agreements*

In the US reverse payment agreements usually occur as a settlement of a patent dispute within the Hatch-Waxman Act procedure between the originator pharmaceutical company, i.e. the patent owner, that sues for patent infringement and the generic company, i.e. the alleged infringer, that countersues for patent invalidity. In the EU these agreements may occur out of court proceedings. The essence of these settlements is the agreement between the originator company and the generic company according to which the former agrees to transfer substantial amount of money (or other value transfers such as licences) in return to a promise by the latter not to enter the market.

The pharmaceutical industry claims that these are lawful agreements under patent law as the patent grants exclusionary powers to its owner, and therefore, while the patent is pending, the originator company has the right to exclude its competitors. Also companies use the patent validity doctrine claiming that a patent is deemed valid until the court decides the opposite. It is also argued that it is in line with the public policy that favours dispute settlement. However, competition authorities are critical of such settlements, arguing that the originator company in fact pays off its competitor to stay out of the market, substantially delaying generic competition. It is claimed that patent litigation may result in the invalidation of a weak patent, eliminating unlawful monopoly as a result, and thus generic company could enter the market earlier. Instead the competitors decide to settle and share unlawful market monopoly profits – the benefit of both parties is, however, to the detriment of the consumer as it has to pay monopoly price for a longer period.

In the US pay-for-delay agreements have been litigated by the FTC for the last decade in different appellate circuits that employed different tests of assessment (i.e. *per se* illegality, scope of patent test, rule of reason and quick look test) and focusing on different facts (presumption of patent validity, transfer of funds etc.) that led to divergent outcomes. Finally, in 2013, the US Supreme Court provided some guidance in its landmark *FTC v. Actavis* decision, where it held that these type of agreements are not immune from antitrust scrutiny and firmly rejected the settled ‘scope of patent’ test largely used by the courts, as well as the FTC’s ‘quick look’ test, suggesting that reverse payment agreements must be analysed under the antitrust ‘rule of reason’ test.<sup>14</sup>

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<sup>13</sup> OECD, ‘Annex to the Summary Record of the 121<sup>st</sup> Meeting of the Competition Committee held on 18-19 June 2014. DAF/COMP/M(2014)2/ANN6/FINAL’ (10 February 2015) <<http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/M%282014%292/ANN6/FINAL&doclanguage=en>> accessed 10 May 2016.

<sup>14</sup> For the detailed analysis of this decision see Olga Gurgula, ‘US Supreme Court decision on reverse payment agreements: new era in patent litigation settlements – *FTC v Actavis, Inc.*’ (2013) Vol. 3 No. 4. Queen Mary Journal of Intellectual Property 325.

As recently reported by the FTC the number of the potentially anti-competitive agreements has fallen significantly following the Supreme Court's decision in *FTC v. Actavis*.<sup>15</sup> The total number of such deals filed with the FTC has dropped to 21 in 2014 from 29 in 2013, and 40 in 2012 prior to the *Actavis* ruling. Also since the *Actavis* decision, the FTC announced a \$1.2 billion settlement resolving its antitrust suit against Cephalon, Inc. for illegally blocking generic competition to its blockbuster sleep-disorder drug Provigil.<sup>16</sup>

In the EU, reverse payment agreements have been subject to attention by the European Commission. In 2008 the European Commission carried out a sector inquiry into the pharmaceutical industry to investigate the reasons for the apparent lack of competition in the market for human medicines in Europe.<sup>17</sup> The Commission identified reverse payment agreements as one of the practices that delay generic competition. Since the Pharmaceutical Sector Inquiry the Commission has carried out annual patent settlement monitoring exercises, the main purpose of which is to identify those that potentially unduly delay market entry of generic medicines to the detriment of the EU consumers. The proportion of potentially problematic patent settlements remains low, i.e. 12% in 2014 (11% in 2011, 7% in 2012 and 8% in 2013).<sup>18</sup>

The Commission also launched investigations and issued decisions against several pharmaceutical companies including fining Servier €330 million and several producers of generic medicines €97 million in 2014 for delaying market entry of generic high blood pressure medicine perindopril; fining Johnson & Johnson and Novartis €16 million in 2013 for delaying market entry of generic pain-killer fentanyl and fining Lundbeck €93.8 million and several producers of generic medicines €52.2 million in 2013 for delaying market entry of generic antidepressant citalopram. The Commission found that in all three cases the agreements have caused consumer harm by delaying generic entry and maintaining unnecessarily high prices. The Lundbeck and Servier cases are currently under appeal.<sup>19</sup>

Other jurisdictions have also started to pay an interest in this type of agreement. In 2014, the Competition Commission of India (CCI) began scrutinising and investigating pharmaceutical patent settlement agreements between originator and generic companies for potential anti-competitive effects.<sup>20</sup> The CCI is examining two sets of settlements resolving patent litigation in India that involve U.S, Swiss and Indian companies.<sup>21</sup> In 2015 China's National Development and Reform Commission announced that the regulator will pay attention to abuse of intellectual property rights in the pharmaceutical industry, including pay-for-delay agreements.<sup>22</sup>

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<sup>15</sup> The 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/news-events/press-releases/2016/01/ftc-report-drug-patent-settlements-shows-potential-pay-delay>> accessed 10 May 2016.

<sup>16</sup> The FTC Press Release, 'FTC Settlement of Cephalon Pay for Delay Case Ensures \$1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go To Purchasers Affected By Anticompetitive Tactics' (28 May 2015) <<https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill>> accessed 10 May 2016.

<sup>17</sup> Pharmaceutical Sector Inquiry (n 12).

<sup>18</sup> <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/>.

<sup>19</sup> [http://ec.europa.eu/competition/sectors/pharmaceuticals/antitrust\\_en.html](http://ec.europa.eu/competition/sectors/pharmaceuticals/antitrust_en.html).

<sup>20</sup> <http://www.livemint.com/Companies/RVVDhRh7oTfpqIphkb6jM/CCI-to-scan-drug-patent-settlements.html>.

<sup>21</sup> <https://www.wsg.com/WSGR/Display.aspx?SectionName=publications/PDFSearch/wsgalert-CCI.htm>.

<sup>22</sup> <http://mlexmarketinsight.com/editors-picks/chinas-ndrc-faces-challenges-in-scrutiny-of-pharma-pay-for-delay-agreements/>.

### 2.1.2. Anti-competitive unilateral strategies

In order to extend market monopoly, pharmaceutical companies employ various strategic patenting practices to delay generic entry. Such strategies include patent thickets (or patent clustering), product switching and defensive patenting.<sup>23</sup> Competition enforcement in this context has the potential to compensate for the failures of the IP and regulatory systems.<sup>24</sup> However, although competition enforcement is crucial in these cases, nevertheless such practices lack the attention of competition authorities.

#### (a) Patent thickets

Patent thickets, also known as patent clusters, allow originator companies to extend patent protection of their product to a maximum. This is usually done via multiple filings of patent applications often with overlapping claims on new formulations, processes, additional pharmaceutical indications and forms.<sup>25</sup> Such practices create numerous layers of protection and, if the competitor invalidates the basic patent before it expires other patents in the patent thickets, may still preclude generic market entry. One aspect of patent thickets is divisional patent applications that occur when the applicant divides a parent patent application into one or more narrower patent applications (this may happen either voluntarily or at the request of a patent office).<sup>26</sup>

The denser the web of patents in the patent thickets the more difficult for the generic company to enter the market with its generic equivalent. Although there is an understanding that many of the patents in such patent thickets might be declared invalid if challenged, there is an absence of certainty about which of them are weak and at risk of being litigated, and which are strong and will be infringed upon the entrance to the market. Thus, the generic company has two choices: either to wait until all patents in the patent thicket expire, or enter the market and run the risk of litigation. These patent thickets are also used by originator companies as a tool to threaten and/or commence patent infringement litigation that might create considerable obstacles to the market entry of generics via legal and search costs and court injunctions that prevent the sale of the generic product.<sup>27</sup>

One example of patent thickets can be found in the Abbott's patenting practices relating to its two key antiretroviral drugs for the management of HIV: ritonavir (Norvir) and lopinavir/ritonavir (Kaletra). 108 patents were identified that protect these two drugs. Abbott Laboratories' Norvir (ritonavir) was approved by the Food and Drug Administration in 1996, and Kaletra (lopinavir/ritonavir) was approved in 2000. The base compound for ritonavir was protected by the patent filed in 1995, originating from patent applications dating back to 1989. Including patent term adjustments and extensions, the expected patent expiration for the active ingredient in ritonavir was 2014. The patent for the active ingredient in

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<sup>23</sup> Other strategies include disinformation tactics, refusal to give access to essential patents, intervention before the regulatory bodies, sham litigation, etc.

<sup>24</sup> OECD, DAF/COMP/M(2014)2/ANN6/FINAL (n 13).

<sup>25</sup> Pharmaceutical Sector Inquiry (n 12) para 491.

<sup>26</sup> European Commission, 'Executive Summary of the Pharmaceutical Sector Inquiry Report' (2008) <[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf)> accessed 10 May 2016; See also UNCTAD, 'The role of competition in the pharmaceutical sector and its benefits for consumers' (2015) <[http://unctad.org/meetings/en/SessionalDocuments/trbpconf8d3\\_en.pdf](http://unctad.org/meetings/en/SessionalDocuments/trbpconf8d3_en.pdf)> accessed 10 May 2016.

<sup>27</sup> Ibid.

lopinavir was first filed in 1995 and has an expected expiration date of 2016. It is estimated that all 108 patents together can delay generic competition until at least 2028 - twelve years after the expiration of the patents on the drugs' base compounds and thirty-nine years after the first patents on ritonavir were filed. Amin and Kesselheim argue that some of the secondary patents were found to be of questionable inventiveness with overlapping claims.<sup>28</sup> The study shows that generic versions of Kaletra will not be available in the US for few more years, despite already being on the market in India for several years.

(b) *Product switching*

Product switching (or product hopping) is a practice of originator companies that involves the introduction of a new version of a patented drug that will shortly face expiration of a patent protection. Although this might seem to be a beneficial change, as the consumer will get the new improved version of the older drug, this nevertheless may raise competition concerns. In the situation when the new version of the drug enjoys longer patent protection, whereas the patent protection of the older drug will soon expire, the originator company has an incentive to switch doctors and patients from the first generation drug to the second generation. In order to induce such product switch originator companies may employ different tactics, such as withdrawing the old drug from the market, raising the relative price of the old drug, or promoting the new drug differentially.

In some jurisdictions where pharmacies are allowed to swap the generic equivalent for a branded drug (the substitution rules) a withdrawal of the old version of a drug means that physicians will cease to prescribe it. This effectively eliminates the possibility of substitution, and as a result blocks generic competition.<sup>29</sup> In *State of New York v. Actavis*, for example, the 2<sup>nd</sup> Circuit found that product hopping amounted to an antitrust violation when the older product was withdrawn from the market.<sup>30</sup>

(c) *Defensive patenting*

As defined by the European Commission in its Pharmaceutical Sector Inquiry, defensive patenting occurs when the originator company maintains and uses patents to block the development of a new, competing product rather than to protect its own invention.<sup>31</sup> It refers to inventions which the applying company considers to have little or no prospect of being developed and commercialised, and which, once granted, the company holds primarily to protect itself against actual or potential competition. As one of the companies' corporate documentations stated:

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<sup>28</sup> Tahir Amin, Aaron S. Kesselheim, 'Secondary Patenting Of Branded Pharmaceuticals: A Case Study Of How Patents On Two HIV Drugs Could Be Extended For Decades' (2012) Vol.31, No.10 Health Affairs, 2286 <<http://content.healthaffairs.org/content/31/10/2286.long>> accessed 10 May 2016; See also Chilton, Adam S., 'India's Evolving Patent Laws and the WTO Obligations: The Rejection of Abbott Laboratories' Application for a New Kaletra Patent' (2011) Journal Articles, Paper 4281 <[http://chicagounbound.uchicago.edu/journal\\_articles/4281](http://chicagounbound.uchicago.edu/journal_articles/4281)> accessed 10 May 2016.

<sup>29</sup> GN Addy and E Douglas, 'Canada considers hopping on board with a product-hopping case' (2014) Vol. 3, No. 2 Competition Policy International, Antitrust Chronicle Competition Policy; See also OECD, 'Summary Record of the Discussion on Competition and Generic Pharmaceuticals' (2014) <<http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/M%282014%292/ANN3/FINAL&doclanguage=en>> accessed 10 May 2016.

<sup>30</sup> *State of New York v. Actavis PLC*, No. 14-4624 (2nd Cir. May 22, 2015).

<sup>31</sup> Pharmaceutical Sector Inquiry (n 12) para 1117.

*Defensive patents ... serve to protect compounds closely related to [our company's] candidates or products. They do not cover [our company's] candidates or products. They protect compounds that would be of interest to a direct competitor.*

The fact that pharmaceutical companies may apply for patents to protect their inventions is a just and lawful right granted by patent law in order to reward the innovator. However, in circumstances, when a company uses patent strategies that interfere with the development of competing medicines and these strategies focus on excluding competitors without pursuing innovative efforts, such strategies should raise competition law concerns as being exclusionary. These patenting practices block dynamic competition and deprive consumers of access to new medicines.

### *2.1.3. Competition law rules and abuses of IP by pharmaceutical companies*

In the leading jurisdictions competition law contains provisions that deal with anti-competitive contracts and unilateral practices. Section 1 of the Sherman Act and Article 101 of the TFEU prohibit anti-competitive agreements between competitors that restrict competition. An agreement between an originator and its potential generic competitors that prevents generic entry in exchange for a value transfer from the originator is a restriction of competition contrary to Section 1 of the Sherman Act and Article 101 of the TFEU.

Anti-competitive practices of pharmaceutical companies that enjoy a dominant position are dealt with under Section 2 of the Sherman Act and Article 102 of the TFEU and, despite some variations in the treatment of monopoly power, they both condemn abuses of such monopoly, including abuses of intellectual property rights. Despite being a legal monopoly, intellectual property will not escape competition law enforcement when the exercise of IP is deemed anti-competitive. Thus, these provisions may be relevant to strategic patenting. A few modest steps were taken in this respect in the cases of product switching, but competition authorities are still hesitant to intervene into the evergreening and patent thickets practices, fearing that this might damage the fragile balance between the competition and incentive to innovate.

When dealing with these practices developing countries should use competition law more rigorously in order to prevent delays of generic competition. Defining competition law objectives, as well as defining relevant pharmaceutical market narrowly may be useful practical steps toward the facilitation of access to medicines.

## **Conclusions**

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. One way to deal with these practices is through the improvement of the patent system, for example by raising the bar of patentability requirements and increasing the registration fees. While some changes may indeed decrease the scale of the abuse, it will not resolve the problem entirely or even may create new difficulties. For instance, strengthening patentability requirements may harm innovation. While it might

be potentially beneficial for generic competition as the number of patents in patent thickets may potentially decrease, it may also lead to the difficulties of inventing around. This can affect other innovator companies that work in the same field trying to develop substitute products without facing patent infringement. Therefore, although some changes to the patent system will be important in order to reduce the number of weak and potentially invalid patents,<sup>32</sup> such changes should be implemented with caution.<sup>33</sup>

The counter argument, raised by pharmaceutical companies, is that IP strategies are in line with patent law, and therefore legal. If the invention meets the patentability requirements, the company is entitled to a patent. And once the patent is granted the owner has the right to protect its invention by excluding its competitors. That well may be so, but this does not take into account the abuse of the patent system in general. Patent law is neither equipped with the necessary legal tools that would enable it to deal with the abusive practices, nor it is the aim of this body of law. The purpose of patent filings, as well as the further use of these patents is beyond the scope of the patent system.

Competition law, on the other hand, may be an effective tool in dealing with these types of practices. In the pharmaceutical industry, competition policy benefits consumers in the form of increased access to affordable medicines by detecting, halting, and correcting anti-competitive practices.<sup>34</sup> Even immature and inexperienced regimes can gain successful results by resolving cases of excessive prices on essential medicines. Nowadays, competition authorities in developed countries and some developing countries are dealing with important issues of restrictive agreements and abuses of dominance in the pharmaceutical industry. However, some of the practices of pharmaceutical companies that delay and even block generic and innovative competition still lack attention. Practices such as reverse payment agreements and strategic patenting should become the focus of greater attention by competition agencies around the world.

Countries should be able to retain freedom to utilise to the full flexibilities available in the TRIPS Agreement to ensure access to medicines. Existing or future trade and investment treaties must not undermine these flexibilities. In addition to in-built flexibilities in the TRIPS Agreement, countries should be able to utilise competition law to facilitate access to medicines. Tools that can contribute to this include: the existence of flexibilities in any future international harmonised competition law instrument; best practices and model laws to consolidate competition law enforcement globally; fact-finding missions by international organisations to provide information on the current status of competition law, its application in the pharmaceutical sector and its impact on access to medicines; the design and delivery of analytical tools that can be used by competition authorities seeking to identify

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<sup>32</sup> According to the Pharmaceutical Sector Inquiry, para 501:

*As later shown the final outcome in 60 % of opposition and appeal procedures against originator company's patents examined in this report was a revocation of the disputed patent. In addition to this, the scope of the patents was reduced in another 15%. These procedures almost exclusively concerned secondary patents. Furthermore in 55 % of the patent litigation cases between originator and generic companies that involved a question of the disputed patent's validity and that reached a final judgement, the patents were annulled (43 of 78 cases).*

<sup>33</sup> A toolbox has been designed for developing countries to shape the broad scope of exclusive rights before a patent is issued (pre-grant) and after a patent has been granted (post-grant), and thus ensure the accessibility of generic medications. See UNCTAD, 'Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide' (2011) New York and Geneva, United Nations publication <<http://unctad.org/en/pages/PublicationArchive.aspx?publicationid=437>> accessed 10 May 2016.

<sup>34</sup> UNCTAD, 'The role of competition in the pharmaceutical sector and its benefits for consumers' (2015) <[http://unctad.org/meetings/en/SessionalDocuments/tdrbpconf8d3\\_en.pdf](http://unctad.org/meetings/en/SessionalDocuments/tdrbpconf8d3_en.pdf)> 10 May 2016.

potentially abusive practices in the pharmaceutical sector; and technical assistance, capacity building and best practice to contribute to the delivery of more effective policies on potentially abusive practices in the pharmaceutical sector in support of access to medicines.