Discussion Points

Presented by the Business and Industry Advisory Committee (BIAC) to the OECD Competition Committee

Roundtable on Generic Pharmaceuticals

October 22, 2009

I. Introduction

1. The research-based pharmaceutical industry is one of the leading global high technology industries spending more on research and development (R&D) than any other industry.¹ It is a strategically important sector in terms of public health, economic growth, and employment. The industry in Europe directly employs about 635,000 people, of which 117,000 work in R&D. Direct employment in the US is over 686,000 with an estimated 3.2 million jobs indirectly tied to the sector.

2. The generic industry also plays an important role: increased competition on prices when products lose exclusivity enables sustainable treatment of more patients with less resources, and creates financial headroom for the funding of speedier patient access to innovative medicines. BIAC supports swift generic entry on originators’ loss of exclusivity and policies that facilitate generic uptake and effective competition among generic producers.

3. BIAC welcomes the broad scope of the Roundtable agenda and the opportunity to provide its views on the functioning of competition in the pharmaceuticals sector, and as it relates to generic pharmaceuticals in particular. It is only through 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 in Europe and beyond.

¹ European Commission 2007 EU Industrial R&D Investment Scoreboard, October 2007, p. 12. The scoreboard considers the world’s top 1,400 companies with R&D spend over a minimum threshold comprising the top 400 EU and 1,000 non-EU companies. In Europe, the industry spends about 18% of sales on R&D. A 2006 Congressional Budget Office report similarly found that the US biopharmaceutical industry leads the nation in terms of R&D spend (Congressional Budget Office Research and Development in the Pharmaceutical Industry (Washington, D.C. CBO, October 2006)). In 2008, 20.3% of sales by biopharmaceutical companies was invested in domestic R&D (Pharmaceutical Research and Manufacturers of America, Pharmaceutical Industry Profile 2009 (Washington, DC: PhRMA, April 2009)).
4. This paper focuses on the following key issues:

- the importance of intellectual property rights for dynamic competition in the pharmaceutical sector;
- the highly regulated nature of pharmaceutical markets and the impact on competition;
- the functioning of off-patent markets and the factors that influence generic market entry; and
- the rationale for settlement agreements in disputes between originator and generic pharmaceutical companies.

II. The Importance of Intellectual Property Rights for Dynamic Competition in the Pharmaceutical Sector

5. The costs of developing and launching a new pharmaceutical product are extraordinarily high and are estimated to have increased almost ten-fold between 1975 (USD 138m) and 2006 (USD 1.318bn).² It is widely recognised that strong intellectual property protection is the cornerstone of pharmaceutical innovation.³ Without sufficient patent protection, innovators will not create the new drugs which generics, in due time, will copy. Patent protection also creates the incentives that drive the race by innovators to be the first to develop products to exploit a scientific discovery, knowing that their rivals may be pursuing parallel research.⁴

6. Patent portfolios are established over time and reflect new compounds studied and the technical hurdles overcome in the course of the 10 to 15 year drug development process. A variety of patentable new formulations, combinations, forms or uses may be developed during this time. These later patents reflect the continuous innovative process and are common in any high technology industry. It is axiomatic that there can be no double patenting of the same invention: once the protection of the originally marketed product expires, the system facilitates generics’ copying of the medicine.

7. R&D funding – in a sector where development costs are extraordinary and only two out of 10 new molecular entities reaching the market are commercially successful – requires the ability

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³ Competition, Patents and Innovation, OECD 2 January 2008, page 209 (“[F]or certain sectors like the pharmaceutical sector, patents are recognised as being very important for the appropriation of the revenues from innovation”). The European Commission’s sector inquiry final report of 8 July 2009 notes that the window of exclusivity increased by 3.5 years from an average of 10.5 years in 2000 to 14 years in 2007. Even if this period of exclusivity is maintained, which is open to doubt, it is still shorter than the period intended by the legislature of 15 years of effective protection.

to obtain, enforce and defend a patent. Under prevailing regulatory systems, patents are properly granted only after expert scrutiny and the patent system provides ample legal remedies to seek to oppose, revoke or obtain declaratory judgment in respect of a patent. Patent rights are intangible and are of no value if the right holder cannot enforce them by seeking effective protection in the courts: the Commission’s sector inquiry report recognises that patent enforcement through the courts is a fundamental right guaranteed by the European Convention of Human Rights.

8. The sector inquiry report also acknowledges the fundamental importance of patent protection to encourage high-risk R&D investment and the importance of dynamic efficiencies – the gains that result from technological change and new breakthrough products; in other words, the competition for innovation. Against this background, BIAC welcomes the Commission’s statement that it will abide by existing case law according to which the exercise of intellectual property rights can only be a competition law infringement in exceptional circumstances.

III. The Highly Regulated Nature of Pharmaceutical Markets and the Impact on Competition

9. In Europe and in many other countries, competition in pharmaceutical markets must be assessed against the backdrop of state controls operating on both the supply side (to control prices or volumes) and demand side (to control demand from physicians’ prescribing budgets or patients’ co-payment incentives). The fragmented and complex nature of these price, supply and expenditure controls have long been a cause for concern in relation to innovation and competition. They tend to under-reward innovators whilst failing to reap the benefits of an efficient generics market: year on year price cuts, price freezes and paybacks signal that healthcare buyers are not prepared to fund new medicines or to create a climate for such investment. A World Health Organisation report has observed that this “unpredictable lottery” of price controls in Europe “has a direct effect on which medicines are produced by innovator companies.”

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6 Sector inquiry Communication, section 3.2.2 on patent-related exchanges and litigation.

7 Sector inquiry Communication, p. 2 on the key role of innovation.

8 Final report of 8 July 2009, paragraph 1568.

9 Simply the process of pricing and reimbursement decision-making can delay market entry for both originator and generic products for as long as 18 months in some countries, to be contrasted with those countries where no formal bar to accessing the market exists (e.g., the US, Germany and the UK).


11 Priority Medicines for Europe and the World, World Health Organisation, November 2004, p. 104. The distorting effects of state controls are also amplified where price controls that undervalue the innovative medicine have extraterritorial effect: (i) by means of wholesaler arbitrage in potentially all higher priced countries where the vast majority of the price differences are kept by intermediaries; and/or (ii) in potentially any state, whether in the EU or elsewhere, which uses international price referencing.
10. In particular, the grouping of new innovative products together with less effective rivals, including unpatented or generic products within a therapeutic reference class for reimbursement purposes, signals to innovators that the advantages of the patented drug (suitability for patient groups resistant to other drugs, better safety or efficacy profile or reduced side effects) are not valued. Therapeutic reference pricing, coupled with the use of cost effectiveness assessments as a tool for rationing, pricing and reimbursement, are perhaps the biggest threat to new investments in novel treatments.

11. The competitive impact of these state controls is felt not only by innovators, but also, at a later stage, by generics. If price controls are set at a level that undervalues the patented drug, there will be insufficient margin to encourage generics companies to enter the market. In the long run, the efficiencies of a competitive off-patent market are replaced by less efficient state regulation of prices. Moreover, the use of reference pricing tends to set a floor rather than a ceiling since generic entrants tend to price at the top of the state reference price suggesting that the normal interplay of market forces would be more likely to result in significant price reductions and more effective cost containment.

12. Striking the right balance between the desire for cost containment and the need to ensure incentives for continued innovation is not easy but must be achieved if innovation is to thrive. The industry is working with governments around the world and with the EC institutions at many levels (inter alia, the G10, the High Level Pharmaceutical Forum and IMI) to establish a clear roadmap for creating a climate for innovation and addressing the inefficiencies caused by state controls. BIAC welcomes the OECD’s engagement in this complex debate.

IV. How Off-Patent Markets Function and the Factors that Influence Generic Market Entry

13. The innovator model of pharmaceutical competition is characterized by costly upfront investments, limited prospects of products reaching the market and producing a return, strict price controls imposed by state buyers, and reimbursement policies that significantly delay market access and diminish the value of intellectual property. Generic entry requires access to limited capital, but little or no investment in invention or innovation although, increasingly, generics are developing new formulations, dosage forms and delivery methods since such products are more likely to receive rapid regulatory approval and have the potential for higher reimbursement rates. Generic companies also pursue patent strategies to protect their products.

14. Generic entry is actively facilitated by the legal framework once the innovator’s exclusivity period expires. Because the patent discloses the invention in a way that enables copying and the exclusivity period provides a body of experience, extensive pre-clinical and clinical trials are not required. Marketing authorisation can be obtained on the basis of an abridged data package demonstrating that the copy is accurate (with the same qualitative and quantitative composition in active substances and same pharmaceutical form) and bioequivalent to the reference product. There are other measures to facilitate speedy generic approvals: generics can usually refer to

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12 International Prices and Availability of Pharmaceuticals in 2005, Patricia Danzon and Michael Furukawa, Health Affairs, Vol. 27, No. 1 (2008), pp. 230-231. These findings are corroborated by the econometric analysis carried out by the Commission as part of its sector inquiry (final report, paragraphs 1477-1480).

13 Sector inquiry report, paragraphs 93 and 94.
and rely on the innovator’s safety and efficacy trials data; generics are permitted to conduct bioequivalence studies or trials necessary to obtain market authorisation even prior to patent expiry, etc.

15. The consequence is that generic companies can enter the market very swiftly after the originator’s exclusivity expires. Looking at the medicines which lost exclusivity protection in 2000-2007, the data show that products representing approximately 85% of the value of pre-expiry sales in the main five European markets are subject to generic competition. Of these, approximately 70% faced entry within three to four months. In 2007, generics represented 67% of prescriptions filled in the United States, up from 19% in 1984. In the U.S., when a generic version of a medicine becomes available for the first time, it can capture as much as 86 to 97% of the market within the first month.

16. The data show that the speed of entry has accelerated over time in response to different public policy choices, in some countries dramatically so. Generics are attracted to commercial opportunities, swiftly copying innovative products with high annual sales prior to exclusivity. Conversely, commercial and regulatory factors such as limited market value, safety, liability risk, complex manufacturing processes, specialised delivery devices, existing generic or other competitors, patient monitoring, as well as certain national pricing systems, can deter rapid generic entry in some cases.

17. Many national health systems fail to fully exploit the full potential of competitive off-patent markets and this has been confirmed by a regression analysis carried out as part of the Commission’s sector inquiry. The econometric analysis illustrates that price caps and mandatory discounts correlate with a lower number of entrants and, in the longer run, lead to higher prices in comparison with non-cap schemes. For this reason, open-price competition appears to be the policy option that maximizes long run consumer welfare.

18. BIAC welcomes the commitment made by the Commission, in concluding the sector inquiry, to facilitate Member State cooperation and the exchange of best practices on generic policies that create headroom for innovation.

V. The Rationale for Settlement Agreements in Disputes between Originator and Generic Pharmaceutical Companies

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15 See Factors Affecting Generics in Europe, CRA International, appended to EFPIA submission of 13 June 2008 to the European Commission in relation to the pharmaceutical sector, at page 23. These estimates were largely confirmed by the European Commission’s subsequent findings in the final report at paragraphs 177 et seq.


18 Sector inquiry final report, paragraphs 1478 – 1480.
19. Settlement agreements to resolve a reasonably asserted patent infringement claim should be regarded as pro-competitive, allowing the parties to focus investments on those areas where they may legally compete without infringing the other’s rights and without the need for litigation. Patent litigation cases are fact-intensive, legally complex and unpredictable in outcome. By definition, a settlement will be made in circumstances where no final adjudication has occurred. A settlement should therefore be legitimate where the parties settle a claim in circumstances where, as the European Commission has said, both parties believe “they have … good and valid reasons to believe that a blocking position exists”.

20. The terms of the settlement will be as highly fact-specific as the underlying dispute. As the European Court of Justice has noted, such agreements are to be assessed under the antitrust rules in the same manner as any other agreement. Any per se or other stricter approach would be untenable.

21. A settlement is a negotiated position that will reflect the parties’ evaluation of the respective merits based on perceived probabilities, imperfect information, an assessment of risk and the level of costs incurred and anticipated, their exposure to damages claims, legal costs incurred and likely to be incurred, and the risks of a judgment in one jurisdiction being influential for other jurisdictions where the patent is at issue. It will, therefore, not necessarily involve a decisive outcome in the sense that the generic concedes that it cannot enter a market or that the patent holder concedes that it may. Rather, a negotiated position could involve one or more of the following: (i) an agreement to respect the patent term or some shorter duration; (ii) value transfers from one party to another (or from each to the other); or (iii) a distribution or licensing arrangement for the products in dispute or other products.

22. The policy statements of the US Federal Trade Commission with respect to settlements in the US system must be evaluated in the context of the incentives created by the Hatch-Waxman Act. By virtue of this statute, litigation prior to generic entry is actively encouraged by the US market authorization process and tends to focus on the first generic applicant who is eligible for a 180 day period of exclusivity against subsequent filers. Thus, there are specific features of the US system that provoke litigation and, in due course, settlement.

23. Given the system of incentives created by the Hatch-Waxman Act, the FTC has taken the policy position that so-called “reverse payments” are presumptively unlawful, and that ancillary

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19 The competitive gains that may be made from settlements are recognised in the Guidelines on the Technology Transfer Block Exemption: “[L]icensing … in the context of settlement agreements … is not as such restrictive of competition since it allows the parties to exploit their technologies post agreement … Licensing in the context of settlement agreements is treated like other license agreements”. The same Guidelines recognise that if the parties’ own technologies are in a ‘one-way’ or ‘two-way’ blocking position, they are considered not to be competitors on that technology market. A generic and innovator will be in a one-way blocking position to the extent that the innovator’s patent blocks the generic’s access to the market which means that an agreement between them does not restrict competition. (OJ 2004 C 101/2).


business transactions that might accompany settlement of the patent case are often a disguised payment for delayed generic entry.

24. BIAC notes that the policy position of the agencies is not the prevailing view of US jurisprudence. Most US courts have held that the mere inclusion of a “reverse payment” is not a sufficient basis for finding a settlement unlawful. Instead, they have focused on a range of important considerations, including the public policy favouring settlements, full consideration of the counterfactual of generic exclusion and the need for a case-by-case assessment of settlement agreements and side arrangements.23

“[T]he size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.”

“We fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic’s entry date, and in an ancillary transaction, pays for other products licensed by the generic. Such a result does not represent the confluence of patent and antitrust law.”

Schering-Plough Corp. v. Federal Trade Commission, 402 F.3d 1056, 1075 and 1076 (11th Cir. 2005)

25. While courts have articulated somewhat different tests, the weight of US judicial authority holds that settlements are lawful for as long as (i) the underlying litigation was not a sham, (ii) the patent was not procured by fraud, and (iii) the exclusion of generic competition is no greater than would have been occasioned by the patent in any event. In other words, the settlement is not anti-competitive if it goes no further than the protection conferred by the underlying patent.24 Liability would only arise for conduct seeking to extend the exclusive rights conferred by the patent.25

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23 This approach also finds support in economic literature which recognizes that settlements can be pro-competitive since they lower costs and uncertainty. A ban on some potentially pro-competitive settlements would narrow the available patent protection and, on the margin, lower incentives to innovate. It would also increase the cost and risk of bringing a generic drug to market and, on the margin, lower the incentives of generic manufacturers to challenge patents in the first place. (“An Economic Assessment of Patent Settlements in the Pharmaceutical Industry”, Dickey, Orszag, Tyson, March 2009).

24 See Tamoxifen, 466 F.3d at 212-23 (upholding dismissal of private challenges to Hatch-Waxman settlement, and stating that “[w]e generally agree …that ‘simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law,’ unless the ‘exclusionary effects of the agreement’ exceed the scope of the patent’s protection”), amending 429 F.3d 396 (2d Cir. 2005); Schering-Plough, 402 F.3d at 1076 (reversing FTC decision that had invalidated Hatch-Waxman settlements including “reverse payments” because restrictions were “no more broad than the patent’s own exclusionary power”); Valley Drug, 344 F.3d at 1312 (“reverse payment” settlement subject to antitrust scrutiny only if “found to have effects beyond the exclusionary effects of [defendant’s] patent”); Cipro III, 363 F. Supp. 2d at 535 (granting defendants’ motions for summary judgment where Hatch-Waxman settlement restrained “competition . . . only within the scope of the patent”).

25 See United States v. Line Material Co., 333 U.S. 287, 304 (1948) (“Within the limits of the patentee’s rights under his patent, monopoly of the process or product by him is authorized by the patent statutes.”); see also United States v. Singer Mfg. Co., 374 U.S. 174, 196-97 (1963) (“T]he possession of a valid patent … does not give the patentee any exemption from the provisions of the Sherman Act beyond the
In BIAC’s submission, an automatic prohibition of specific settlement terms would not be appropriate. There is no indication that such settlements should be deemed as “always or almost always” unlawful, as normally is required to justify such per se treatment, especially in light of the legally and factually complicated nature of such arrangements. This is reflected in the weight of U.S. jurisprudence. The European Commission has recognised this in its sector inquiry report which correctly states that any assessment of a particular settlement requires an in-depth analysis of the individual agreement, taking into account the factual economic and legal background.\textsuperscript{26}

\textit{limits of the patent monopoly."}; \textit{United States v. Masonite Corp.}, 316 U.S. 265, 277 (1942) (“The owner of a patent cannot extend his statutory grant by contract or agreement.”) (emphasis added); \textit{Tamoxifen}, 466 F.3d at 302 (citing \textit{Singer}); \textit{Schering-Plough}, 402 F.2d at 1067 (same); \textit{Valley Drug}, 344 F.3d at 1312 (citing \textit{Masonite}); \textit{Cipro III}, 261 F. Supp. 2d at 248 (citing \textit{Singer}).

\textsuperscript{26} Sector inquiry report, paragraph 763.