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Intellectual Property & Antitrust

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Contributing editors Peter J Levitas and Matthew A Tabas

Arnold & Porter Kaye Scholer LLP

Lexology Getting The Deal Through is delighted to publish the 15th edition of *Intellectual Property & Antitrust*, which is available in print and online at www.lexology.com/gtdt.

Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

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Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editors, Peter J Levitas and Matthew A Tabas of Arnold & Porter Kaye Scholer LLP, for their assistance with this volume.



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INTELLECTUAL PROPERTY

Intellectual property law

Under what statutes, regulations or case law are intellectual property rights granted? Are there restrictions on how IP rights may be enforced, licensed or otherwise transferred? Do the rights exceed the minimum required by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)?

US federal law governs three types of intellectual property: (1) patents (35 USC, section 101 et seq), (2) copyrights (17 USC, section 101 et seq) and (3) trademarks (15 USC, section 1051 et seq). State law primarily governs the protection of trade secrets, with most states having adopted the Uniform Trade Secrets Act, or some variation. In 2016, Congress passed the Defend Trade Secrets Act (DTSA) allowing the owner of a trade secret to sue in federal court for misappropriation. The DTSA largely mirrors the Uniform Trade Secrets Act, but notably does not pre-empt state law.

Holders of IP rights generally can transfer and assign their rights. The transfer and licensing of IP rights may be subject to pre-merger notification requirements under the Hart–Scott–Rodino Antitrust Improvements (HSR) Act. The sale or licensing of IP rights is evaluated under the same antitrust statutes that apply to conduct involving tangible property, including the Sherman, Clayton and Federal Trade Commission (FTC) Acts. The US views TRIPs as setting a minimum standard for the protection and enforcement of IP rights and US standards frequently exceed TRIPs minimum standards.

Responsible authorities

Which authorities are responsible for granting, administering or enforcing IP rights?

The US Patent and Trademark Office (USPTO) and the US Copyright Office are the main IP authorities in the United States. An agency of the US Department of Commerce, the USPTO has the authority to grant patents and register trademarks, and it also advises the President of the United States, the Secretary of Commerce and bureaus of the Department, and other government agencies, on domestic and global intellectual property issues.

The Copyright Office does not grant IP rights – copyright protection is created the moment that a work is created and fixed in a tangible form. The Office administers the Copyright Act's mandatory deposit provisions and various compulsory and statutory licensing provisions set forth in the Act, including collecting and distributing royalty fees. The Office also advises Congress on copyright policy.

The US International Trade Commission (ITC), pursuant to section 337 of the Tariff Act of 1930 (19 USC, section 1337), investigates claims regarding IP rights and infringement by imported goods.

Proceedings to enforce IP rights

What types of legal or administrative proceedings are available for enforcing IP rights? To the extent your jurisdiction has both legal and administrative enforcement options for IP rights, briefly describe their interrelationship, if any?

US federal courts resolve patent, copyright and trademark infringement suits, largely brought through private party civil litigation. Although state courts normally resolve trade secret violations, federal courts might resolve these disputes as part of disputes involving federal law issues

Administrative proceedings are handled in numerous different tribunals. The ITC adjudicates private claims of infringement by imported goods under section 337. The USPTO also holds administrative proceedings. The America Invents Act of 2011 created the Patent Trial and Appeal Board (PTAB) within the USPTO, which conducts trials dealing with inter partes review, post grant review, covered business method patent reviews and derivation proceedings, and hears appeals from adverse patent examiner decisions in patent applications and re-examination proceedings. Relatedly, the USPTO's Trademark Trial and Appeal Board (TTAB) is responsible for adjudicating petitions opposing proposed trademark registrations and appeals from USPTO examiners denying registration of marks, as well as handling concurrent use and interference proceedings. Appeals from the USPTO and ITC can be further appealed to the US Court of Appeals for the Federal Circuit.

The FTC can also bring an administrative enforcement action before an administrative law judge in the instance that private enforcement of IP rights violates competition laws.

Remedies

What remedies are available to a party whose IP rights have been infringed? Do these remedies vary depending on whether one utilises judicial or administrative review or enforcement?

US IP statues provide numerous remedies for infringement. For patent and copyright infringement, IP owners can receive monetary relief (actual or statutory damages), preliminary or permanent injunctions, exclusion orders and seizures of imported items. For wilful or deliberate infringement, patent and copyright owners may win increased damages, which can be up to three times the compensatory damages. Additionally, costs may be recoverable, and in cases of wilful infringement, attorneys' fees are also recoverable.

Federal courts evaluate a request for an injunction to remedy patent infringement under the Supreme Court's decision in $eBay\ v$ MercExchangeLLC, 547 US 388 (2006). Under eBay, a plaintiff must demonstrate that: (1) absent an injunction it would suffer irreparable injury; (2) monetary damages are inadequate; (3) that balance of

hardships between the plaintiff and defendant favours an injunction; and (4) an injunction is not contrary to the public interest.

Trademark owners also have numerous remedies available for infringement: injunctions, a court order requiring the destruction or forfeiture of infringing articles, damages (again, which may be trebled in cases involving bad faith) and disgorgement of the infringer's profits. For dilution, the most likely remedy is an injunction against further dilution. However, if the trademark owner can prove wilfulness, they can seek attorneys' fees, monetary damages and even treble damages.

Although state and federal courts can grant injunctive relief and monetary damages for IP holders, administrative tribunals (such as the ITC) can usually offer injunctive relief such as exclusion and cease-and-desist orders. Temporary exclusion and cease-and-desist orders can be granted in certain exceptional circumstances.

Nexus between competition and IP rights

Do any statutes, regulations or case law in your jurisdiction address the interplay between competition law and IP law?

The federal antitrust agencies and courts treat antitrust and intellectual property as complementary areas of law that work together to promote competition, innovation and consumer welfare. The acquisition or assertion of intellectual property rights is neither particularly suspect nor immune from scrutiny under the antitrust laws.

For the purposes of antitrust enforcement, courts and agencies apply the same antitrust rules to matters involving IP rights as they apply to matters involving tangible property. Antitrust claims based on the acquisition, assertion or transfer of intellectual property rights are evaluated primarily under sections 1 and 2 of the Sherman Act, section 7 of the Clayton Act, or section 5 of the FTC Act.

A wide body of federal case law provides guidance on the application of the antitrust laws to particular fact patterns. Key Supreme Court cases provide foundational principles that apply broadly to antitrust claims based on the acquisition or assertion of IP rights. The Supreme Court has held that although patents confer a bundle of rights that may include the right to exclude, patents do not confer monopoly power for purposes of establishing a claim under the antitrust laws. *Illinois Tool Works v Independent Ink*, 547 US 28 (2006). In addition, the Supreme Court has held that the First Amendment to the US Constitution provides IP owners with immunity for antitrust claims based primarily on the assertion of their rights unless the assertion is both objectively and subjectively baseless. *Prof'l Real Estate Inv'rs, Inc, v Columbia Pictures Indus, Inc,* 508 US 49 (1993).

The two federal antitrust agencies, the United States Department of Justice (DOJ) and FTC, have issued guidance materials on federal antitrust enforcement policy relating to IP.

Competition is addressed in statutes and case law on intellectual property rights as well. Patent misuse is an affirmative defence to patent infringement (not an independent cause of action). Patent misuse sometimes, but not always, requires a showing of market power or competitive harm. In a controversial decision, the Supreme Court held that the payment of post-expiration royalties constitute per se misuse despite appeals from academics that licensing agreements providing for post-expiration royalties can be efficient and should be evaluated under a rule of reason standard. Kimble v Marvel Entm't, LLC, 135 S. Ct. 2401 (2015). Claims of patent misuse based on tying or package licensing are typically evaluated under a reasonableness standard and so typically require a showing of competitive harm. Section 271(d) of the Patent Act bars a defence of misuse based solely on a unilateral refusal to license IP and requires a showing of market power to support a misuse defence based on tying. Federal courts have recognised a defence of misuse for copyright infringement. The

Lanham Act, the principal federal trademark law, expressly provides for an antitrust defence to a trademark violation claim, 15 USC, section 1115(b)(7).

Patent cooperation treaties and other agreements

6 Does your jurisdiction participate in any patent cooperation treaties or other similar agreements?

The US is party to the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Patent Cooperation Treaty, the Geneva Patent Law Treaty and all other major global agreements on IP.

Remedies for deceptive practices

With respect to trademarks, do competition or consumer protection laws provide remedies for deceptive practices?

The Lanham and FTC Acts both provide remedies for false advertising and deceptive practices. The FTC has sole authority to enforce the FTC Act. Where the FTC finds a violation, it has the authority to issue a cease and desist order to enjoin deceptive practices and prevent a future violation. The FTC also has the authority to pursue civil penalties in federal court. Private parties may bring false advertising claims in federal and state court under the Lanham Act. A plaintiff may be awarded both an injunction against further unlawful practices and monetary damages as compensation for lost profits. Most states have similar laws that provide protection against false advertising, which may be enforced by either the state attorney general or through private rights of action.

Technological protection measures and digital rights management

8 With respect to copyright protection, is WIPO protection of technological protection measures (TPMs) and digital rights management (DRM) enforced in your jurisdiction?

Do statutes, regulation or case law limit the ability of manufacturers to incorporate TPM or DRM protection limiting the platforms on which content can be played? Has TPM or DRM protection been challenged under the competition laws?

The US implemented the WIPO protections on digital rights in 1998 through passage of the Digital Millennium Copyright Act (DMCA). The DMCA prohibits the circumvention of technological protections on copyrighted works or certain rights management information. Violations of the DMCA can give rise to both civil and criminal penalties. There are no laws that limit the use of TPM or DRM protection on platforms. In certain cases, TPM or DRM software that blocks market access to unprotected aspects of a product or technology may give rise to antitrust liability, including claims for monopolisation or attempted monopolisation, if the other elements of a claim, including market power and anticompetitive exclusion, are established.

Industry standards

9 What consideration has been given in statutes, regulation or case law to the impact of the adoption of proprietary technologies in industry standards?

The activities of standards-development organisations (SDOs) are typically treated as agreements subject to section 1 of the Sherman Act. Courts have held that although the development of industry standards can limit competition, where standards are developed through transparent procedures and without undue capture by any single group of stakeholders, standards can also provide enormous procompetitive value. For those reasons, the activities of SDOs are almost always evaluated under the rule of reason standard. *Allied Tube & Conduit Corp v Indian Head Inc.* 486 US 492 (1988). These same principles apply to

the development of standards that include technologies covered by IP rights.

There are no special antitrust rules that apply to the assertion or licensing of standard-essential patents. Federal case law defines the application of section 2 of the Sherman Act to the unilateral conduct of essential patent owners. A claim for monopolisation or attempt to monopolise requires a showing that (among other things) deception during the standards-development process harmed the competitive process by excluding rivals. However, absent exclusionary behaviour during the development process, the later breach of an agreement to provide access to essential patents on reasonable and non-discriminatory (RAND) terms does not alone provide the basis for an antitrust claim. Broadcom Corp v Qualcomm Inc 501 F. 3d 297 (Third Circuit 2007), Rambus Inc. v FTC, 522 F.3d 456 (DC Circuit 2018). Instead, claims that an essential patent owner has breached a RAND assurance are typically evaluated under principles of contract law. Microsoft Corp v Motorola, Inc, 795 F 3d 1024 (Ninth Circuit 2015).

In two matters, the FTC has alleged that an essential patent owner that seeks an injunction against a firm willing to abide by a RAND licence may violate section 5 of the FTC Act. *Robert Bosch GmbH*, FTC Docket No. C-4377, *Motorola Mobility LLC*, Docket No. C-4410. Both matters were resolved through settlement agreements that lack broader precedential value. Federal courts have held that merely seeking relief in court, including seeking an injunction, is immune from antitrust liability under the *Noerr-Pennington* doctrine, providing further limits on the precedential value of the FTC's settlements. *Apple, Inc v Motorola Mobility, Inc*, 886 F Supp 2d 1061 (Western District Wisconsin 2012), *TCL Commc'ns Tech. Holdings, Ltd v Telefonaktienbolaget LM Ericsson*, 2016 US Dist. LEXIS 140566 (Central District California 2016).

COMPETITION

Competition legislation

10 What statutes set out competition law?

The Sherman Act, passed by Congress in 1890 and the FTC Act and Clayton Act, both passed in 1914, are the three core US federal antitrust laws in effect today. The Sherman Act prohibits unreasonable restraints of trade, monopolisation, attempts to monopolise and conspiracies to monopolise. The Clayton Act prohibits acquisitions that may substantially lessen competition, as well as certain other issues such as tying. The FTC Act, which is enforced solely by the Federal Trade Commission (FTC), prohibits unfair methods of competition as well as unfair or deceptive acts and practices. Though the FTC's authority to challenge unfair methods of competition technically reaches beyond letter of the Sherman Act, the precise scope of the FTC's 'unfair methods of competition' authority has been a subject of some controversy. The FTC has most often used its antitrust authority falling outside the scope of the Sherman and Clayton Acts to challenge invitations to collude, where no agreement forms. Beyond that, the FTC typically pursues claims for an unfair method of competition under the same standards federal courts apply to Sherman Act claims.

In addition to these federal statutes, most states have their own antitrust statutes – generally modelled after the federal antitrust laws – enforced by the state attorneys general or private plaintiffs.

IP rights in competition legislation

11 Do the competition laws make specific mention of any IP rights?

US antitrust statutes do not specifically mention IP rights. However, the Department of Justice (DOJ) and FTC have issued antitrust licensing guidelines (first in 1995, and most recently in 2017) and other guidance

materials that outline the agencies' antitrust enforcement policy towards the licensing of intellectual property and other conduct involving IP such as patent pools, bundled or package licensing arrangements and unilateral refusals to deal

Review and investigation of competitive effects from exercise of IP rights

Which authorities may review or investigate the competitive effect of conduct related to exercise of IP rights?

The DOJ and FTC jointly enforce the federal antitrust laws. However, only the DOJ has the authority to bring criminal enforcement actions – though the FTC can refer matters to the DOJ for criminal enforcement. Additionally, under section 5 of the FTC Act, the FTC may bring civil challenges to conduct that violates section 5 of the FTC Act (which covers but is not limited to claims that could be brought under sections 1 or 2 of the Sherman Act) either in administrative proceedings or federal court.

Coordination between DOJ and FTC is governed loosely by an informal memorandum of understanding, which distributes enforcement authority by industry expertise and knowledge. For example, the FTC is typically responsible for industries including healthcare providers, pharmaceuticals, and food and retail. The DOJ is typically responsible for telecommunication, agriculture and insurance.

Competition-related remedies for private parties

Can a private party recover for competition-related damages caused by the exercise, licensing or transfer of IP rights?

Private parties can recover for competition-related damages from the exercise, licence or transfer of IP rights under either federal or state antitrust law. Under federal law, the Clayton Act creates a private right of action for parties to recover damages from injuries flowing from a violation of the antitrust laws. Damages are typically trebled and plaintiffs may also recover court costs and attorneys' fees (15 USC, section 15(a)). Plaintiffs may also win an injunction requiring the defendant to end the offending conduct. To win relief, a plaintiff must establish antitrust injury, which requires that it suffered harm because of the restriction in competition that forms the basis for the violation. The alleged anticompetitive conduct must proximately cause the injury.

Forty years ago, the Supreme Court barred, with limited exceptions, indirect purchasers from seeking and recovering antitrust damages. *Illinois Brick Co v Illinois*, 431 US 720 (1977). Over half of US states have enacted 'Illinois Brick repealer' statutes allowing for indirect purchasers to recover. On 13 May 2019, the Supreme Court affirmed the Ninth's Circuit's decision that because Apple sold iPhone apps directly to consumers, Apple should be treated as a distributor and consumers as direct purchasers with standing to sue Apple for alleged monopolisation of the market for iPhone apps. *Apple v Pepper*, 139 S. Ct. 1514 (2019).

Competition guidelines

14 Have the competition authorities, or any other authority, issued guidelines or other statements regarding the overlap of competition law and IP?

The DOJ and FTC have issued joint guidance materials on federal antitrust enforcement policy relating to IP. In 2007, the agencies issued a report outlining agency enforcement policy on a range of competition issues involving IP, including unilateral refusals to license, the incorporation of patents into standards, patent pools, tying and bundling. For purposes of antitrust analysis, the agencies distinguished unconditional from conditional refusals to licence. Under US enforcement policy, unconditional unilateral refusals to license patents 'will not play a meaningful part in the interface between patent rights and antitrust

protections'. Conditional refusals to license, such as a licence that includes exclusivity provisions, may raise antitrust concerns if restrictions in the licence lead to competitive harm.

In 2017, the DOJ and FTC issued updated Antitrust Guidelines for the Licensing of Intellectual Property. The Guidelines incorporate the core principles from the 1995 Guidelines and remain consistent with the principles in the broader 2007 Antitrust IP Report. The 2017 Guidelines cover the antitrust treatment of licences involving patents, copyrights, or trade secrets. Although the Guidelines do not apply expressly to trademark agreements, 'the same general antitrust principles that apply to other forms of intellectual property apply to trademarks as well.'

The 2017 Guidelines incorporate several key principles.

- The agencies will apply the same antitrust principles to conduct involving IP as to conduct involving other forms of property.
- IP rights do not create a presumption of market power under the antitrust laws.
- IP licensing allows firms to combine complementary assets and is thus generally procompetitive.

The vast majority of restrictions in licensing arrangements are evaluated under the rule of reason and are not likely to harm competition if the restriction does not limit competition that would have existed in the absence of the licence.

Exemptions from competition law

15 Are there aspects or uses of IP rights that are specifically exempt from the application of competition law?

Courts have developed a number of exemptions and immunities from the antitrust laws, such as the state action doctrine or protection for the solicitation of government action (known as *Noerr-Pennington* immunity). These general exemptions apply equally to conduct involving IP rights. *Noerr-Pennington* immunity protects IP owners from antitrust liability for pursuing infringement claims unless the underlying claims are both objectively and subjectively baseless. *Professional Real Estate Investors v Columbia Pictures Industries*, 508 US 49 (1993). Petitioning immunity extends to conduct associated with seeking relief such as sending infringement notices or other marketplace communications relating to infringement. Some courts have recognised an exception to petitioning immunity where the IP owner files repeated lawsuits without regard to individual merit. *USS-Posco Industries v Contra Costa County*, 31 F.3d 800 (Ninth Circuit 1994).

The Federal Circuit has held that a mere unconditional unilateral refusal to license or share IP is lawful and cannot give rise to antitrust liability. In re Independent Service Organizations Antitrust Litigation, 203 F.3d 1322 (Federal Circuit 2000). One appellate court has held that although a refusal to license is presumptively lawful as a legitimate exercise of the statutory right to exclude, but the presumption can be overridden by evidence that the refusal was a pretextual effort to harm rivals. Image Technical Services, Inc v Kodak Co, 125 F.3d 1195 (Ninth Circuit 1997). However, in reversing a district court decision, the Ninth Circuit more recently held that patent owner has no antitrust duty to deal with rivals except in limited circumstances articulated by the Supreme Court. FTC v Qualcomm, 969 F.3d 974 (Ninth Circuit 2020), citingVerizon Communications Inc v Law Offices of Curtis v Trinko LLP, 540 US 398 (2004).

Copyright exhaustion

16 Does your jurisdiction have a doctrine of, or akin to, 'copyright exhaustion' (EU) or 'first sale' (US)? If so, how does that doctrine interact with competition laws?

The first sale doctrine is codified under section 109(a) of the Copyright Act. Under the first sale doctrine, a party that lawfully acquires the tangible embodiment of a copyright work, such as a book or a compact disc, may resell the item without violating the copyright. Efforts to control the price at which the acquiring party resells the product are evaluated under state and federal antitrust laws relating to resale-price maintenance. The first sale doctrine does not apply to computer software that is licensed rather than sold and thus the copyright owner can exert greater control over subsequent distribution by licensing rather than selling the tangible product. *Vernor v Autodesk*, 621 F.3d 1102 (Ninth Circuit 2010). The party asserting the first use defence bears the burden of proving ownership through lawful acquisition.

Import control

17 To what extent can an IP rights holder prevent 'grey-market' or unauthorised importation or distribution of its products?

An IP owner can challenge the unauthorised importation of infringing products by filing a complaint with the US International Trade Commission (ITC) under section 337 of the Tariff Act. Section 337 bars unfair methods of competition, including through importation of items that infringe US patent, copyright or trademark rights. The primary remedy in a 337 investigation is an exclusion order, which blocks entry of infringing items at the border. The ITC may also stop the sale of infringing items already in the US through a cease and desist order. A trademark owner may also file suit in federal court under section 42 of the Lanham Act. Relief under the Lanham Act may include injunction relief to stop infringing imports as well as monetary relief.

Jurisdictional interaction between competition laws and IP rights

18 Are there authorities with exclusive jurisdiction over IP-related or competition-related matters? For example, are there circumstances in which a competition claim might be transferred to an IP court to satisfy subject matter jurisdiction? Are there circumstances where the resolution of an IP dispute will be handled by a court of general jurisdiction?

US district courts have exclusive jurisdiction over claims brought under the patent and copyright acts. The Federal Circuit has exclusive jurisdiction to hear appeals in cases 'arising under' that patent laws. A case that involves both a patent and antitrust claim will be appealed to the Federal Circuit. However, the Federal Circuit will apply the law of the appropriate regional circuit to pure antitrust questions such as relevant market and competitive effects.

Antitrust enforcement occurs at both the state and federal level. Actions are brought by the FTC, DOJ, state attorneys general, as well as through private litigation. The FTC has sole authority to enforce the FTC Act, which it may do in federal court or in its own administrative tribunal. Administrative decisions are appealed to the Commission and may be ultimately reviewed by federal appellate courts.

MERGER REVIEW

Powers of competition authority

19 Does the competition authority have the same authority with respect to reviewing mergers involving IP rights as it does with respect to any other merger?

Acquisitions involving IP rights are reportable under the HSR Act if the value of the IP rights triggers statutory thresholds and the parties otherwise meet the standard regulatory requirements for premerger notification. The FTC and DOJ review both reportable and non-reportable mergers and acquisitions involving IP rights under the same statutes that apply to other mergers (the Sherman, Clayton and FTC Acts). State attorneys general also have the authority to review and challenge mergers, and that authority includes mergers that involve IP.

Certain IP licensing agreements that fall short of a full transfer or assignment of rights may also be reportable. Based on informal guidance from the FTC Premerger Notification Office, exclusive patent or trademark licences may be reportable under the HSR Act. Such licences may be reportable even if exclusivity extends only to a particular geographic region. Although non-exclusive licences are generally not reportable, the FTC issued a rule in 2013 that requires reporting for certain non-exclusive pharmaceutical patent licences that transfer 'all commercially significant' rights, even where the licensor retains manufacturing rights.

Analysis of the competitive impact of a merger involving IP rights

Does the competition authority's analysis of the competitive impact of a merger involving IP rights differ from a traditional analysis in which IP rights are not involved? If so, how?

The same principles apply to the evaluation of mergers and acquisitions involving IP rights as to transactions involving other forms of property. However, in analysing mergers involving IP, the agencies may consider competitive effects in upstream technology markets for the IP rights themselves as well as downstream product markets.

In limited cases, the agencies may also consider the impact of a merger on research and development activities and the analysis of the competitive effects on research and development (R&D) may be more likely in merger that involves the transfer of significant IP. However, potential anticompetitive effects in an 'R&D' or 'innovation' market has not played a meaningful role in merger investigations outside the pharmaceutical sector, where the agencies will evaluate the pipeline products of the merging parties. However, even those matters can be understood as focusing on potential competition rather than pure R&D.

Challenge of a merger

21 In what circumstances might the competition authority challenge a merger involving the transfer or concentration of IP rights? Does this differ from the circumstances in which the competition authority might challenge a merger in which IP rights were not a focus?

The US agencies will apply the same statutes and legal standards towards evaluating the competitive effects of mergers involving IP as to other transactions and will take both horizontal and vertical effects into account. For example, the agencies may consider whether the transfer of a patent portfolio would combine ownership over technologies that would otherwise compete in upstream technology markets and whether that combination may substantially lessen competition. The agencies may also evaluate whether the acquisition will change the incentives of the merging parties towards licensing potential downstream rivals. In 2011 and 2012, the DOJ investigated a series of transactions involving

the transfer of large patent portfolios that included standard-essential. The agencies evaluated how the transfer would change incentives to share IP with downstream product market rivals. The DOJ allowed the transactions to proceed after certain acquiring parties made public assurances regarding their future licensing behaviour. (Statement of the DOJ's Antitrust Division, 13 February 2012.) Challenges to the aggregation of patents by patent assertion entities are likely to fail where plaintiffs are unable to show that the defendant enhanced its market power in any technology market consisting of patents that cover technical substitutes. *Intel Corporation v Fortress Investment Group LLC*, 2020 U.S. Dist. LEXIS 158831 (Northern District of California 15 July 2020.)

Remedies to address the competitive effects of mergers involving IP

What remedies are available to address competitive effects generated by a merger when those effects revolve around the transfer of IP rights?

The normal range of remedies is available to restore competition that may be lost in mergers that involve IP rights, including divestiture and behavioural remedies. In some cases, one of the merging parties may own IP that creates a barrier to entry into the relevant market. To resolve competitive concerns with the merger, the agencies may require the merging parties to provide a licence to new entrants to ameliorate the potential anticompetitive effects from the merger. In 2012, the DOJ at least informally appeared to require certain technology companies acquiring stakes in large patent portfolios to provide assurances regarding their willingness to provide downstream competitors with access to standard-essential patents that were part of the portfolios. (Statement of the DOJ's Antitrust Division, 13 February 2012.) In other cases, intellectual property rights owned by one of the merging parties may act as a barrier to entry, in which case the agencies may require that the merging parties either divest certain intellectual property rights or to make licences available to new entrants to resolve competitive concerns associated with the merger. Courts also have the authority to require divestiture of assets, including IP rights, to remedy an anticompetitive merger.

SPECIFIC COMPETITION LAW VIOLATIONS

Conspiracy

23 Can the exercise, licensing or transfer of IP rights create price-fixing or conspiracy liability?

The same antitrust rules apply to price-fixing and conspiracy claims involving IP as to horizontal conduct involving tangible property. Most licensing arrangements expand competition by allowing parties to share complementary assets. Thus, the transfer or licensing or IP is seldom treated as per se unlawful. When evaluating a licensing arrangement, the agencies will ask whether the licence restricts competition between the parties that would have existed in the absence of a licence. In cases where the licensee requires a licence to participate in the market, a licence expands competition, even if the parties agree on the resale price of licensed products or agree to operate in different territories. However, a licence or cross-licensing arrangement may support a price-fixing claim if it is used as a sham to control the price for products or technologies where the parties would be actual or potential competitors without the licence.

In *Continental Auto Systems v Avanci*, a district court dismissed claims filed by upstream component manufacturers alleging that a patent pool covering 5G SEPs that offered licences solely to end-device manufacturers constituted an unlawful conspiracy. Applying the rule of

reason, the court held that the pool agreement did not harm competition because it did not preclude pool members from individually negotiating licences that excluded the pool's field of use restriction. 2020 U.S. Dist. LEXIS 17399 (Northern District of Texas, 10 Sept. 2020). Agreements among technology users on the price at which they will accept a licence may also give rise to a price-fixing claim. Recently, the DOJ has expressed concerns that users of standardised technologies (acting collectively through a standards-development organisation) may engage in de facto price fixing by imposing policies that improperly shift bargaining leverage towards licensees and signalled its intention to scrutinise such conduct.

Scrutiny of settlement agreements

24 How would a settlement agreement terminating an IP infringement dispute be scrutinised from a competition perspective? What are the key factors informing such an analysis?

While IP settlements are not immune from antitrust scrutiny, settlement of legitimate infringement actions is typically procompetitive and lawful under a rule of reason standard. However, patent infringement settlements in the pharmaceutical sector that involve a reverse payment from the infringer to the patent owner are often the subject of antitrust scrutiny. The Court rejected the assertion that a settlement that fell within the legitimate scope of the patent owner's rights should be immune from scrutiny, concluding that a large unexplained payment from the patent owner to the alleged infringer suggests that the patent would not survive challenge. As such, the presence of the reverse payment raises legitimate concerns that the settlement could be used primarily as a tool to restrain competition. However, the same antitrust standard applies. The Supreme Court held in FTC v Actavis that reverse payment patent settlements are subject to antitrust scrutiny under a rule of reason standard, the same standard that applies broadly to agreements with the potential for procompetitive benefit.

Reverse payment patent settlements

25 How have the competition laws been applied to reverse payment patent settlements in your jurisdiction?

Patent settlements in the pharmaceutical sector that include a reverse payment from the owner of a patent on a branded drug to an alleged generic infringer have been the subject of scrutiny from enforcement agencies and have been widely litigated by private plaintiffs as well.

In a significant 2013 decision, FTC v Actavis, Inc, the Supreme Court held that even in cases where the underlying infringement claim was not a sham, reverse payment settlements are subject to antitrust scrutiny under a section 1 rule of reason standard. The Court explained that an 'unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival', suggesting the objective of the settlement is to preserve and share monopoly profits by avoiding price competition. However, the court refused to find that reverse payment settlements were presumptively unlawful, which would effectively shift the burden to the settling parties to prove that the agreement was pro-competitive. The Court held that the anticompetitive effects of a settlement depended on a variety of factors including the size of the payment relative to likely litigation costs and whether the payment provided compensation for other services, and that a plaintiff 'must prove its case as in other rule-of-reason cases'.

Since Actavis, most district courts have concluded that a non-cash transfer of value from the branded pharmaceutical to the potential generic can constitute a reverse payment. The Third Circuit has held that the branded pharmaceutical firm's agreement to refrain from introducing an authorised generic during the first-filer's 180-day exclusivity period can constitute a reverse payment and support an antitrust claim.

Additionally, in 2016, the First Circuit followed the Third Circuit in holding that these no authorised generic agreements may violate the antitrust laws, holding that to limit the holding of *Actavis* to only cash payments would put form over substance.

There are still numerous reverse payment lawsuits that continue to be litigated. See, eg, In re Glumetza Antitrust Litig., Case No. C 20-01198 WHA, 2020 U.S. Dist. LEXIS 39649, 2020 WL 1066934 (Northern District of California 5 Mar. 2020) (partially granting and partially denying the motion to dismiss in reverse payment putative class action); In re Zetia (Ezetimibe) Antitrust Litig., MDL No. 2:18-md-2836, 2020 U.S. Dist. LEXIS 152380, 2020 WL 4917625 (Eastern District of Virginia 21 Aug. 2020) (partially granting class certification in reverse payment case). Government agencies also continue to actively litigate such cases. See, eg, Fed. Trade Comm'n v. AbbVie Inc, 976 F.3d 327 (Third Circuit 2020) (reversing the lower court's grant of motion to dismiss but also finding that disgorgement is not a remedy the FTC can seek under section 13(b) of the FTC Act); see also Ass'n for Accessible Med. v Becerra, 822 Fed. Appx. 532 (2020) (affirming lower court's refusal to grant a preliminary injunction blocking California law that purportedly prohibits reverse payment settlement agreements). However, private plaintiffs who previously entered into arbitration agreements with pharmaceutical manufacturers may have a harder time bringing lawsuits. In 2019, the Third Circuit found that a lawsuit alleging that a pharmaceutical manufacturer engaged in anticompetitive behaviour to protect its monopoly over a drug called Remicade was subject to an arbitration clause, even though that arbitration clause was part of a distribution agreement and not directly related to antitrust. In re Remicade (Direct Purchaser) Antitrust Litig, 938 F.3d 515, 524-56 (Third Circuit 2019); but see In re Rotavirus Vaccines Antitrust Litig, Civil Action No. 18-CV-1734, 2020 U.S. Dist. LEXIS 217565, 2020 WL 6828123 (Eastern District of Pennsylvania Nov. 20, 2020) (finding that physician buying groups did not have authority to bind their members to arbitration provisions).

(Resale) price maintenance

26 Can the exercise, licensing, or transfer of IP rights create liability under (resale) price maintenance statutes or case law?

The Supreme Court has long held that where an IP owner licenses a product market competitor, it may restrict the price at which its competitor sells the licensed product. United States v General Electric, 272 US 476 (1926). However, for many years the liberal treatment afforded resale price maintenance for licensed products stood in contrast to the per se rule against vertical price fixing more generally. Then, in 2007, the Supreme Court reversed the per se rule for vertical price fixing and held that, given the potential for procompetitive benefits, an agreement between vertically related entities on minimum resale prices will be evaluated under the rule of reason. Leegin Creative Leather Products v PSKS, 551 US 877 (2007). The rule of reason requires a showing that the agreement harmed competition and that the harm was not outweighed by countervailing competitive benefits. Competitive harm is unlikely in a situation where the licensor and licensee would not have competed in the same relevant market absent the licence. Thus, the law covering licensed and unlicensed products is now better aligned under federal law. However, resale price maintenance remains per se unlawful under many state antitrust statutes

Exclusive dealing, tying and leveraging

27 Can the exercise, licensing, or transfer of IP rights create liability under statutes or case law relating to exclusive dealing, tying and leveraging?

Exclusive dealing and trying arrangements involving IP are evaluated under sections 1 and 2 of the Sherman Act, section 3 of the Clayton Act

and section 5 of the FTC Act. These arrangements are subject to the same standards as arrangements involving tangible property and are almost always evaluated under the rule of reason standard. In the 2017 Antitrust Licensing Guidelines, the FTC and DOJ explained that tying and package licensing arrangements can provide substantial efficiencies and provided guidance on the application of the rule of reason to these arrangements. The agencies will challenge such arrangements only if the IP owner has market power in the tying product or technology, and the arrangement has an adverse effect on competition that is not outweighed by countervailing efficiencies. In evaluating an exclusive dealing arrangement, the agencies will consider both the extent to which exclusivity enables the IP owner to realise the value of its rights more efficiently and the extent to which the arrangement forecloses competition that would have existed absent the licence. Though the term is used loosely in some opinions, US courts generally do not recognise leveraging as a distinct theory of harm. Any claim that a firm is using a licence to leverage power from one market to the next must meet the standards for anticompetitive exclusion to succeed.

Abuse of dominance

28 Can the exercise, licensing, or transfer of IP rights create liability under statutes or case law relating to monopolisation or abuse of dominance?

US antitrust law does not recognise a claim for abuse of dominance. Single-firm conduct associated with the exercise or acquisition of monopoly power is evaluated under section 2 of the Sherman Act and section 5 of the FTC Act. Monopolisation under section 2 requires a showing that a firm has acquired or maintained monopoly power through the anticompetitive exclusion of rivals, rather than creating 'a superior product, business acumen, or historic accident.' *United States v Grinnell Corp.*, 384 US 563 (1966). However, US antitrust laws do not prevent a lawful monopolist from charging prices or setting other terms of trade that reflect its lawfully acquired dominance of the market. *Verizon Communications Inc v Law Offices of Curtis v Trinko LLP*, 540 US 398 (2004). Though the FTC may have authority under section 5 to bring a monopolisation case that falls outside the scope of section 2, the bounds of the FTC's section 5 authority are unclear and the FTC has not prevailed in court on a different theory.

Refusal to deal and essential facilities

29 Can the exercise, licensing, or transfer of IP rights create liability under statutes or case law relating to refusal to deal and refusal to grant access to essential facilities?

The US agencies stated in a 2007 report that they are unlikely to bring an enforcement action challenging the unconditional unilateral refusal to license patents. Similarly, the Federal Circuit has held that a refusal to license or share IP is lawful and cannot give rise to antitrust liability. In re Independent Service Organizations Antitrust Litigation, 203 F3d 1322 (Federal Circuit 2000). One appellate court has held that although a refusal to license is presumptively lawful as a legitimate exercise of the statutory right to exclude, the presumption can be overridden by evidence that the refusal was a pretextual effort to harm rivals. Image Technical Services, Inc v Kodak Co., 125 F3d 1195 (Ninth Circuit 1997). Although Kodak has not been overruled, it has not been followed widely and has been criticised for its reliance on the subjective intent of the IP owner and the court's failure to provide sensible guidance on distinguishing a legitimate versus pretextual exercise of the right to exclude. In reversing a district court decision, the Ninth Circuit more recently held that patent owner has no antitrust duty to deal with rivals except in the limited circumstances described by the Supreme Court. FTC v Qualcomm, 969 F.3d 974 (Ninth Circuit 2020), citingVerizon Communications Inc v Law Offices of Curtis v Trinko LLP, 540 US 398 (2004).

REMEDIES

Remedies for violations of competition law involving IP

What sanctions or remedies can the competition authorities or courts impose for violations of competition law involving IP?

There are no special sanctions or remedies to resolve antitrust matters involving IP. Private civil antitrust matters in federal court may give rise to treble damages as well as injunctive relief. The Supreme Court has recognised compulsory licensing as an acceptable antitrust remedy in appropriate circumstances though district courts have rarely required a compulsory licence in practice. More commonly, courts will refuse to enforce patent rights as a remedy for patent misuse. The FTC has the authority to seek a range of equitable remedies through administrative litigation and has ordered compulsory licensing on reasonable rates as a remedy to a section 5 violation. Both the DOJ and FTC may require a compulsory licence or divestiture of IP as part of settlement agreement resolving the potential anticompetitive effects of a merger. Though criminal antitrust matters involving IP are unusual, criminal matters can give rise to both fines and imprisonment.

Competition law remedies specific to IP

31 Do special remedies exist under your competition laws that are specific to IP matters?

Special remedies specific to IP matters do not exist under US competition laws.

ECONOMICS AND APPLICATION OF COMPETITION LAW

Economics

32 What role has competition economics played in the application of competition law in cases involving IP rights?

Economics has changed the way that IP rights are viewed under the antitrust law. The incorporation of economics into antitrust law has led to the recognition that strong IP rights promote competition by creating incentives to invest in the development of new technologies and products. Most antitrust matters involving IP are evaluated under a rule of reason standard, which requires a showing of competitive harm, typically based on fact-intensive economic analysis and evidence.

RECENT CASES AND SANCTIONS

Recent cases

Have there been any recent high-profile cases dealing with the intersection of competition law and IP rights?

On 21 May 2019, a federal district court in the Northern District of California ruled in favour of the Federal Trade Commission (FTC) in its antitrust case against Qualcomm (FTC v Qualcomm, 2019 U.S. Dist. LEXIS 86219 (Northern District of California 21 May 2019)). After a 10-day bench trial, the court ruled that the FTC had shown that Qualcomm had unlawfully monopolised two markets for modem chips by requiring its modem chip customers to separately license Qualcomm's patented technology (rather than exhausting those rights through the sale of the chips themselves), refusing to provide licences for its standard-essential patents to its modem chip rivals, and engaging in exclusive dealing arrangements with Apple. Qualcomm appealed the decision to the Ninth Circuit, which

stayed key aspects of the district court injunction order pending appeal. The United States Department of Justice (DOJ) Antitrust Division filed an amicus brief supporting Qualcomm's appeal. On 11 August 2020, the Ninth Circuit reversed the district court and vacated the remedy. FTC v Qualcomm, 969 F.3d 974 (Ninth Circuit 2020). The Ninth Circuit rejected each of the FTC's substantive theories of harm. The court held that Qualcomm had no antitrust duty to deal with rivals and that Qualcomm's licensing policies did not harm competition because chipset customers paid the same royalty rate for Qualcomm's patents regardless of whether they sourced their chips from Qualcomm or a competitor; its licensing model was 'chipset neutral'. The court did not reach the question of whether Qualcomm had breached its licensing commitment to two specific standards-development organisations because a breach alone would not constitute an antitrust claim. The FTC sought rehearing, which was denied on 28 October 2020.

On 10 September 2020, the DOJ Antitrust Division updated a 2015 Business Review Letter to the Institute of Electrical and Electronics Engineers (IEEE). The Antitrust Division took the unusual step of revisiting a prior review letter out of concerns that the 2015 letter had been misunderstood as an endorsement of a particular IEEE policy, rather than a statement of its antitrust enforcement intentions. In issuing the revised letter, DOJ stated that its action was 'meant to align the now outdated analysis in the 2015 letter with the current US law and policy, which has evolved in important ways over the last five years in relation to the licensing of standard-essential patents, and the governance of standards development organizations'. DOJ Press Release, Justice Department Updates 2015 Business Review Letter to the Institute of Electrical and Electronics Engineers, 10 September 2020.

A Third Circuit opinion in 2020 provided further guidance on reverse payment settlements. The FTC sued AbbVie and other pharmaceutical companies for attempting to monopolise and restrain trade over the drug Androgel. Federal Trade Commission v AbbVie, Inc., 976 F.3d 327, 338 (Third Circuit 2020). The FTC claimed that Abbvie had pursued sham litigation claims against generic competitors Perrigo and Teva. The agency also claimed that the defendants had executed an anticompetitive reverse payment settlement agreement with Teva through a favourable supply agreement for a separate product, Tricor. The district court agreed with the FTC that the defendants had pursued sham patent infringement claims and ordered disgorgement as a remedy. However, the district court dismissed the FTC's claims that were based on reverse payment settlements. Even though the Teva patent settlement and Tricor supply agreements were executed on the same day, the district court analysed the agreements separately and found neither anticompetitive standing alone. On 30 September 2020, the Third Circuit reversed, finding that the district court's analysis put form over substance and would allow parties to avoid antitrust liability by merely creating a separate contractual vehicle for the reverse payment. The Third Circuit remanded with instructions to reevaluate the agreement under the proper framework. The Third Circuit also reversed the district court's order on disgorgement under section 13(b) of the FTC Act, reasoning that to sue under section 13(b), the FTC must have reason to believe an antitrust violation is imminent or ongoing, which is inconsistent with a remedy that deprives a wrongdoer of past gains, not current or imminent gains. The Third Circuit denied the FTC's and the defendants' petitions for rehearing and the case continues to be litigated at the district court.

In 2020, a federal district court dismissed a separate antitrust lawsuit brought against prescription drug maker AbbVie. The plaintiffs alleged that AbbVie had cornered the market for Humira, which is an anti-inflammatory drug, by amassing a large number of patents related to the drug and using those patents to keep out competitors. The district court found that AbbVie had simply 'exploited advantages conferred on it through lawful practices' and found that the alleged patent amassing practices AbbVie had engaged in were not violations of antitrust law. *In*

re Humira (Adalimumab) Antitrust Litig, No. 19-CV-1873, 2020 U.S. Dist. LEXIS 99782, 2020 WL 3051309 (Northern District of Illinois 8 June 2020).

In 2019, a trio of cases limited the jurisdiction of courts to hear pharmaceutical antitrust cases. First, on 25 February 2019, the Third Circuit upheld the dismissal of the FTC's complaint against Shire Viropharma, Inc. From 2006 to 2012, Shire submitted a total of 43 FDA filings and instituted three federal court proceedings in an attempt to block the approval of generic versions of a drug called Vancocin. The FTC alleged that these filings were meritless filings that were an attempt to block generics from entering the market, and in 2017, sought an injunction against Shire by bringing suit under section 13(b) of the FTC Act. However, by 2014, Shire had already divested its Vancocin holdings. The district court said that Shire was not currently violating the law and was not about to violate the law, and thus the FTC did not have the authority to obtain an injunction under section 13(b). FTC v Shira Viropharma, Inc, 917 F.3d 147, 159-60 (Third Circuit 2019). On 13 September 2019, the Third Circuit found that a plaintiff's antitrust claims were subject to an arbitration agreement. Rochester Drug Cooperative (RDC) sued Johnson & Johnson (J&J), alleging that J&J imposed anticompetitive clauses on insurers in an effort to keep the price of Remicade inflated. But RDC had entered into a distribution agreement with J&J regarding Remicade that had an arbitration clause. The Third Circuit found that because the price RDC paid for Remicade was directly intertwined with the distribution agreement, the antitrust claims were subject to the arbitration agreement. In re Remicade (Direct Purchaser) Antitrust Litia, 938 F.3d 515, 524-56 (Third Circuit 2019).

On 5 November 2019, the Second Circuit upheld the dismissal on Foreign Trade Antitrust Improvements Act grounds of an antitrust complaint brought against a pharmaceutical company. Biocad, a company that made biosimilars to a set of drugs called mAbs, sued F. Hoffmann-La Roche on the grounds that La-Roche had taken anticompetitive action in Russia to prevent Biocad from earning enough capital in Russia to be able to expand into the United States. The Second Circuit affirmed that the case should have been dismissed, holding that even if La-Roche's actions were taken with the intent to block Biocad from the US market, there were no actions taken in the US or that affected the US import market directly. Biocad JSC v F. Hoffmann-La Roche, Docket No. 17-3486, 2019 U.S. App. LEXIS 33011, 2019 WL 5700347 (Second Circuit 5 Nov. 2019).

Remedies and sanctions

34 What competition remedies or sanctions have been imposed in the IP context?

The full range of remedies is available in competition matters involving IP. International Trade Commission unfair competition claims involving infringing imports are subject to exclusion and cease and desist orders to prevent US sales of infringing items.

UPDATE AND TRENDS

Key developments

35 Are there any emerging trends or hot topics in the law of IP and antitrust policy? Have changes occurred recently or are changes expected in the near future that will have an impact on the application of competition law to IP rights?

Since taking over as Assistant Attorney General for Antitrust, Makan Delrahim has focused on restoring greater balance to competition policy and enforcement involving IP rights, particularly regarding the licensing of standard-essential patents subject to a reasonable and nondiscriminatory licensing assurance. On 10 November 2017, AAG Delrahim delivered his first public remarks on the topic. Delrahim stated that antitrust enforcers have recently focused too narrowly on the risk that firms that have agreed to license essential patents on reasonable and

non-discriminatory terms will breach those assurances and demand licensing terms that exceed reasonable levels. Delrahim explained that this narrow focus has led antitrust enforcers to misuse antitrust law to police private contractual arrangements in ways that risk harm to continuing incentives to innovate and participate in the standardsdevelopment ecosystem. Delrahim also stated that the narrow focus on policing private contracts has led US enforcement agencies to ignore the greater risk that firms implementing standardised technologies, acting collectively through standards-development organisation, will impose policies that shift the bargaining leverage in licensing negotiations towards licensees, behaviour that is tantamount to buver-side price fixing. Delrahim advised SDOs and their members to exercise caution in discussing or imposing licensing policies through collective action that disadvantage either licensors or licensees, and to ensure that standards are developed through transparent procedures with due process for all relevant stakeholders. Delrahim has delivered several additional speeches since November elaborating on his views and emphasising the risk that misdirected antitrust enforcement involving IP can generate for competition and innovation.

AAG Delrahim has continued his strong advocacy in 2020, including through DOJ amicus filings in several matters involving standardessential patents. DOJ's goal was to both direct the development of US law and advocate for greater balance by international enforcers. While DOJ's amicus program has likely influenced the development of law at the intersection of antitrust and IP, the impact of its softer competition advocacy work on future US enforcement activity or internationally remains to be seen. With a new administration and recent changes in the Congressional balance of power, the Congress and the enforcement agencies are likely to consider various antitrust reforms in 2021, including new legislation and regulatory changes that could affect the intersection of antitrust and IP, and the antitrust enforcement landscape more broadly (House Judiciary Subcommittee on Antitrust, Commercial and Administrative Law, Investigation of Competition in Digital Markets, Majority Staff Report and Recommendations) (6 October 2020). The Supreme Court's copyright decision in Google v Oracle, which is expected in 2021, may also influence the enforcement landscape for digital platforms with regard to antitrust duties or risks associated with restrictions on platform interoperability and data portability.

Coronavirus

36 What emergency legislation, relief programmes and other initiatives specific to your practice area has been implemented to address the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

On 24 March 2020, the DOJ and the Federal Trade Commission issued a joint statement providing guidance to businesses responding to the covid-19 crisis on how to engage with competitors without running afoul of the antitrust laws. The agencies acknowledged that the pandemic 'will require unprecedented cooperation among federal, state, and local governments and among private businesses' and reiterated that competitor collaborations often yield procompetitive benefits. The agencies went on to suggest that, in the midst of the covid-19 crisis, the antitrust laws may permit extensive collaboration in production, distribution and service provision, ostensibly even between direct competitors. The guidance suggests that such collaboration is more likely permissible where it is 'limited in duration', 'necessary to assist patients, consumers, and communities affected by COVID-19', and 'a necessary response to exigent circumstances' that might provide 'products or services that might not be available otherwise'. The agencies also pledged to provide expedited review of such proposals via the DOJ's Business Review



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process and the FTC's Advisory Opinion process. However, the joint statement also recognised that during the crisis some individuals and businesses may seek to exploit the vulnerable and undermine competition through conspiracies, illegal monopolistic behaviour or agreements to increase prices, lower wages, decrease output, or reduce quality. The agencies warned that they remain vigilant and stand ready to prosecute all civil and criminal antitrust violations, as well as other fraudulent schemes. In April 2020, the Department of Justice issued two business review letters. The first approved a competitor collaboration among several major distributors of medical equipment and medications that was intended to help the federal government's efforts to 'expedite and increase manufacturing, sourcing, and distribution' of personal-protective equipment (PPE) for medical professionals and first responders and medications used to treat covid-19 patients. The second approved a competitor collaboration proposed by a distributor of medical equipment and medications that was 'focused on facilitating the government's efforts to guide medications and other healthcare supplies to the places where they are needed most [during COVID-19 crisis]'. The DOJ concluded that the proposed collaborations would significantly aid the federal government's efforts to respond to the covid-19 pandemic because '[a]ddressing potential disruptions to the global medical supply is central to the US government's effort to save American lives and livelihoods from the destructive effects of COVID-19'. Relying on well-established precedent, the DOJ stated that it will not prosecute covid-19 related competitor collaborations where (1) the collaboration is 'compelled by an agreement with a federal agency or a clearly defined federal government policy' and (2) a federal agency supervises the conduct.

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