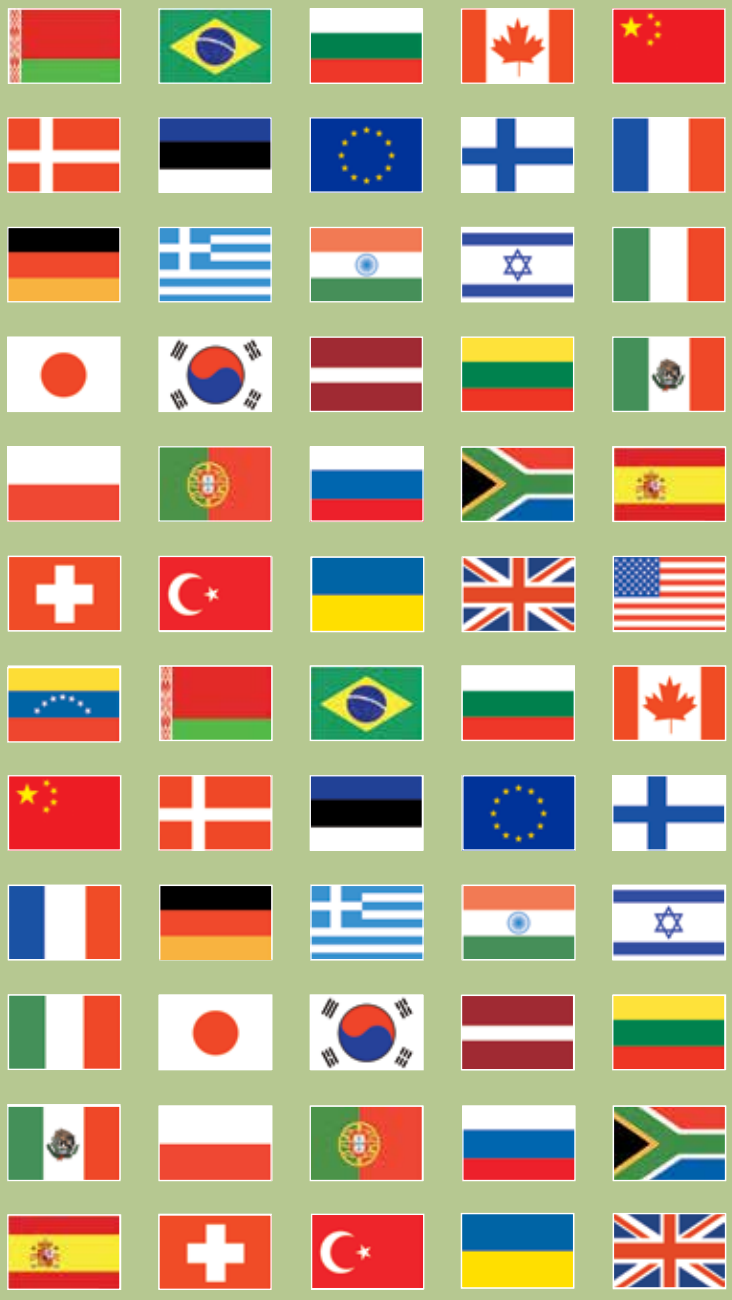
GETTING THE DEAL THROUGH

Pharmaceutical Antitrust

in 31 jurisdictions worldwide

2014

Contributing editor: Marleen Van Kerckhove



Published by
Getting the Deal Through
in association with:

Anderson Mōri & Tomotsune
Arzinger
AZB & Partners
Bech-Bruun
bnt attorneys-at-law
Caiado Guerreiro & Associados, RL
Calavros & Partners Law Firm
CMS, Russia
ELİG, Attorneys-at-Law
Fasken Martineau
Fortak & Karasiński Legal Advisors LLP
Hammarström Puhakka Partners, Attorneys Ltd
Hogan Lovells
Intuity
Kim & Chang
King & Wood Mallesons
Legal and Economic Avantgarde SC
Martínez Lage, Allendesalazar & Brokelmann
McDermott Will & Emery Studio Legale Associato
Meyerlustenberger Lachenal Avocats – Attorneys at Law
Oppenhoff & Partner
Pavlov and Partners Law Firm in cooperation with CMS
Reich-Rohrwig Hainz
Souza, Cescon, Barrieu & Flesch Advogados
Tadmor & Co Attorneys at Law
Torres, Plaz & Araujo
Torys LLP

Pharmaceutical Antitrust 2014

Contributing editor: Marleen Van Kerckhove Arnold & Porter LLP

Getting the Deal Through is delighted to publish the fully revised and updated seventh edition of *Pharmaceutical Antitrust*, a volume in our series of annual reports, which provide international analysis in key areas of law and policy for corporate counsel, cross-border legal practitioners and business people.

Following the format adopted throughout the series, the same key questions are answered by leading practitioners in each of the 31 jurisdictions featured. New jurisdictions this year include Israel, Poland and Spain.

Every effort has been made to ensure that matters of concern to readers are covered. However, specific legal advice should always be sought from experienced local advisers. *Getting the Deal Through* publications are updated annually in print. Please ensure you are always referring to the latest print edition or to the online version at www.GettingTheDealThrough.com.

Getting the Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. Getting the Deal Through would also like to extend special thanks to contributing editor Marleen Van Kerckhove at Arnold & Porter LLP for her continued assistance with this volume.

Getting the Deal Through
London
April 2014

Belarus 3
Alexander Liessem
bnt attorneys-at-law

Brazil 8
Fabíola Carolina Lisboa Cammarota de Abreu, Joyce Midori Honda and Luciano Inácio de Souza
Souza, Cescon, Barrieu & Flesch Advogados

Bulgaria 15
Dessislava Fessenko
Pavlov and Partners Law Firm in cooperation with CMS Reich-Rohrwig Hainz

Canada 19
R Jay Holsten and Dany H Assaf
Torys LLP

China 25
Susan Ning and Zhifeng Chai
King & Wood Mallesons

Denmark 31
Klaus Ewald Madsen, Jesper Kaltoft and Mark Gall
Bech-Bruun

Estonia 37
Aet Bergmann
bnt attorneys-at-law

European Union 42
Maxim Kleine, Daniel Dohrn and Julian Grosse
Oppenhoff & Partner

Finland 50
Klaus Nyblin and Tuomas Saraste
Hammarström Puhakka Partners, Attorneys Ltd

France 56
Christophe Hénin and Anne Servoir
Intuity

Germany 65
Maxim Kleine and Daniel Dohrn
Oppenhoff & Partner

Greece 73
Despina Samara
Calavros & Partners Law Firm

India 79
Samir R Gandhi, Kamya Rajagopal and Karan Vir Khosla
AZB & Partners

Israel 84
David E Tadmor, Shai Bakal and Ido Cnaan
Tadmor & Co Attorneys at Law

Italy 90
Veronica Pinotti, Martino Sforza and Nicolò di Castelnuovo
McDermott Will & Emery Studio Legale Associato

Japan 97
Yusuke Nakano and Junya Kubota
Anderson Mōri & Tomotsune

Korea 103
Hwa Soo Chung and Kyungsun Kyle Choi
Kim & Chang

Latvia 109
Theis Klauberg and Renārs Gasūns
bnt attorneys-at-law

Publisher
Gideon Roberton
gideon.roberton@lbresearch.com

Subscriptions
Rachel Nurse
subscriptions@gettingthedealthrough.com

Business development managers
George Ingledew
george.ingledew@lbresearch.com

Alan Lee
alan.lee@lbresearch.com

Dan White
dan.white@lbresearch.com

Law Business Research

THE QUEEN'S AWARDS FOR ENTERPRISE: 2012

Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 7908 1188
Fax: +44 20 7229 6910

First published 2008
Seventh edition
ISSN 1757-6288

Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112

CONTENTS

Lithuania 115
Yvonne Goldammer
bnt attorneys-at-law

Mexico 121
León Ricardo Elizondo
Legal and Economic Avantgarde SC

Poland 127
Sławomir Karasiński
Fortak & Karasiński Legal Advisors LLP

Portugal 133
Joana Gomes dos Santos
Caiado Guerreiro & Associados, RL

Russia 139
Maxim Boulba, Elena Andrianova and Maria Ermolaeva
CMS, Russia

South Africa 145
Stephen Langbridge
Fasken Martineau

Spain 152
Helmut Brokelmann, Mariarosaria Ganino and Claudia Fernández
Martínez Lage, Allendesalazar & Brokelmann

Switzerland 159
Simon Holzer, Pranvera Këllezi, Christophe Rapin and Kilian Schärli
Meyerlustenberger Lachenal Avocats – Attorneys at Law

Turkey 165
Gönenç Gürkaynak and K Korhan Yıldırım
ELİG, Attorneys-at-Law

Ukraine 172
Timur Bondaryev and Svitlana Malynovska
Arzinger

United Kingdom 179
Angus Coulter and Tim Capel
Hogan Lovells

United States 187
Robert F Leibenluft, Leigh L Oliver and Lauren E Battaglia
Hogan Lovells US LLP

Venezuela 195
Juan Domingo Alfonzo, Alejandro Gallotti and Maritza Quintero
Torres, Plaz & Araujo

United States

Robert F Leibenluft, Leigh L Oliver and Lauren E Battaglia

Hogan Lovells US LLP

Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs?

The Federal Food, Drug, and Cosmetic Act (FFDCA) and the Public Health Service Act (PHSA) provide the basic statutory framework for regulating drugs, and are primarily implemented by the Food and Drug Administration (FDA).

Generally, small molecule drugs are regulated under the FFDCA, which has distinct approval processes for innovator (brand name) and generic products, and a monograph system for some over-the-counter (OTC) products. Innovator drugs come to market by way of an approved New Drug Application (NDA), which requires proof of safety and efficacy. Generic drugs are approved under an Abbreviated New Drug Application (ANDA), which requires showing that the product is the same as, and bioequivalent to, an already approved product. Some OTC drugs come to market by meeting the standards in an FDA-established monograph, but other OTC products require an NDA or ANDA. Biologics generally are licensed under the PHSA. Innovator biologics are approved under a biologics licence application (BLA), which requires demonstrating safety and efficacy, and there also is an abbreviated approval process for follow-on biologics (see Update and trends).

The Drug Price Competition and Patent Restoration Act of 1984 (as amended), commonly known as the Hatch-Waxman Act, amended the FFDCA to establish a process by which generic drugs are approved. It provides incentives for innovator drugs by giving them five or three-year periods of exclusivity and a process by which to litigate certain patents related to the drug before a generic is approved. It encourages development of generic drugs by allowing them to be approved on the basis of sameness to an already approved innovator drug, and by providing 180 days' exclusivity for the first generic to challenge an innovator drug patent.

The Medicare Prescription Drug, Improvement and Modernisation Act of 2003 (MMA) (as amended) revised rules regarding certain approval stays and exclusivities under the Hatch-Waxman Act. It also requires innovator and generic companies that enter into certain types of litigation settlements to file copies of their agreement with the Federal Trade Commission (FTC) and the antitrust division of the Department of Justice (DoJ).

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) (as amended) created an abbreviated approval pathway for 'biosimilars', which are biologic drugs that are similar, but not identical, to an already approved biologic. Biosimilars also must demonstrate safety and efficacy, but the burden can be lessened to some degree by relying on the FDA's finding of safety and efficacy for the already approved product. For a biosimilar to be interchangeable with an already approved product requires additional data and a separate finding by the FDA. The biosimilars process provides periods of exclusivity for innovator biologics, as well as a process for the exchange of patent-related information to permit litigation on patents before approval of the biosimilar.

Generally, the advertising and promotion of prescription drug products and biologics is regulated under the FFDCA. The statute and regulations prohibit false and misleading representations and establish requirements regarding what information may be communicated, and how. Advertising for OTC drugs is governed by the Federal Trade Commission Act (the FTC Act), which prohibits false or misleading representations, and requires adequate substantiation for claims.

The pricing of pharmaceuticals purchased by commercial payers and private individuals is generally not subject to regulation in the United States. However, special pricing rules apply to certain purchases made pursuant to certain federal programmes. The Medicaid Drug Rebate Programme requires manufacturers that seek to have their drugs covered by Medicaid and Medicare Part B to enter into a rebate agreement with the Department of Health and Human Services (HHS), whereby the manufacturer must report the Average Manufacturer Price (AMP) for the drug, and in the case of innovator products (those approved under NDAs and BLAs), the manufacturer's 'best price' for the drug, which is defined in general as the lowest price at which the manufacturer has made that drug available to any commercial customer. The manufacturers are then required to pay quarterly rebates to state Medicaid programmes based on those numbers. The Veterans' Health Care Act of 1992 established what is known as the 340B drug pricing programme, which sets a mandatory price ceiling on the sale of covered drugs to certain government grantees, qualified hospitals, and other safety net providers. It also provides for discounts on pharmaceuticals purchased through the Federal Supply Schedule by several large federal agencies, including the Departments of Defense and Veterans Affairs. Finally, for drugs reimbursed under the Medicare Part B programme, such as physician-administered drugs, manufacturers must report the average sales price (ASP) on a quarterly basis, which is defined in general as the average of prices charged to all commercial customers. Those prices are then used to determine the reimbursement rates for the drugs under the Part B programme.

Several federal laws apply to the marketing of pharmaceuticals that are reimbursed under the Medicare or Medicaid programmes. The federal Anti-Kickback statute makes it a felony for any person to solicit or receive anything of value in return for influencing a person to use a particular drug, where that drug would be paid for under a federally funded health-care programme, unless a safe harbour is available. Recently, as part of health-care reform, Congress passed what is known as the Physician Payment Sunshine Provision. This provision generally requires pharmaceutical manufacturers to track payments worth $10 or more to physicians and other health-care workers and organisations. This information will then be made publicly available through an online database. Many states have enacted analogous state laws governing kickbacks and physician payments.

2 Which bodies are entrusted with enforcing these regulatory rules?

The FDA is responsible for the authorisation of drug products, monitoring the safety and efficacy of already approved drugs, and regulating the labelling and marketing of drug products and biologics. The FDA shares authority with the FTC for oversight over the advertising of OTC drugs. The Justice Department and the Office of the Inspector General of HHS share authority for investigating fraud and abuse violations related to the Medicare and Medicaid programmes. Specifically, the Justice Department focuses primarily on criminal cases and on enforcement of the False Claims Act, while the OIG has administrative enforcement authority to impose civil money penalties and to exclude individuals and entities from the Medicare and Medicaid programmes for fraud and abuse violations. HHS oversees certain federal drug pricing programmes.

3 Which aspects of this legislation are most directly relevant to the application of competition law to the pharmaceutical sector?

The sector-specific legislation described above affects competition by setting the conditions for the entry and marketing of pharmaceutical products in the US, and provides the regulatory context for analysing competition issues in pharmaceutical markets. The FFDCA prohibition against off-label marketing, for example, can limit the competitive significance of drugs with respect to the indications for which they are unapproved.

The legislation that has been most relevant to competition issues has been the Hatch-Waxman Act provisions that regulate the approval and entry of generic drugs. Enforcers and private plaintiffs have alleged that brand-name pharmaceutical manufacturers have abused or improperly manipulated this process to delay or restrict generic entry, and that the Hatch-Waxman framework provides opportunities and enhanced incentives for brand-name and generic manufacturers to enter into anti-competitive patent litigation settlements.

The BPCIA is only now being put into force; it remains to be seen to what extent it creates situations similar to what has occurred under the Hatch-Waxman Act.

Competition legislation and regulation

4 Which legislation sets out competition law?

The principal federal competition statutes in the United States are the Sherman Act, the Clayton Act, the FTC Act and the Robinson-Patman Act. Section 1 of the Sherman Act prohibits unreasonable restraints of trade, including per se illegal conduct such as price fixing and market allocation, as well as other forms of agreements that are evaluated under the 'rule of reason'. Section 2 of the Sherman Act also prohibits certain unilateral conduct, including obtaining or maintaining a monopoly through predatory or exclusionary means. Section 7 of the Clayton Act prohibits mergers and other acquisitions 'where the effect […] may be substantially to lessen competition or tend to create a monopoly in any line of commerce'. The Hart-Scott-Rodino Antitrust Improvements Act of 1976 amended the Clayton Act to require companies to notify the DoJ and FTC in advance of any planned mergers or acquisitions (or certain joint ventures) exceeding certain size thresholds. The FTC Act authorises the FTC to bring enforcement actions against 'unfair methods of competition' and 'unfair or deceptive acts or practices'. The FTC Act generally prohibits the same types of conduct that would violate the Sherman Act. The Robinson-Patman Act prohibits certain forms of price discrimination in the sale of commodities, including pharmaceuticals, to resellers or distributors.

The vast majority of states have adopted antitrust laws, most of which are modelled on the federal antitrust laws or are interpreted consistently with their federal counterparts. Several states, however, have antitrust laws that substantively extend beyond federal antitrust law.

5 Are there guidelines on the application of competition law that are directly relevant to the pharmaceutical sector?

No guidelines have been issued by the DoJ or FTC specifically addressing the application of competition law to the pharmaceutical sector. However, the federal antitrust agencies have issued joint guidelines of more general application that may be particularly relevant for pharmaceuticals, including the Horizontal Merger Guidelines (2010), the Antitrust Guidelines for the Licensing of Intellectual Property (1995), Antitrust Guidelines for Collaborations Among Competitors (2000) and Statements of Antitrust Enforcement Policy in Health Care (1996).

6 Which authorities investigate and decide on pharmaceutical mergers and the anti-competitive effect of conduct or agreements in the pharmaceutical sector?

The FTC and DoJ enforce most of the federal antitrust laws, but only the DoJ enforces criminal antitrust prosecutions. The agencies utilise an informal process to allocate responsibility between them for particular investigations. However, in practice, non-criminal matters relating to the pharmaceutical industry are generally handled by the FTC, thus making it the primary federal antitrust enforcement body regularly encountered by pharmaceutical companies. State attorneys general can enforce both state and federal antitrust laws on behalf of the state's residents, as well as pursue claims on behalf of the state with respect to purchases by state agencies.

7 What remedies can competition authorities impose for anti-competitive conduct or agreements by pharmaceutical companies?

Criminal violations of the Sherman Act are generally punishable by fines of up to $100 million for a corporation and $1 million for an individual, though those fines may be increased to twice the amount gained by the conspirators or double the amount lost by the victims. Individuals may also be sentenced to imprisonment for up to 10 years. For civil antitrust violations, the DoJ and FTC may seek civil penalties and injunctive relief and, in unusual circumstances, the disgorgement of ill-gotten gains. HSR-related and other procedural violations are generally punishable by civil penalties.

For example, in 2009 Bristol-Myers Squibb was fined $2.1 million in penalties for alleged failure to notify the FTC and DoJ of a provision in a patent settlement agreement it had reached with a generic manufacturer (*FTC v Bristol-Myers Squibb Company*, Case 1:09-cv-00576, www.ftc.gov/os/caselist/0610235/090327bristolmyersjdgmt.pdf). In 2008, the FTC sought the disgorgement of alleged unlawful profits earned by Ovations Pharmaceuticals Inc after it acquired the drug Neoprofen. See www.ftc.gov/opa/2008/12/ovation.shtm (the FTC, however, was ultimately unsuccessful in proving that the acquisition was unlawful).

8 Can private parties obtain competition-related remedies if they suffer harm from anti-competitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

The Clayton Act authorises private parties to bring suit under the federal antitrust laws for treble damages and injunctions where they have been the victim of an antitrust violation; successful plaintiffs also can recover attorneys' fees and costs. In *Illinois Brick Co v Illinois*, 431 U.S. 720 (1977), the Supreme Court held that only direct purchasers of goods or services may recover damages for antitrust violations. Many states, however, have passed laws allowing indirect purchasers to recover for antitrust violations under state laws. Private antitrust suits often take the form of class action lawsuits.

9 May the antitrust authority conduct sector-wide inquiries? If so, have such inquiries ever been conducted into the pharmaceutical sector and, if so, what was the main outcome?

The antitrust agencies do not generally issue subpoenas in the absence of cause to believe that there has been a legal violation. However, the FTC occasionally conducts hearings or issues reports on a particular sector, including pharmaceuticals. For example, in August 2011, the FTC issued a report on 'Authorised Generic Drugs: Short-Term Effects and Long-Term Impact'. Each year, the FTC has been reporting on the number and nature of patent litigation settlements that have been filed under the MMA.

10 Is the regulatory body for the pharmaceutical sector responsible for sector-specific regulation of competition distinct from the general competition rules?

The FDA does not have jurisdiction to enforce the competition laws.

11 Can antitrust concerns be addressed with industrial-policy type arguments, such as strengthening the local or regional research and development activities?

Industrial policy arguments are not generally taken into account by courts or antitrust agencies in addressing the legality of conduct under the antitrust laws. Evidence that certain conduct or a merger will create efficiencies, and result in lower costs, improved quality, or increased innovation, however, is typically highly relevant to the antitrust inquiry and will weigh in favour of a finding of lawfulness.

12 To what extent do non-government groups play a role in the application of competition rules to the pharmaceutical sector?

Non-government organisations can play an important role in providing input to the competition authorities, either by informing the authorities about a potential competition issue, or by providing input with respect to an ongoing investigation of specific conduct or merger. The most weight, however, is given to information furnished by market participants, especially customers, that are directly affected by the conduct at issue. Private antitrust litigation can only be brought by parties that have standing because they are directly affected by the challenged conduct and have sustained the kind of injury that the antitrust laws were designed to prevent.

Review of mergers

13 To what extent are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?

The antitrust enforcement agencies make no explicit distinction in their approach to merger review based on industry, but the agencies will take the applicable regulatory context into account when analysing the competitive effects of a transaction. The FTC/DoJ Horizontal Merger Guidelines provide the framework for the agencies' review.

Entry that is timely, likely, and sufficient to counteract anticompetitive effects can be a defence to the assertion that a merger will substantially reduce competition. However, entry in the pharmaceutical industry can be time-consuming and expensive due to the regulatory approval process for new drugs. As an example, the FTC's December 2011 complaint against Valeant Pharmaceuticals International, Inc's proposed acquisition of Sanofi's dermatology business alleged that entry into the relevant markets would not be timely because 'the combination of topical drug development times and US Food and Drug Administration approval requirements take more than two years' (*In the Matter of Valeant Pharmaceuticals International, Inc*, FTC File No. 111-0215, www.ftc.gov/os/caselist/1110215/111209valeantsanoficmpt.pdf).

When a merger would combine two firms that are independently developing drugs for the same indication (or that otherwise may be competitive), the combination of these two firms could be considered to eliminate potential future competition. In analysing the likely competitive effects of a transaction, the agencies will consider the stage of development of the drugs and likelihood of approval. For example, the FTC included a potential competition claim in its 2012 complaint against Novartis relating to its combination with Fougera. Fougera was the only maker of branded product Solaraze, which uses the active ingredient diclofenac sodium. The complaint alleged that Novartis is best positioned to become the first generic competitor for the drug. (*In the matter of Novartis AG*, FTC Case No. 121 0144, www.ftc.gov/caselist/1210144/index.shtm). In reviews of mergers among generic pharmaceutical manufacturers, the FTC has taken into account the position of the merging firms and competitors with respect to their ability to compete for and during the initial 180-day marketing exclusivity period for new generics. In the FTC enforcement action relating to Teva's acquisition of Cephalon, the FTC required Teva to extend its supply agreement with Par so that Par continued to compete during the initial 180 days, and it required Teva to enter into a licensing agreement with Mylan in order to establish an independent competitor to Teva after the exclusivity period had run (*In the Matter of Teva Pharmaceuticals Industries, Ltd and Cephalon Inc*, FTC File No. 111 0166, www.ftc.gov/os/caselist/1110166/index.shtml).

14 How are product markets and geographic markets typically defined in the pharmaceutical sector?

When defining pharmaceutical markets, the antitrust agencies focus specifically on the nature of the transaction and products at issue; the ultimate question is what alternatives customers could turn to in the face of an attempted price increase by the merged firm. In some instances, the relevant product market is defined by the treatment of the illness or condition that the drug is approved to treat (eg, *In re Pfizer and Pharmacia*, FTC File No. 021-0192, www.ftc.gov/os/2003/04/pfizercmp.htm (one relevant market defined as drugs for treatment of erectile dysfunction)). In other instances, the agency will define markets based on the particular mechanism by which the pharmaceutical works or the manner in which it is administered (eg, *In the Matter of Amgen Inc and Immunex Corporation*, FTC File No. 021-0059, www.ftc.gov/os/2002/07/amgenanalysis.htm (one relevant market defined as drugs that inhibit a specific type of cytokine that causes inflammation)). Product markets also have been limited to a specific drug and its generic substitutes, or even solely the generic form of a particular drug (eg, *In the Matter of Teva Pharmaceutical Industries and Barr Pharmaceuticals*, FTC File No. 08102224, www.ftc.gov/os/caselist/0810224/081219cmp0810224.pdf (in merger between generic manufacturers, FTC identified numerous relevant markets limited to generic forms of specific drugs)). The FTC has said that where a 'branded drug manufacturer may choose to lower its price and compete against generic versions of the drug', in that case the brand 'is a participant in the generic drug market'. *In the matter of Mylan Inc, Agila Specialties Global Pte Limited*, Analysis of Agreement Containing Consent Orders to Aid Public Comment, FTC File No. 131-0112, www.ftc.gov/sites/default/files/documents/cases/130926mylananalysis.pdf.

Generally, because of the regulatory scheme for drug approvals and sales in the United States, the agencies define the relevant geographic market to be the United States.

15 In what circumstances will a product and geographical overlap between two merging parties be considered problematic?

Section 7 of the Clayton Act prohibits mergers if 'in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen

competition, or to tend to create a monopoly'. The US antitrust agencies review mergers using the 2010 Merger Review Guidelines. The issue is whether the merger will 'encourage one or more firms to raise prices, reduce output, diminish innovation, or otherwise harm customers as a result of diminished competitive constraints or incentives'. The Guidelines identify two types of potential anti-competitive effects – unilateral and coordinated effects.

Unilateral effects occur due to the elimination of competition between the two merging firms that allows the merged firm to unilaterally raise prices. The analysis hinges on the degree to which the products of the merging firms are reasonable substitutes for each other. The agencies use a variety of indicia to determine whether products are reasonably interchangeable. Evidence that might be relevant in an analysis of pharmaceuticals include the views of physicians, evidence of switching by customers or patients in response to price or other factors, and other evidence of head-to-head competition, such as competition for favourable placement on a payer's formulary. The more closely the products of the merging companies compete, the more likely it is that the merged firm will be able to profitably raise prices above competitive levels because sales lost due to a price increase will more likely flow to the product of the merger partner.

Under a coordinated effects analysis, a merger could be anti-competitive if it facilitates coordination among competitors. A market is susceptible to coordinated conduct when a number of characteristics are present, such as a history of collusion, observable actions of competitor firms, the possibility of quick responses by rivals to a firm's competitive actions, small and frequent sales in the market, and inelastic demand.

In *Grifols/Talecris*, the FTC alleged both unilateral and coordinated effects. The FTC alleged that the combined company would be able to unilaterally increase prices without experiencing a reduction in demand. The FTC also alleged the transaction would facilitate coordinated interaction because of the characteristics of the industry and the fact that there had been prior allegations of collusion in the industry (*In the Matter of Grifols, SA and Talecris Biotherapeutics Holdings Corp*, FTC File No. 101-0153, www.ftc.gov/os/caselist/1010153/110601grifolsacmpt.pdf.

In reviewing a merger of two firms, the antitrust agencies will evaluate all of the products marketed by both firms to determine if there is an overlap, as well as the pipeline portfolio of each firm to determine whether the firms are developing any potentially competitive products.

16 When is an overlap with respect to products that are being developed likely to be problematic?

Pharmaceutical products in development raise concerns when there are few substitute products on the market or in development from other firms, and the product in development appears likely to receive FDA approval and be a close substitute for a product sold or being developed by the second firm. An example of a challenge based in part on a future competition theory is *In the Matter of Perrigo Company and Paddock Laboratories Inc*, FTC File No. 111-0083, www.ftc.gov/os/caselist/1110083/110726perrigocmpt.pdf (the FTC alleged acquisition would eliminate future competition between the companies in the market for the sale of three generic drugs for which both companies planned entry).

17 Which remedies will typically be required to resolve any issues that have been identified?

Divestiture is the most typical remedy, as the agencies generally prefer not to implement conduct remedies that require ongoing agency monitoring. The antitrust agency could require the merging parties to divest to an acceptable buyer some or all of the assets of the overlapping business, such as manufacturing facilities, research and development, intellectual property, employees, and other components of the business that would allow the buyer to enter the market quickly and profitably. The agencies also have mandated licensing arrangements. The consent in *Grifols/Talecris* mandated a combination of divestitures and a licensing arrangement to Kedrion, an Italian company. It required Grifols to divest Talecris's fractionation facility in New York and US haemophilia treatment business, including a brand name, and two plasma collection centres to Kedrion. Grifols also entered a seven-year manufacturing agreement with Kedrion to fractionate and purify Kedrion's plasma to make the products at issue for Kedrion to sell in the United States (*In the Matter of Grifols, SA and Talecris Biotherapeutics Holdings Corp*, FTC File No. 101-0153, www.ftc.gov/os/caselist/1010153/110722grifolsdo.pdf).

18 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

The acquisition of patents or exclusive licences may be subject to the Hart-Scot-Rodino Antitrust Improvements Act of 1976 reporting requirements if the value of those patents or exclusive licences meet the threshold requirements for pre-merger notification, and the transaction is not otherwise exempt.

On 16 December 2013, the FTC implemented a revised HSR rule that broadens the scope for when exclusive licences of pharmaceutical patents are reportable. The rule targets licensing agreements that transfer the exclusive use and sale of a patent, but allow the licensor to retain manufacturing rights for that patent. Under the new rule, a transfer of 'all commercially significant rights' to a pharmaceutical patent – defined as including biologics, in vitro diagnostics and pharmaceuticals – is reportable if it otherwise meets the HSR Act's size-of-transaction and size-of-person thresholds. 'All commercially significant rights' is defined as 'the exclusive rights to a patent that allow only the recipient of the exclusive patent rights to use the patent in a particular therapeutic area (or specific indication within a therapeutic area)'. A transfer of 'all commercially significant rights' occurs even if the patent holder retains the right to manufacture solely for the recipient (licensee) or retains the right to assist the recipient in developing and commercialising products covered by the patent. This reporting rule in the pharmaceutical area creates a distinction between the pharmaceutical industry and other industries with respect to the treatment of the transfer of exclusive licences where the transferor retains a right to manufacturer.

Anti-competitive agreements

19 What is the general framework for assessing whether an agreement or practice can be considered anti-competitive?

Section 1 of the Sherman Act prohibits agreements that unreasonably restrict trade. Agreements among competitors receive the closest scrutiny. Some such 'horizontal' agreements (eg, price fixing or market allocation) are considered illegal per se – meaning that the plaintiff need not define the affected relevant market or prove anti-competitive effects, and the defendant cannot put forward justifications for the agreement. Horizontal agreements that are reasonably necessary to achieve efficiencies are judged under the 'rule of reason', which requires the plaintiff to define the relevant product and geographic market, and establish that the agreement's anti-competitive effects outweigh any pro-competitive benefits. Agreements between suppliers and customers are more likely to have legitimate business justifications and less likely to have anti-competitive effects than horizontal arrangements, and therefore these 'vertical' agreements are judged under the rule of reason. In the pharmaceutical industry, antitrust enforcers have applied especially exacting antitrust scrutiny to agreements that have the effect of restricting or delaying generic competition.

Section 2 of the Sherman Act also prohibits exclusionary or predatory conduct by firms with monopoly power or a dangerous probability of achieving a monopoly. Pharmaceutical companies are at particular risk of challenges under section 2 because they may be accused of having a monopoly position in a narrowly defined product market, perhaps limited to a single therapeutic product.

20 Describe the nature and main ramifications of any cartel investigations in the pharmaceutical sector.

The US antitrust agencies have not made any pharmaceutical cartel investigations public. However, there have been many investigations by antitrust agencies of individual pharmaceutical manufacturers for allegedly colluding with other pharmaceutical manufacturers in bilateral agreements, especially where the agreement is between a brand name and generic pharmaceutical manufacturer and has the potential to delay or restrict generic competition.

21 To what extent are technology licensing agreements considered anti-competitive?

Technology licensing agreements are generally analysed under the rule of reason, where the legality of the licensing agreement depends on weighing the agreement's pro-competitive and anti-competitive effects. However, if a court or agency concludes that a licensing agreement is merely a means towards accomplishing a per se illegal objective (eg, a market allocation scheme), then the per se rule might be applied.

Restrictions in licensing agreements can raise antitrust risks, and some types of restrictions raise higher risks than others. Exclusivity provisions, for example, may be challenged if they foreclose competition unreasonably. Courts assessing the foreclosure effect of such agreements will examine the term and scope of the exclusivity, the market share of the parties, the business justifications for the exclusivity, and the availability of less restrictive alternatives. A requirement that the licensee acquire other products or licences from the licensor as a condition for obtaining the licence also can raise antitrust issues.

The antitrust agencies have published Antitrust Guidelines for the Licensing of Intellectual Property, and these Guidelines apply to pharmaceutical licensing transactions. For licensing agreements that are not subject to per se condemnation, these Guidelines provide for a safe harbour where the parties involved have no more than a 20 per cent share of each market affected by the licensing arrangement.

22 To what extent are co-promotion and co-marketing agreements considered anti-competitive?

Co-promotion and co-marketing agreements, like other joint ventures or competitor collaborations, are analysed under the rule of reason. The antitrust agencies have released Competitor Collaboration Guidelines that explain how they evaluate these types of agreements. To determine whether an agreement is a legitimate competitor collaboration entitled to rule of reason treatment, an agency or court will first look to whether the agreement integrates the resources of the companies to develop potential efficiencies. For example, joint marketing or promotion agreements might result in the combination of complementary assets that will permit the participants to commercialise products faster or more efficiently. These types of arrangements are likely to be considered lawful as long as the pro-competitive effects are not outweighed by the likely anti-competitive effects.

If, however, the arrangement will merely make it easier for the participants to exercise market power or increase prices – or if the potentially anti-competitive effects outweigh the efficiency-enhancing aspects of the arrangement – then the arrangement may violate antitrust laws.

In addition, the FTC has challenged co-promotion or co-marketing agreements entered into by brand name and generic pharmaceutical companies together with patent settlements, contending that such transactions can serve as a mechanism for compensating generic companies for agreeing to delay entry.

23 What other forms of agreement with a competitor are likely to be an issue? Can these issues be resolved by appropriate confidentiality provisions?

The antitrust agencies have also investigated research joint ventures, production joint ventures, and joint-purchasing arrangements, among others. All of these types of agreements raise more significant antitrust risks when the participants have a high combined share of the relevant market. Courts and agencies will be especially concerned about restrictions in the collaboration agreement that may impact competition outside the scope of the collaboration and are not reasonably necessary to achieve the pro-competitive effects of the arrangement.

Even if there is no direct agreement to reduce competition outside of the collaboration, information obtained by the participants as a result of the collaboration sometimes can have 'spill-over effects' that reduce competition between the participants, and in some cases these effects can outweigh the pro-competitive effects of the collaboration. Companies entering into competitor collaborations can reduce antitrust risk by limiting the participants' access to competitively sensitive information from the other party or the joint venture.

24 Which aspects of vertical agreements are most likely to raise antitrust concerns?

Vertical agreements are evaluated under the rule of reason under US law to determine whether the potential anti-competitive effects outweigh the pro-competitive effects. Vertical agreements typically raise antitrust issues when they have the effect of foreclosing competitors from a significant proportion of the market, which may create or enhance the market power of one of the parties to the agreement. For example, if a dominant seller enters into an exclusive dealing arrangement with customers or suppliers that account for more than 30 per cent of the relevant market, then that might make it more difficult for competitors of the seller to compete, and create or enhance the seller's market power. 'Loyalty discounts' that condition significant discounts on a customer purchasing most or virtually all of its volume from the seller can have similar foreclosure effects and have been challenged.

Tying arrangements also may have the effect of foreclosing competitors from a significant portion of the market, and can raise similar antitrust issues. Tying occurs where a seller requires a purchaser of one product (the tying product) to also purchase a second product (the tied product). Such an arrangement where the seller has market power in the tying product can foreclose competition from rivals selling products that compete with the tied product. Bundled discounts may have similar effects where they require a customer that purchases one product to purchase a bundle of products in order to obtain significant discounts on the product that the customer wants (eg, *Ortho Diagnostics Sys, Inc v Abbott Lab, Inc*, 920 F. Supp. 455 (S.D.N.Y. 1996); *SmithKline Corp v Eli Lilly & Co*, 427 F. Supp. 1089, 1094 (E.D.Pa. 1976)).

25 To what extent can the settlement of a patent dispute expose the parties concerned to liability for an antitrust violation?

Settlements of patent litigation between brand-name and generic pharmaceutical companies raise antitrust risks where the agreement has two elements: the generic company agrees to wait until a certain date to enter the market; and there is a flow of consideration from the brand-name manufacturer to the generic. These types of

Update and trends

Biologic medicines and follow-on biologics are the topic of much discussion currently and given their increasingly significant role in the market, they are likely to remain an area of increasing focus in the future. Unlike small-molecule drugs that are chemically synthesised, biologics are created through biological processes. Biologics are also typically more expensive to develop and manufacture than standard drugs because they are more complex. Examples of biologics include vaccines, blood products, human cells and tissues, and gene therapies.

The Biologics Price Competition and Innovation Act (BPCIA) enacted in 2010 created an abbreviated licensure pathway for products that are 'biosimilar' to or 'interchangeable' with an FDA approved biologic. Biosimilars are defined as products that are 'highly similar notwithstanding minor differences in clinically inactive components' to a reference biologic drug and are not meaningfully different in terms of 'safety, purity, and potency'. In order to constitute an interchangeable biologic, a product must not only be biosimilar to an FDA-approved biologic, but it must also be established that it 'can be expected to produce the same clinical result as the reference product in any given patient'. Additionally, where a biological product is administered more than once to a given patient, it must be shown that 'the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product' without alternation or switching. Interchangeable biologics can be substituted for the reference biologic without further involvement by the prescriber, whereas biosimilars cannot be substituted in this manner.

In 2014, the FTC held a workshop to evaluate issues related to the competitiveness of follow-on biologic products – the latest in a series the agency has held on this issue in recent years. In particular, the FTC focused on the role of state laws regulating the substitution of generic and follow-on products in place of reference products and the extent to which those mechanisms might affect price competition among follow-on biologics and reference products. In its public comments on the workshop, the FTC also emphasised that the question of whether follow-on biologics are permitted to use the same product names as reference biologics products is likely to have a significant impact with respect to these issues. The FTC also looked at the effect these issues may have on the incentives for biologics firms to develop follow-on biologic products.

As efforts by the FDA, the FTC and state governments to formulate rules related to biologics and follow-on biologics are ongoing, this is likely to remain an area of rapid development in the coming years.

arrangements have been referred to by detractors as 'pay for delay' or 'reverse payment' patent settlements. The FTC believes that these types of settlements essentially result in a payment to the generic manufacturer in return for an agreement to delay entry.

In 2013, the Supreme Court ruled in *FTC v Actavis* that the antitrust legality of a reverse payment patent settlement should be analysed under the rule of reason. Notably, the Court declined to endorse either the FTC's position – that such agreements should be presumptively unlawful, or the defendant's position – that the 'scope of the patent' test should prevail. Instead, the Court held that 'the likelihood of a reverse payment bringing about anti-competitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.' The Court specifically identified two potential justifications for a reverse payment settlement agreement – where the payment approximates avoided litigation costs or 'fair value' for other services – but left open the possibility that there may be other justifications. The Court also stated that it would normally not be necessary to litigate patent validity to determine antitrust liability because the size of an unexplained reverse payment is a 'workable surrogate' for a patent's weakness (ie, the larger the payment, the more likely it is that the patent is weak). It is important to note that the Court left much of the work in terms of developing the detailed rule of reason analysis to trial courts and so this remains an area of law that is still developing, and which is likely see important developments in 2014.

Notably, the FTC has also taken the position that a promise by a brand-name manufacturer not to launch an authorised generic can potentially constitute a 'reverse payment' (but so far the FTC has not brought a case based on this theory, and early indications suggest a split among district courts that have considered the question – see question 32).

Anti-competitive unilateral conduct

26 In what circumstances is conduct considered to be anti-competitive if carried out by a firm with monopoly or market power?

Exclusionary or predatory conduct carried out by a firm with monopoly or market power may be deemed unlawful under section 2 of the Sherman Act, which prohibits monopolisation, attempts to monopolise and conspiracies to monopolise. Prohibited conduct may include vertical restrictions that limit competitors' access to supplies or customers, such as exclusive dealing, tying, or loyalty or bundled discounts. Other types of conduct that have been deemed predatory or exclusionary include predatory (below-cost) pricing, engaging in baseless litigation for an anti-competitive purpose, abuse of the standard-setting processes and, in rare cases, a refusal to deal with a competitor. Section 2 does not prohibit the mere possession of monopoly or market power, or the acquisition of such power through conduct that is no more than lawful competition on the merits.

27 When is a party likely to be considered dominant or jointly dominant?

A party is likely to be considered dominant – that is, to have monopoly power – when it has the ability to control or exclude competition in a 'relevant market'. Courts frequently use a party's market share in a relevant market as a proxy for assessing whether that party has market power. Though there are no bright line rules, most successful monopolisation claims involve market shares of at least 70 per cent. To succeed on a claim for 'attempted monopolisation,' the plaintiff must show that the defendant has a 'dangerous probability' of obtaining monopoly power, which generally requires a market share of at least 50 per cent. US antitrust law does not recognise joint dominance of a market in section 2 cases.

Market share is not, however, the sole determinant of whether a firm has monopoly power. A firm with a high market share may not have monopoly power if there are no or weak barriers to entry, and the threat of such entry prevents the firm from acting anti-competitively. Additionally, market power may be proved by direct evidence in the absence of proof that the defendant has a high market share.

28 Can a patent holder be dominant simply on account of the patent that it holds?

Generally, no. In *Illinois Tool Works Inc v Independent Ink, Inc*, 547 U.S. 28 (2006), the US Supreme Court ruled that a patent holder is not presumed to have market power simply on account of the patent it holds.

29 To what extent can an application for the grant of a patent expose the patent owner to liability for an antitrust violation?

Application for the grant of a patent does not, by itself, expose the patent owner to antitrust liability. Enforcement of a fraudulently

obtained patent, however, may violate section 2 of the Sherman Act if used to exclude lawful competition from the market (*Walker Process Equipment, Inc v Food Machinery & Chemical Corp*, 382 U.S. 172 (1965)).

30 To what extent can the enforcement of a patent expose the patent owner to liability for an antitrust violation?

In addition to enforcement of a fraudulently obtained patent, a patent owner can be liable for an antitrust violation if it pursues patent litigation with no reasonable chance of success, solely to cause direct harm to the competitor's business as a result of the litigation process. Under the Noerr-Pennington doctrine, private entities are generally immune from antitrust liability for petitioning the government, including the filing of lawsuits in the courts. The 'sham' exception to this doctrine, however, allows liability where the patentholder files a suit that is objectively baseless, in the sense that no reasonable litigant could realistically expect success on the merits, and for the purpose of harming a competitor directly (eg, if the cloud of litigation discourages others from doing business with the defendant). The FTC is also reportedly investigating brand-name pharmaceutical companies for refusing to sell samples of their products to generic companies for bioequivalence studies (which are sometimes necessary for generics to obtain regulatory approval), in situations where FDA-imposed distribution restrictions have prevented the generic company from making use of alternative channels to acquire such samples. Private litigation in the US District Court for the district of New Jersey regarding this issue was recently settled before the court addressed the substantive question (see *Actelion Pharmaceuticals Inc v Apotex Inc et al*). Thus, significant uncertainty regarding this issue remains.

31 To what extent can certain life-cycle management strategies expose the patent owner to liability for an antitrust violation?

Manufacturers whose branded products are coming off-patent often seek to improve their products, patent the improvement and move their customers to the improved products. There have been several antitrust challenges to this type of conduct, however, where it was alleged that the new drug did not reflect any real improvements and was solely used as an effort to thwart generic competition.

Patent owners may also be exposed to antitrust liability for improperly listing patents in the Orange Book as a means to extend exclusivity and thereby impede generic competition (eg, *In the Matter of Bristol-Myers Squibb Co*, Docket No. C-4076 (2003), www.ftc.gov/os/caselist/c4076.shtm). Similarly, drug manufacturers can be subject to antitrust liability for filing a citizen petition with the FDA that is solely intended to delay or prevent competition with the drug, and not based on a reasonable chance of success.

32 Do authorised generics raise issues under the competition law?

Authorised generics – that is, generic pharmaceutical products sold not by a separate firm under a generic drug authorisation, but rather by the brand-name manufacturer itself (or its licensee) under the brand-name drug authorisation – do not by themselves create antitrust liability. Though US law grants 180 days of exclusivity to the first generic drug to reach the market through a patent challenge, that exclusivity does not preclude a brand name manufacturer from launching an authorised generic during the 180-day exclusivity period. A 31 August 2011 FTC report concluded that authorised generics generally result in modestly lower generic prices for consumers and substantially reduce the profits of the first generic entrant, but it found little to no empirical evidence that authorised generics diminish the incentives of generic firms to challenge patents or bring their products to market.

The FTC, however, is increasingly concerned that brand-name pharmaceutical manufacturers are using the threat of launching an authorised generic to induce generic companies to delay bringing their drugs to market. As noted above, the FTC views a promise by the brand-name manufacturer not to launch an authorised generic to constitute an unlawful 'reverse payment' if included as part of a patent settlement that delays generic entry. The FTC has yet to bring such a case and district courts that have considered the issue to date are split on the question. One court recently rejected the FTC's position on this issue (See *In re Lamictal Direct Purchaser Antitrust Litigation*, Civ. No. 12-995 (Order dated 24 January 2014)), however, two other federal district court rulings have suggested a broader interpretation of 'payment' under *Actavis* sufficient to capture non-monetary forms of payment (See *In re Lipitor Antitrust Litigation*, 2013 WL 4780496 (D.N.J. 5 September 2013) and *In re Nexium (Esomeprazole) Antitrust Litigation*, Civ. No. 12-2409 (Order dated 11 September 2013)).

33 To what extent can the specific features of the pharmaceutical sector provide an objective justification for conduct that would otherwise infringe antitrust rules?

Except in cases of per se unlawful agreements between competitors (eg, price-fixing or market allocation agreements), courts evaluating

Hogan Lovells

Robert F Leibenluft **robert.leibenluft@hoganlovells.com**
Leigh L Oliver **leigh.oliver@hoganlovells.com**
Lauren E Battaglia **lauren.battaglia@hoganlovells.com**

555 13th Street, NW
Washington, DC 20004
United States

Tel: +1 202 637 5600
Fax: +1 202 637 5910
www.hoganlovells.com

antitrust claims typically place significant weight on a defendant's pro-competitive justifications for its conduct. Thus, conduct that increases the safety or efficacy of drugs, or makes it easier for patients to comply with drug regimens, is likely to be viewed favourably by the antitrust agencies and courts. Such justifications, however, will be weighed against possible anti-competitive effects and the existence of less restrictive alternatives.

Additionally, when analysing antitrust issues, US courts keep in mind the regulated nature of the pharmaceutical sector and the economic importance of patent protection and generic substitution.

34 Has there been an increase in antitrust enforcement in the pharmaceutical sector in your jurisdiction? If so, please give an indication of the number of cases opened or pending and their subject matters.

Antitrust enforcement in the pharmaceutical sector continues to be a major focus of the US antitrust agencies, especially the FTC's fight against 'pay for delay' or 'reverse payment' settlements. The agency also devotes a significant amount of resources to investigating pharmaceutical transactions and studying the industry. It regularly releases speeches and reports on pharmaceutical competition issues, and recently completed a study on authorised generics.

35 Is follow-on litigation a feature of pharmaceutical antitrust enforcement in your jurisdiction? If so, please briefly explain the nature and frequency of such litigation.

Follow-on litigation is a typical feature of governmental enforcement actions in the United States; enforcement actions in the pharmaceutical sector have been consistent with this trend (eg, *In re AndroGel Antitrust Litigation* (No. II), 687 F. Supp. 2d 1371 (N.D. Ga. 2010) (dismissing follow-on private lawsuit arising out of FTC challenge to patent settlement)).

PHARMACEUTICAL ANTITRUST 2014 ISSN 1757-6288