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The European, Middle Eastern and African Antitrust Review 2019

A Global Competition Review Special Report

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Global Competition Review is delighted to publish 2019 edition of *The European, Middle Eastern & African Antitrust Review*, one of a series of three special reports that have been conceived to deliver specialist intelligence and research to our readers – general counsel, government agencies and private practice lawyers – who must navigate the world's increasingly complex competition regimes.

Like its sister reports, *The Antitrust Review of the Americas* and *The Asia-Pacific Antitrust Review*, *The European, Middle Eastern & African Antitrust Review* provides an unparalleled annual update, from competition enforcers and leading practitioners, on key developments in the field.

In preparing this report, *Global Competition Review* has worked with leading competition lawyers and government officials. Their knowledge and experience – and above all their ability to put law and policy into context – give the report special value. We are grateful to all of the contributors and their firms for their time and commitment to the publication.

Although every effort has been made to ensure that all the matters of concern to readers are covered, competition law is a complex and fast-changing field of practice, and therefore specific legal advice should always be sought. Subscribers to *Global Competition Review* will receive regular updates on any changes to relevant laws over the coming year.

Global Competition Review

London June 2018

Economics: Overview

David N Mishol and Joshua White Analysis Group

Introduction: pharmaceutical market definition and pricing

The pharmaceutical industry has been under increasing scrutiny over the past few years by several different agencies. This includes the European Commission Directorate-General for Competition (DG Comp) as well as a number of national competition authorities (NCAs), such as the UK's Competition and Markets Authority (CMA). Many of the cases in question concerned antitrust allegations against branded pharmaceutical manufacturers; collectively, they have resulted in nearly €750 million in fines, with a number of active investigations still pending.

The cases thus far have largely pertained to two types of pharmaceutical company conduct: 'pay-for-delay' and excessive pricing. In the pay-for-delay cases, the allegations relate to payments or considerations made by a branded pharmaceutical manufacturer to generic manufacturers in exchange for an agreement to delay generic entry, thereby allegedly reducing the potential competitive constraints faced by the branded manufacturer. This reduction in competitive constraints allows the manufacturer to continue to charge a price in excess of what would prevail if the generic were to enter in a more timely way. In the excessive pricing cases, drug manufacturers allegedly take advantage of weak competitive constraints to charge supra-competitive prices.¹

A key question in both types of cases is whether the drugs under investigation face competition from other drugs already on the market or soon to be on the market. In the case of excessive pricing allegations, existing competitive constraints may prevent the accused manufacturer from charging supra-competitive prices, while in the case of pay-for-delay, preventing generic entry may have limited competitive effects if there are already strong competitive constraints from substitutable drugs. Assessing the nature of these competitive constraints requires a market definition exercise whereby the authority considers the extent to which other treatments, including patented and generic drugs, can serve as effective substitutes for the drugs under investigation.

Market definition is a well-understood concept in competition and antitrust economics, with standardised tools such as the hypothetical monopolist test (HMT). However, the pharmaceutical industry has a number of unique features - including price regulation, drug certification and patient response to therapeutic options - that can complicate attempts to use standard techniques to define the product market. Nonetheless, there are a number of economic analyses that, when combined with a careful assessment of regulatory pricing schemes across Europe, can be used to assess the extent of competitive constraints facing a drug. In the remainder of this article, we first describe a number of possible product market definitions observed in the pharmaceutical industry and discuss findings by DG Comp and NCAs with regard to market definition in their recent pay-for-delay and excessive pricing findings. We then set out a number of economic analyses that can be used to assess relevant pharmaceutical product markets and consider the complexity of comparing prices across geographic markets, before concluding with some thoughts on the implications for future investigations.

Pharmaceutical product market definition: what are the options?

Prior to conducting an empirical analysis, there are multiple hypothetical options for defining a product market in the pharmaceutical industry.

The narrowest market definition would include only the branded drug while it is still on patent.² In this case, the drug has a monopoly within its relevant product market, and therefore, by definition, the manufacturer of that drug is dominant within the relevant market. If an authority were to define the market in this way, Prozac, for example, would be considered its own relevant product market while it was on patent, even though there were other branded selective serotonin reuptake inhibitors (SSRIs) on the market at the time.

The next wider potential relevant product market would include not only the branded drug but also generic versions of the same drug.³ Under this definition, the competition within the market would be considered to be between both the branded version and the generic versions of the same molecule (again excluding other branded and generic drugs based on different molecules). When a drug is still under patent, this relevant market would consider the potential entry of generic competitors. Continuing with the Prozac example, the relevant product market under this definition would include all other drugs based on the molecule fluoxetine.⁴

Broadening the market further, another option might be to include similar therapeutic treatments in the same class of drugs. Under this market definition, for example, all branded and generic SSRIs would be included in Prozac's relevant product market.⁵ Depending on the therapeutic class of drugs, the move from the Anatomical Therapeutic Chemical Classification System (ATC) Level 5 market to the ATC Level 4 market may significantly broaden the potential competitive constraints for the drug at issue.

Finally, the broadest relevant product market contains other therapeutic treatments that may be based on different classes of molecules but are available substitutes to treat a patient's condition. Again, using the example of Prozac, this widest potential relevant product market would include not only all branded and generic SSRIs, but potentially other types of antidepressants (eg, one or more drugs from the ATC Level 3 category of antidepressants such as non-selective monoamine reuptake inhibitors) as well.

While the appropriate market definition is a matter for empirical analysis, from a conceptual standpoint, definitions that include a wider range of products will increase the number and strength of the competitive constraints facing the drug under investigation. As such, if an empirical review suggests that a broader market definition is appropriate, a drug is less likely to be dominant within such a relevant product market, and the potential effect of any agreement between the branded manufacturer and generic manufacturers lessens.

Overview of recent pay-for-delay and excessive pricing matters

Historically, in its assessment of mergers of pharmaceutical companies, DG Comp has started with an ATC Level 3 market determination (all relevant therapeutic substitutes) and then proceeded to narrow the market based on specific factors.⁶ Recently, however, both DG Comp and other NCAs have appeared to depart from this broad-to-narrow approach and have adopted very narrow market definitions in their pay-for-delay and excessive pricing findings.

For example, in recent pay-for-delay matters where decisions have been released, the authority found that the relevant product market was the drug molecule (ATC Level 5), implying that other molecules do not provide significant competitive constraints.

In 2013, DG Comp fined Lundbeck €94 million for entering into agreements in 2002 with generic manufacturers to delay the entry of generic versions of Lundbeck's best-selling antidepressant based on citalopram to the EU market. As part of the decision, DG Comp defined the relevant product market as products with the active ingredient citalopram. However, DG Comp noted that even in a broader market that consisted of all antidepressant drugs, Lundbeck still would have held a significant market share in most European Economic Area countries.

Similarly, in 2014, DG Comp fined Servier \in 331 million for entering into agreements with generic manufacturers to delay generic entry for its blood pressure medication based on the perindopril molecule. In finding that the relevant product market was for products with the perindopril molecule, DG Comp commented that 'perindopril faced no significant constraints and therefore the single product market represents the relevant dimension for the product market,'⁷ and that 'the limited effectiveness of constraints imposed by other medicines stands in stark contrast to the strength of the constraint expected from (and eventually introduced by) perindopril's own generics.'⁸

In 2016, the CMA fined GlaxoSmithKline (GSK) £37.6 million for engaging in a pay-for-delay scheme relating to its antidepressant based on paroxetine. In 2018, the Competition Appeals Tribunal (CAT) handed down a decision confirming the CMA's finding of a molecule-level relevant product market, thereby excluding other SSRIs from the relevant product market.⁹ Notably, while the CAT ultimately agreed with the CMA's market definition findings, it disagreed with the CMA's application of an HMT in the pharmaceutical market in the UK, noting that 'with a prescription medicine, the choice of product is not made by the person who pays for it: the prescribing doctor chooses the drug, whereas it is the NHS, by reimbursing the pharmacy, which pays the price. Hence, at least at the relevant time, GPs were relatively insensitive to price¹⁰

With respect to excessive pricing matters, while DG Comp's investigation of Aspen with regard to the excessive pricing of a number of oncology drugs is ongoing, both the Italian Competition Authority and the CMA have similarly defined very narrow relevant product markets in their decisions.

In 2016, the Italian Competition Authority fined Aspen \in 5.2 million for abusing its dominant position to charge excessive prices for four chemotherapy drugs. In coming to its conclusion, the Authority determined that the relevant product market was at the molecule level, and cited the limited substitutability of other chemotherapy treatments as justification for its narrow definition.

Also in 2016, the CMA fined Pfizer and Flynn Pharma £89.4 million for charging excessive prices to the UK's National Health Service (NHS) for phenytoin sodium capsules, an antiepilepsy drug. In reaching its decision, the CMA defined a very narrow relevant product market: Pfizer-manufactured phenytoin sodium capsules. Despite credible evidence of the entrance of a new competitor (NRIM) that captured approximately 30 per cent market share, the CMA did not consider it sufficient to discipline pricing behaviour by the parties, as pharmacists were reluctant to switch patients away from their existing medication.

These recent decisions suggest that the European competition regulators are defining pharmaceutical product markets narrowly. While for certain products – especially those for which there are significant differences in side effects, dosage regimens or pharmacodynamics between treatments – narrow market definition might be appropriate, in many other cases the appropriate relevant product market is broader. Defining a product market too narrowly will lead authorities to a finding of dominance by the manufacturer where none exists, and to associated violations and fines that may not be warranted.

Defining the correct relevant product market requires empirical analysis, particularly in a world where regulatory authorities have power over pricing and use competing brands as a basis to set prices for new molecules. In the remainder of this paper, we consider a number of economic analyses to assess the appropriate relevant product market in pharmaceutical markets from an economic perspective.

Potential tools for an economic assessment of relevant pharmaceutical product markets

With the number and types of medical treatments increasing every year, what sources of data and what types of analyses are useful in assessing product market definition in pharmaceutical markets? As the CAT pointed out in its *GSK* decision, the traditional economic market definition tool, the HMT, is likely to be of limited usefulness in pharmaceutical markets, since at least some physicians may be less price-sensitive than consumers or payors as they seek the most appropriate treatment for a condition.

There are, however, a number of analyses – based on prescription patterns and switching data, marketing spend, and quality-adjusted prices – that can provide useful information to companies and authorities on the borders of the relevant product markets.

What can evidence on substitutability tell us about the relevant product market?

When assessing the degree of competition among pharmaceutical products for market definition purposes, the starting point for analysis should be an investigation of the potential set of treatments that physicians consider for a given condition or a given patient. Once a set of potential treatments is identified – from the academic literature, the product labels, or treatment guidelines from medical associations or medical regulators – data on the relative sales of these drugs over time can be compiled. The effect of new branded or generic drug entry, revised indications, safety warnings, and changes in patent status can all provide useful input with which to assess how the sales of a particular drug respond to the presence and sales of other drugs. It is important when undertaking this type of analysis to include all potential competitive alternatives, so that the resulting relevant product market is not defined too narrowly.

One approach that may help delineate and inform product market definition is an assessment of individual-level switching data, to determine what drugs are actually competitive alternatives within a therapeutic class. Patients with long-standing or chronic conditions often switch among treatments for a number of reasons, including the presence of side effects, efficacy of a specific treatment, easier dosage regimen or safety, but also price. Administrative claims data (available in several different European countries) can be well-suited to this type of analysis because they provide detailed profiles of patient experiences when treated with a specific drug, as well as any switching patterns among competing drugs in a therapeutic class. Results from this type of analysis can thereby provide key insights for delineating the potential boundaries of a product market and can complement the analysis of more aggregate data.

An example is provided by a review of the administrative claims history for selected patients in the US being treated for depression in the 2000–2005 period (during the period of time that Lundbeck entered into the allegedly anticompetitive agreements with generic manufacturers). The review showed that many of the patients being treated for depression during this time were switching frequently, not just between the branded and generic versions of the same molecule, but also across a number of different molecules within the SSRI class of drugs (including switching between brands). These findings suggest that the relevant product market could be at least as broad as all SSRIs.¹¹

For some patients, the switching may be driven by clinical considerations, which may suggest that the alternative SSRIs are not perfect substitutes for the patient. However, in other cases, particularly when significant levels of switching are observed, this may reflect the substitutability of the products via economic considerations. The fact that physicians have a number of drugs to choose from, all of which are equally appropriate for patients, at least ex ante implies that price can be a significant determinant of choice, and that the market should be defined to be wider than the molecule.

Furthermore, claims data can also be used to assess product market boundaries by providing detail on the impact from generic entry. For example, in 2001 Prozac became the first SSRI antidepressant to go off patent, resulting in an immediate and dramatic drop in Prozac sales, coupled with a rise in sales of generic fluoxetine. Shortly after generic entry, however, an analysis of the switching patterns for patients still being treated with branded Prozac showed that only a small percentage of them were switching into generic fluoxetine from branded Prozac, while significant numbers of patients being treated by both Prozac and generic fluoxetine were switching to other branded SSRIs. This analysis suggests that in the early 2000s, fluoxetine was not only competing with the branded version of the same compound, Prozac, but also with other SSRIs in the same therapeutic category, indicating a relevant product market broader than the molecule level. This competition between fluoxetine and the branded products suggests, in turn, that Prozac was also in competition with the other branded SSRIs.

The analysis of claims data, where available, can therefore provide helpful boundaries to delineate a potential product market, both at a single point in time and across time. However, while such evidence is a very useful starting point, further analysis or other sources – including company documents, marketing strategies or testimony – can be used to further distinguish between switching for economic rather than clinical reasons.

Marketing data: evidence of competition among branded products

Manufacturers of branded pharmaceuticals incur significant expenditures marketing their on-brand products (via detailing, sampling and advertising, and more recently in the form of online and digital initiatives), in an effort to promote their products. Economic and marketing literature has shown that when scientific advances are associated with a specific pharmaceutical product, its manufacturer tends to spend more on marketing (eg, increasing expenditure when new indications are approved).¹² Importantly for the assessment of product market definition, these marketing efforts can also be directed at encouraging switching between different products within therapeutic classes. There is evidence that marketing intensity for branded products also increases as more on-brand products in a given therapeutic class enter the market, providing some indication of between-brand competition within a therapeutic class.¹³ The evidence also shows that certain marketing efforts, such as detailing and drug samples, have a positive effect on new prescription behaviour, although the effects may be modest.¹⁴

Furthermore, when an on-brand product faces patent expiration, marketing efforts by the branded manufacturer tend to decline markedly. As generic products typically have significantly lower prices than branded products, the positive effect of marketing expenditures on sales can be outweighed by the increase in patients switching to the generic products. Crucially, however, there is also evidence of a reduction in marketing spend by other branded manufacturers within the same therapeutic class, indicating that other manufacturers see the entry of a generic competitor as a strong competitive constraint, even when that generic is based on a different molecule.¹⁵

A number of companies provide marketing spend data for pharmaceutical companies at the brand level, and, as such, marketing data may be analysed econometrically to determine the extent to which manufacturers demonstrate a competitive response to new product entry (both branded and generic). Significant responses both to other branded drugs and to generics based on other molecules entering the market would be an indication that the relevant product market is broader than the molecule level. Finally, a qualitative review of the marketing materials (eg, competitive intelligence, marketing strategy) produced by branded manufacturers can provide contemporaneous evidence of the alternative treatments that the manufacturer considers to be within its market.

Regulatory considerations of pharmaceutical prices

Another consideration in an assessment of the relevant product market is how regulatory schemes in different countries affect the pricing of drugs. Pharmaceutical manufacturers do not sell directly to the consumer in Europe, or indeed, in most of the world. Governments and private third parties are heavily involved (along with the manufacturer) in the determination of prices, but the process varies across jurisdictions and over time. Recent studies of cross-country pharmaceutical price setting showed high levels of heterogeneity across European countries.¹⁶ In a number of countries all pharmaceutical products are price-regulated, while in others only some products are regulated. In a number of countries, the regulator groups pharmaceutical products into classes and applies reference pricing such that all products within the class are reimbursed at the same rate. Some regulators extend this reference pricing to consider the price of the same or similar products in other 'comparable' countries. Furthermore, in some countries the regulator sets an exfactory price, in others it sets the pharmacy reimbursement price, while in yet others it regulates the profit level of manufacturers.

These regulatory considerations must be taken into account as part of any market definition exercise. As a starting point, consider the fact that in several countries noted above, governments rely on a group of similar products for determining reference prices. Doing so suggests that these products are in the same market (which may be inconsistent with the finding that single molecules comprise the relevant product market). Pricing decisions by regulators, in particular, are partial determinants of the extent of price competition among drug manufacturers, and therefore suggest that the government considers these drugs to be in the relevant product market. Secondly, despite price controls, a manufacturer often still has some flexibility in setting its price. Investigating what other factors determine product prices (eg, underlying R&D costs, product quality, entry and prices of similar products) may provide further insight on market definition. Finally, there is evidence that regulatory involvement in the determination of pricing also impacts entry patterns of new drugs, typically delaying or reducing the likelihood of a product launch not only in the country involved in setting the price, but in other countries as well.¹⁷

Differences in the way prices are determined across Europe underscore the importance of a carefully measured approach to estimating prices and the impact of any alleged dominant position. Negotiated price targets, price ceilings and reference price systems imply that prices for the same product sold in different European countries are unlikely to be the same. Understanding the differences in these regulatory schemes across jurisdictions, as well as any intertemporal changes within jurisdictions, is relevant to any further analysis of prices as part of a market definition exercise.

Impact of product characteristics on price and assessment of competition

Frequently, competition investigations rest in part on observations of price differentials across products deemed similar or across time. In that context, differential regulatory schemes across countries must be carefully considered when interpreting price differences as indicative of an exercise of market power. Furthermore, comparisons across drugs that are superficially similar risks amalgamating compounds that are different in their therapeutic effect, side-effect profile, dosage, convenience or tolerability. Quality-adjusted price analyses are useful to ensure that comparisons are apples-to-apples and that observed price differentials are purged of any regulatory or quality-related effects before being compared and used as indicia of market power or excessive pricing.

The link between quality and prices can be an important consideration, for example, in assessments of market power and price-fixing, as well as in delineating the boundaries of a product market. Berndt, Cockburn and Griliches¹⁸ examine the impact of quality improvements (eg, better efficacy, improved safety, reduced drug interactions and more convenient dosing) on price indexes for antidepressant drugs using a combination of third-party pricing information and US Food and Drug Administration attribute information. After filtering out changes in these types of quality improvements, they find that price indexes for antidepressant products have lower growth rates than price indexes calculated without accounting for such quality improvements. Similarly, Suslow¹⁹ uses product attribute data to estimate a quality-adjusted price index for anti-ulcer drugs, which isolates pure price movements from those that are due to changes in quality. Overall, she finds a lower rate of price inflation for anti-ulcer products that are quality-adjusted compared to prices that are not adjusted for product characteristics. Lucarelli and Nicholson²⁰ focus on colorectal cancer drugs and estimate a price index that takes into consideration product characteristics such as efficacy and side effects, as well as the value assigned to drug quality by doctors. They show that a price index that does not account for these characteristics greatly overstates the price increase, but a quality-adjusted price index shows that prices have actually decreased slightly over the study period.²¹

As an example, the extent of price competition was raised as an indication of anticompetitive harm in a recent antitrust matter.²² In this matter, an analysis of nominal prices per patient-day of therapy showed that they roughly doubled between 1998 and 2003. While a portion of this increase was attributable to general inflation, much of the observed price rise appeared driven by the entry of new branded products with improved product characteristics and higher nominal prices compared to existing products within the same therapeutic class.

However, a quality-adjusted price analysis that included several different product characteristics – such as the number of approved indications, the number of adverse drug interactions, dosage strengths and frequency, and the existence of line extensions – showed that the quality-adjusted price of products in this therapeutic area was not rising over time, and even decreased as additional products with increasingly better quality characteristics entered the market. This, in turn, provided evidence of a significantly more price-competitive environment than was indicated by the simple analysis of the price of a patient-day of therapy. These results were used to counter the assertion of market power within this particular therapeutic class.

Conclusions

Market definition analysis is at the core of many recent cases brought forth by European agencies. The rulings in these pay-fordelay and excessive pricing cases indicate that governments appear to be adopting very narrow market definitions, typically limited to the molecule. This ignores the role of alternative-brand pharmaceuticals and generics that are different molecules but provide similar therapeutic benefits. Nonetheless, there are a number of economic analyses – combined with a careful assessment of regulatory pricing schemes across Europe (some of which consider the market to be broader than a single molecule) – as well as relevant regulatory, business and third-party documents, which can provide a more accurate assessment of the market. Such analyses help illuminate competitive constraints that are determinants of the relevant market, and will often point to a product market that is broader than a single molecule.

Notes

- 1 The legal framework for excessive pricing matters is based on the *United Brands* case and considers: (i) whether the price level bears any relation to costs; and (ii) whether it is unfair when compared to prices of competing products.
- 2 We are abstracting from an even narrower relevant product market, which considers only the branded drug at a specific dosage and method of release. For example, under this definition, Prozac 10mg/day delayed release tablets would be considered a distinct product market from Prozac 20mg/day immediate release.
- 3 The US Food and Drug Administration defines a generic drug as a drug containing the same active or key ingredient (molecule), having the same strength, and dosed and administered in the same way.
- 4 This product market is sometimes referred to as an ATC Level 5 product market. ATC stands for the Anatomical Therapeutic Chemical Classification System, and the Level 5 coding includes all drugs from the same molecule, eg, N06AB03 for fluoxetine.
- 5 This product market is sometimes referred to as an ATC Level 4 product market, eg, N06AB for all SSRIs.
- 6 For example, in the *Teva/Barr* merger, DG Comp started with ATC Level 3, and then identified specific drugs where that definition would not be appropriate (eg, DG Comp identified limited substitutability between

drugs in the LO1C ATC Level 3 classification, and then proceeded to narrow the market to the molecule level for paclitaxel). In the *Sanofi-AventislZentiva* merger, DG Comp again used ATC Level 3 classification as a starting point, and then narrowed a number of the markets based on information relating to substitutability. Notably, none of the resulting relevant product markets was defined at the molecule level.

- 7 Commission Decision, AT.39612 PERINDOPRIL (SERVIER), Directorate-General for Competition, 9 July 2014, paragraph 2535.
- 8 Id, paragraph 2545.
- 9 The CAT found that prior to generic entry the relevant product market would have included other SSRIs, but that the competitive constraint from a generic competitor was strong enough that following generic entry, the relevant market would be only those drugs based on the molecule paroxetine. The CAT, however, did refer the question of market definition to the Court of Justice of the European Union for further consideration.
- Judgment in Case No. 1252/1/12/16, UK Competition Appeals Tribunal, 8 March 2018, paragraph 384.
- 11 For a more detailed discussion of the example, see Greenberg, P, Mishol, D, Sisitsky, T, and Bruno, C, 'Appendix – Economists' Use of Data in Pharmaceutical Antitrust Cases,' *Pharmaceutical Industry Antitrust Handbook*, pp 409–412 (2009).
- 12 See, for example, Berndt, E, Bhattacharjya, A, Mishol, D, Arcelus, A, and Lasky, T, 'An Analysis of the Diffusion of New Antidepressants: Variety, Quality, and Marketing Efforts,' *Journal of Mental Health Policy and Economics*, Vol 5, No 1, pp 3–19 (2002).
- 13 ld.
- 14 See, for example, Mizik, N, and Jacobson, R, 'Are Physicians 'Easy Marks'? Quantifying the Effects of Detailing and Sampling on New Prescriptions,' *Management Science*, Vol 50, No 12, pp 1704–1715 (2004).

- 15 See, for example, Berndt, E, Kyle, M, and Ling D, 'The Long Shadow of Patent Expiration. Generic Entry and Rx-to-OTC Switches,' Scanner Data and Price Indexes, Feenstra, R, and Shapiro, M (eds), pp 229–274 (2003).
- 16 See Vogler, S, and Martikainen, J, 'Pharmaceutical Pricing in Europe,' Pharmaceutical Prices in the 21st Century, Babar, Z-U-D (ed), pp 343–370 (2015), and Kanavos, P, Fontrier, A-M, Gill, J, and Kyriopoulos, D, The Implementation of External Reference Pricing within and across Country Borders (2017).
- 17 See Kyle, M, 'Pharmaceutical Price Controls and Entry Strategies,' *The Review of Economics and Statistics*, Vol 89, No 1, pp 88–99 (2007).
- 18 See Berndt, E, Cockburn, I, and Griliches, Z, 'Pharmaceutical Innovations and Market Dynamics: Tracking Effects on Price Indexes for Anti-Depressant Drugs,' *Brookings Papers on Economic Activity: Microeconomics 1996*, pp 133–188 (1996).
- 19 See Suslow, V, 'Measuring Quality of Change in the Market for Anti-Ulcer Drugs,' Competitive Strategies in the Pharmaceutical Industry, Helms, R (ed), pp 49–72 (1996).
- 20 See Lucarelli, C, and Nicholson, S, 'A Quality-Adjusted Price Index for Colorectal Cancer Drugs,' National Bureau of Economic Research, Working Paper 15174 (2009).
- 21 An analysis of quality-adjusted prices does not always find that nominal prices overstate the actual price increase. Cockburn and Anis find that quality and price appear to be inversely correlated in the market of drugs used to treat rheumatoid arthritis. That is, they find that lower-quality products are associated with higher prices. See Cockburn, I, and Anis, A, 'Hedonic Analysis of Arthritis Drugs,' *Medical Care Output and Productivity*, Cutler, D, and Berndt, E (eds), pp 439–462 (2001).
- 22 For a more detailed discussion of the example, see Greenberg, P, Mishol, D, Sisitsky, T, and Bruno, C, 'Appendix – Economists' Use of Data in Pharmaceutical Antitrust Cases,' *Pharmaceutical Industry Antitrust Handbook*, pp 408–409 (2009).

ECONOMICS



David N Mishol Analysis Group

Dr Mishol specialises in antitrust, pharmacoeconomics, finance, microeconomic theory, statistics and econometrics. He has managed large, complex damages analyses for Fortune 500 companies; consulted in the areas of antitrust, securities, class certification, breach of contract and intellectual property; and provided expert testimony in general commercial litigation and damages cases. His work has included development of economic arguments and damages analyses in the pharmaceutical and medical device industries; development of economic analyses and econometric models to assess damages in the airline industry and personal computer hardware and software markets; development of econometric models to analyse loss causation in the structured finance market; and economic and quantitative analyses related to allegations of securities fraud in 10b-5, mortgage-backed securities and ERISA matters. Dr Mishol has also provided economic and quantitative analyses in several merger investigations, presenting findings to the US Federal Trade Commission and the US Department of Justice.

In non-litigation activities, he has used sophisticated econometric modelling techniques to help major pharmaceutical companies make product entry decisions by assessing the impact of market factors on the demand for prescription pharmaceuticals.

Dr Mishol holds a BA in economics from Brandeis University and a PhD in economics from Boston College.



Joshua White Analysis Group

Mr White is a consulting economist who specialises in applying microeconomics and sophisticated econometric modelling to address complex litigation questions, primarily in matters involving the healthcare, financial services and technology industries. Across a diverse set of engagements, he has implemented complex econometric models that quantify pricing differences between private hospitals, simulated consumer demand for computer processors, estimated ex ante default probabilities for structured investment vehicles and utilised auction data to value smart phone features, among other things.

Mr White has worked in a number of jurisdictions, including the United States, the United Kingdom, Canada, Japan and Belgium. He has served as a testifying expert in the Upper Tribunal (Lands Chamber) on competition matters related to restrictive land covenants. Mr White has supported several clients before the European Commission on cartel and merger matters, and has provided support to a number of European financial and competition regulators in coordinated conduct investigations. In addition, he has provided testimony and submissions to the UK's Competition and Markets Authority on behalf of clients involved in market investigations and mergers.

Mr White holds a BA in socio-political economics from Boston University and an MA in economics from the University of British Columbia.



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Analysis Group is one of the largest economics consulting firms, with more than 850 professionals across 14 offices in North America, Europe and Asia. Since 1981, we have provided expertise in economics, finance, healthcare analytics and strategy to top law firms, Fortune Global 500 companies and government agencies worldwide. Our internal experts, together with our network of affiliated experts from academia, industry and government, offer our clients exceptional breadth and depth of expertise.

Competition has been at the core of our work since our inception. We integrate industrial organisation theory, econometrics and industry-specific expertise, along with the latest quantitative analytical methods, to understand the conduct and market dynamics at issue in antitrust litigation, competition reviews and merger investigations. We have expertise in complex assignments related to collective actions and class certification, liability, quantum of damages, and the competitive effects of proposed mergers and acquisitions. Our competition work covers a range of industries and markets, including healthcare and pharmaceuticals, multisided markets, financial products, manufacturing and consumer products, high tech, insurance, and agriculture. We have provided support to internal and external experts in significant mergers and government competition investigations; have been involved in numerous high-profile monopolisation cases involving such companies as Microsoft and Intel; and have worked on some of the largest cartel cases in industries including credit cards, optical disc drives, vitamins, TFT-LCD panels, cathode ray tubes and auto parts. We have also been involved in a number of recent high-profile reverse-payment, product-hopping and delayed generic entry matters in the pharmaceutical industry.

