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**Article — Published Version**

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Intereconomics

*Suggested Citation:* Boscheck, Ralf (2015) : Intellectual property rights and the evergreening of pharmaceuticals, Intereconomics, ISSN 1613-964X, Springer, Heidelberg, Vol. 50, Iss. 4, pp. 221-226, <https://doi.org/10.1007/s10272-015-0546-y>

This Version is available at:

<https://hdl.handle.net/10419/172664>

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Ralf Boscheck

# Intellectual Property Rights and the Evergreening of Pharmaceuticals

Escalating healthcare expenditures and the need to ensure access to affordable medicine in both emerging and emerged economies are fuelling calls to contain the so-called evergreening practices of drug producers around the world. But such practices are the necessary outcome of a system that responds to market incentives and appears to be already sufficiently controlled by established patentability standards and policies that determine patent term extension. The key issues surrounding current trade disputes lie deeper. This article examines the link between technological advances and intellectual property rights in general and the presumably special case of drug supplies. It focuses on strategies for extending the market exclusivity for pharmaceuticals products and evaluates safeguards against such evergreening.

On 26 April 2015, celebrations to commemorate the 40th anniversary of the World Intellectual Property Organization could not mask the fundamental dissent amongst its member states. Already in October 2014, a meeting of Trans-Pacific Partnership (TPP) ministers had failed to resolve differences on whether and how to transition countries from lower to higher levels of intellectual property (IP) protection, particularly in the area of pharmaceuticals.<sup>1</sup> Whereas “access to medicine” advocates proposed measures based on national income levels, branded drug producers supported a more predictable, time-based transition schedule; others again argued for patent protection to be linked with the United Nation’s Human Development Index – a relative scale with frequently changing outcomes and policy implications.

Similarly, in early April 2015, India’s Prime Minister Narendra Modi and German Chancellor Angela Merkel discussed the India-EU free trade agreement and the effect of more stringent patent enforcement.<sup>2</sup> Modi expressed concerns that heightened IP standards would annul the

benefits of his government’s “Make in India” campaign and threaten the country’s role of “pharmacy of the developing world”. Conversely, the Merkel team reiterated the EU’s 2014 Action Plan for the enforcement of intellectual property rights.<sup>3</sup> The EU’s strategy targets commercial scale infringers that discourage innovation, cause fiscal losses and undermine European competitiveness and job creation. In the end, the parties agreed to disagree. To avoid any further delay in their discussions, negotiators simply removed crucial provisions regulating data exclusivity and the extension of patent terms for pharmaceuticals from the proposed trade accords.

In either case, the seeds for future conflicts had been sown. Except these quarrels are unlikely to be fuelled by the different industrial policy interests of the so-called emerged and emerging economies,<sup>4</sup> or the global concern for ensuring low-cost access to advanced medicine without dampening pharmaceutical research. They will rather centre on the legitimacy of additional policy intervention in the area of intellectual property rights. This paper discusses concerns related to extending patent protection for pharmaceuticals.

<sup>1</sup> TPP ministers fail to bridge gaps over pharma IP transition mechanisms, *Inside U.S. Trade*, Vol. 32, No. 4331, 2014.

<sup>2</sup> Fears over EU plan for strict drug patent regime, *Times of India*, 14 April 2015.

<sup>3</sup> European Commission: Towards a renewed consensus on the enforcement of Intellectual Property Rights: An EU Action Plan, COM/2014/0392 final, 2014; see also Council Resolution on the EU Customs Action Plan to combat IPR infringements for the years 2013 to 2017, *Official Journal of the European Union*, 2013/C 80/01, 19 March 2013.

<sup>4</sup> For a perspective, see R. Boscheck: Intellectual Property & Compulsory Licensing: The Case of Pharmaceuticals in Emerging Markets, in: *World Competition*, Vol. 35, No. 4, 2012, pp. 621-634.

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### Technological advance, intellectual property and the “special case” of pharmaceuticals

A society’s ability to generate, exploit and share technological advances is widely accepted as the single most important source of economic value creation.<sup>5</sup> And yet there is startlingly little advice on which types of markets, firms or even institutional supports are most conducive to innovative performance.<sup>6</sup> Unsurprisingly, policy makers make every effort to promote non-specific conditions to incentivise entrepreneurial risk-taking. Patents are a key example of this. They are typically thought to stimulate risky research by temporarily excluding followers from competing away supra-normal profits; they also involve the disclosure of information that may allow others to circumvent the original design and thereby foster innovation and diffusion. But while there is little convincing data to support the idea that patents indeed promote higher levels of innovative activity,<sup>7</sup> there are some obvious risks and costs associated with them.

*Ex ante*, overburdened patent officers may confer monopoly status to some pre-existing but unrecognised prior design. *Ex post*, patents may result in welfare-reducing monopolistic pricing, licensing or standard-setting behaviour. To remedy the former, technology assessments may be expanded by encouraging third parties to challenge the validity of patents in court. Addressing the latter requires price discrimination to remove welfare losses or compulsory licensing to increase market choice. Each response is laden with conceptual and practical difficulties related to patenting, reference pricing, parallel trade and valuation.

All of this may explain why patents in general have received rather critical reviews lately. And yet, even outspo-

ken critics seem to exclude the pharmaceutical sector from their indictments.<sup>8</sup> US Federal Judge Richard Posner, for example, after dismissing a high-profile lawsuit between Apple and Motorola, recently went public with his view that “most industries could get along fine without patent protection. ...*The prime example of an industry that really does need such protection is pharmaceuticals.*”<sup>9</sup> He provided three reasons: the high cost of drug development, the relatively short effective recoupment period and the low cost of manufacturing, which allows low-priced copies and would make it impossible for inventors to ever recover their investments. But defending intellectual property rights in pharmaceuticals quickly becomes contentious if seen to limit access to affordable medicine through international trade or for the purpose of domestic cost containment.

In fact, for many years, drugs were simply deemed too important to leave vulnerable to monopoly abuse. Japan and Switzerland did not offer product patents for drugs until 1976/77. Spain, Portugal, Greece and Norway followed in 1992. At that time, at least 40 developing countries, including India and Brazil, provided no patent protection for pharmaceuticals, while others, like Mexico and Argentina, recognised only a limited set of intellectual property rights. However, mounting costs and risks in drug development and the difficulty of otherwise securing commercial advantage eventually tipped the balance in favour of legally enforceable exclusivity. Following the inclusion of the agreement on trade-related aspects of intellectual property rights (TRIPS) in World Trade Organization (WTO) rules in 1994,<sup>10</sup> members were obliged to honour pharmaceutical patent protection by 2016. The TRIPS Agreement relies on national patentability criteria with respect to incremental innovation or functional equivalency and provides for enforcement, dispute settlement and transition mechanisms to ensure minimum standards for protecting intellectual property rights.

Developed countries, particularly the United States, usually try to persuade emerging economies to commit to more stringent, so-called TRIPS-plus intellectual property right rules in exchange for bilateral concessions in oth-

5 See A. Toynbee: *Mankind and Mother Earth: A Narrative History of the World*, London 1978, Granada; R.M. Solow: Technical Change and the Aggregate Production Function, in: *Review of Economics and Statistics*, Vol. 39, No. 3, 1957, pp. 312-317; R.M. Solow: *Growth Theory and After*, Nobel Prize Lecture, Stockholm, 8 December 1987.

6 Prominent biases in favour of public ownership as opposed to private or particular levels of inventive rivalry do not stand up to empirical tests, nor is there any support for the popular intuition in favour of either “small, nimble inventors” or “large-scale, resourceful innovators”. See J.A. Schumpeter: *Theorie der wirtschaftlichen Entwicklung*, Leipzig 1912, Duncker & Humblot; K.J. Arrow: *Economic Welfare and the Allocation of Resources for Invention*, in: *Universities-National Bureau of Economic Research (eds.): The Rate and Direction of Inventive Activity: Economic and Social Factors*, Princeton, NJ 1962, Princeton University Press, pp. 609-626; P. Aghion, N. Bloom, R. Blundell, R. Griffith, P. Howitt: *Competition and Innovation: An Inverted-U Relationship*, in: *Quarterly Journal of Economics*, Vol. 120, No. 2, 2005, pp. 701-728.

7 For a critical review of this assumption, see S. Basheer: *The Invention of an Investment Incentive for Pharmaceutical Innovation*, in: *Journal of World Intellectual Property*, Vol. 15, No. 5-6, 2012, pp. 305-364.

8 See for example W.M. Landes, R.A. Posner: *The Economic Structure of Intellectual Property Law*, Cambridge, MA 2003, Harvard University Press; J. Bessen, M.J. Meurer: *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk*, Princeton, NJ 2008, Princeton University Press; A. Kapczynski, S. Chaifetz, Z. Katz, Y. Benkler: *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, in: *Berkeley Technology Law Journal*, Vol. 20, 2005, pp. 1031-1114.

9 R.A. Posner: *Why there are too many patents in America*, in: *The Atlantic*, 12 July 2012 (emphasis added).

10 See Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, Morocco, 15 April 1994.

er areas of trade. These typically involve an extension of patent terms and data exclusivity as well as limits to parallel trade and accelerated marketing approval for generic producers. They argue that strengthening intellectual property rights incentivises research on diseases that are specific to developing countries, promotes technology transfer through the localisation of R&D and production investments, and thereby contributes to improving typically inadequate health service infrastructures. For many observers in emerging economies, however, mere TRIPS-compliant patent enforcement translates into higher prices for life-saving drugs, delayed generic competition and weakened local production.<sup>11</sup> As a result, countries like India have taken the lead in employing patentability criteria that may set new standards – for emerging and possibly emerged markets alike.<sup>12</sup>

In 2005, in line with TRIPS requirements, India amended its 1970 patent law but inserted section 3(d) – a provision that prevents the patentability of salts, esters, polymorphs, metabolites, isomers, and other derivatives and combinations of previously patented compounds, as well as the patenting of new uses of known compounds. Interpreted to relate to the therapeutic efficacy of a drug, not its physical characteristic or stability, section 3(d) has since been used to deny drugs such as Sutent, Pegasys, Tarceva or Glivec the same patent protection in India that is available to them elsewhere. In the case of Glivec, Novartis's patent application had been rejected by the Chennai Patent Office, as the drug appeared to be a slightly different version of the company's 1993 patented drug to treat leukaemia. Novartis appealed to the Indian Supreme Court, holding that section 3(d) was not TRIPS-compliant and that the discretionary power of the Patent Controller to determine enhanced efficiency violated Article 14 of the Indian constitution. In 2014 the Court rejected the appeal, concluding that the amendment was intended to (a) discharge the government's constitutional obligation of providing healthcare to Indian citizens; (b) provide easy access to India's citizens for life-saving drugs; and (c) prevent "evergreening" of patents.<sup>13</sup> India's stance has since been linked to some "hidden cost of low prices: limited access to new drugs."<sup>14</sup> A review of 184 drugs concluded that in 2010 only 60 per cent of the products in the US markets were available to Indian patients; 50 per

cent of the drugs had a launch lag of more than five years and 25 per cent of more than nine years.<sup>15</sup> Nevertheless, key stakeholders across the world seem willing to follow the Indian example.<sup>16</sup> In 2013/14, the South African government proposed a National Policy on Intellectual Property Rights to eliminate the practice of multiple patenting. China followed India in employing compulsory licensing to break or threaten to break patents to the benefit of local generic producers. Patent extension regulations in the US and Europe have come under regulatory scrutiny, and activists have invoked the America Invents Act of 2011 to fight "abusive patenting" and cut healthcare costs.<sup>17</sup> The surrounding debates, however, often fail to clarify the legitimacy of private motives, the effectiveness of existing safeguards and the rationale for public interference.

### Evergreening drugs: market logic, strategies and existing regulatory safeguards

Milton Friedman's assertion that "[t]he social responsibility of business is to increase its profits" is hardly fashionable today, but that does not make it wrong.<sup>18</sup> As long as investors allocate funds to maximise returns, managers have no right to do anything but maximise profit. In addition, a firm that is able to maximise profit through differential pricing based on customers' willingness to pay maximises feasible output and welfare and eliminates losses to society at large. Enforcing and accepting any other condition leads to suboptimal performance and, in the extreme, is apt to threaten the viability of the enterprise and to require income support that is not market-based. Hence, publicly traded pharmaceutical producers must be expected to maximise the return on their R&D investments. This requires:

- Attaining dominance within the therapeutic class/reference based on a compound's superior efficacy and side-effect profile. Important therapeutic gains typically fetch substantial price multiples relative to existing drugs used for the same purposes; simple duplication merely heats up the competitive pressures "at the bottom" of the market. Hence, to maximise profit, claim profiles, trial designs, and entry and pricing decisions

11 For a review, see F.M. Scherer, J. Watal: Post-TRIPS Options for Access to Patented Medicines in Developing Countries, in: *Journal of International Economic Law*, Vol. 5, No. 4, 2002, pp. 913-939.

12 For a discussion of India's broader industrial policy to support its generic pharmaceutical sector see R. Boscheck, *op. cit.*

13 For a perspective, see R. Sushmita: EverGreening: An Abuse of the Patent System, *Academike*, 16 January 2015.

14 E.R. Berndt, I.M. Cockburn: The Hidden Cost of Low Prices: Limited Access To New Drugs In India, in: *Health Affairs*, Vol. 33, No. 9, 2014, pp. 1567-1575.

15 *Ibid.*

16 See T. Staton: China now carries a big compulsory-licensing stick, *FiercePharma*, 11 June 2012; E. Palmer: South Africa writes IP policy making it harder to get drug patents, *FiercePharma*, 11 September 2013.

17 U.S. hedge fund plans to take on big pharma over patents, *Reuters*, 7 January 2015.

18 M. Friedman: The Social Responsibility of Business is to Increase its Profit, *NYT Magazine*, 13 September 1970.

need to be adapted and sequenced to ensure superiority and the largest commercial uptake.<sup>19</sup>

- Sustaining that position of therapeutic advance through patenting active compounds, preferred formulations, manufacturing methods, protein modifications or co-specialised delivery systems, etc.
- Using life-cycle management to delay substitution through (a) continued differentiation of branding, dosing, formulation or mode of action, (b) sustained market segmentation through exclusive distribution<sup>20</sup> or blocked re-imports,<sup>21</sup> (c) pricing<sup>22</sup> and product strategies, including the use of so-called authorised generics<sup>23</sup> and OTC-switching<sup>24</sup> in expectation of entry, as well as (d) legal strategies to protect trademarks<sup>25</sup> and patents.
- Seeking to expand a compound's market through approvals for new indications based on extensive clinical trials and by not interfering with its increased off-label use.<sup>26</sup>

Critical reviews of these so-called evergreening strategies<sup>27</sup> bemoan the foregone benefits of generic substitu-

tion, but they also usually neglect the existence of regulatory and market responses that limit the risk of abusive patenting.

Of course, the benefits of generic substitution are substantial. As patents expire, the first generic competitor typically enters the market with a 20 to 30 per cent discount relative to the branded product, capturing about 44 to 80 per cent of total sales within the first full year after launch.<sup>28</sup> Subsequent entry quickly erodes prices to a cost-plus standard.<sup>29</sup> However, such public benefits must be weighed against the often private costs of drug development: the current average drug development cost per compound (pre-approval) is estimated to be around \$1.4bn, and the average new drug requires \$0.5bn sales to earn a return just above the industry cost of capital.<sup>30</sup>

Next, systemic and effective safeguards are embedded in the practice of patenting itself. Creating new drugs is an incremental process. Not all inventions take place in development; some will be forced by discoveries once the product has been put in use, and some will come in pursuit of expanded market opportunities and applications to address previously unrecognised therapeutic needs. In the process, concerns about minor variations, me-too products or superfluous, double patenting are addressed by the fact that patentability typically requires an invention to be novel, non-obvious and useful in the sense of being capable of industrial application. An invention – whether a fundamental breakthrough or an incremental step – is either novel and non-obvious or not. Patent systems are not intended to provide differential incentives based on level of inventiveness or type of research. The colouring and scoring of a drug may be considered to be purely aesthetic, but if it can be shown to improve patient compliance and thereby efficacy and is novel and not obvious, it must be patentable. Moreover, patents do not eliminate fundamental choices. Patented improvements do not limit followers from copying the original invention once its patent has expired; patients and prescribers can choose to not “upgrade” to a new formulation but rather stick to the old product. In short, patent systems, properly designed and implemented, already deal with some of the criticisms often levied against evergreening.

19 See, among others, Z.J. Lu, W.S. Comanor: Strategic pricing of new pharmaceuticals, in: *The Review of Economics and Statistics*, Vol. 80, No. 1, 1998, pp. 108-118.

20 For a discussion, see F.M. Scherer: How US Antitrust Can Go Astray: The Brand Name Prescription Drug Litigation, in: *International Journal of the Economics of Business*, Vol. 4, No. 3, 1997, pp. 239-256.

21 In 2004 Pfizer Inc., for example, unveiled a plan to deeply discount its drugs for people without health insurance, a move blunting rising political criticism, while curbing consumer demand for drugs from Canada.

22 In 2006 Merck, cutting the price of Zocor below that of the generics, claimed that lower prices benefit consumers. Producers of generics argued that these prices made it impossible to fund the development of future generic alternatives. For a discussion of an earlier case and the claim of predatory pricing, see J.P. Cairns: Predatory Pricing: Notes on Hoffmann-La Roche, in: *The Canadian Business Law Journal*, Vol. 9, No. 2, 1984, pp. 242-254.

23 For a discussion, see E.R. Berndt, R. Mortimer, A. Bhattacharya, A. Parece, E. Tuttle: Authorized Generic Drugs, Price Competition, And Consumers' Welfare, in: *Health Affairs*, Vol. 26, No. 3, 2007, pp. 790-799.

24 For a recent discussion, see L. Noah: Product Hopping 2.0: Getting the FDA to Yank Your Original License Beats Stacking Patents, in: *Marquette Intellectual Property Law Review*, Vol. 19, No. 2, 2015.

25 In 2005, Eisai of Japan took twelve generic producers to court to protect its pharmaceutical trade dress embodied by the pill colour and the PTP packaging.

26 For a discussion of the off-label conundrum, see R. Boscheck: Off-label Drugs vs. the Merits of Centralised Regulatory Control, in: *Inter-economics*, Vol. 43, No. 5, 2008, pp. 277-281.

27 See, for example, G. Dwivedi, S. Hallihosur, L. Rangan: Evergreening: A deceptive device in patent rights, in: *Technology in Society*, Vol. 32, No. 4, 2010, pp. 324-330; S. Midha: Strategies for Drug Patent Evergreening in the Pharmaceutical Industry, in: *International Journal of Pharmaceutical Sciences and Business Management*, Vol. 3, No. 3, 2015, pp. 11-24; D.H. Gleeson, H. Moir, R. Lopert: Costs to Australian taxpayers of pharmaceutical monopolies and proposals to extend them in the Trans-Pacific Partnership Agreement, in: *Medical Journal of Australia*, Vol. 202, No. 6, 2015, pp. 306-309.

28 Congressional Budget Office: How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry, Washington DC 1998.

29 Bernstein Research: US Specialty Pharmaceuticals, Paragraph IV Reaching Saturation, 2007, p. 28.

30 See R. Boscheck: Constraining Drug Supply: Product Position, Patent Protection & Regulatory Standards, in: *World Competition: Law & Economics Review*, Vol. 31, No. 4, 2008, pp. 485-494.



Furthermore, patent term extension provisions in the EU and the US are rather restrictive. US legislation, codified at 35 U.S.C. §156, offers approved drugs some period of marketing exclusivity to restore a fraction of a patent's term that had been lost while awaiting marketing approval. Similarly motivated, European Supplementary Protection Certificates (SPCs) can extend patent protection by a maximum of five and a half years. In both cases, such evergreening applies only to selective cases. US case law links term extensions to the approved active ingredient, which makes them inappropriate to deal with delays associated with regulatory endorsement of a different dosage or use of a previously approved product.<sup>31</sup> Also, while patents may be obtained for combination ingredients, patent extensions require that none of them had been previously marketed; patents for metabolites are not eligible for any term extensions. Similarly, rulings by the Court of Justice of the European Union limit the one-time use of SPCs to active ingredients with independent therapeutic effects and existing patent protection in force. In both systems, patent owners are cautioned to steer clear of overstating any patent claims and needs for extension in order to avoid any opposite, overly restrictive regulatory outcomes.

Finally, both the US and EU systems allow legal challenges to patents to potentially speed up generic substitution. In Europe, generic companies have nine months to revoke a patent through a post-grant opposition process that is centrally administered by the European Patent Office. In the US, the Hatch-Waxman Act offers producers of bioequivalent generics that certify not to be infringing any valid patent surrounding the original compound an Abbreviated New Drug Application (ANDA).<sup>32</sup> If the patent holder brings an infringement suit within 45 days, the FDA's ANDA approval is automatically delayed, as is the generic's chance to reach the market, by 30 months. In the absence of a suit, the ANDA may be immediately approved. The US situation is not only more complicated than that of the EU, but some of the US intricacies are often distorted to drive an attack against "Big Pharma's" alleged evergreening tactics.

To clarify, the first successful ANDA is granted a 180-day period of exclusivity, calculated from the day of the first commercial marketing of the generic drug, during which

no second ANDA filer may enter the market. A second filer will only be able to overcome the generic bottleneck if a court decides that the patent supporting the 180-day exclusivity period is invalid or not infringed. This, however, requires that the brand-name company sues the subsequent ANDA filer and thereby allows it to obtain a favourable court decision. If the branded product manufacturer does not do this, generic entry may be forestalled.

For patent owners facing a patent challenge, entry is uncertain, but the impact of a challenge, as outlined above, is roughly known. Hence, patent owners will assess the chances of successfully sustaining the patent, the timing of entry in case of failure, and the effect on sales, efficiencies and opportunity costs for different potential market scenarios. In case of a successful challenge, the monopoly may quickly turn into a duopoly, unless the parties decide to settle. Settlement would clearly be very valuable for the incumbent, especially if both the incumbent and the first filer have a weak patent case relative to the second one. But what is at least as important here is that if entry occurs before litigation would be terminated or the patent expires – whichever comes first – a settlement could improve consumer welfare. So the question is whether settlements involving compensation from the patent holder (incumbent) to the ANDA filer (potential competitor) should be legal or not.<sup>33</sup>

Three arguments support a rule of reason approach for dealing with these so-called reserve payments. The first argument holds that due to the complexity and uncertainty of patent litigation, settlements will typically involve entry prior to the expiration of the patent term; hence, blocking reverse payments per se means blocking settlement. Another argument maintains that proper patents are inherently anticompetitive and entail the right to exclude others from utilising the patented invention. Finally, because of the asymmetry of stakes and information involved, the Hatch-Waxman Act disadvantages the brand holder who should be able to redress the inequity by offering compensation in return for delayed entry.

Proponents of regulating or even banning reverse payments present the following argument. Given the *ex ante* risk that patents cover prior knowledge, patents need to be challenged, are therefore probabilistic, and their validity and associated right are uncertain prior to litigation. Consequently, a ban on reverse payments, first, does not interfere with the patent owner's right to exclude, and second, would potentially bar settlement and thus force the patent holder to establish a patent's validity. Seen this

31 For a discussion, see J.R. Thomas: Non-patent protection of pharmaceuticals in the USA, in: *Pharmaceuticals Policy and Law*, Vol. 16, No. 1-2, 2014, pp. 89-123; and I. Kirby, C. Stothers, P. Abbott: Extended Protection for Pharmaceutical Patents in Europe: Where Are We Now?, in: *Intellectual Property & Technology Law Journal*, Vol. 26, No. 5, 2014, pp. 17-23.

32 The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1984, codified as amended 21 U.S.C. §355 (1994).

33 For a detailed discussion on the various elements of either position, see R. Boscheck: *Constraining Drug Supply ...*, op. cit.

way, reverse payments not only buy more protection from competition than congressionally granted intellectual property rights afford, they magnify the *ex ante* risk inherent in them.

For more than 15 years, pay-for-delay deals have extended the life of contested pharmaceutical patents, and given the indeterminate impact on consumer welfare, the US Supreme Court has been unwilling to take a definitive position either way. Most recently, on 17 June 2013, the Court decision in *FTC v. Actavis, Inc.* left it to lower courts to find on the legality of reverse payments using a rule-of-reason test to balance conceivable benefits and costs.<sup>34</sup> Just as in other areas of dispute between intellectual property rights and antitrust law – such as judging technology standards, licensing restrictions or the aggregation of patent portfolios and their use<sup>35</sup> – settlement deals present a substantial conceptual challenge to be translated into efficient regulatory standards. Such difficulty does not justify a call for additional actions against the evergreening of pharma patents or the use of any regulatory short-cuts – other policy agendas, however, might.

### Healthcare costs, industrial policy and global intellectual property rights

Escalating healthcare expenditures and the need to ensure access to affordable medicine in both emerging and emerged economies are fuelling calls for containing the so-called evergreening practices of drug producers around the world. But such practices are the necessary outcome of a system that responds to market incentives and appears to be already sufficiently controlled by established patentability standards and policies that determine patent term extension. The key issues surrounding current trade disputes lie deeper.

Adam Smith would have called healthcare a *necessary*, “that is not only a commodity which is indispensably necessary for the support of life but whatever the custom of the country renders it indecent for credible people, even of the lowest order, to be without.”<sup>36</sup> Access and externality concerns typically justify national governments to get involved in financing, providing and regulating healthcare. And healthcare access, by now, is often considered to be a human right. But there is little regulatory guidance for

markets to deliver on this promise.<sup>37</sup> In fact, in no other sector have conflicts between the rationales for market and non-market coordination led to more public or corporate posturing and less effective governance.

Of course, developing countries around the world are said to be “recognizing that a sustainable healthcare system promotes long-term economic stability and (...) that healthy people generate wealth while the sick generally draw on it.”<sup>38</sup> And yet, the bulk of individual healthcare bills in these countries continue to be settled through out-of-pocket payments. Access to vital medicine may be deemed important, but in many cases it is clearly not important enough to top the national priority list. Of course, the developed world is outraged by recurring news about far-away health crises, but particularly at times of domestic fiscal austerity, there is strong political support for healthcare cost containment that, through its relentless focus on drug expenditures, reduces any chance for cross-subsidising healthcare efforts elsewhere.

Of course, challenging patents provides India and a growing number of emerging markets with a means to sustain a generics business model in a TRIPS-compliant fashion. However, for any of these economies to advance from here, they must focus their research efforts on product technology and, for their own benefit, insist on the nation-blind enforcement of intellectual property rights.

Of course, the TRIPS Agreement has granted some flexibility to emerging markets to manage necessary adjustments in the area of intellectual property rights and to deal with cases of monopolistic abuse or national emergency. But the TRIPS Agreement, as part of the WTO system, is constitutional for much of global trade and must serve as a reliable guide for the commercial and investment decisions of profit-maximising firms. The TRIPS Agreement is not a vehicle for promoting national policy objectives, whether these take the form of supporting particular industrial structures or delivering on a country's universal healthcare promise.

<sup>34</sup> *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

<sup>35</sup> See H.J. Hovenkamp: Intellectual Property and Competition, in: P. Menell, B. Depoorter, D. Schwartz (eds.): *Research Handbook on the Economics of Intellectual Property*, forthcoming, Edward Elgar.

<sup>36</sup> A. Smith: *The Wealth of Nations*, 1776, New York 1937, Modern Library, p. 821.

<sup>37</sup> However, today many international observers of healthcare policy are concerned about establishing a new set of principles for effective healthcare governance. In particular there is a growing recognition of the need (1) to define basic healthcare requirements in view of particular circumstances such as social context, access to water, sanitation and food; (2) to rely on a hierarchy of interventions and the assumption of national responsibility wherever possible; and (3) to clearly coordinate policy roles and distinguish regulatory structures. For a review of the literature and positions across diverse policies, see E. Hesselmann, C. Ulbert: *Globale Gesundheitspolitik im Wandel*, in: INEF: *Globale Trends*, DTV, 2010, pp. 223-248.

<sup>38</sup> BMI: *Emerging Markets Healthcare*, 2012.