GETTING THE DEAL THROUGH

GCR
GLOBAL COMPETITION REVIEW

Pharmaceutical Antitrust

The application of competition regulation in 27 jurisdictions worldwide

2011

Contributing editor: Marleen Van Kerckhove

Published by
Getting the Deal Through
in association with:

Albuquerque & Associados Law Firm
Anderson Mōri & Tomotsune
Arnold & Porter LLP
Arzinger
Bell Dewar
bnt Attorneys-at-law
Chitale & Chitale Partners
Cornejo, Méndez, González y Duarte, SC
D&B David si Baias
De Matteis Studio Legale
Hájek Zrzavecký advokátní kancelář, sro
Hammarström Puhakka Partners, Attorneys Ltd
HHP Attorneys-At-Law
Homburger AG
Intuity
Kim & Chang
Lett Law Firm
LO Baptista Advogados Associados
Oppenhoff & Partner Rechtsanwälte
Preslmayr Rechtsanwälte
Tark Grunte Sutkiene
Wiesner & Asociados Ltda Abogados
YükselKarkınKüçük Attorney Partnership

GETTING THE DEAL THROUGH®

Pharmaceutical Antitrust 2011

Contributing editor:
Marleen Van Kerckhove
Arnold & Porter LLP

Business development managers
Alan Lee
George Ingledew
Robyn Hetherington
Dan White

Marketing managers
Ellie Notley
Sarah Walsh
Alice Hazard

Marketing assistants
William Bentley
Sarah Savage

Subscriptions manager
Nadine Radcliffe
Subscriptions@gettingthedealthrough.com

Assistant editor
Adam Myers
Editorial assistant
Lydia Gerges

Senior production editor
Jonathan Cowie
Chief subeditor
Jonathan Allen
Subeditor
Davet Hyland

Editor-in-chief
Callum Campbell
Publisher
Richard Davey

Pharmaceutical Antitrust 2011
Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 7908 1188
Fax: +44 20 7229 6910

ISSN 1757-6288

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

Law Business Research

CONTENTS

United States

Asim Varma and Barbara Wootton
Arnold & Porter 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 US laws governing the authorisation and marketing of pharmaceuticals (that require a doctor's prescription) are codified in the Food, Drug and Cosmetic Act (FDCA) and enforced by the Food and Drug Administration (FDA) (see 21 USC section 355). Generally, the FDA regulates the testing, manufacturing, labelling, advertising, marketing, efficacy and safety of pharmaceuticals. Additionally, a number of states have enacted laws that regulate certain aspects of the marketing of pharmaceuticals within the particular state (see, eg, Vermont Acts No. 80). The Drug Price Competition and Patent Term Restoration Act of 1984, codified at 21 USC section 355, known as the Hatch-Waxman Act, governs the approval of generic drugs. The Act allows FDA approval of a drug through the Abbreviated New Drug Application (ANDA) process, which permits the generic drug manufacturer to rely on the FDA's finding of safety and efficacy of a previously approved brand name drug without submission of a full new drug application (NDA).

At the time an NDA is filed it must include information about patents that claim the drug. The FDA is required to list the patent information in an agency publication entitled 'Approved Drug Products with Therapeutic Equivalence', commonly known as the 'Orange Book'. The ANDA application must include a certification regarding any patents listed in the Orange Book that claim the referenced brand name drug. Under one form of certification, known as 'paragraph IV certification', the ANDA applicant certifies that the patents listed in the Orange Book are either invalid or unenforceable or will not be infringed by the manufacture, use or sale of the generic drug. The paragraph IV certification must be provided to the patent owner and NDA holder for the listed drug. If the NDA sponsor or patent owner files a patent infringement suit within 45 days of the receipt of the certification, the FDA may not approve the ANDA until the earliest of:

- the date the patent expires;
- a court decision in the patent infringement case; or
- the expiration of 30 months from the receipt of the paragraph IV certification.

To encourage generic drug manufacturers to challenge patents, the Act provides that the first generic manufacturer to file an ANDA containing a paragraph IV certification is awarded 180 days of marketing exclusivity. The Act does not include biologics, namely, drugs created from living cells or through biotechnology, in the ANDA approval process. Biologics are approved pursuant to a biologics licensing application (BLA) instead of an NDA. As part of Healthcare Reform, in March 2010, Congress, for the first time, approved a pathway to approval of follow-on biologic (FOB) drugs. (See 'US-Europe Overview for more discussion.)

Since January 2004, agreements (including settlements of paragraph IV litigation) between a brand name company and a generic applicant relating to the 180-day exclusivity, or which concern the manufacture, marketing or sale of the brand drug or of the generic drug, must be filed with the Federal Trade Commission (FTC) and the Department of Justice (DoJ). See section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernisation Act of 2003 (Pub L No. 108-173, 117 Stat 2066).

There is no legislation in the United States that regulates the pricing of pharmaceuticals covered by commercial payers. The Medicaid Drug Rebate Statute (the drug rebate statute) requires manufacturers to enter into rebate contracts with the federal government in order to have their products covered by government insurance programmes (see 42 USC section 1396r-8). The rebate agreements require the manufacturers to supply their products to the government at the lowest price (net of rebates) offered to other purchasers; that is, the manufacturer's 'best price'. Other statutes also cap prices for drugs purchased by certain government entities or entities that receive government funding to treat low income individuals (see, eg, 38 USC section 8126 (Veterans Health Care Act) and 42 USC section 256b).

In addition, the marketing of pharmaceuticals is subject to the Medicare-Medicaid Anti-Fraud and Abuse Act (the anti-kickback statute), which, subject to certain safe-harbour provisions, prohibits providing or receiving anything of value to induce a person to use a drug paid for by a federal government insurance programme (42 USC section 1320a-7b(b)(2)). Many states have similar laws. Some states have also imposed limits on gifts that pharmaceutical companies can give physicians and other states require companies to report all gifts provided to physicians in the state (see, eg, California Health & Safety Code, section 119402; Maine Revised Statutes Annotated, title 22, section 2698-A). One state requires individuals engaged in the practice of pharmaceutical detailing to maintain licences (DC SafeRx) and other states (Massachusetts, Nevada and California) require compliance with marketing codes that are at least as stringent as the 2009 version of the Code for Interactions with Healthcare Professionals issued by the Pharmaceutical Research and Manufacturers of America.

2 Which bodies are entrusted with enforcing these regulatory rules?

The FDA has the responsibility to authorise and regulate the marketing of pharmaceuticals. The Centers for Medicare and Medicaid Services administers the Medicaid Drug Rebate Program. The anti-kickback statute and the drug rebate statute are enforced by the DoJ and the Office of the Inspector General of the Department of Health and Human Services. Individual states enforce their own anti-kickback laws and can enforce the drug rebate statute under state False Claims Acts.

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

The FDCA and federal and state statutes governing drug marketing or drug rebate programmes do not directly address the application of competition law in the pharmaceutical sector. However, the FDCA provisions relating to the approval of generic drugs have encouraged competition from generic drugs and established a framework to balance the incentives that patent rights provide for continued innovation by brand name firms with entry by generic drug firms.

Competition legislation and regulation

4 Which legislation sets out competition law?

The principal US competition laws are the Sherman Act, the Clayton Act, the Robinson-Patman Act, and the Federal Trade Commission Act (FTC Act). Section 1 of the Sherman Act prohibits concerted activity that unreasonably restrains trade. Section 2 of the Sherman Act outlaws monopolisation, attempted monopolisation and conspiracies to monopolise. Section 7 of Clayton Act prohibits mergers and acquisitions where 'the effect of such acquisition may be to substantially lessen competition, or to tend to create a monopoly'. Section 7A of the Clayton Act, otherwise known as the Hart-Scott-Rodino Act, requires parties to mergers and acquisitions meeting certain thresholds to file notifications with the US antitrust authorities prior to consummating such transactions. The Robinson-Patman Act prohibits price discrimination in the sale of commodities, including pharmaceuticals. Section 5 of the FTC Act prohibits 'unfair methods of competition'. The FTC has asserted authority under section 5 to challenge conduct that may not violate the Sherman Act (see, eg, *In re Negotiated Data Servs*, FTC file No. 051 0094 (23 January 2008)). State antitrust laws generally have been construed to apply the same standards as federal antitrust laws.

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

There are no guidelines promulgated by the US antitrust authorities that are specifically directed at the pharmaceutical sector. The FTC and the Antitrust Division of the DoJ have jointly issued generally applicable competition guidelines, including the Antitrust Guidelines for the Licensing of Intellectual Property (1995), the Horizontal Merger Guidelines (2010) and the Antitrust Guidelines for Collaborations Among Competitors (2000).

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

The DoJ and the FTC share jurisdiction for the enforcement of US antitrust laws. There is no statutory allocation of responsibility between the agencies and responsibility for investigating matters is determined through an informal 'clearance' process between the agencies based on each agency's industry expertise. The FTC generally handles investigations relating to pharmaceutical markets, including review of pharmaceutical mergers. The DoJ has sole authority to prosecute cartel activity such as price-fixing and bid-rigging as antitrust criminal violations for all industry sectors. State attorneys general also have jurisdiction to investigate conduct under either federal antitrust or state antitrust laws.

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

For criminal antitrust violations, the DoJ may seek fines against offending companies in an amount double the gain obtained by cartel participants or double the loss suffered by victims of the cartel. Individual executives can also be subject to fines and imprisonment. For certain procedural civil violations, such as HSR Act violations and breach of consent decrees, the agencies can seek civil fines. For substantive civil violations, the agencies may seek injunctive relief. Some courts have interpreted the express authorisation to seek broad equitable remedies, such as injunctions and restraining orders, as implied authority to seek all equitable remedies including restitution and disgorgement. To date, only the FTC has exercised its implied authority to seek monetary equitable remedies. See *FTC v Mylan Labs*, 62 F Supp 2d 25 (DDC 1999) (upholding FTC right to seek disgorgement).

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?

Private parties are entitled to recover treble their damages from the anti-competitive conduct as well as attorneys' fees and injunctive relief (15 USC sections 15(a) and 26). Competitors and direct purchasers, such as drug wholesalers, generally have the right to sue for damages under federal antitrust law. Indirect payers, which in the United States can include consumers and private insurers, can sue for damages under many state antitrust or consumer protection laws. Direct and indirect purchaser suits are often brought as class actions. State attorneys general can also sue under the federal antitrust laws on behalf of the state as a direct purchaser or proceeding as parens patriae on behalf of its citizens, namely, on behalf of indirect purchasers.

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?

In June 2009, the FTC issued 'Authorised Generics: An Interim Report', which presents the first set of results from a study to examine the short-term and long-term effects of authorised generics on competition in the prescription drug industry. In the report, the FTC concluded that consumers benefit when an authorised generic competes during the 180-day exclusivity period awarded the first filer under Hatch-Waxman. Such competition, the report concluded, also 'substantially' reduced the first generic firm's revenues. Moreover, the report expressed concern over the increasing number of patent litigation settlements that include provisions restricting the branded company's launch of the authorised generic combined with an agreement with the generic filer to delay entry. The Report stated that the FTC had not yet drawn any conclusions about the long-term effects of the reduction in revenues of the first generic firm on incentives for generic entry.

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

The FDA implements the Hatch-Waxman Act but does not address or apply general competition rules to the pharmaceutical sector.

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

Antitrust concerns cannot generally be addressed by industrial policy arguments.

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

Non-governmental groups are active in petitioning the government on the authorisation, marketing and pricing of pharmaceuticals. From time to time, they address antitrust concerns relating to the use of intellectual property and life-cycle management strategies and their effect on competition. Non-governmental entities have also assisted consumers and direct purchasers in bringing litigation challenging settlements of paragraph IV patent litigation.

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 US antitrust authorities apply the same substantive test for mergers in the pharmaceutical sector that they apply in other sectors (see Horizontal Merger Guidelines (2010)). The ultimate question is whether the transaction will lead to a substantial lessening of competition in a goods market or reduced innovation in an innovation market. Unique features of the pharmaceutical industry, such as substantial sunk costs and long timelines involved in the extensive research and development and regulatory approval process are taken into account in assessing whether entry sufficient to counteract the anti-competitive effects of the merger likely would occur in a timely manner.

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

Courts and the federal enforcers have adopted a variety of product market definitions relating to pharmaceuticals. In some cases, the relevant product market has been defined by the treatment or disease indications for the which the drug is approved (or, if in clinical trials, will be seeking approval), though prescription and non-prescription drugs are generally deemed to be in separate markets. In other cases, markets are defined more narrowly, often on the basis of a mechanism of action (for example, two drugs that treat a specific cancer through different mechanisms would not be deemed in the same market). Other cases have limited markets to drugs used to treat a specific condition that have the same dosage form (such as injectable versus tablet). The agencies have also taken the position that in some cases a product market can be defined to include only a brand name and its generic equivalents or even just generic equivalents, excluding the branded drug. The geographic relevant market is generally viewed as the US domestic market because the FDA's drug authorisation authority is restricted to the US.

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

The focus of government merger analysis is on structural competitive effects. The government applies two broad analytical frameworks in assessing competitive effects:

- does the merger increase market power by facilitating coordinated interaction among rival firms; and
- does the merger enable the merged firm to unilaterally raise prices or otherwise exercise market power?

In pharmaceutical markets, the primary concern is usually unilateral effects. Revised Guidelines issued in 2010 state that market share and concentration will no longer operate as direct proxies for the likely competitive effects of a merger, although they still are 'one useful indicator' (Horizontal Merger Guidelines section 5.3). The new Guidelines, reflecting a move away from structural presumptions toward a focus on competitive effects, appear to have dropped the prior 35 per cent combined market share presumption to trigger unilateral effects challenges, instead providing a more extensive discussion of unilateral effects analysis. Section 6 of the Guidelines addresses the use of 'diversion ratios' to attempt to quantify the rate of substitution between merging firms' products due to price increases and also use of merger simulation models where data is available to quantify unilateral price effects. The Guidelines indicate that profit margins, profitability and marginal costs are increasingly used by the FTC and the DoJ as proxies for market power and competitive effects. This focus on profit margins and marginal costs, without qualification, may be problematic for merging firms in the pharmaceutical sector in particular, given the industry is characterised by high fixed costs and low marginal costs.

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

Pipeline products play a role in the competitive effects analysis for pharmaceuticals because of the long timeline and large sunk costs associated with drug development and FDA approval. While the agencies have not drawn any bright lines, a drug in the later stages of pre-approval clinical trials (Phase II or Phase III) will usually be treated the same way as a marketed product for purposes of analysing competitive effects. A merger of firms also involves the combination of research and development programmes, which has the potential to reduce competition in overlap areas and result in one or both firms forgoing the development of pipeline drugs in the pre-clinical stage. Thus, the government also assesses the competitive effects of a pharmaceutical merger on innovation markets and will assess the potential impact on pre-clinical pipeline products.

One interesting example involved the effect of a pipeline product on impact of competition from generic entry. In the *Cephalon/Cima Labs* merger, Cephalon marketed the only FDA approved product and was in the process of developing a new formulation for launch. Cima had a product in Phase III clinical trials. The FTC alleged that the acquisition could delay or end the launch of the Cima product and also 'undermine generic entry' by allowing Cephalon to shift patients to the patent-protected product 'prior to generic launch, depriving consumers of the full benefits of generic competition' (Analysis of Proposed Consent Order to Aid Public Comment, *In re Cephalon, Inc and CIMA Labs, Inc*, FTC File No. 041-0025 (9 August 2004)). The FTC required Cephalon to license and transfer all know-how for its approved product to a generic manufacturer.

Recently the FTC filed a lawsuit challenging a prior acquisition of a product in development that did not meet HSR reporting thresholds. On 16 December 2008, the FTC sued Ovation Pharmaceuticals, Inc, seeking divesture of its 2006 acquisition of rights to the drug NeoProfen, which at the time of acquisition was pending FDA approval. According to the FTC complaint, Ovation had previously acquired Indocin, the only other treatment for patent ductus arteriosus, a congenital heart disorder in premature newborns (*Federal Trade Commission v Ovation Pharmaceuticals, Inc*, FTC File No. 0810156 at www.ftc.gov/os/caselist/0810156/081216ovationcmpt.pdf). The FTC claimed that after the acquisition, Ovation raised the price of Indocin 1300 per cent and set the price for NeoProfen at the same levels. The FTC sought disgorgement of profits in addition to divestiture. But on 31 August 2010, the court dismissed the actions, finding that the FTC had not proved that NeoProfen and Indocin compete in the same product market and, therefore, had failed to demonstrate that the acquisition substantially lessened competition or maintained a monopoly.

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

The remedy preferred by US agencies in any transaction that they believe is likely to result in anti-competitive effects is divestiture of

one of the merging firm's assets in the market adversely affected. The government will either require that the package of divested assets include all components of the business or that those components not included be otherwise economically available. Such components generally include manufacturing facilities, research and development capability, technology and other intellectual property, access to personnel, marketing and distribution capabilities, customer relationships, capital resources and anything else necessary to compete effectively. For example, on 14 October 2009, the FTC challenged Pfizer's proposed $68 billion acquisition of Wyeth and required divestitures in 21 US markets for the manufacture and sale of various animal pharmaceuticals and vaccines (see *In the Matter of Pfizer Inc and Wyeth*, FTC File No. 091-0053, Complaint, 14 October 2009, at www.ftc.gov/os/caselist/0910053/091014pwyethcmpt.pdf, and Decision and Order, 29 January 2010 at www.ftc.gov/os/caselist/0910053/100129pwyethdo.pdf). In some cases, the FTC has accepted licensing of IP rights rather than divestiture as a remedy to restore pre-merger levels of competition. For example, in the *Amgen/Immunex* merger, Amgen had a TNF inhibitor in development while Immunex had one of two drugs already on the market. Competitors had two other drugs in development. A third competitor, Sereno, was developing a drug in Europe but did not have the patents rights necessary to sell the product in the US. The FTC required Amgen to license patent rights to Sereno so it could compete in the US and thereby maintain pre-merger levels of competition. Amgen retained rights to develop its product (*In re Amgen, Inc and Immunex Corp*, docket No. C-4056 (12 July 2002)).

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 a patent is subject to reporting requirements if it is valued at or above the HSR reporting thresholds. This reporting requirement applies even if the acquiring party is required to give the seller a licence or the acquiring party must take the intellectual property rights subject to pre-existing licence grants. The grant of an exclusive patent licence (one that is not subject to existing licences) is also reportable if the regulatory reporting thresholds are met.

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 restrain trade. Horizontal agreements, namely, agreements between competitors, are subject to stricter scrutiny than vertical agreements, for example, agreements between a manufacturer and its distributor. Certain categories of horizontal agreements are per se unlawful, including agreements:

- fixing prices or other terms of sale;
- to limit output;
- to allocate geographic territories or customers; and
- that are deemed group boycotts.

Agreements between competitors that may produce efficiencies, such as research and development agreements or joint production agreements, are analysed under the rule of reason. Under a rule of reason analysis, courts review the totality of circumstances, including market structure and the economics of the agreement, to determine whether the pro-competitive effects exceed the anti-competitive effects of the conduct. The Antitrust Guidelines for Collaborations Among Competitors (2000) (Competitor Collaboration Guidelines) describe the analytical framework the agencies will apply in analysing competitor collaborations including safe harbours where the participants collectively account for no more than 20 per cent of any affected relevant market.

20 Have there been cartel investigations in the pharmaceutical sector?

In the past decade, the US enforcement agencies have not made public any cartel investigations in the pharmaceutical sector.

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

Technology licensing agreements in the pharmaceutical sector are examined under the same antitrust framework as technology licensing agreements in other sectors. The Antitrust Guidelines for the Licensing of Intellectual Property (the IP Guidelines) set forth the approach of the antitrust agencies in analysing whether licenses are anti-competitive. The IP Guidelines proceed from three general principles:

- the antitrust agencies regard intellectual property as essentially comparable to other forms of property;
- intellectual property is not presumed to create market power; and
- intellectual property licensing generally is pro-competitive because it allows firms to combine complementary factors of production.

Licensing restrictions are analysed under the rule of reason, unless they involve conduct that traditionally is viewed as per se unlawful under US antitrust law (eg, horizontal price fixing). For licensing restrictions that are not subject to per se condemnation, the IP Guidelines provide a 'safety zone' where the parties involved account for less than 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?

The Competitor Collaboration Guidelines describe the analytical framework the US enforcement agencies apply in analysing co-promotion and co-marketing arrangements. The agencies evaluate whether such agreements involve a true integration of resources in a way that is efficiency-enhancing; that is, may lead to lower prices, better products, faster time to market or otherwise benefit consumers. Such arrangements will be considered anti-competitive if they increase market power or facilitate the exercise of market power by limiting independent decision-making or by combining in the collaboration control over competitively significant assets.

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

'Naked' agreements among competitors that involve coordination on pricing or output or allocate customers raise serious antitrust concerns and are typically deemed illegal per se, without regard to any purported pro-competitive justifications. However, joint ventures that have the potential to increase efficiency, reduce costs or bring new products to market (including research, manufacturing or marketing joint ventures), will generally be analysed under the rule of reason and will not raise antitrust concerns if on balance their competitive impact will be neutral or benign. A common concern in even pro-competitive joint ventures is that they may result in anti-competitive 'spillover' effects on products that are not included in the joint venture. Parties can reduce the risk that a collaboration will be found to facilitate collusion if they establish appropriate safeguards to govern information exchange; for example, by limiting access to competitively sensitive information only to certain individuals or to independent third parties.

Update and trends

A hot topic in pharmaceutical and antitrust regulation will continue to be the treatment of reverse payment settlements of paragraph IV patent infringement litigation between brand name and generic firms. The Obama administration's FTC Chairman Leibowitz has continued an aggressive two-pronged attack on such agreements: continuing to look to challenge such settlements in courts, particularly in Circuit Courts of Appeal that have yet to weigh in on the issue; and supporting legislation that would ban patent settlements involving payments.

On 27 January 2009, the FTC brought its newest complaint challenging brand drug manufacturer Solvay's settlement agreements with generic firms in relation to two pending ANDAs to sell generic AndroGel. The FTC alleges that these settlements involved agreements that Solvay pay the generic companies to cooperate in the sales, promotion and/or manufacturing of AndroGel in exchange for the generic firms to delay entry for nine years until 2015. Complaint, *FTC v Watson Pharmaceuticals, Inc et al*, No.: CV 09-598 MRP (PLAx) (CDCalif 28 January 2009). While the FTC had filed suit in the Ninth Circuit, which has yet to weigh in on patent settlement issues, defendants succeeded in transferring the case to the US District Court for the Northern District of Georgia as a more appropriate forum because that court had handled underlying patent suits. The district court, applying the standards of the Eleventh Circuit Court of Appeals (which has upheld several such settlements), dismissed the FTC and related private claims, concluding that the plaintiffs had not adequately alleged that the settlements between the defendants exceeded the scope of the patent at issue (*In re Androgel Antitrust Litigation*, No. 1:09-MD-2084-TWT, 2010 WL 668291 at *7 (ND Georgia 22 February 2010) ('Because the Plaintiffs do not allege that the settlements exceed the scope of the [...] patent, it does not matter if the Defendants settled their patent disputes with reverse payments.')). In doing so, the district judge rejected the FTC's argument that the scope of the patent standard should include an assessment of the likelihood that a patent holder could successfully enforce its patent (*In re Androgel Antitrust Litigation*, 2010 WL 668291 at *6-7). The FTC has appealed the district court ruling to the Eleventh Circuit.

The US antitrust enforcement agencies have in the past split over how to assess the competitive effects of reverse payment settlements. The FTC takes the position that any cash consideration (beyond de minimis litigation costs) to the generic is to compensate the generic for delaying market entry and therefore a restraint in trade. While the DoJ also has concerns about such settlements, differences between the agencies' views on how they should be evaluated came to light when the Solicitor General of the US (the government's advocate in the Supreme Court) and the Antitrust Division of the DoJ filed a brief opposing the FTC's petition for a writ of certiorari to the Supreme Court for review of the Eleventh Circuit's ruling in *Schering-Plough Corp v FTC*, 402 F.3d 1056 (11th Cir 2005) (where the Eleventh Circuit reversed a unanimous decision by the FTC and held that a reverse payment settlement was lawful under the antitrust laws). The DoJ argued that the FTC's position did not adequately take into consideration public policy in favour of settling litigation or the patent grant permitting right of patentees to exclude competition within the scope of the patent. According to the DoJ, the proper standard for evaluating such reverse settlements should include an objective assessment of the merits of the patent claims, viewed ex ante, and other relevant factors surrounding the parties' negotiations of the reverse payment settlement. Brief for the United States as amicus curiae, *FTC v Schering-Plough Corp*, 126 S Ct 2929 (2006) (No. 05-273).

With the change in presidential administration, it appears that the DoJ's approach is converging closer to the FTC's position. On 6 July 2009, the DoJ filed an amicus brief with the Second Circuit in the *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (Cipro) case, aligning itself with the position of the FTC in an earlier-filed amicus brief. The DoJ stated that, while settlements involving reverse payments should be evaluated under the rule of reason, reverse payments in the Hatch-Waxman context should be treated as 'presumptively unlawful' under Section 1 of the Sherman Act because the 'anti-competitive potential of reverse payments in the Hatch-Waxman context in exchange for the alleged infringer's agreement not to compete and to eschew any challenge to the patent is sufficiently clear' (Brief for the United States in Response to the Court's Invitation, *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, Nos. 05-2851-cv(L) 05-2852-cv (CON), 05-2863-cv (CON), at 10 (6 July 2009), at www.justice.gov/atr/cases/f247700/247708.pdf). The burden would then shift to defendants to 'rebut that presumption by providing a reasonable explanation of the payment.' In the DoJ's view, a plaintiff can establish a prima facie case by showing the generic manufacturer abandoned its challenge to the validity of the brand's patent in an agreement in which the patent holder provided consideration to the generic manufacturer (Brief for the United States at 24). The defendant could then rebut that prima facie case through a rule of reason analysis showing that the reverse payment settlement did not unreasonably restrain competition, such as by showing that the consideration paid was equivalent to the patent holder's expected litigation costs (Brief for the United States at 28-32). If, however, the settlement banned generic competition for the life of the patent, 'defendants will be unable to carry their burden' (Brief for the United States at 29). On 29 April 2010, the Second Circuit panel concluded the Tamoxifen ruling compelled it to uphold the legality of the settlement agreement, but appeared to invite the Second Circuit to revisit that ruling through en banc review (see *Arkansas Carpenters Health and Welfare Fund v Bayer AG*, 604 F.3d 98 (2d Cir 2010)). Purchaser plaintiffs petitioned for rehearing and rehearing en banc, and the FTC filed an amicus brief in support of en banc review. The Second Circuit denied the petition without comment (*Arkansas Carpenters Health and Welfare Fund v Bayer AG*, 625 F3d 779 (2d Cir 2010)). The plaintiffs then petitioned the US Supreme Court to hear the matter, but on 7 March 2011, the Court declined to grant certiorari (*Louisiana Wholesale Drug Co, Inc v Bayer AG*, 131 S Ct 1606, 2011 WL 767662 (7 March 2011)).

On the legislative front, as part of Health Care Reform both the House and the Senate introduced bills in early 2009 aimed at eliminating reverse payment settlements (HR 1706, the Protecting Consumer Access to Generic Drugs Act of 2009, and S 369, the Preserve Access to Affordable Genetics Act). Neither provision survived to be enacted, and legislative efforts appear to have stalled in Congress. The FTC issued a report in January 2010 estimating that such reverse payment agreements cost consumers $3.5 billion per year and keep generic alternatives off the market for an average of 17 months longer than settlements that do not include a payment (see Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions, at www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf).

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

Vertical agreements are evaluated under the rule of reason to determine whether the anti-competitive effects outweigh pro-competitive effects. While vertical agreements can be challenged under either section 1, as unreasonable restraints of trade, or section 2, as exclusionary conduct by a dominant firm, vertical agreements that raise antitrust concerns are alleged to unreasonably foreclose competitors' opportunities to compete. In the pharmaceutical sector, recent vertical agreement challenges involve exclusive dealing, loyalty discounts, and bundling. For example, the FTC and state attorneys general brought restraint of trade and monopolisation claims alleging that drug manufacturer Mylan Laboratories' exclusive licensing arrangements for the supply of an essential raw material for a drug foreclosed competition and allowed Mylan to dramatically increase the price of the drug (see *FTC v Mylan Labs*, Inc, 62 F Supp 2d 25 (DDC 1999)). Private parties have also challenged as unlawful exclusive dealing pharmaceutical manufacturer's contracts with private insurers where rebates were provided in exchange for coverage of the drug (see, eg, *JBDL et al v Wyeth-Ayerst Labs*, 485 F3d 880 (6th Cir 2007)).

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

The FTC and private parties have challenged as antitrust violations 'reverse payment settlements' of Hatch-Waxman patent litigation. In reverse payment settlements, the NDA holder pays the generic ANDA filer cash or non-cash consideration to settle the patent challenge and delay entering the market. (See 'Update and trends' for more detailed discussion.)

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?

Section 2 of the Sherman Act prohibits monopolisation, attempts to monopolise and conspiracies to monopolise. Illegal monopolisation requires the possession of monopoly power and the acquisition, enhancement or maintenance of that power through exclusionary conduct. Attempted monopolisation requires showing that a defendant engaged in exclusionary conduct, with a specific intent to achieve a monopoly and with a 'dangerous probability' of success. Section 2 does not prohibit the possession of monopoly power, but rather prohibits the abuse of monopoly power by exclusionary conduct. Types of exclusionary conduct that can create antitrust liability under section 2 include vertical restrictions limiting competitors' access to markets or supplies (eg, exclusive dealing, tying, loyalty discounts and bundling), predatory pricing, misuse of governmental and standards-setting processes, and improper patent enforcement. In rare cases, a refusal to deal with a competitor has been deemed anti-competitive.

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

To be considered dominant (ie, have monopoly power), a party must have the ability to control price or exclude competition in a properly defined relevant market. While there are no bright lines and an assessment of the competition in the relevant market is necessary, most cases require a market share of at least 70 per cent to support a monopolisation claim and courts have rarely found monopoly power where shares are below 50 per cent. The 'dangerous probability of success' required for an unlawful attempt to monopolise generally requires a share of at least 50 per cent and shares below 30 per cent have rarely sufficed to support an attempt claim. US antitrust law does not recognise joint dominance of a market.

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

Application to the patent office and the issuance of a patent does not, standing alone, expose the patent owner to liability for an antitrust violation. However, if the patent is granted as a result of fraud or inequitable conduct before the patent office, liability may arise if and when a patent owner attempts to improperly enforce such patent. Acquisition of a patent from a third party is subject to the rules governing asset acquisitions.

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

Application to the patent office and the issuance of a patent does not, standing alone, expose the patent owner to liability for an antitrust violation. However, if the patent is granted as a result of fraud or inequitable conduct before the patent office, liability may arise if and when a patent owner attempts to improperly enforce such patent. Acquisition of a patent from a third party is subject to the rules governing asset acquisitions.

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

Enforcement of a patent can create antitrust liability if the patentee knowingly enforces a fraudulently obtained patent or, alternatively, if the patent owner filed an infringement suit that was 'objectively baseless', in that no reasonable litigant could realistically expect success on the merits: for example, the patent owner bringing the suit knew the patent was not infringed, not enforceable, or not valid; and for the purpose of harming a competitor.

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

Recently, antitrust plaintiffs have challenged product or market 'switching' practices whereby a brand drug company introduces a new drug when an older drug is about to lose patent protection, in some cases withdrawing the NDA for the old drug, thereby precluding an ANDA application for a generic version. Private parties have alleged that such practices are anti-competitive attempts to switch patients to new, but not necessarily better, drugs and hamper generic competition. In *Abbott Labs v Teva Pharm USA*, 432 F Supp 2d 408 (D Del 2006), plaintiffs alleged that Abbott and Fournier's product reformulation and simultaneous withdrawal of the NDA of an earlier formulation of TriCor had the intent and effect of precluding generic entrants and constituted illegal monopolisation. The court held that plaintiffs had adequately plead an antitrust claim and focused on the withdrawal of the NDA as potentially reducing consumer choice (*Abbott Labs v Teva Pharm USA,* 432 F Supp 2d at 422). In contrast, another court dismissed a monopolisation claim where plaintiffs alleged Astrazeneca introduced patent-protected Nexium, a 'virtually identical drug' to its prior formulation, Prilosec, in an effort to switch patients away from Prilosec before it went off-patent and would be subject to state laws mandating generic substitution (*Walgreen Co v AstraZeneca Pharms LLP*, 534 F Supp 2d 146 (DDC February 2008)). Significant to the court's decision to dismiss the antitrust claims was the fact that Astrazeneca had not removed Prilosec's NDA and therefore not prevented generic entry upon patent expiration,

Arnold & Porter LLP

Asim Varma **asim.varma@aporter.com**
Barbara Wootton **barbara.wootton@aporter.com**

555 12th St NW
Washington, DC 20004-1206
United States

Tel: +1 202 942 5000
Fax: +1 202 942 5999
www.arnoldporter.com

but rather had introduced additional products and increased consumer choice.

The FTC and private plaintiffs also have challenged the improper listing of patents in the Orange Book as a means to impede generic competition (see, eg, *In the Matter of Bristol-Myers Squibb Co*, docket No. C-4076 (2003)). Additionally, the FTC and private plaintiffs have alleged that pharmaceutical companies' filing of 'citizen petitions' with the FDA constituted sham government petitioning intended to delay generic competition.

32 Do authorised generics raise issues under the competition law?

With increasing frequency, brand drug manufacturers have begun to market authorised generics at the beginning of the 180-day marketing exclusivity period awarded a 'first-filer' paragraph IV generic. The likely effects of the practice have been debated. In the short run, an authorised generic increases competition during the 180-day period. However, the potential introduction of such a product, some argue, may decrease the expected value of the 180-day exclusivity period granted to the first ANDA filer. The increased introduction of authorised generics by brand manufacturers may, in the context of paragraph IV litigation, also provide leverage to the brand manufacturer and increased incentive to the generic manufacturer to settle. To date, there have been no FTC enforcement actions challenging authorised generics. However, FTC Chairman Leibowitz has expressed concerns about patent settlements in which brand companies agree to forgo selling an authorised generic and cutting into the 180-day exclusivity period to induce generic companies to delay entry (source: Congressional Daily PM, 2/19/2009).

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

The specific features of the pharmaceutical sector are taken into account in assessing the competitive effects of any challenged conduct or an acquisition. However, once a violation of the antitrust laws is found, specific features of the pharmaceutical sector do not provide any objective justification for the infringement.