DG Competition Discussion Paper on the Application of Article 82 EC Treaty to Exclusionary Abuses

Public Consultation

Observations by the European Federation of Pharmaceutical Industries and Associations ("EFPIA")
## CONTENTS

<table>
<thead>
<tr>
<th>Paragraph</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction</td>
<td>1</td>
</tr>
<tr>
<td>2. Executive Summary</td>
<td>2</td>
</tr>
<tr>
<td>3. The Objective of Article 82</td>
<td>5</td>
</tr>
<tr>
<td>3.1 The Lisbon Agenda</td>
<td>5</td>
</tr>
<tr>
<td>3.2 Consumer Welfare</td>
<td>6</td>
</tr>
<tr>
<td>3.3 Form or Effect?</td>
<td>10</td>
</tr>
<tr>
<td>4. The relationship of Article 82 with other provisions</td>
<td>11</td>
</tr>
<tr>
<td>4.1 Efficiencies, proof and conduct that is not abusive</td>
<td>11</td>
</tr>
<tr>
<td>4.2 Overlaps with sector specific regulation</td>
<td>12</td>
</tr>
<tr>
<td>5. Market definition</td>
<td>13</td>
</tr>
<tr>
<td>5.1 Markets can be reliably defined without a SSNIP test</td>
<td>13</td>
</tr>
<tr>
<td>6. Dominance</td>
<td>16</td>
</tr>
<tr>
<td>6.1 Form-v-effect</td>
<td>16</td>
</tr>
<tr>
<td>6.2 Barriers to Entry</td>
<td>19</td>
</tr>
<tr>
<td>7. Abuse</td>
<td>20</td>
</tr>
<tr>
<td>7.1 Some General Observations</td>
<td>20</td>
</tr>
<tr>
<td>7.2 Competition on the merits</td>
<td>20</td>
</tr>
<tr>
<td>7.3 Pricing: Rebates</td>
<td>23</td>
</tr>
<tr>
<td>7.4 Refusal to supply</td>
<td>26</td>
</tr>
<tr>
<td>7.5 Refusal to provide access to intellectual property rights</td>
<td>28</td>
</tr>
<tr>
<td>7.6 A lowering of the bar for a finding of abuse?</td>
<td>31</td>
</tr>
<tr>
<td>8. Conclusion</td>
<td>33</td>
</tr>
</tbody>
</table>
1. INTRODUCTION

The European Federation of Pharmaceutical Industries and Associations ("EFPIA") is a European trade association representing the interests of some 29 (24 of which are in the European Union) national pharmaceutical industry associations and 45 leading pharmaceutical companies involved in the research, development and manufacture of medicinal products in Europe for human use.

Among the most important of EFPIA’s missions is "[t]o promote, in the interests of patients, pharmaceutical research and development in order to discover and bring to the market new prescription medicines which improve human health worldwide".

EFPIA has been specifically mandated by the European pharmaceutical industry to express the views of the European pharmaceutical industries on various issues, in particular legislation and regulations, in which context it is concerned to ensure that the law creates and is consistent with a beneficial environment for pharmaceutical investment, research and development, competitiveness in Europe and the improvement of human health worldwide.

In the context of all of the above, EFPIA welcomes the Discussion Paper ("DP") and the opportunity to comment on it.

The issues the Commission has brought together for consideration and debate are difficult ones. EFPIA hopes the Commission will ensure, through full consultation with all the relevant DGs, that a modernised Article 82 and enforcement policy will improve and enhance the ability of R&D intensive, intellectual property-based industries (such as the pharmaceutical industry) to thrive in Europe on a long term basis.

A modernised Article 82 regime which seeks to maximize consumer welfare in a way that is consistent with the Lisbon Agenda, patient health and access to medicines should have as its fundamental principle that government intervention should be exceptional and undertaken only when rules are clear so that uncertainty does not impede competition and innovation.

In this paper, we will comment on the objective of a modernised Article 82, the relationship of Article 82 with other provisions of the EC Treaty, market definition, dominance, and on two of the exclusionary abuses, rebates and refusal to supply. Our observations on these matters will be dealt with in turn below following an executive summary.
2. **EXECUTIVE SUMMARY**

2.1 **Consumer Welfare**

The Commission in its DP presents the enhancement of consumer welfare as the framework for an Article 82 analysis. EFPIA supports the approach.\(^1\)

There should be a clear analytical framework, with economics-based guidelines, to ensure that consumer welfare is enhanced by protecting competition; and this framework should recognise the Lisbon Agenda goals. Short-term interventions under Article 82 and longer term policy considerations may differ, and this should be recognised so that the wider and future public interest is not jeopardised. This is particularly important in the context of intellectual property, where the interests of society are that firms should be encouraged to invest in R&D – and thereby obtain intellectual property rights which provide the incentive to introduce new and innovative products – in this industry, life saving and life sustaining medicines. A regime which recognizes strong intellectual property protection will incentivise innovation.

2.2 **The relationship of Article 82 with Other Provisions**

EFPIA welcomes the potential alignment of the analytical framework of Article 81(3) and merger control with Article 82. However:

(a) Companies should not be required to prove efficiencies. Under Regulation 1/2003 the burden of establishing abuse is on the accuser. EFPIA urges the Commission to re-consider its approach to this matter.

(b) There should be "safe harbours" for certain types and/or degrees of conduct that would not be abusive.

(c) The Commission in its DP should address the inter-relationships between the rules on abuse of a dominant position and sector specific regulation. This is a significant matter for highly regulated industry sectors.

2.3 **Market Definition**

This is a critical issue. In highly regulated industries the importance of non-price factors should be emphasised, and the SSNIP test/cellophane fallacy de-emphasised. We suggest the DP should explore these issues further, with a view to establishing a framework which is truly based on the identification of product substitutes in the context of the characteristics of the industry concerned. Failing this, the tendency to define product markets too narrowly will persist and companies will wrongly be found dominant. The consequent chilling of competition, innovation and investment will create a real tension between Article 82 and the Lisbon Agenda, to the detriment of citizens requiring a thriving pharmaceutical industry and the achievement of the goals of the Lisbon Agenda.

\(^1\) DP, paragraph 4.
2.4 Dominance

Presumptions of dominance are inconsistent with an effects-based approach, lead to false positives and inhibit healthy competition on the market. Market shares, for example, do not themselves give compelling information about the degree of competition to innovate. Of particular concern in the DP is the extreme notion that a market share as low as 25% may indicate dominance; this is not realistic, risks stifling healthy competition by firms, and very likely would encourage frivolous complaints by competitors and other private parties, further increasing costs to innovative, competitive industries and, ultimately, to consumers. Moreover, such low market shares are inconsistent with approaches that have been taken elsewhere (e.g. in the US, a market in which competition and innovation thrive and enhance consumer welfare, up to 70% rarely confers monopoly power).

EFPIA urges the Commission to consider "safe harbours" so that there would be no finding of abuse below a market share of at least 40% and to develop guidelines appropriate for such safe harbours.

2.5 Abuse

Competition on the merits should be assessed on the basis of clear, objective criteria. Unless these are developed, the question of whether or not conduct comprises competition on the merits risks an open-ended subjective analysis which would be problematic for industry and likely inconsistent with the objective of enhancing consumer welfare. For example, there would be considerable potential for the concept being confused with the protection of competitors. We urge the Commission to develop clear guidelines that include safe harbours to assist businesses.

2.6 Pricing: rebates

The DP does not draw a line under the current position (widely recognised as flawed and confusing), nor does it establish clear guidelines on the basis of "effects". It would seem from this that under the DP a dominant company competing on the merits and granting rebates would be vulnerable to inappropriate legal attack. This would chill normal competitive behaviour. Clear parameters for the assessment of rebates, including safe harbours, should be established.

2.7 Refusal to Supply

EFPIA welcomes the DP’s statement that factors to be taken into account in assessing whether or not a refusal is abusive are "highly dependent on the specific economic and regulatory context in which the case arises". We urge the Commission to include state regulation as a factor in assessing whether or not conduct is abusive and to include in a safe harbour that unilateral refusals to supply are not abusive.

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2 See the EFPIA Report: "Article 82 EC: Can it be applied to controlled sales by pharmaceutical manufacturers to wholesalers?", November 2004, section IV.

3 See footnote 18 and Syfait.
2.8 Refusal to provide access to Intellectual Property Rights

We support the DP’s acknowledgement that a refusal to license an intellectual property right will only be abusive in exceptional circumstances. There is considerable EU, and US, jurisprudence on this subject. We believe that a straightforward refusal should be included in a "safe harbour".

We are concerned that, notwithstanding this, the DP appears to be using competition law to interfere unduly in the rights and the nature of the rights that are conferred under the law on intellectual property rights. The Commission appears to be extending the circumstances in which a refusal to licence an intellectual property right would be abusive. It says that abuse might occur if a refusal to license "might prevent the development of the market for which the licence is the indispensable input to the detriment of the consumer", or where the intellectual property is "indispensable as a basis for follow-on innovation". This introduces uncertainty and confusion, and dilutes the value of intellectual property which is essential to incentivising innovation and a competitive European industry. The Commission should adhere to the narrow concept of "exceptional circumstances", as in IMS Health, and should not re-open the debate.

2.9 Conclusion

National regulatory authorities, national courts, lawyers and their clients will look to the final DP for guidance. It is essential therefore that in the DP the Commission provides clear and understandable guidelines and establishes realistic safe harbours so as not to deter innovation, competition and the enhancement of consumer welfare.

The DP is limited to exclusionary abuses, it does not deal with exploitative abuses or discriminatory abuses. In the light of the number of overlapping issues there are in relation to these classes of abuse and the need for consistency in approach to them by competition authorities and the courts, it would be useful if the Commission could expand the DP to include other forms of abusive conduct.

EFPIA would be happy to meet with the Commission to discuss issues relative to the modernisation of Article 82 and the pharmaceutical industry.

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4 See footnote 57.
3. THE OBJECTIVE OF ARTICLE 82

This section will be in two parts. The first part will take a brief look at the Lisbon Agenda. The second part will look at the issue of consumer welfare. Naturally both parts have overlapping issues.

3.1 The Lisbon Agenda

In 2000, the Commission contributed to set out the goals of the Lisbon Agenda at the European Council. It began its analysis on the premise that the European economy was not as dynamic and innovative as its major competitors. The EU faces increasing challenge from emerging economies such as China and is falling behind the US in terms of economic growth and innovation. Furthermore this gap with the US in innovation and R&D is widening. In its contribution, the Commission pointed out that in a "knowledge based society", technology and research translate into economic growth and job creation.

At present Europe is weak in translating the results of research into innovative products and services that can boost competitiveness. In March 2005 the Commission initiated a mid-term review of the Lisbon Agenda. The review was based in part on the recommendations of a high level group which reiterated the need to realise a knowledge society by (a) boosting R&D spending to 3% GDP by 2010; (b) making Europe more attractive to researchers and innovators; and (c) promoting new technologies. In addition, the report highlighted the need to protect intellectual property in order to promote innovation because "companies will only invest in R&D and innovation if they have the certainty that they will be able to reap the rewards of that investment".

Following these recommendations the Commission decided to re-focus the Lisbon strategy on an agenda aimed primarily at making Europe more attractive for investment and to promote R&D and innovation. The Commission highlighted the fact that the EU invests a third less than the US in R&D and 80% of the gap is due to under-investment from the private sector, meaning that the EU needs to provide powerful incentives and a more favourable framework for private companies wishing to invest in R&D.

The Commission, in its review of the economic costs of not implementing the Lisbon goals, reaffirmed that R&D and innovation contribute to economic growth by creating new markets in the forms of new products and services. This kind of innovation increases economic growth and productivity, triggers knowledge diffusion and ultimately benefits society as a whole.

More recently, Commissioner Kroes has expressed the view that "an effective, well-managed competition policy is both a pre-requisite and a key tool for delivering the Lisbon Agenda". In its review of the Lisbon Agenda, the Commission commented that EU competition policy has played a key role in shaping competitive markets, which have contributed to increasing productivity and innovation.

The goal of the Lisbon Agenda is to make Europe more dynamic and innovative so that it is better able to compete on the world stage. The pharmaceutical sector is almost exclusively based on innovation. Innovation in the pharmaceutical sector is high risk and very costly. Only one in approximately 435 drugs ever considered make it to market. It costs an average of €414 million in capitalised costs to get a new drug to market. It follows that investment in innovation will be made only if the few successes are sufficient to compensate the many losses. Intellectual property protection is a way of protecting innovation. Intellectual property rights also offer the holder of them the opportunity of monopoly profits, though this is of course limited to the effective life of the patent. An intellectual property monopoly is invaluable, as it stimulates socially valuable innovation and creation. Over layering it with competition law other than in the most exceptional of circumstances would risk upsetting the delicate balance of risk in investment and innovation. It is important in this context that the monopoly rights that are conferred on holders of intellectual property rights are not confused with "monopoly" or "dominance" in the competition law sense. The concepts do not necessarily go hand in glove and it would be highly damaging to the balance we have referred to above were such a misconception to be a feature of a modernised Article 82.

3.2 Consumer Welfare

The DP presents the enhancement of consumer welfare as the framework for an Article 82 analysis.

The DP says that:

"With regard to exclusionary abuses the objective of Article 82 is the protection of competition as a means of enhancing consumer welfare ..."\(^9\).

In the light of the above stated objective, the Commission says that in applying Article 82, the Commission will therefore adopt an analytical approach:

"which is based on the likely effects on the market in which context it is competition, not competitors, that are to be protected"\(^11\). (emphasis added)

We support the Commission in its shift away from the current form-based approach to an effects-based approach. An effects-based approach focused on consumer welfare and the promotion of economic growth is consistent with the reforms of Article 81 and EC merger control. However, we think it is very important that the Commission


\(^10\) DP, paragraph 4.

\(^11\) DP, paragraph 54.
provides clear guidance as to what the "protection of competition as a means of enhancing consumer welfare" actually means in practice. Such guidelines are important so as to ensure that the conduct of a firm is evaluated, as far as possible, under objective standards thereby ensuring that only truly exclusionary conduct is condemned. In the absence of clear guidance from the Commission, there is a very real risk that an Article 82 assessment would be an open-ended subjective analysis of the effect of potentially exclusionary conduct. Such an approach would be problematic for industry and would most likely be counter-productive.

An economics-based approach to the application of Article 82, particularly as it takes efficiencies into consideration, is likely to promote competitiveness and growth. Moreover, by focusing on effects on consumer welfare rather than on forms of conduct, such approach will improve the regulatory environment in which firms operate, contribute to reducing their regulatory burden and thus allow them to become more competitive and innovative, while safeguarding consumer welfare. We believe such an approach would be consistent with the objectives of the Lisbon Agenda.

We firmly believe that a true effects-based approach to Article 82 is capable of providing a flexible framework that will foster increased productivity and growth to the benefit of consumers. However, if this is to be achieved it is imperative that the DP includes a clear analytical framework within which the question of whether or not the conduct of a firm enhances consumer welfare is to be assessed. That analytical structure ought to include economics-based guidelines which provide a high level of legal certainty by making it clear that single firm conduct that enhances efficiency and benefits consumers is not abusive. This might even be regardless of the form of the conduct and the amount of market power of the firm concerned.12

In paragraph 58 of the DP, the Commission provides a structure for an Article 82 analysis. This comprises three steps for establishing whether or not a firm is infringing Article 82 as follows:

(a) Is the conduct capable of foreclosure? If so,

(b) Is the conduct likely to foreclose? If so,

(c) Are there any countervailing pro-competitive effects? Namely, can the conduct be objectively justified or is there an efficiency defence?

The DP links the assessment of whether or not single firm conduct is likely to foreclose, to an assessment of the likely impact on the market in terms of price and quality. These issues are directly related to consumer welfare and yet they are matters that are not developed in the DP.

The benefits the DP identifies as flowing from effective competition13 principally relate to the economics of Article 82. They do not relate back to the Lisbon Agenda

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12 Such guidelines are essential if inconsistencies in enforcement across Member States are going to be avoided. This is particularly in the light of the fact that increased enforcement by national competition authorities and national courts is to be expected.

13 DP, paragraph 4.
and its goals. Unfortunately, the DP does not explore the inter-relationship between the purposes of competition law and the wider public interest issues embodied in the Lisbon Agenda.

The DP should address how the aims of a modernised Article 82 will contribute to the pursuit of the objectives of the Lisbon Agenda to make Europe more dynamic and innovative and thereby better able to compete on the world stage.

It is widely accepted that consumer welfare does not necessarily equate to the public interest more generally. Short term consumer welfare and the wider public interest may differ. The differences may be particularly pronounced in certain industry sectors, for example, in highly regulated industry sectors, highly innovative industry sectors and markets that are fast-moving. The DP needs to tackle these issues.

One of the objectives of the Lisbon Agenda is sustainable economic growth. The Lisbon Agenda refers to the stimulation of competitiveness and innovation as one of the policy tools.

EFPIA believes that, while it is implicit that competitive markets are essential in order to provide an incentive for innovation and R&D, it is also clear from the objectives set out in the Lisbon Agenda that competition policy should not be used to achieve the opposite result, i.e. to stifle incentives to invest in R&D and innovation. Both aspects need to be considered so as to allow the Commission's policies in these areas to produce a result that favours the public interest.

EFPIA thinks that Article 82 should not be applied in isolation and be interpreted in a way, for example, that limits the ability of firms to protect their intellectual property rights. The benefits of R&D are also defined by the ability to commercialise new products over the long term. The interests of society as a whole in terms of economic growth and productivity are best served by ensuring that firms that invest in R&D are able to reap the benefits of these investments. This is particularly important for industry sectors that face high sunk costs and rely heavily on R&D in order to compete effectively in the market place. Intellectual property rights create incentives to innovate by rewarding investment with some exclusivity.

In particular, EFPIA considers that consumer welfare should include ensuring the continuing provision of (and access to) innovative medical treatments; that there are sufficient supplies of needed medicines; and protection from supply risks in the supply chain that will arise from counterfeit products and defective packaging, etc. With the demographics in Europe leading to a significant increase in the retired population relative to the working population, a health maintenance crisis is looming. There must be a vital role for the innovative pharmaceutical industry to play in producing new medicines and ways of improving disease management.

As recognised by the Commission, there is no "inherent conflict between intellectual property rights and the Community competition rules" as "both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources." Intellectual property laws, like competition laws, are intended to enhance consumer welfare: businesses are encouraged to innovate and invest in new technologies leading to improved products and lower prices. It is essential therefore that the DP addresses how a modernised Article 82 deals with these matters so as to
ensure that consumer welfare will in fact be enhanced. Unless the Commission is very clear about the aims and objectives of a modernised Article 82, there is a danger that Article 82 will be applied in a way that would have a chilling effect on investment in R&D.

The EAGCP Report on An Economic Approach to Article 82\(^{14}\) endorsed a prudent approach when it comes to the relationship between competition law enforcement and intellectual property rights. It maintains that even when suppliers refuse to licence intellectual property rights, a refusal to deal may harm consumers in the short-run, but it will be socially beneficial in the long-run, pointing to the need to preserve the incentive to innovate.

Furthermore, the Commission has recently released a consultation document on state aid for innovation which, among other things, identifies the problems affecting innovation in Europe. Among those problems, the Commission emphasises the "unsatisfactory IP protection" and the "unattractive risk/reward ratios for investing in radically innovative products."

These arguments illustrate the need for a balance to be achieved in this area. The application of Article 82 cannot be viewed exclusively in relation to short term consumer welfare, but rather in conjunction with other policy areas that are intended to enhance the welfare of society as a whole.

On the basis that competitive harm and the protection of "competition" are assessed with reference to consumer welfare, it will be incumbent upon the relevant competition authority to examine the actual working of competition in the particular market without prejudice and to explain the harm for consumers from the practice in question. This routine will provide an essential discipline. Without it the competition authority may be tempted to identify the "protection of competition" with the preservation of a particular market structure, for example, one that involved actual competition by a given company. Its policy intervention may then merely have the effect of protecting the other companies in the market from competition. This would enable them to maintain their presence in the market even though their offerings do not provide consumers with the best choices in terms of prices, quality or variety.

In some cases, concerns for the protection of competition from certain forms of inappropriate behaviour may be the right thing to do. However, this is certainly not true for all cases; moreover, competitors themselves should not be protected from competition by the authorities’ intervention. In each case, the competition authority must assess these matters without prejudice for any particular structure. Their consumer welfare standard in the context of an effects-based approach ought to provide a suitable criterion for distinction. The competition authorities receive more complaints and more material from competitors, so the procedure tends to be biased towards the protection of competitors. It is essential therefore that clear means for assessing consumer welfare effects are developed to provide a counterweight to this bias.

EFPIA is not arguing in favour of having more or less intervention, but of more effective intervention, so as to ensure, as far as possible, that the right cases are pursued. The Commission should be aiming to identify and pursue important competitive harms, while preserving and encouraging efficiency.

In conclusion, by focusing on consumer welfare, the Commission should be careful that it does not use competition policy as a tool for active policy intervention designed to correct any inefficiencies associated with dominance so as to maximise some measure of welfare. As is argued in the EAGCP report, competition policy is based on the principle that competition itself is the best mechanism for avoiding inefficiencies, so that competition authorities should not let their own intervention replace the role of competition in the market place. The powers given to the competition authority are, with very few exceptions, powers to prohibit certain behaviours and certain developments. The powers are not, and should not be confused with powers to actively determine what the market participants should be doing instead.

3.3 Form or Effect?

It seems from the DP that, notwithstanding the Commission's declaration that the application of Article 82 will be effects based, the Commission is in fact finding it difficult to wrestle itself away from the form-based approach with which it is familiar. So that, for example, in paragraph 60 of the DP the Commission talks of when competition on the merits will in fact be "presumed not to be competition on the merits but abusive". In paragraph 222, the Commission talks about the circumstances in which a refusal to supply will be "presumed to have negative effects" and therefore to be abusive. Presumptions of abusive conduct are not consistent with an effects-based approach.

It is important for the sake of legal certainty that the Commission is clear on whether or not its approach will be wholly effects based (as it currently maintains it will be) or will comprise both form and effects based approaches. If the application of Article 82 is to have elements of an effects and a form based approach, then the Commission must be clear about what aspects will be effects based and which will be form based.

We think the best interests of industry would be served were a modernised Article 82 to be effects-based but that, for reasons not least of predictability and accountability, the approach should be accompanied by some very clear rules of law. ¹⁵

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¹⁵ See further EFPIA’s observations on abuse, below.
4. THE RELATIONSHIP OF ARTICLE 82 WITH OTHER PROVISIONS

4.1 Efficiencies, proof and conduct that is not abusive

We have referred above to the three step test the DP\textsuperscript{16} suggests is followed for assessing whether or not a firm is infringing Article 82 EC Treaty. In circumstances where the first and second criteria are satisfied, the third criteria includes a test as to whether or not there are any countervailing pro-competitive effects of the firm(s) conduct. This is the efficiency argument.

In this context the DP comes close to aligning the analytical framework of Article 81(3) and EC merger control on the one hand with Article 82 on the other hand. This is an important objective and EFPIA commends the Commission on the progress it has made in this connection.

However, the DP explains that whilst the existence of efficiencies may provide a defence to alleged exclusionary and abusive conduct, this is provided the dominant company can show that the efficiencies outweigh the likely negative effects on competition. The DP is clear that the onus is on the dominant firm to prove that efficiencies are realised or are likely to be realised as a result of the conduct and that, in this context, the conduct satisfies each of four efficiency criteria (which are essentially the same as the criteria for exemption under Article 81(3) EC Treaty):

- that it will contribute to improving production or distribution of products or promoting technical or economic progress by, for example, improving product quality or reducing costs;
- that the conduct concerned is indispensable to realising the efficiencies: that there are no economic practicable, less anti-competitive alternatives;
- that the efficiencies benefit consumers: that the efficiencies are likely, to enhance the dominant firm’s ability and incentive, to act pro-competitively for the benefit of consumers. The later in time benefits are expected to materialise, the less weight can be assigned to them;
- that competition in respect of a substantial part of the product concerned is not eliminated. This condition is very unlikely to be satisfied in circumstances where the firm has a market share in excess of 75%.

It is in relation to the proof of the efficiencies that EFPIA parts company with the Commission.

It may be reasonable to expect dominant firms to indicate the efficiencies, but it is for the Commission, and not the dominant company, to establish that the efficiencies shown by the dominant firm are outweighed by the actual or likely anti-competitive effects. On this issue, EFPIA questions whether the approach suggested by the Commission in the DP is compatible with Regulation 1/2003. Under Regulation

\textsuperscript{16} DP, paragraph 58.
1/2003\(^\text{17}\) the burden for establishing abuse is on the authority/person alleging illegality.

In addition, in *Syfait*, Advocate General Jacobs casts doubt on the alternative approach the Commission is advocating in the DP. In *Syfait*, Advocate General Jacobs says:

"Article 82 EC, by contrast with Article 81 EC, does not contain any explicit provision for the exemption of conduct otherwise falling within it. Indeed, the very fact that conduct is characterised as an "abuse" suggests that a negative conclusion has already been reached, by contrast with the more neutral terminology of "prevention, restriction or distortion of competition" under Article 81 EC. In my view, it is therefore more accurate to say that certain types of conduct on the part of a dominant undertaking do not fall within the category of abuse at all."

As Advocate General Jacobs maintains, it may well be that the particular nature or structure of an industry sector, in whole or in large part, renders certain types of conduct by dominant firms in that sector impossible to classify as abusive. However, this is not for firms to prove, there would simply be no per se abuse.

If dominant firms are to compete aggressively and benefit consumers, they need more certainty than has been conferred at present in relation to the efficiency defence. Dominant firms need assurance that there are enough incentives to invest. In this context, EFPIA urges the Commission (a) to rethink its approach relative to who bears the burden of proof and (b) to try and follow Advocate General Jacobs' lead and to include in the DP a safe harbour for types of conduct and/or degrees of conduct that would not fall within the category of abuse at all.

### 4.2 Overlaps with sector specific regulation

The DP does not address the position and potential for overlap with sector specific regulation. For many of the most important sectors of the economy, and many that are the most significant, sector specific regulation has been applied to foster the development of competition, often with regimes of state control and so on. The DP should also address the relationship between the rules on abuse of a dominant position and the sector specific rules. This is a significant matter that requires clarification for those active in industries that are highly regulated, such as the pharmaceutical sector.

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18 Case C-53/03, *Synetairismos Farmakopoion Aitoliás & Akarnánias (Syfait) and Others v GlaxoSmithKline AEVE*, Opinion of Advocate General Jacobs, 28 October 2004, paragraph 72.
5. **MARKET DEFINITION**

5.1 **Markets can be reliably defined without a SSNIP test**

The Commission Notice on Relevant Market Definition,\(^\text{19}\) says that market definition is essential since it makes it possible to calculate market shares that convey meaningful information regarding market power for the purposes of assessing dominance. This is significant because the definition of the relevant market in both its product and its geographic dimensions has a decisive influence on the assessment of a competition case.

In paragraphs 12 and 13 of the DP, the Commission repeats parts of the Commission Notice on Relevant Market Definition. The DP does this to identify the purpose of market definition and the methods by which a market may be defined. In this context, the DP says that the main purpose of market definition is "to identify in a systematic way the immediate competitive constraints faced by an undertaking". As to the means of identifying the relevant market, the DP says "it is necessary to rely on a variety of methods for checking the robustness of possible alternative market definitions".\(^\text{20}\)

EFPIA does not suggest that in the DP the Commission should reopen the Commission Notice on Relevant Market Definition. However, EFPIA does suggest that the Commission should use the modernisation of Article 82 to give clear and robust guidance on the governing principles of relevant market analysis. In particular, the principles that:

(a) a variety of methods should be relied on for checking the robustness of possible alternative market definitions;

(b) each of the methods will have varying degrees of importance depending on the case that is under review; and

(c) for certain sectors, some methods will in fact be of no relevance.

Whilst the DP makes reference to the first two principles above\(^\text{21}\), it does not draw them together in any meaningful way. Moreover, it does not deal with the fact that there will be cases where only some of the methods of market analysis are appropriate. This needs the Commission's attention as does the issue that a market definition will be no less reliable because certain methods of analysis might be inappropriate. Industry needs clear guidelines on these matters.

The most widely used tool to assess demand-side substitution is the extent to which price variations in one product affect demand for another product in which respect the Commission applies the SSNIP test.

The DP acknowledges that the so-called SSNIP test and the "cellophane fallacy" may not be effective means of identifying relevant markets. The DP concedes that, subject


\(^{20}\) DP, paragraphs 12 and 13. See also paragraph 25 of the Commission Notice on the definition of a relevant market.

\(^{21}\) See for example, DP, paragraph 13, last sentence.
to the particular industry sector, the SSNIP test and the cellophane fallacy may not provide a sound basis upon which to assess whether or not the firm in question is subject to effective competitive constraints.

We agree with the Commission. The SSNIP test and the cellophane fallacy can never really be reliable indicators of dominance in highly regulated industries such as the pharmaceutical industry. Indeed, it is perfectly plausible that, on occasion, the SSNIP test will in fact be of no relevance to market definition in highly regulated industries and, in particular, those that are subject to price regulation.

In a report recently published by EFPIA\(^{22}\), we explained that the application of the SSNIP test is difficult, if not impossible in the pharmaceutical sector, given national regulation of pharmaceutical prices and reimbursement levels.

More specifically, comparing the extent to which price variations in one product affect demand for another product is not possible in practice when final consumers are insensitive to price levels due to the existence of State reimbursement in one form or another. Manufacturers will also be constrained, directly or indirectly, by national regulations on pharmaceutical prices. As a result, the basic assumptions underlying the SSNIP test regarding the ability of a firm or group of firms to profit-maximise by increasing price realistically cannot be applied.

In the light of all of the above, we think that the Commission should consider placing particular emphasis on the importance of non-price factors in the assessment of highly regulated industries and perhaps also in relation to highly innovative industries and fast-moving industries.

We would suggest that the Commission ought to develop a clear set of alternative methods of analysis. In addition, or in the alternative, we suggest that the Commission acknowledges that there are some industry sectors in which price-based analysis are inappropriate and where possible, it identifies those industry sectors. We also suggest that the Commission recognises that there are some markets that can be reliably defined on the basis of non-price factors. In other words, that a relevant market can be wholly and reliably defined without a SSNIP test.

The DP lists other factors that may be relied on when defining the market, such as the characteristics and intended use of the products\(^{23}\). However, the DP does not explain what weight should be given to these factors and whether or not these factors would have different levels of importance according to the industry sector that is under review. It would be useful in this context if the DP could draw on the Commission's Notice on Relevant Market Definition which emphasises that the relevance of each category of evidence will vary, depending on the features of the industry and products or services at issue.\(^{24}\) In this connection it would be useful for industry if the DP could identify the factors the Commission would consider particularly significant relative to individual industry sectors. This would not necessarily be according to the

\(^{22}\) EFPIA Paper, "Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers?", November 2004, page 21.

\(^{23}\) DP, paragraph 18.

\(^{24}\) Commission Notice on Market Definition, page 5.
activity of the sector (telecommunications, motor vehicle manufacturing, media or pharmaceutical etc) but according to whether or not the industry sector is highly regulated, R&D intensive, highly innovative, and/or fast moving.

There are a significant number of cases in which the Commission has adopted a very narrow market definition, unconnected with the cellophane fallacy and contrary to the principles set out in the Commission's Notice on Market Definition.

With reference to the pharmaceutical industry, for example, the Commission maintains that it attributes great weight to differences between medicines’ mode of action (that is, the manner in which they produce their therapeutic effect) in defining markets. The logical extension of these kinds of arguments is that each product itself constitutes a relevant market. This approach is misconceived as a matter of law and economics. The purpose of market definition is to identify which products are sufficiently close substitutes for each other in order to assess the competitive constraints that undertakings face. For the purposes of market definition, the fact that two products have different modes of action is of little, if any, significance if those products are in fact viewed as being therapeutically substitutable by the relevant decision-makers.

A more economics-based approach to Article 82 not only means avoiding the SSNIP test and the cellophane fallacy but, also, importantly, avoiding artificially narrow market definitions. If the Commission carries over into the modernisation of Article 82 its current tendency to define markets artificially narrowly, it will create a tension between the aims of Article 82 and those of the Lisbon Agenda which could very well make the objectives of the latter more difficult to achieve. Were that to occur the Commission will have failed in protecting consumer welfare through an application of a modernised Article 82.

25 Case COMP/A.37.507/F3 – AstraZeneca, recital 373 and footnote 468; Case COMP/M.1397 – Sanofi/Synthelabo, paragraph 30; Case COMP/M.140 – AstraZeneca, paragraph 36.
6. **DOMINANCE**

6.1 **Form-v-effect. Market Shares and Presumptions of Dominance**

The approach in the DP to the issues of market share and barriers to entry is severely limited and apparently confused. Of particular concern is that the DP is not clear on the extent to which an assessment of dominance will be effects based. The DP maintains that it will be, yet it also appears to be trying to hold on to a "presumption of dominance approach". So that in paragraph 31 of the DP, for example, the Commission explains that a firm could be presumed dominant on the sole basis that the firm has a market share of 25%. Presumptions of dominance on the basis of market share are not consistent with an effects-based analysis.

From an economic perspective, dominance is measured according to the ability of an undertaking to raise its prices above a competitive level for a substantial volume of sales and over a substantial period of time.

In the words of Commissioner Kroes, "market shares are not - on their own - sufficient to conclude a dominant position exists" and that to show dominance, "a full economic analysis of the overall situation is necessary".

Market share is one factor in the analysis and ought not to be conclusive of dominance. Mere numbers do not determine whether or not the undertaking concerned has power over the market. Market shares do not themselves communicate useful information about the degree of competition to innovate. A high market share may be just as consistent with successful innovation in an intensely competitive market. There are a range of factors more significant in evaluating market power than an assessment of whether or not a firm has succeeded in accreting a certain market share at a certain time. Very material issues around market share are the length of time it has taken a firm to obtain a certain market share, how long the firm has managed to hold on to that market share and what the effect of that has been on consumer welfare. Noteworthy in this context is the approach taken under US law where a measure of market power is the extent to which a firm can maintain market share over a significant period of time.

Not least for the above reasons an assessment of market power based on market share alone should be treated with caution.

It is disappointing then that the DP struggles with the notion that market shares alone do not prove dominance. Whilst paragraphs 28 and 29 the DP appear to abandon the notion that market shares alone are sufficient for a finding of dominance, paragraph 31 of the DP appears to say that dominance will be presumed where there are high market shares and regardless of any other factors. Presumptions of dominance above a certain market share threshold are not consistent with an effects-based approach and the concept that market shares alone do not prove dominance.

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In the DP the Commission says that a market share of 25% could be sufficient for a finding of dominance. This is a development of considerable concern.

It is unacceptable for the Commission to establish for itself a right to find a company with a market share as low as 25% dominant. By doing so, the Commission is taking a retrograde step and introducing a degree of legal uncertainty in a dominance assessment that currently does not exist. If the Commission maintains this approach it risks subjecting to judicial scrutiny almost every action of any business with a 25% market share. This would in turn threaten to discourage the competitive enthusiasm that competition law ought to be seeking to promote. It could encourage frivolous and vexatious actions and thereby significantly increase the number of complaints that are made. In short, the Commission will be courting the danger that the application of a modernised Article 82 will have effects that directly undermine the objectives of the Lisbon Agenda.

EFPIA believes that competition law needs to encourage companies to compete and to do so by continuing to take risks and by continuing to invest in business in Europe. Innovative industries need to, and should be, encouraged to compete aggressively on the merits. Aggressive competition promotes consumer interest. Striving for monopoly power also induces risk-taking that in turn produces innovation and economic growth. Undertakings will be risk averse if the threshold for dominance under EC competition law is set as low as 25% because of the regulatory scrutiny it will expose them to. We are also concerned that it would lead to an increase in the number of complaints made to regulatory authorities, the majority of which would be simply opportunistic.

The Commission itself has acknowledged for some time that innovation is where Europe appears to lag most behind its main competitors. It has identified a need for the European Union to become more innovation-friendly - in its most recent publication on the progress of its competitiveness initiative, Enterprise Europe No 20, it states: "...innovation and research require a predictable and accommodating regulatory environment that facilitates bringing new ideas to market. Regulation may foster or hamper innovation depending on the cost of compliance and whether it reduces commercial risks and legal uncertainties". It is inconsistent with this policy for the Commission to amend its approach to Article 82 in such a way as to create greater uncertainty for a greater number of companies in innovative industries – an uncertainty that is compounded by the problems with market definition.

By contrast, (a) the approach that is being taken by some national competition authorities and (b) the US approach are noteworthy. In the recent *Drogheda* case27 the Irish Competition Authority determined that a newspaper publisher with a market share of 75% was not dominant. Particularly important to the finding of no dominance was the fact that the publisher's sole competitor was large, well-resourced and innovative.

US law addresses monopolies and the creation or maintenance of monopoly power. In the US many courts have indicated that a market share below 50% precludes

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27 Decision of the Irish Competition Authority under the Competition Act 2002, Case COM/05/03, 7 December 2004.
finding monopoly power, that a market share of less than 70% would rarely be sufficient for a monopoly finding and that a market share in excess of 70% is required to infer monopoly power. By way of analogy with the developments that are occurring at Member State level and with the position in the US, EFPIA would submit that, not least as far as innovative industries and consumer welfare are concerned, a high market share should not be viewed with suspicion.

In the DP, the Commission suggests a sliding scale approach between market share, market power and effect on consumer harm for a dominance assessment. This is an interesting concept that could lead to findings of market power of a nature and degree sufficiently reliable for a finding of dominance. Unfortunately, however, the DP does not develop this notion. This kind of approach to measuring market power requires a proper, structured analysis. Consequently if the Commission is intending to hold on to a sliding scale approach, it needs to provide a detailed explanation of how, and the parameters within which such an approach will work.

In the interests of promoting legal predictability and legal certainty, industry would be materially assisted were the DP to provide safe harbours for undertakings with a market share below a certain threshold and/or that meet other specified criteria. A certain approach of the kind EFPIA is suggesting would ultimately be in the interests of consumer welfare. Firms want clear guidance on the parameters within which a certain market share could lead to them having to revise their business conduct, to having to cease engaging in certain conduct or to not even commencing certain conduct.

The Commission has sought to defend the absence of safe harbours in the DP on the basis that the provision of them would be ultra vires the Commission's powers. EFPIA questions the Commission's position in this regard. The provision of safe harbours must certainly be within the Commission's competence. The Commission has provided safe harbours in connection with the application of Article 81 so that, for example, The Vertical Agreements Block Exemption, The Technology Transfer Block Exemption and the R&D Block Exemption all contain safe harbours. Parties to an agreement know that if a certain threshold market share is exceeded, their arrangement may infringe Article 81(1) unless the criteria for exemption in Article 81(3) can be satisfied. There would seem to be no good reason why this step wise approach could not or ought not to be adopted in relation to an Article 82 analysis. The DP provides dominant firms with an efficiency exemption from the application of Article 82 similar to that contained in Article 81(3) EC Treaty. However, different from the situation relative to Article 81, is that firms engaged in unilateral conduct have no guidance on the point when they ought to be considering an Article 82 efficiency defence. One of the aims in the modernisation of Article 82 is to achieve an alignment between the application of Article 81, Article 82 and EC merger control. If a true alignment is going to be achieved, the DP ought to include safe harbours.

The safe harbours would have to be in the form of guidelines. They ought not to operate, by default, as presumptions of dominance. In all cases a full economic analysis should be a prerequisite for a finding of dominance. Subject to these

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28 DP, paragraphs 31 and 59.
provisos it would be very useful for industry if the Commission could provide developed guidance on:

- The threshold below which a firm would not be dominant. A threshold for the Commission to consider would be at least 40% below which there would be no dominance finding.

- Complex areas (perhaps in highly regulated markets, highly innovative markets; and fast moving markets) where particular care needs to be taken before a finding of dominance could be arrived at.

It would also assist if the Commission could develop some screening mechanisms to determine the safe harbours. Such mechanisms will reduce uncertainty in the commercial environment and allow undertakings in the safe harbours to engage in robust and creative competition to the benefit of consumer welfare.

6.2 Barriers to Entry

The discussion on barriers to entry (paragraph 40) suggests that any one of the identified barriers to entry (such as intellectual property rights) is sufficient for a finding of dominance. Such an approach carries with it the risk that dominance will be presumed on the basis of limited market analysis. This ought not to be so. Such an approach is inconsistent with an effects-based approach. If there is to be a proper effects-based application of Article 82, it follows that there must be a comprehensive assessment of barriers to entry, recognising of course that subject to the particular case under review, the barriers to entry will have varying degrees of significance.

There is no discussion of the extent to which first mover advantage can be a barrier to entry. EFPIA would maintain that the Commission should develop this as an issue. In the pharmaceutical sector, for example, it would be impossible for a company to be dominant immediately following the launch of a new product in circumstances when there is an entrenched incumbent product.

In fast-moving markets, a first mover advantage may be temporal. In R&D intensive markets a first mover advantage may be prolonged but may be the only time in which a firm may recoup its investment, before generic market entry or before the launch of a new and alternative medicine by another pharmaceutical manufacturer. The firm's survival will then be dependent on its ability to invent a new product that will confer on it a first mover advantage and so the cycle continues. The DP needs to consider this issue and to develop it.
7. **ABUSE**

In this section we will open with some general observations on the assessment of exclusionary conduct. We will then consider the concept of competition on the merits and two forms of exclusionary abuse, rebates and refusals to supply.

7.1 **Some General Observations**

Firms need certainty in order that a reliable assessment can be made of the extent to which its conduct is not prohibited by Article 82. National courts and national regulators, who will all be applying Article 82 and increasingly so, also need clarity and certainty, not least for reasons of predictability, accountability and the consistent application of competition law across the community.

"To say that the law on abuse of dominance should develop a strong economic foundation is not to say that rules of law should be replaced by discretionary decision-making based on whatever is thought to be desirable in economic terms case by case. There must be rules of law in this area of competition policy, not least for reasons of predictability and accountability".\(^{29}\)

The application of competition policy can be difficult because the means of illicit exclusion, like the means of legitimate competition, are myriad. "False positives" are therefore inevitable and they will harm consumers by chilling any legitimate conduct that is sometimes mistakenly found to be exclusionary.

Consequently, EFPIA believes that the Commission should allow for the possibility of error in assessing potentially exclusionary conduct. The Commission should also account for the impact of its actions on incentives to take risks and innovate. Consumers are best served by a policy that avoids chilling legitimate competition and discouraging innovation. Zealous efforts to promote consumer welfare can have the opposite effect: denying successful competitors the fruits of their efforts discourages the innovation and risk taking from which consumers derive enormous benefits.

7.2 **Competition on the merits**

A monopolist no less than any other competitor is permitted, and indeed encouraged, to compete aggressively on the merits.

The DP identifies competition on the merits as a type of objective justification for conduct that would otherwise be abusive.\(^{30}\) However, there is limited discussion on what the concept comprises and such discussion as there is, appears confused.

The DP says that conduct that is "clearly not competition on the merits" will be presumed to be abusive.\(^{31}\) First, if the DP does not identify what competition on the merits is, a firm cannot be expected to be able to defend its conduct on the basis either that it is in fact objectively justifiable or efficiency producing. Second, if the


\(^{30}\) DP, Paragraph 60.

\(^{31}\) DP, paragraph 60.
application of Article 82 truly is going to be effects-based, there can be no place for presumptions of abusive conduct.

The DP needs a clear set of guidelines as to the type of conduct that is competition on the merits and not therefore abusive. In this context the nature of the approach that is taken to competition on the merits under US antitrust law is noteworthy. One of the most important principles that governs the application of US antitrust law has been articulated by the Supreme Court in *Spectrum Sports Inc. v McQuillan*\(^\text{32}\). *Spectrum* says the principle of competition law:

"is not to protect businesses from the working of the market; it is to protect the market from the failure of the market. The law directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself. It does so not out of solicitude for private concerns but out of concern for the public interest".

This has been articulated by one US judge and antitrust scholar as follows:

"Competition is a ruthless process. A firm that reduces cost and expands sales injures rivals – sometimes fatally … these injuries to rivals are by-products of vigorous competition, and the antitrust laws are not balm for rival's wounds. The antitrust laws are for the benefit of competition, not competitors".\(^\text{33}\)

Commissioner Kroes maintains in her speech at Fordham\(^\text{34}\) that:

"I like aggressive competition – including by dominant companies – and I don't care if it might hurt competitors – as long as it ultimately benefits consumers. This is because the main and ultimate objective of Article 82 is to protect consumers, and this does, of course, require the protection of an undistorted competitive process on the market.

We need to take into account not only short-term harm but also medium- and long-term harm arising from the exclusion of competitors. I am well aware of the difficulty associated with predicting medium- or long-term harm but I believe that we should focus only on, for instance, the short-term price effects of a certain form of conduct, but also take into account the medium- to long-term effects that should residual competitors be foreclosed. Consumer prices may fall in the short run but end up being higher in the medium- to long-term because of the likely foreclosure effects. We cannot just wash our hands of responsibility and say that competition law cannot or should not protect the consumer against negative medium- to long-term effects just because it is difficult to assess."

In identifying the constituent elements of the abuse, the Commission should make it clear that, while harm to competitors is necessary for conduct to be an abuse, it is not sufficient. Naturally, inventing better products or more efficient methods of


\(^{34}\) Speech/05/537. Date 23 September 2005.
distribution, reducing price or offering better terms of trade for the benefit of consumers, and more quickly adapting to changes in the market can disadvantage rivals and it may even cause them to abandon business. However, these forms of conduct can comprise competition on the merits and enhance efficiency and consumer welfare, and should thus not be prohibited by Article 82.

Perhaps in the light of the above a means of identifying competition on the merits is to identify what it is not. On the basis of this approach, conduct that does not promote efficiency and consumer welfare is not competition on the merits. But even this approach takes us little of the way forward. It leaves the concept exposed to an open ended subjective analysis of what could or could not be competition on the merits in any particular circumstance. This is an uncertain and therefore unacceptable basis on which to proceed.

As is perhaps signalled in Commissioner Kroes' statement, the Commission might be tempted to argue that even conduct that increases efficiency can be an abuse if it excludes competitors on the ground that, in the long run, the loss of competitors will reduce competition and, ultimately, consumer welfare. Were the Commission to adopt such an approach it would require the Commission to establish the long run harm for the reduction in competition exceeds the short run increases in consumer welfare and the long run improvement in efficiency attributable to the dominant undertakings conduct. The Commission should be very reluctant to treat conduct as an abuse on the basis of such a trade off. Projecting and estimating the magnitude of long run harm to competition is almost always very difficult and uncertain. More importantly, were the Commission to attempt to meet that burden, it should explain how it addresses the risk of overstating long run competitive harm in the particular circumstances of the case under consideration. Indeed, dynamic, Schumpeterian competition inherently brings forth new innovations and new entries that were not anticipated and could not have been predicted. Efforts to assess long run harm to efficiency and to consumers as a result of exclusion of competitors clearly risks grossly overstating the harm, if they fail to take account of these likely developments. Consequently, in cases where the conduct at issue generates short term efficiency and the Commission nevertheless considers prohibiting such conduct, it ought to be the duty of the Commission to demonstrate that the balancing test, between short- and long-term effects, avoids the risk of overstatement of long-term consumer harm.

The above discussion illustrates the scope there is for a subjective, open-ended analysis of what could be competition on the merits. This is no good for business, and it is no good for the consistent application of a modernised Article 82 throughout the Community. The DP needs to include a clear set of objective guidelines on the type of conduct and the circumstances in which the conduct would comprise competition on the merits. It is vital for investment and innovation that the law is predictable and it is critical as a matter of law that those who are subject to it know how it applies to them.

Furthermore, EFPIA thinks that conduct that can be categorically labelled "competition on the merits" should be placed in a prudential safe harbour and not be subject to any enquiry into actual effects. Improved product quality, energetic market penetration, successful research and development, cost reducing innovations and the like cannot, EFPIA would submit, violate the law.
7.3 Pricing: Rebates

In relation to the issue of rebates, the current decisional practice of the Commission and the European Courts is controversial. This is because the cases state that it is generally unlawful for a dominant firm to use loyalty and target rebates, even though other competitors may compete using such practices. The key cases are British Airways v Commission (BA/Virgin) and Michelin v Commission (Michelin II). In both BA/Virgin and Michelin II, the Court of First Instance, has stated that there is no legal requirement to show that the rebate in question actually produced anti-competitive effects. In each case the rebates were condemned as having the likely effect of being loyalty inducing.

The CFI summarised the relevant law in BA/Virgin as follows:

"For the purposes of establishing an infringement of Article 82, it is not necessary to demonstrate that the abuse in question had a concrete effect on the markets concerned. It is sufficient in that respect to demonstrate that the abusive conduct of the undertaking in a dominant position tends to restrict competition, or, in other words, that the conduct is capable of having, or likely to have such an effect." (emphasis added)

This is a form-based approach and it has been heavily criticised. The critics have argued that a very different approach applies in the US, where proof of anti-competitive harm resulting from allegedly exclusionary behaviour is required.

In Michelin II, the CFI suggested that a dominant firm could advance an objective efficiency justification for its rebates by showing economies of scale due to increased sales to the particular customer. However, the CFI maintained that Michelin had not produced sufficiently detailed information in this respect.

In BA/Virgin, the position was similar. The CFI noted that if an increase in quantity results in a lower cost for the supplier, the supplier is "entitled to give the customer the benefit of that reduction by means of a more favourable tariff … Quantity rebates are thus deemed to reflect gains in efficiency and economies of scale achieved by the dominant undertaking". However, again, the CFI considered that BA had not discharged the burden of proving efficiency considerations linked to its rebates. In particular, the CFI objected to the rebate being calculated on total rather than incremental sales.

The above comments by the CFI in each of Michelin II, and BA/Virgin recognise there is a place for efficiencies in what is currently a strict form-based approach. As such, the comments are therefore welcome. However, this does not get us away from the fact that these developments have created a legal doctrine which has serious

35 Case T-219/99, British Airways plc v Commission, on appeal to the ECJ. See also Opinion of Advocate General Kokott, 23 February 2006, Case C-95/04P. The opinion directs the ECJ to reject BA’s appeal against the judgment of the CFI in its entirety.

36 Case T-203/01, Manufacture française Des Pneumatiques Michelin v Commission.

37 BA/Virgin, paragraph 293.

38 BA/Virgin, paragraph 246. See also Michelin II, paragraph 58.
consequences for dominant undertakings and which seriously restricts pricing structures and arrangements that they are permitted to establish.

Particularly worrisome is that the decisional practice to-date overlooks the fact that rebates can increase allocative efficiency and consumer welfare by increasing output and reducing prices. They are often preferred by customers to alternative arrangements and are often the result of hard bargaining by customers to get the best price from undertakings that, because they are dominant, would otherwise charge higher prices. Conduct of this nature should be subject to Article 82 only if there is a compelling economic basis for doing so. Increases in allocative efficiency and consumer welfare ought to be regarded as objective justifications for rebates and should negate the assumption that such rebates are exclusionary by their very nature.

In the current climate, dominant companies fear that they are being prevented from competing, as they see it, "normally" with their smaller rivals, with the same type of rebate schemes as these smaller companies use. Some critics argue that the CFI's argument that BA's competitors could not have matched the level of rebates being offered by BA also risks the CFI being accused of protecting competitors rather than competition. The CFI's arguments have been endorsed in their entirety by Advocate General Kokott in her consideration of BA's appeal to the ECJ against the judgment of the CFI. Perhaps more worrisome, however, is the fact that in her Opinion she rejects the Commission's drive to modernise Article 82 as barely significant. Advocate General Kokott remarks:

"Moreover, even if its administrative practice were to change, the Commission would still have to act within the framework prescribed for it by Article 82 EC as interpreted by the Court of Justice".\(^{39}\)

It is critical therefore that the Commission draws a line under the current position, identifies the position it will be taking and establishes clear guidelines for an effects-based approach to an assessment of whether or not the operation of a rebate scheme by a dominant company is abusive. Dominant companies, like their non-dominant competitors, need clear and practical rules.

Unfortunately, the DP fails to distinguish the current position from any new approach under a modernised Article 82. The DP also fails to give any clear guidance on what rebates will be abusive.

The section on single branding and rebates is complex (and therefore not easy to follow and apply), it is confused, it hangs on to a formalistic analysis of rebates, it is overwhelmingly negative and provides a strong indication that, in the vast majority of cases, rebates will be presumed abusive.

In respect, for example, of retrospective rebates on all purchases, the DP comments that such rebates can have a strong loyalty enhancing effect if the threshold is set above the "level that the buyer would in any event purchase" from the dominant company in the absence of any rebate.\(^{40}\) The DP is silent on how that level would be

\(^{39}\) Ibid, paragraph 28.

\(^{40}\) DP, paragraph 152.
determined. Would it, for example, be based on past purchases without any rebate? But what happens if, for example, demand is not stable or if data on past purchases is not available?

In respect of conditional rebates on incremental purchases, for example, the DP comments that where it is established that most of the buyers are purchasing more or less the same amount and that the standard volume target happens to work as an individualised volume target for these buyers or where it is established that the standard volume rebate happens to target selectively buyers that are of particular importance for the possibilities of entry and expansion of competitors, the system may have loyalty enhancing effects and the rebates will be presumed predatory and therefore abusive.\footnote{DP, paragraph 169.}

In respect of unconditional rebates, the DP says that unconditional rebates differentiate the purchase price between customers and may have exploitative and exclusionary effects. Selectivity will be taken as an important part of the evidence to show that there is \textit{an intent to predate} and the Commission will presume predation and therefore that the rebate is abusive in circumstances where the price for the additional unit purchased by the buyer is below average total cost.\footnote{DP, paragraph 171.}

In addition, the DP says that rebates cannot be defended on the basis of a "meeting competition defence".\footnote{DP, paragraph 176.} It is not clear why this should be so. If a firm (X) reduces prices, (Y) can follow. If X starts to use single branding, why should Y not use single branding? Y may be dominant with a market share of approximately 40%. X may be nearly as large. On the basis of the approach set out in the DP, Y could not defend itself from X's advances on its position by single branding or offering rebates. It would seem that Y would have to wait until X had a market share in the region of 40% before Y could respond to X's conduct and then only through a legal challenge to its conduct by way of a complaint to a competition authority or to a national court. This is not good law.

In conclusion, the Commission's approach to the assessment of rebates lacks legal certainty and confers on the Commission a wide discretion for a finding of abuse. The Commission's approach to rebates is confused, the Commission introduces complex concepts for which it provides no clear guidance, its approach comprises presumptions of abuse largely based on the concepts of "commercially viable amount/share" and "required share", it also includes presumptions of abuse on the basis of intentions to predate. Presumptions of abuse on the basis of intentions to predate or otherwise, is a form based approach and is not consistent with an effects based application of Article 82.

The DP is hostile to rebates. It would seem that rebates would mostly all be presumed abusive and that once the presumption has been made it would be almost impossible for the dominant company to rebut the presumption. This is because the efficiencies/objective justification principles in paragraphs 172 to 176 inclusive would be extraordinarily difficult for a dominant firm to establish.
The DP needs to clearly distinguish the current decisional practice of the Commission and the European Courts and clearly explain how it is going to move from a form-based to an effects-based approach. It needs to provide clear parameters within which rebates will be assessed and clear guidelines on what types of rebates will be abusive and in what circumstances. In this context, we would suggest that safe harbours could be provided for some forms of rebates.

7.4 Refusal to supply

EFPIA has dealt in detail with the issue of refusal to supply in the context of the pharmaceutical industry and will therefore refrain from repeating those arguments here. Nevertheless, EFPIA's earlier observations are broadly relevant to the approach that has been taken in the DP to refusals to supply and, in this context, EFPIA recommends the Commission has reference to its earlier observations.\(^{44}\)

Freedom of contract is a general principle of EC and national law. As a starting point firms must be entitled to plan the distribution of their products in the way that most efficiently serves the requirements of their customers in the territory in which the products are distributed and that ensures continuity and quality of supplies.

An exception to the freedom of contract must be very strictly circumscribed, clearly defined and benefit final consumers.

The DP says that for a refusal to supply to be abusive, it must "have a likely anti-competitive effect on the market which is detrimental to consumer welfare".\(^{45}\)

The Commission cautions against finding a refusal to supply abusive on the basis that forcing companies to supply can have both negative and positive effects on investment incentives. The DP says "[T]he knowledge they may have a duty to supply against their will might lead companies not to invest in the first place or to invest less. Other companies may be tempted to free ride on the investment made by the dominant company instead of investing themselves ...."\(^{46}\)

The DP continues:

"Given these considerations, any obligation to supply pursuant to Article 82 can be established only after a very close scrutiny of the factual and economic context; the factors which go to demonstrate that an undertaking's conduct in refusing to supply is abusive are highly dependent on the specific economic and regulatory context in which the case arises."\(^{47}\)

The clarity of the Commission's approach in this context is welcome. However, it is noteworthy that of all the issues the Commission says that it will look at in considering whether or not a refusal to supply is abusive, the Commission makes no

\(^{44}\) EFPIA Report: "Article 82 EC: Can it be applied to controlled sales by pharmaceutical manufacturers to wholesalers?", November 2004, section IV.

\(^{45}\) DP, paragraph 210.

\(^{46}\) DP, paragraph 213.

\(^{47}\) DP, paragraph 214.
mention of the extent to which state regulation would, in whole or in large part, preclude any anti-competitive effects flowing from a refusal to supply. We think that state regulation is a particularly important consideration in the assessment of anti-competitive effects in relation to refusals to supply in industries that are highly regulated. In *Syfait*, Advocate General Jacobs said:

"It is impossible, when assessing conduct of the kind at issue in the present proceedings [namely refusal to supply], to ignore the pervasive and diverse regulation to which the pharmaceutical sector is subject both at national and Community levels, and which appear to me to set it apart from all other industries engaged in the production of readily traded goods." \(^{48}\)

In all member states, pharmaceutical companies are under a public service obligation to ensure a continuous supply of the prescription medicines they sell in order to meet the requirements in each Member State. In such circumstances the national regulatory regimes are clearly ensuring that consumer welfare is protected by the continued supply of the right volume and quality of products to meet national demand. In such circumstances it is perhaps beyond the realms of the possible that a refusal by a pharmaceutical company to supply any quantities over and above this amount would be against the consumer interest and thereby abusive. It would seem that, in this set of circumstances, the intervention of competition law would very likely upset or undermine the equilibrium in the balance of interests that has been achieved by national regulation.

As Advocate General Jacobs said in *Syfait*:

"In the pharmaceutical industry, what prevents wholesalers from exporting products in their possession is apparently the position of public service obligations, which require them to maintain sufficient stock to meet domestic demand. The market-partitioning effects associated with the restriction of supply results from the measures of the national authorities in the State of export."

In particular, Advocate General Jacobs remarks that:

"...given the specific economic characteristics of the pharmaceutical industry, a requirement to maintain supply would not necessarily promote either free movement or competition, and might harm the incentive of pharmaceutical undertakings to innovate" \(^{49}\).

Moreover, Advocate General Jacobs recognises that if pharmaceutical companies were at risk of being forced to maintain supplies, such obligation could be materially detrimental to the consumer interest. Such obligation may have the effect, he recognises, that pharmaceutical companies might delay the launch of new products in those member states as a result of which the levels of output and consumer welfare generated by some pharmaceutical products would therefore fall within the Community.

\(^{48}\) *Syfait v GSK*, Case C-53/03, paragraph 77.

\(^{49}\) Ibid, paragraph 100.
We consider that given the pervasive regulation to which certain industry sectors are subject, a refusal to supply above and beyond which is required under the public service obligation could never be abusive. As we have discussed above, in Syfait, Advocate General Jacobs suggested that there may be certain types of conduct that are just not abusive. We suggest that the DP includes safe harbours for certain kinds of conduct and that in respect of highly regulated industries such as the pharmaceutical industry, such a refusal to supply is included in that safe harbour.

7.5 Refusal to provide access to intellectual property rights

The DP acknowledges the established principle under EC competition law that a refusal to licence an intellectual property right will only be abusive in exceptional circumstances. The underlying reason for this approach is the need to preserve companies' incentives to engage in research and development and other ventures aimed at generating innovative products and services. The DP acknowledges this and says there would be a chilling effect on innovation in the event that third parties were to have a right to a successful company's intellectual property rights as soon as the company became dominant. We support the Commission in its approach. However, such are the exceptional circumstances that would render a refusal to licence an intellectual property right abusive, we think that a straightforward refusal to licence an intellectual property right should be included in a safe harbour as a form of conduct that is not abusive. We think that an analysis of the leading cases in the EC support such an approach. We also think that the approach that has been taken in the US is noteworthy. We will look at the position in the US first.

The general rule in the US is that a firm, even a monopolist, is not obliged to cooperate with its competitors. In Trinko, for example, it is said that a refusal "is not exclusionary or predatory" unless it would make no economic sense for the defendant but for its tendency to eliminate or lessen competition. In Trinko the court emphasised strongly that it is not unlawful for a firm to exploit its market power. The rule is that a monopolist has a right to refuse to deal with other firms and that exceptions to the rule will be rare.

Also in Trinko the court highlighted the policy reasons behind limiting duties to share:

"Compelling that firms share the resources that give them a competitive advantage is in tension with the underlying purposes of the antitrust laws. A duty to share lessens incentives for a firm, and its rivals, to invest in developing those resources. Forced sharing also requires the courts to determine when resources are competitively advantageous and indispensable and at what price they should be made available, a set of decisions better left

50 In Syfait, AG Jacobs decided that a refusal is justifiable as a reasonable and proportionate measure in defence of an undertaking's commercial interests. This is the case where the price differential giving rise to the parallel trade is the result of State intervention in the country of export to fix the price at a level lower than that which prevails elsewhere in the EU, combined with the specific economic and regulatory characteristics of the pharmaceutical industry.

51 DP, paragraph 239.

52 DP, paragraph 238.

to the market. Compelling cooperation between competitors may facilitate collusion, "the supreme evil of antitrust".\(^{54}\)

The policy reasons expressed in *Trinko* accord with the principles set out in the Lisbon Agenda. They all support the principle that a per se refusal to licence an intellectual property right would not be abusive.

The case-law of the ECJ on the exercise of proprietary rights and/or essential facilities provides that, *by exception* to the general principle that a refusal to grant access is not abusive, there is a very narrow range of circumstances in which a dominant undertaking will be obliged to licence its intellectual property rights or open up its facilities. But for such to be the case some *exceptional* harm to competition must be shown. Notable cases include *Magill*\(^{55}\), *Ladbroke*\(^{56}\) and *IMS*\(^{57}\) which consider access to intellectual property rights and *Oscar Bronner*\(^{58}\) which considers access to infrastructure. These cases will be looked at in turn.

In *RTE and ITP v Commission* ("*Magill*")\(^{59}\), the ECJ confirmed the judgment of the CFI that television broadcasters in Ireland had abused the dominant position which they held on the market for their television programme schedules, by invoking their copyright over such listings so as to prevent third parties from publishing a single weekly guide which would have competed with the guides which each publisher published for its own programmes. The ECJ held:

(a) The exercise of a proprietary right, even if it is the act of an undertaking holding a dominant position, cannot *in itself* constitute abuse of a dominant position, but may, *in exceptional circumstances*, involve an abuse (paras 49-50).

(b) The exceptional circumstances in *Magill* were constituted by the fact that the refusal in question concerned a product (information on the weekly schedules of certain television channels) the supply of which was *indispensable* for carrying on the business in question (the publishing of a general television guide), in that, without that information, the person wishing to produce such a guide would find it *impossible* to publish it and offer it for sale (para 53), the fact that such refusal prevented the emergence of a new product for which there was a potential consumer demand (para 54), the fact that it was *not*

\(^{54}\) Ibid, paragraph 408.


\(^{59}\) See footnote 46 above.
justified by objective considerations (para 55), and it was likely to exclude all competition in the secondary market (para 56).\(^{60}\)

In \textit{Tiercé Ladbroke}\(^{61}\) it was claimed that French horse racecourses were unlawfully refusing to give a copyright licence to Ladbroke to transmit live pictures of French races in its betting shops in Belgium. The CFI held:

"[T]he refusal to supply could not fall within the prohibition laid down by Article [82] unless it concerned a product or service which was either essential for the exercise of the activity in question, in that there were no real or potential substitutes, or was a new product whose introduction may be prevented, despite specific, constant and regular potential demand on the part of consumers."

Such was not in fact the case.

In \textit{IMS Health}\(^{62}\), the ECJ held that, in order for a refusal by an undertaking to give access to a proprietary right which it owns and which is indispensable for carrying on a particular business to be treated as abusive, three cumulative conditions must be satisfied, namely, that the refusal:

(i) prevents the emergence of a new product for which there is a potential consumer demand;

(ii) is unjustified; and

(iii) is such as to exclude any competition on a secondary market.

In relation to proprietary rights, the case-law of the ECJ is clear that exceptional circumstances will present in circumstances only where access to an intellectual property right of a dominant company is genuinely essential to market entry, and where lack of access to it is likely to exclude all competition, and where there is no objective justification for refusing access to it. If those exceptional circumstances exist, only then will the dominant company be obliged to provide access to it. The case-law of the ECJ is clear that it is not sufficient that access would be convenient or "suitable" for competitors to have access\(^{63}\); access to the facility must be indispensable\(^{64}\).

In \textit{Oscar Bronner}\(^{65}\), the dominant company did not enjoy a proprietary right. The issue before the ECJ concerned the extent to which a dominant undertaking is obliged, under Article 82 EC, to make its physical infrastructure available to competitors, to

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\(^{60}\) See the summary of the \textit{Magill} judgment in Case C-418/01 \textit{IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG} [2004] ECR I-5039 para 37. (see footnote 48 above)


\(^{62}\) Case C-418/01, \textit{IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG} [2004] ECR I-5039 para 38. (see footnote 48 above)


\(^{64}\) See footnote 48 above.

\(^{65}\) See footnote 49 above.
assist them in competing with it. The ECJ was asked whether it constituted an abuse for a newspaper group holding a substantial share of the market in daily newspapers to refuse to allow access to its delivery network to the publisher of a competing newspaper. The ECJ held (para 41) that such a refusal could only constitute an abuse if:

(a) it would be likely to eliminate all competition in the daily newspaper market on the part of the person requesting the service;

(b) the refusal was incapable of being objectively justified; and

(c) the service requested was indispensable for the carrying on of the business of the person requesting the service.

In order to prove that the service requested was indispensable, it was not enough for the competing newspaper to argue that it was not economically viable for it to set up its own distribution system given its own small circulation. It had to be shown that it was not economically viable to create a second home-delivery scheme with a circulation comparable to that of the daily newspapers distributed by the existing scheme (paras 45-46).

7.6 A lowering of the bar for a finding of abuse?

Another reason why we have referred to the above cases in a degree of detail is because notwithstanding the pronouncement in the DP that a refusal to licence an intellectual property right will only be abusive in exceptional circumstances, it seems that the DP introduces some matters that it says need to be looked at to ascertain whether those exceptional circumstances exist. Those new matters appear to point to a lowering of the bar for a finding of abuse and introduce an element of uncertainty in connection with an assessment of whether or not a refusal to licence is abusive, which did not previously exist.

In paragraph 239, for example, the DP maintains that there will be an abuse if the effect of the refusal to grant access to the intellectual property right "might prevent the development of the market for which the licence is an indispensable input to the detriment of the consumer". The DP provides no guidance on what any of this means. What does "might" mean? "Might" is a very low threshold test. Moreover, in practice it is very likely to operate as a catch all. What does "prevent the development of the market" mean? Whose "market" are we talking about? Might there be an abuse, for example, if a pharmaceutical company were to deny a generic a licence without which the generic would not be able to manufacture a competing product? Might there be an abuse if a pharmaceutical company refused a competitor a licence to develop a new non-competing product?

In paragraph 240 of the DP, the Commission says that a refusal to licence an intellectual property right will be abusive if it is "indispensable as a basis for follow-on innovation" by competitors even if it is not going to be incorporated or used in the production of clearly identifiable new goods. Again, there is no guidance in the DP on what this means. Might a generic product be "follow-on innovation"? Is combination therapy "follow-on innovation"? If the intellectual property right is indispensable for the follow-on innovation, does it follow that the intellectual property
right is an essential facility? If so, it would seem that the intellectual property right would then have to be licensed to all comers, including direct competitors? What is an identifiable new good? For industries built on innovation, these are material issues.

Moreover, in the light of the developed case law, all of the above issues represent a retrograde approach to IP licensing and the circumstances in which a refusal to licence would be abusive. Worryingly the Commission appears to be taking a purposeful stride towards compulsory licensing in a variety of ill-defined circumstances.

As we have said above, our view is that a straightforward refusal to grant access to an intellectual property right is not abusive and should be included in a safe harbour for conduct of a type that is not abusive. Intellectual property rights are an important reward for investment in research and development and any step towards diluting their value through the application of competition law would be directly counter to the principles of IP law and the Lisbon Agenda. It is perfectly plausible that such a development could have a chilling effect on risk taking in fast-moving innovative industries and could lead to a dilution in investment in R&D in the EU.

The Commission’s position for a modernised Article 82 ought to be that a refusal to grant access to an intellectual property right is per se legal. A refusal will be abusive in exceptional circumstances only and those exceptional circumstances do not go beyond those identified in IMS Health66.

66 Ibid, see footnote 48 above.
8. **CONCLUSION**

In short, we think that for a clear and coherent application of a modernised Article 82 it is essential that:

- the objective of Article 82 is clearly identified. What is meant by consumer welfare?
- it is recognised that a SSNIP test is an inappropriate test for defining the relevant market in some industry sectors and the Commission develops a framework which is truly based on the identification of close product substitutes in the context of the characteristics of the industry concerned;
- there is a rigorous effects-based approach that includes a thorough screen for dominance requiring a demonstration of substantial and durable market power;
- the mean for assessing consumer welfare effects is developed to provide a counterweight to any bias towards the protection of competitors;
- there would be no finding of dominance below a market share of at least 40%. Safe harbours would not operate, by default, as presumptions of dominance;
- there are clear legal rules and safe harbours for conduct that is competition on the merits such as the introduction of new products certain forms of rebates and certain kinds of refusals to supply;
- a refusal to grant access to an intellectual property right is per se legal. A refusal will be abusive in exceptional circumstances only and those exceptional circumstances ought not to go beyond those identified in *IMS Health*;
- conduct is deemed lawful, even if it is potentially exclusionary, where there is no workable and adequate remedy;
- conduct is assessed on the basis of objective standards. There should be no place for either subjective intent to injure a competitor or for subjective concepts of fairness.

In the speech Commissioner Kroes delivered at Fordham last year, she remarked that the Commission would be searching for sensible "rules" that would enable the Commission to reach preliminary conclusions about when conduct may exclude competition, and at the same time allow companies to know when they are on safe ground. The DP needs to be variously developed and clarified in a significant number of areas before the DP satisfies the benchmark that has been set by Commissioner Kroes. We have sought in this paper to identify some of those areas.

**EFPIA**

30 March 2006