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GENERIC PHARMACEUTICALS

-- Note by BIAC --

18-19 June 2014

This note is submitted by BIAC to the Competition Committee FOR DISCUSSION under Item VI of the agenda at its forthcoming meeting to be held on 18-19 June 2014.

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1. Introduction/executive summary

1. BIAC welcomes this opportunity to provide its views on the functioning of competition in the pharmaceuticals sector, and as it relates to generic pharmaceuticals in particular. Since the OECD's last roundtable discussion on this topic in 2009, the regulatory landscape has continued to evolve and the commercial reality is now that generic companies can and regularly do enter the market promptly after the originator loses its exclusivity.

2. The generic industry plays an important role: increased price competition upon loss of patent exclusivity enables sustainable long-term treatment of patients with fewer resources, and creates financial headroom for the funding of speedier patient access to innovative medicines.[1] Accordingly, BIAC is in favour of swift generic market entry upon loss of patent exclusivity.

3. At the same time, BIAC recognizes the critical importance of promoting innovation in the development of pharmaceuticals, and the need to incentivize the extraordinary risk and investment levels inherent in pharmaceutical R&D by providing successful originators with an exclusive patent period within which to market their products. A balance must therefore be struck between these two objectives that cannot favor exclusively short-term pricing benefits over long-term innovation incentives. Likewise, enforcers should recognize that cost saving measures to secure affordable access to medicines for all citizens of all OECD countries must be appropriately balanced. It is only by taking a holistic view of the need for coherent public policies that recognize the importance of R&D incentives, strong and effective intellectual property rights, and swift patient access to life-saving drugs, that the pharmaceutical sector will thrive and be in a position to continue to contribute effectively to the health and wealth of citizens of all OECD countries and beyond.

4. Achieving long-term sustainable healthcare systems that ensure universal patient access to affordable and safe medicines whilst delivering value for money is a key policy objective for all countries. An efficient off-patent market which ensures that cost savings are adequately passed on will balance patients' and payors' interest in benefiting from faster market access and reduced prices while maintaining sufficient innovation incentives[2].

5. In this debate, it is important to bear in mind that the pharmaceutical industry is one of the leading global high technology industries, and spends more on research and development (R&D) than any other industry. It is a strategically important sector in terms of public health, economic growth, and employment. The industry in Europe directly employs about 700,000 people, of which 117,000 work in R&D. Globally the industry directly employs more than 1.8 million people. Strong intellectual property protection of validly patented inventions is the cornerstone of pharmaceutical innovation, given the unique risks and scale of costs entailed in pharmaceutical R&D. Patent incentives also drive the race to be the first to develop products to exploit a scientific discovery, knowing that their rivals may be pursuing parallel research. Investment in innovation and R&D can and will deliver "reduct[ions in] healthcare costs and improve[ments] the quality of care " in the long-term. Competition law enforcement therefore should not

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1 As noted at Page 19 of the Background Note by the Secretariat in the OECD Report on the 2009 Policy Roundtables on Generic Pharmaceuticals (the "2009 Report"): "In Brazil, there is evidence that generic entry saved approximately USD 5 billion for the healthcare system between 2001 and 2007. In Canada, the prescription of generic drugs saved approximately CAD 3 billion in 2008, with estimated further savings of up to CAD 800 million per year if further generic competition could be encouraged."

2 As discussed in BIAC's paper "Competition issues in the distribution of pharmaceuticals" presented at the OECD Global Forum on February 28, 2014.

call into question the patent system, and competition law regulators should refrain from making value judgments concerning the merits or strengths of individual patents or categories of patents.

6. The degree of competition reflected by generic entry can be very significant, but will depend on the existing level of competition within the relevant market for the pharmaceutical treatment in question. While a pharmaceutical patent accords the right to exclude others from exploiting the patented invention, there may well be competition among different patented (or non-patented) molecules or pharmaceutical products. In these cases, the existing patented formulation may not have market power and the impact of generic entry may be less competitively significant than in the case of a patented pharmaceutical that holds a dominant or monopolistic position. This is consistent with the general principle that a patent does not necessarily confer market power.[3]

7. BIAC welcomes the OECD's sustained engagement in this complex debate and is pleased to comment on the pharmaceutical companies' practices which have come under competition scrutiny, as described in the invitation for this submission

2. Unilateral Practices

8. Originators use a variety of common and lawful commercial practices in order to protect and encourage innovative improvements and developments during a product's lifecycle. These commercial practices normally are pro-competitive, and serve to encourage investment in R&D and innovation, and to facilitate the development of superior therapeutic products and faster patient access. Generally, competition law should only intervene in cases where a company has a dominant position and is abusing it by engaging in practices that go beyond lawful competition on the merits, without objective justification.

2.1 Duration of Patent Protection - "Evergreening"

9. The duration of patent protection may be impacted by acts of the originator that occur after the initial patent is granted. Such steps can include, for example, taking out new patents (for example, in respect of new formulations or delivery systems), or by gaining approval for new dosage strengths of the previously patented product (sometimes called "switching").

10. Originators are well positioned to invest in improvements to the original product, having conducted the underlying research. After product launch, feedback from the clinical practice (from doctors, pharmacists, patient associations and opinion leaders) can also highlight the need for further inventive development work. A continuum of inventive development may be observed during a product's lifecycle. New uses of an existing substance, new formulations or other modifications to an established product can have significant consequences for patient care, providing superior therapy for a number of patients[4]. Only those improvements that meet the patentability requirements will qualify to be patented and enjoy a period of exclusivity. Incremental innovation also encourages stronger competition between products in a specific therapeutic class as innovators anticipate improved products reaching the market faster and faster. It stimulates further pharmaceutical research by competitors.

11. At the same time, certain of these practices can create concerns that the originator is using unfair competitive means to exclude generic entry by improperly "evergreening" their patent protection and extending the duration of their exclusivity. Evergreening has been described by the Supreme Court of

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3 See Illinois Tool Works Inc. v. Independent Ink, Inc., 547 U.S. 28 (2006)

4 Examples show the benefits in terms of the new disease indications addressed, better safety profiles, greater efficacy for patients and more convenient delivery for patients (for example where the number of tablets per day is reduced through a slow release mechanism).

Canada as a commercial strategy employed by innovative drug companies to add "bells and whistles" to a pioneered product after the original patent for that product has expired.[5]

12. Accordingly, while further inventive development work may be undertaken during a product's lifecycle, and while new uses of an existing substance, new formulations or other material modifications to an established product can significantly improve patient care, by providing superior therapy for a number of patients, concern must be had that evergreening is not utilized as a technique to improperly extend patent protection[6] for the purpose of stifling competition by generic manufacturers and maintaining a dominant position.

13. Competition law regulators should monitor for any behavior properly characterized as evergreening, while contemporaneously ensuring that any steps taken do not disturb and/or undermine the incentives for such innovation.

2.2 Product Switching

14. Product switching is a rational economic behaviour for originators who need to ensure a steady finance stream for re-investment in R&D efforts to develop and maintain an effective pipeline of new products. While there is nothing inherently suspicious about originators pursuing commercial strategies to promote new products and persuade prescribers of their superior therapeutic benefits, concern must be had that such strategies do not result in the unlawful preservation of a dominant position through exclusionary means and competition law is an appropriate mechanism to ensure that generic manufacturers are not improperly excluded.

15. Lifecycle management strategies are generally lawful. Companies with market power remain free to formulate commercial strategies to prevent market share erosion by generics as long as they compete on the merits.[7]

16. Absent factors such as fraud, misrepresentation or misuse of the regulatory process, legitimate lifecycle management strategies designed to successfully manage a product's transition from patent protection to loss of exclusivity and to lawfully inform prescribers of the proven therapeutic benefits of an alternative medicine should not, prima facie, be considered as an infringement of competition law.

2.3 Patent Clustering

17. Patent clustering describes the practice of having patent portfolios protecting different aspects of an innovation. The basic legal principle is that no later patent can extend an earlier patent's term or protection. The patent on the basic molecule is central to the medicinal product and tends to be the first to expire, after which generics are free, in principle, to manufacture less expensive versions of the medication for the public.

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5 AstraZeneca Canada Inc. v. Minister of Health (Canada), [2006] 2 SCR 560 at para. 39

6 Through fraud or misrepresentation or other misuse of the regulatory process.

7 Case C-457/10 P, AstraZeneca v Commission, dated 6 December 2012 (not yet published), para. 129 ("[T]he preparation by an undertaking, even in a dominant position, of a strategy whose object it is to minimise the erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process, provided that the conduct envisaged does not depart from practices coming within the scope of competition on the merits, which is such as to benefit consumers.")

18. Subsequent or additional patent applications must be for different inventions and generally have narrower claims covering further developments of the medicinal product. Patents should only be granted if the claimed invention is novel, has an inventive step and otherwise meets the applicable criteria for patentability. If an invention does not satisfy these criteria, a patent should not be granted.

19. Competition regulators should not substitute their views for those of the patent system regarding what constitutes a patentable invention. Such a role would usurp the functions of patent office and the intellectual property courts. While competition law clearly applies to transactions (i.e., acquisitions, conspiracies, anti-competitive agreements, etc. relating to patents) and competition policy is relevant to and needs to be factored into the development of the patent system, competition law authorities should avoid using competition law enforcement to modify or undermine the test for patentability.

20. The EU Courts and decisional practice of the EU Commission has recognised that obtaining patent rights and the creation of portfolios of patentable inventions does not infringe EU competition law.[8] Competition law should not now be used to constrain lawful patent portfolios. Such an approach could be damaging to innovation because (i) it would invite free-riding on the original, published invention and deter innovation across all industry sectors; and (ii) frustrate an important source of incremental innovation, denying patients access to beneficial improvements. This could have a chilling effect on R&D investment and undermine the application of the patent regime. However, where it was demonstrated that patent clustering was being carried out without lawful means, i.e., where a prolonged monopoly had been obtained by virtue of un-patentable products, competition law may be an appropriate mechanism by which appropriate sanctions could be applied to manufacturer found to have engaged in such practice.

2.4 Essential Patents

21. The concept of a "standard essential patent" is not one that would appear to be applicable in the pharmaceuticals sector. An invention that satisfies the applicable patentability criteria is eligible for patent protection. There is no hierarchy of patents: no patent is intrinsically more valuable or worthy of protection than others. Whilst the basic molecule patent is undeniably central to the medicinal product, further inventions with respect to that product may also qualify for patent protection.

22. In certain circumstances, EU competition law has recognized a "refusal to supply" doctrine in the context of access to essential facilities. To the extent that these cases involve intellectual property, EU precedents are at odds with some other jurisdictions. Under these EU cases, a refusal to supply IP rights has been held *exceptionally* to constitute an abuse of dominance in limited circumstances where: (i) access to the product/IP right is indispensable for market access; (ii) the refusal eliminates competition and causes consumer harm; (iii) the complainant seeks not to make the same drug, but a product with (a) improved features over the dominant company's drug; or (b) in a different market to the dominant company's drug; and (iv) there is no objective justification for refusal.[9] Mandatory licenses of intellectual property rights

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8 Commission Decision of 24 July 1991 relating to a proceeding pursuant to Article 86 of the EEC Treaty (IV/31043 - *Tetra Pak II*), OJ 1992 L 72, p.1; Case T-83/91 *Tetra Pak International SA v Commission* [1994] ECR II-755, para. 242; Case C-333/94 P *Tetra Pak International SA v Commission* [1996] ECR *I-5951.*

9 Case T-201/04 *Microsoft Corp. v Commission* (17 September 2007) (refusal to license interface information between the Windows operating system and server software.)

are also provided for under certain circumstances under the Canadian Competition Act and the competition or antitrust laws in other jurisdictions.[10]

23. The patent regime in some OECD countries also provides for the possibility to order a compulsory license of a patent in certain circumstances (for example, where the patent is "unworked" and there are high levels of domestic demand, or to address public health problems afflicting many developing and least-developed countries.)[11] Such compulsory licenses are subject to the criteria provided for in Article 30 of the TRIPS agreement.[12]

24. BIAC is of the view that the "refusal to supply" doctrine or "standard essential patent" concept should not be used to force originators holding valid intellectual property rights to license their pharmaceutical patents to facilitate early generic entry. Indeed, mandatory licensing in the area of pharmaceuticals creates a significant risk of upsetting the balance between rewarding innovation and promoting speedy entry of generics and risks deterring innovation of new products.

2.5 Fraudulent Patent Use

(i) Patent applications are reviewed for patentability by the applicable patent office and patents should only be issued if the patent office is satisfied that the patentability criteria have been met.

(ii) The provision of deliberately misleading information to a patent office to obtain a patent is reprehensible and deserving of censure. Mistakes, honestly made by applicants in their dealings with patent offices should be dealt with through the patent system and should not give rise to competition law proceedings. Conversely, where it is established that there have been deliberate attempts to mislead the patent office by a dominant manufacturer, competition law can be used to censure abusive behaviour.

2.6 Sham Patent Litigation

25. The right of access to the courts underpins patent protection. The patent right is an intangible one and of no value if the holder cannot seek to enforce it in court. "[W]ithout effective means of enforcing intellectual property rights, innovation and creativity are discouraged and investment diminished …the means of enforcing intellectual property rights are of paramount importance."[13] Patent litigation tends to be fact-intensive and legally complex, and consequently very expensive to the parties.

26. Access to the courts is a fundamental right[14] and any limitation must be interpreted and applied very restrictively. In *ITT Promedia*, the EU Courts confirmed that a claim in litigation is lawful unless undertaken by a dominant company where (i) it "cannot reasonably be considered to be an attempt to assert

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10 See Section 32 of the Competition Act (Canada) and Robert Pitofsky, The Essential Facilities Doctrine Under United States Antitrust Law (2002) http://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?article=1342&context=facpub.

11 See UK, s48 Patents Act 1977 (compulsory licensing for abuse of monopoly where a patent is unworked, fails to satisfy demand or holds up related innovations.) and Sections 21.01 – 21.19 Patent Act, R.S.C., 1985, c. P-4 (Canada).

12 Trade Related aspects of Intellectual Property Rights ("TRIPS") applies to member states who are part of the World Trade Organisation framework.

13 Recital 3, Directive 2004/48/EC on the enforcement of intellectual property rights [2004] OJ L195/16

14 Article 6, the Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocol No.11 of 4 November 1950 [also EU Charter on Fundamental rights.]

the right of the undertaking concerned and can therefore only serve to harass the opposing party" and (ii) is part of a plan to eliminate the competitor.[15] U.S. courts have also set a test for consideration of sham litigation antitrust claims, which test provides an appropriate remedy where justified by the evidence.[16]

2.7 Authorised Generics

27. An authorized generic is a pharmaceutical product that was originally marketed and sold by a brand company, but is relabeled and marketed under a generic product name. The authorised generic is sold at a lower cost, and as an alternative, to the branded product. Authorised generics compete on a pricing, quality and availability basis with approved generic products.

28. A brand company may choose to launch an authorized generic for a variety of reasons, including to maintain manufacturing capacity for the drug substance or the drug product and to maintain cash flow, albeit at a lowered rate, once generic competition starts.

29. Authorised generics may have either pro-competitive or anti-competitive impacts on the market. On the one hand they can increase competition in the market resulting in lower prices and increased consumer choice. For example, a 2011 US Federal Trade Commission report found that the introduction of authorised generics helped reduce prices (retail drug prices by approximately 4.2% and wholesale drug prices by approximately 6.5 % as compared to pre-generic price) and ensured greater consumer choice (especially during the 180 day exclusivity period for first generics provided by the Hatch-Waxman Act.)[17]

30. An efficient off-patent/generics market will generate substantial savings for patients, ensure continued and uninterrupted supply of vital products and incentivise the reinvestment of costs savings in further R&D and innovation. Antitrust law should only be applied where required to prevent anti-competitive conduct that is likely to harm competition, not just competitors, in the market for the relevant drugs.

2.8 Misleading Representations

31. Pharmaceutical companies, like others, should take care to comply with the laws of general application against making misleading representations while at the same time ensuring that regulators receive all relevant and timely information on the manufacture, sale and promotion of medicines in their territories.

32. Adequate and timely recourse to regulators by originators is essential and in the public interest in any highly regulated industry. Indeed, it can be a regulatory duty to raise concerns. Regulators and the medical community expect that the originator remains vigilant and responsible for the molecules it originates, even when the medicine is sold by generics.

33. While all providers, both brand name and generic, have similar interests in stamping out counterfeit and/or low quality products, and should bring forward *bona fide* concerns to the regulators or others as required by law or otherwise appropriate, all such representations must comply with all applicable laws.

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15 Case T-111/96 *ITT Promedia NV v Commission* [1998] ECR II-2937 para. 55

16 For example see: *Surface Supplied, Inc. v. Kirby Morgan Dive Systems, Inc*., 2013 U.S. Dist. LEXIS 143478 (N.D. Cal. Oct. 3, 2013) (Chesney, J.).

17 Authorized Generic Drugs: Short-Term Effects and Long-Term Impact: A Report of the US Federal Trade Commission, published August 2011 (available online here).

2.9 Distribution and Loyalty Schemes

34. As is the case with misleading representations, all companies must be free to rationally manage their production and supply chain in an efficient manner and in accordance with applicable laws of general application (including antitrust laws applicable to distribution and loyalty schemes, abuse of dominance laws, etc.).

35. Companies are best placed to make the necessary operational decisions about the most efficient organisation of their supply an distribution system in a manner whihc allows them to satisfy their public service and other regulatory obligations (within the limits of the law prohibiting abuse of dominance, where applicable). Competition law should not be applied in a manner which would make it more costly and administratively difficult to organise the supply chain. This could jeopardise security of supply and undermine efforts to ensure patients receive medicines on time.

36. Loyalty inducing schemes in the pharmaceutical industry, as in other industries, should be reviewed according to the sound economics-based approach laid down in most advanced OECD country competition laws that set out a framework for analysis to ensure sufficient protection against exclusionary or predatory conduct.

3. Patent settlement agreements

37. Settlement agreements are generally efficiency enhancing and legitimate when there are *bona fide* grounds for dispute. They allow companies to avoid the significant costs of protracted patent litigation and to focus resources on R&D investment and bringing new products to market. Given highly fragmented patent system, in Europe and other OECD countries, and the economic interests at stake, competition authorities should be circumspect in assessing the lawfulness of patent settlements at the risk of promoting complex, lengthy litigation.

3.1 Patent litigation is fact intensive, complex and often highly unpredictable

38. The competition laws should not encourage patent litigation at all costs as a means of fostering short-term static competition. The fragmented nature of the patent system around the world means that patent disputes are often litigated in multiple jurisdictions with a real risk of divergent outcomes in different national courts.[18] The reality today is that patent litigation is hugely costly and the outcome often inherently uncertain. Patent settlements reflect the parties' respective evaluations of merits based on imperfect information and perceived probabilities in terms of the likely availability of interim relief, the risk of divergent outcomes, the associated costs, and other factors.

3.2 All patents should be viewed as presumptively lawful

39. As a practical matter, for the purposes of competition law enforcement, a presumption of patent validity must be the starting point in any analysis of whether a settlement in patent litigation is capable of being anti-competitive.[19]

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18 One recent dispute has thus far resulted in Dutch, Spanish and US courts holding a disputed patent valid, and three others reaching a different outcome.

19 The European General Court recognised in its *AstraZeneca* ruling (at recital 362): "…When granted by a public authority, an intellectual property right is normally assumed to be valid and an undertaking's ownership of that right is assumed to be lawful. The mere possession by an undertaking of an exclusive right normally results in keeping competitors away, since public regulations require them to respect that exclusive right…".

40. Competition authorities should not use circumstantial evidence to judge whether some patents are "weak" or invalid. Nor should they generalise about patent quality from a small sample of litigated patents. Only the most contentious cases litigate and the outcome of any given case is likely to be a matter of considerable factual and legal uncertainty.

41. The nature of the patents at issue - a process patent rather than the substance patent protecting the molecule - should not be a decisive criterion in determining whether a settlement agreement infringes competition law. Public statements that process patents "provide a more limited protection" and "once the patent over the molecule has lapsed, price competition between the pharmaceutical companies and generics can occur" are incorrect as a matter of patent law.[20] Process patents are a legitimate and important part of the patent system and the innovation incentives that system is carefully calibrated to protect.

42. A competition law regulator should not substitute its own judgment on the perceived "strength" or "value" of a patent for that of the patent authority. Competition law enforcement that undermines the patent system will affect confidence and investment in innovation and will ultimately undermine efficient long-term dynamic competition.

3.3 Value Transfers are not presumptively illegal but rather reflect carefully calibrated risk assessment based on irreparable harm that can be caused by unlawful generic entry

43. Since settlements represent compromise over hard fought litigation with high stakes for both sides, they will normally involve some flow of benefits from one party to the other. The fact that a settlement agreement includes a value transfer from the originator to the generic does not automatically mean that the agreement is anti-competitive:

(iii) Patent settlement agreements in the pharmaceutical sector are a symptom of the uncertainty of litigation. Effective injunctive relief may or may not be available. Settlement avoids the cost associated with multiple and complex patent litigation suits in one or more member states and also reflects the opportunity cost involved with using those financial and employee resources for other commercial projects;

(iv) Settlement agreements reflect the inherent asymmetry of risk between the originator and generic company which influences the settlement negotiations. Launching at risk in one country even for a short period of time can have significant commercial consequences for the originator's business. Originator pharmaceutical companies stand to lose much in terms of revenue if injunctive relief is not available since generic launch at risk will often have an irreversible effect on the reimbursement price that is available for the product in question. It can also affect the price in other countries even where the patent validity has been upheld due to reference pricing system employed by many national authorities when setting pricing terms in each member state. This commercial damage may not be adequately compensated by damages after the event and so this necessarily influences the risk assessment. Quantifying those international losses is difficult, as is seeking their inclusion in a national judge's assessment of damages.

44. These factors cannot be neglected when assessing the merits of a settlement agreement. It is too simplistic to equate a value transfer with the originator's subjective assessment of the perceived chances of success at final litigation.

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[20] Press Release, Eur. Comm'n, Antitrust: Commission Fines Lundbeck and Other Pharma Cos. for Delaying Market Entry of Generic Medicines (June 19, 2013) ("Lundbeck Press Release").

3.4 Patent settlement agreements are legitimate where there are bona fide grounds for dispute and their terms do not manifestly exceed the scope of the disputed patent

45. Competition authorities have a role to play in policing settlement agreements where it can be established that there is clear evidence that the patent litigation between parties is a sham, or where restrictions in the settlement manifestly exceed the scope of the patent.

46. Where there is doubt about whether a settlement that involves a significant value transfer has exceeded the legitimate scope of the relevant patent(s), a careful fact-specific analysis is required. A blanket presumption of unlawfulness is inappropriate. The burden should be on the party or agency challenging the settlement to illustrate that there has been an appreciable and unjustified harmful effect on competition in such circumstances.