



PHARMACEUTICAL IRELAND
Focused on a Healthy Future



Observations on the Preliminary Report of the Pharmaceutical Sector Inquiry

**Joint Submission by the Irish Pharmaceutical
Healthcare Association (IPHA) and
PharmaChemical Ireland (PCI)**

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Introduction

The Irish **Pharmaceutical Healthcare** Association (IPHA) and PharmaChemical Ireland (PCI), the bodies which together represent the various substantial interests of the pharmaceutical and chemical sectors in Ireland, welcome the opportunity to contribute to the examination of competition and innovation in the pharmaceutical sector, a sector vital to the health and welfare of Europeans and a leading player in Europe's innovative economy.

A central focus of the Sector Inquiry Preliminary Report is the tension between patents and competition, healthcare cost containment, the right climate for pharmaceutical innovation which has long been the subject of debate between industry and policy makers. This is a complex policy area. As evidenced by the Communication on the Pharmaceutical Package¹ progress is being made however more needs to be done if the right balance is to be struck.

Ireland is a good case study of the contribution that the research based industry can play in the development of an economy. In the early 1970s the industry in Ireland employed less than 2,000 people and accounted for less than €100 million of exports. Today Ireland is the largest net exporter of pharmaceuticals in the world.² In 2007, pharmaceutical and chemical exports amounted to €42.7 billion making up almost half of all Irish exports.³ One hundred and twenty pharmaceutical and chemical companies have operations in Ireland, including thirteen of the top fifteen worldwide. Twelve of the world's top 25 medicines are manufactured in Ireland.⁴ The sector employs 24,500 people directly and as many again indirectly. IDA Ireland, Ireland's foreign direct investment authority, has estimated that the replacement value of the investment by the sector in the Irish economy exceeds €40 billion.

In Ireland a partnership approach on the part of the State and the industry has ensured that innovation is rewarded, patients, regardless of their means have access to modern therapies and the State gets good value for money with ex-factory prices referenced against those in other European countries.

Proprietary and generic medicines have prompt access to the reimbursement schedules, with the State's agreements with the respective trade bodies, the IPHA for the research based industry and the Association of Pharmaceutical Manufacturers of Ireland (APMI) for the generic companies

¹ *Communication from the Commission: Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector* COM(2008)666 final, 10 December 2008

² IPHA Healthcare Facts and Figures 2008

³ Irish Central Statistics Office data

⁴ IDA Ireland data

providing that in normal circumstances such reimbursement will be granted within 60 days of the relevant application having been submitted.

IPHA/PCI are concerned by the approach taken in the Report and in particular it's seeming characterisation of legitimate and essential business activities common to all innovative sectors of the economy – patent portfolios, patent litigation and settlements, regulation, development and marketing of second generation products – as costly “delaying tactics,”⁵ “shocking facts,”⁶ and inherently suspect conduct.⁷

The Report presents a partial picture of competition in the pharmaceutical sector. Significant factors that impinge on competitive dynamics, entry and innovation in pharmaceutical markets are either omitted or barely treated. The data analysis presented does not support the Report's conclusions. The analysis is further undermined by misunderstandings as to the nature of the patent system, the use of selective quotation, rather than hard data, and over-reliance on agenda driven commentary.

IPHA/PCI would like to take this opportunity to highlight a number of issues in relation to the Report.

[Analysis of competition and its impact on healthcare budgets is impossible without considering the impact of State regulation or the inflated prices paid for generics](#)

The limited analysis of State regulation in the Report is a significant analytical defect. State regulation is central both to the Report's consideration of generic entry, where state controls, not innovator conduct, are responsible for significant delays, and the decline in innovative productivity, where the literature⁸ and expert research commissioned by EFPIA for the inquiry,⁹ show state controls to be a key factor affecting innovative output. The impact of such controls needs to be fully examined in the final Report.

⁵ Commission Press Release of 28 Nov 08 *Preliminary Report on pharmaceutical sector inquiry highlights cost of pharma companies' delaying tactics*

⁶ Deputy Director General Ungerer, Oral Hearing, 28 Nov 08

⁷ Commissioner Kroes, Press Conference, 28 Nov 08

⁸ *Priority Medicines for Europe and the World*, WHO Report commissioned by the Dutch Government, Warren Kaplan, Richard Laing, November 2004 (Price controls create “an unpredictable lottery for companies”); *Pharmaceutical Price Controls in OECD Countries*, US Department of Commerce, December 2004, pp. 27-31 (State controls cause innovative decline equivalent to output of .7-4.1 new molecular entities per year); *Innovation in the Pharmaceutical Sector: A Study Undertaken for the European Commission*, Charles River Associates, 8 Nov 04

⁹ *The Current State of Innovation in the Pharmaceuticals Industry*, CRA International, June 2008 (“CRA Innovation Report”) (Annex 4 to the EFPIA submission of 13 June 08), p15

IPHA/PCI share the concerns expressed by a wide range of stakeholders, the judiciary, industry and payers at the launch of the Report that generic to generic competition is not part of the review. The finding that prices remain on average at 80% of the branded price one year after patent expiry suggests that generics in some countries enjoy margins which would be unparalleled in any other commoditised market. In a genuinely competitive generics market, these margins would be competed away to the benefit of healthcare providers.

In the case of Ireland in recognition of the need to create headroom for innovation the IPHA agreed to 35% two stage price reductions for off patent substitutable products. The first reductions took place in March 2007 with the second significant wave on the 1st January 2009. Whilst the prices of relevant proprietary medicines have been cut the prices of matching generics have not fallen to the same extent significantly reducing the original price differential (approximately 20%) to a figure appreciably less than that.

The London School of Economics has identified potential savings of 44% on generic medicines could be achieved if better generic to generic competition. The lesson from the US is that truly competitive generic markets can offer prices that are 70-80% below the branded price.¹⁰

A compelling example of the potential for savings is provided by events in the Netherlands where Dutch health insurers' success¹¹ in achieving 80% savings by challenging pharmacists' incentives, driven by high margin retentions, to maintain high prices in tacit agreement with generics suppliers, suggest that detailed examination of the generic supply chain would yield substantial savings for Member States. It can immediately be seen that the 5% or €3bn alleged savings possible from quicker access to generic medicines is a fraction of the savings available from more efficient generic to generic competition. Based on its experience the view of the Dutch health insurer is that generic overpayment, not alleged innovator conduct, is "the largest part of the problem."¹²

¹⁰ *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Federal Trade Commission, October 2003, Chapter 3, page 11 ("Studies indicate that the first generic typically enters the market at 70 to 80% of the price of the corresponding brand and rapidly secures as much as a two thirds market share."); Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 28 (July 1998)

¹¹ PR, p124

Time to generic entry is short and getting shorter - the blocking tactics theory outlined in the Report is unsubstantiated

The Report's headline of €3bn for the cost of innovator's blocking tactics has no valid evidential basis. To the contrary, the Report's evidence shows generic entry is by any measure extremely fast - a weighted average of 7 months, under four months for highest value medicines and 2.5 months in some countries.¹³ Generics themselves state that they will not be on the market on day one after patent expiry because of regulatory delays, and that these delays, not innovator conduct, are "costing European ... healthcare systems as much as €100m per medicine per year."¹⁴

The reimbursement rules in Ireland are similar for proprietary and generic medicines, both normally gaining access to the reimbursement schedules within 60 days of the relevant application. Indeed given that significant new proprietary medicines are often now subject to health technology assessment which can extend the timeline from application to reimbursement by a further 90 days it could even be argued that generics now enjoy faster access to the reimbursement schedules.

Neither the regulatory delays nor the many commercial factors influencing entry – such as the choice to launch simultaneously in multiple markets to achieve economies of scale - is the subject of any meaningful analysis in the Report.¹⁵

The Report's description of the "toolbox" of originator strategies alleged to delay generic entry¹⁶ does no more than list legitimate commercial practices that are common to all high technology industries.¹⁷ Calling into question the legality of any of these activities is to invite technological stagnation. It would have a significant and far-reaching chilling effect on innovation, investment and employment across all research based industries upon which Europe depends.

It is worthwhile to look at each of these alleged strategies in some more detail:

¹²Edwin Velzel, CEO, UVIT, presentation at the hearing of 29 Nov 08 ("[T]hat problem we have tackled, the problem of rapid access to generic medicines, but we had another problem in place. That was overpayment ... [the innovator conduct in the report] it is not the whole problem, it is not even the largest part of the problem.")

¹³ It may be noted that the US, a much larger and less regulated market, achieves day one entry, but that has not been practicable in smaller and high regulated European markets.

¹⁴ *Myth & Reality 08 Intellectual property protection EU vs USA* ("Immediate generic competition upon patent expiration ... No ... Pricing & reimbursement decisions create delays in most Member States"); European Generics Association; *Sustaining Generic Medicines Markets in Europe*, (April 06) Prof. Dr. Steven Simoens, Sandra De Coster, Research Centre for Pharmaceutical Care and Pharmacoeconomics, p67; *EGA Board of Directors urges early implementation of "Bolar provision" for Generics to ensure the future of European Research & Development*, EGA Press Release, 25 March 04. (Post-patent expiry regulatory delays cost European health authorities up to EUR 100m per medicine)

¹⁵ *Myth & Reality 08 Intellectual property protection EU vs USA* ("Immediate generic competition upon patent expiration ... No ... Pricing & reimbursement decisions create delays in most Member States"); European Generics Association; *Sustaining Generic Medicines Markets in Europe*, (April 06) Prof. Dr. Steven Simoens, Sandra De Coster, Research Centre for Pharmaceutical Care and Pharmacoeconomics, p67

¹⁶ See, eg, PR, para. 369 ("The purpose of the present chapter is to examine to what extent originator companies employ instruments of the "tool- box" to delay or block the entry of competing generic products on the market")

¹⁷ *Patents and Pharmaceuticals*, Presentation to the Pharmaceutical Sector Inquiry Hearing, 28 Nov 08, Jacob LJ ("[A]ny experienced patent lawyer will tell you that dusters of improvement patents are a feature of nearly all industries. It is a bit worrying that the Commission seems to think that it has discovered something new and special to the pharma industry.")

i) **Patent portfolios** reflect the level of innovation in the pharmaceutical industry as in any high technology sector. The much quoted figure of 1,300 patents or patent applications misleadingly inflates, up to 27 times, the number of parallel patent “families” needed to obtain protection in each of the EU 27 states.¹⁸ The truth, as the US Federal Trade Commission (“FTC”) has observed, is that the medicine is protected by relatively few patent families – on average 12 and generally no more than 40-50 in EFPIA’s experience - compared to the hundreds or even thousands protecting other high technology products.¹⁹ Generic competitors, undeterred by patent portfolios, have shown themselves adept at designing around, challenging patents or, indeed, obtaining their own patents relating to an innovator’s product when they so choose.

The apparent criticism of the patenting of improvements to a product late in the original patent term disregards the importance of incremental improvements as a source of innovation. Such improvements provide real benefits to doctors and patients in terms of potency, reduced side effects and simpler dosing regimens. It would be antithetical for the competition rules to prevent or inhibit an innovator from using its superior knowledge of its own products to devise and protect new and valuable improvements. Denying this source of innovation to the market would be an irrational competitive restraint, denying patients access to beneficial improvements.

ii) **Patent litigation** is essential for intellectual property protection. To extrapolate from a handful of decided cases to brand the pharmaceutical sector as characterised by what the report calls weak secondary patents is, again, without support. The Report commits the “self-selection error” of choosing the most contentious cases – the tiny minority of patents that litigated – to generalise about the rest. The reality is that once the primary patent has expired, imitators are free to copy it. If weak patents are identified, generic companies have demonstrated their ability and willingness to challenge or design around them. Suggesting that certain types of patent litigation may be suspect creates damaging legal uncertainty for innovators who rely on patent enforcement as the only effective means of protecting their investments.

iii) **Patent settlements** are an essential business tool to draw a line under protracted and expensive litigation and move on, allowing the parties to invest in conditions of business certainty. The public interest in facilitating settlement of litigation, both for litigants and overworked courts, is generally recognised. The Report’s implication that settlements can be categorised as suspect or legitimate based on certain commercial terms within them – an approach derived from the FTC’s enforcement practice – is unsustainable. Just as the most

¹⁸ While the average number of countries in which protection is sought is 15 (PR, para. 334), most modern medicines are protected in all 27 countries (PR, para. 1085) and the number of countries in which protection is sought is highest for the most valuable medicines (PR, para. 957), as is likely to be the case with the product in question.

¹⁹ *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Federal Trade Commission, October 2003, p32

recent US case law rejects the FTC's approach, the correct antitrust analysis is that there can be no presumptively good or bad settlements. Restrictions that go no further than the exclusionary effect of the patent generally do not restrict competition.

iv) Recourse to regulators is essential and in the public interest in any highly regulated industry. Indeed, it can be a regulatory duty to raise concerns. Any suggestion that companies should not come forward with *bona fide* concerns – *inter alia* as to generic safety, quality or counterfeits - for fear of *ex-post* antitrust scrutiny is clearly undesirable and fraught with danger. The innovator is likely to be most knowledgeable about its products and the risk of non-compliant generics. It must be permitted to raise any legitimate suspicions. The regulator can and will decide whether companies' concerns are justified.

v) Marketing and development of second generation products are the essence of competition, particularly in high tech industries. It would be absurd to suggest that companies should not introduce next generation products because to do so unfairly disadvantages generics who can copy only old technologies. If next generation products are successful then they will add to the range and choice of products available to doctors and patients, including generic versions of the old products. If they are not, then the cheaper generic versions of the old technology will prevail.

Innovation is robust - the facts do not support the theory that innovators block the development of new products

The Report criticises defensive patenting strategies with no intent to use the patents to bring a new/improved medicine to market, citing 1,100 instances across the EU where an originator's patents in the sample investigated might overlap with the R&D programme and/or patents held by another originator. This allegedly creates "significant potential for originators to find their research activities blocked" with an unquantified detrimental effect on the innovation process.

The Report entirely fails to make its case. Competition amongst innovators is robust. Billions are spent in the race to bring medicines to market to address unmet and, by their nature, increasingly complex medical needs. The data shows steadily increasing R&D spend and projects under development. In 2007 there were almost 4,400 products in clinical development, including 763 for cancer, 224 for cardiovascular diseases, 177 for respiratory diseases and 92 for Alzheimers. Amongst the literature examining the reasons for productivity decline in the sector, including the economic report submitted by EFPIA but not used in the Report, none has stated that patent protection is anything other than an essential precondition for successful innovation.

No quantifiable harm has been established to have resulted from these alleged patent blocks, not least because cross licensing is common practice and the Report finds only one instance of an R&D project being abandoned because of potential intellectual property concerns. All the indications are that late stage attrition is the culprit, particularly at phase II and III, of clinical trials, at a time when the IP position of the candidate drugs will long since have been secured. Innovators face other challenges outlined in detail in EFPIA's submission of 13 June 2008 which the Report has chosen not to address.

The Regulatory Framework

The Report notes the widely reported shortcomings of the current regulatory framework,²⁰ yet is disinclined to make any assessment of its impact beyond the conclusion that a single Community patent and accompanying unified and specialised judiciary is needed. IPHA/PCI strongly supports the recommendations for an efficient and world-class system of patent grants and litigation, but objects to the methodology employed which focuses only on corporate conduct as the cause of concern, rather than the well documented competitive distortions caused by regulatory controls.

Undue competition law intervention in common commercial practices would undermine what is already a limited commercial window of opportunity and risk further increasing legal uncertainty in an industry that is already subject to an unprecedented level of regulatory intervention.

In conclusion IPHA/PCI urge the Commission to fully assess in the final Report - the impact of the fragmented regulatory framework, the scope of savings available if there were more efficient generic markets; and the policy adjustments that will be required to create a genuine climate for innovation in Europe. We believe such an assessment is essential if the final Report is to play a constructive and meaningful role in meeting its stated objectives of establishing the reasons as to - why fewer new medicines are coming to the market and for the apparent delays in generics reaching the market.

²⁰ See, eg, *Communication on the Pharmaceutical Package*, pp5 and 7 ("Allocating healthcare funds to the most effective medicinal products as well as creating the right environment for price competition is of major importance to ensure the sustainability of healthcare systems. Different systems lead to disparities in pricing, time-to-market delays and access inequalities", "Better Regulation for a More Competitive Industry. Requirements that cause a high administrative burden without providing a clear public health benefit have a strong negative impact on the competitiveness of the EU industry.")