U.S. AND EU ANTITRUST: EXPECT ROBUST ENFORCEMENT IN 2021

Authors: D. Bruce Hoffmann, Elaine Ewing, Patrick Bock, Jan Przerwa

U.S. ANTITRUST: DEVELOPMENTS AND OUTLOOK

Antitrust was front-page news in 2020: regulators sued Google and Facebook in some of the biggest antitrust enforcement actions in recent decades. Robust antitrust enforcement can be expected to continue under a Biden administration.

BIG TECH LAWSUITS

In October, the U.S. Department of Justice and 11 states sued Google, alleging its conduct relating to search and search ads violated Section 2 of the Sherman Act. The DOJ alleged that Google achieved its lead in online search, where Google accounts for nearly 90% of all U.S. queries, through exclusionary agreements requiring Google to be the default search engine on devices, and then used those revenues to reinforce its monopoly. The DOJ alleged Google's practices have foreclosed other search engines from meaningfully competing in the United States, harmed consumers by reducing privacy and suppressed competition in advertising. In addition to an injunction against these practices, the DOJ seeks unspecified structural relief. In December, two separate state lawsuits were filed against Google. First, Texas and nine other states filed a suit alleging that Google manipulated digital advertising markets in violation of antitrust laws. The complaint alleges that Google entered into an agreement with Facebook to limit competition in return for special treatment in Google-run ad auctions. A few days later, Colorado and 37 other states sued Google, alleging it leveraged its monopoly in search to limit consumer choice and foreclose competition from specialized search engines. Google has strongly denied all the claims against it and is vigorously litigating in defense of these cases. Three additional states later joined the suit.

In December, the Federal Trade Commission and 48 states sued Facebook, accusing it of abusing its monopoly in personal social networking to swallow up smaller competitors. The FTC alleges that Facebook targeted potential competitive threats to its dominance with its acquisitions of Instagram in 2012 and WhatsApp in 2014, though both deals were cleared by the FTC at the time. The complaint also alleges that Facebook imposed anticompetitive conditions on third-party developers' access to its application programming interfaces. The FTC seeks remedies that could include a mandated divestiture of Instagram and WhatsApp.

Other investigations are ongoing and may result in additional lawsuits against "Big Tech" platforms like Apple and Amazon. Notably, after a year-and-a-half investigation, a Democratic-led House panel recently concluded that Google, Facebook, Apple and Amazon all wield monopoly power and urged greater antitrust enforcement. A potential flood of private

suits following any government action is another source of concern for these companies – numerous such suits have already been filed, and more are likely.

Tech-focused enforcement is not limited to these four household names. In April 2019, the FTC launched a major antitrust case against Surescripts, a leader in the e-prescriptions market. The FTC alleged that the company used anticompetitive agreements to maintain its monopoly in the routing of prescriptions to pharmacies and the market for determining eligibility for prescription coverage and ultimately denying patients the benefits of competition. The FTC's case survived a motion to dismiss and is in discovery. In November, the DOJ sued to block Visa's $5.3 billion acquisition of Plaid Inc., an innovative fintech firm. According to the DOJ, as a monopolist in online debit services, Visa is attempting to acquire a nascent competitor developing a lower-cost option for online debit payments. As a leading data aggregator, Plaid planned to leverage its connections to build a payments network that would disrupt Visa's collection of processing fees. Despite the lack of apparent overlaps between the companies, the complaint relied heavily on Visa's own emails and other internal documents, which DOJ argued revealed the company's plans to roll back Plaid's development of a cheaper alternative debit service.

In December, the FTC also issued orders under Section 6(b) of the Federal Trade Commission Act to nine social media and streaming companies ordering them to provide data on how they gather and use personal information and their advertising practices, including how those affect children and teens.

Beyond tech, state regulators continued to take an active role in antitrust. Most notably, 14 states filed a challenge to the T-Mobile and Sprint merger, even though it had received DOJ and FCC clearance. This unusual suit was publicly opposed by DOJ and ultimately defeated in early 2020.

ENFORCEMENT IN THE BIDEN ADMINISTRATION

Looking forward, stepped-up merger and conduct enforcement should be expected from the DOJ, while the current aggressive levels of FTC enforcement will likely continue, with perhaps a slight uptick and a particular focus on pharmaceutical mergers. However, a major swing toward progressive antitrust enforcement is unlikely.

Similarly, legislative changes will likely be incremental rather than radical. While the Democrats have won control of the Senate, that control is marginal (depending on the Vice President breaking ties), and is far from a filibuster-proof majority. Thus, support from moderate Democrats and Republicans will be necessary to pass legislation. Legislation that is more likely to garner such support includes increasing agency funding, addressing recent adverse court decisions involving the FTC's jurisdiction and remedial authority and other marginal changes. Sweeping proposals such as those considered in the House Judiciary Majority Staff Report on the technology industry mentioned above are not likely to advance (though some of the more modest proposals directed at the tech industry may garner bipartisan support).

By historical standards, DOJ merger enforcement levels have been relatively low under Assistant Attorney General Makan Delrahim, with the notable exception of a set of high-profile cases such as the unsuccessful challenge to AT&T's acquisition of Time-Warner. That will likely change. Even with marginal control of Congress, any Biden nominee for AAG will probably have to come from the mainstream antitrust tradition of the Democrastic party, but that still leaves room for more aggressive merger enforcement. Expect current cases to continue, and mergers to receive more probing scrutiny, with enforcement levels possibly similar to those of the recent FTC. Criminal enforcement may also increase, though the decline in cartel cases we have observed is not limited to the U.S., and so may not result from administration policy. It is also reasonably likely that the Biden DOJ will reverse or step back from the strongly pro-IP "New Madison" approach to IP/antitrust issues advanced by AAG Delrahim, rebalancing toward antitrust enforcement in the IP context. On the other hand, new leadership at the DOJ may continue the aggressive "statement of interest/amicus" program AAG Delrahim developed, which resulted in historically high levels of DOJ court filings (though probably with somewhat different content).

The FTC has been very aggressive in recent years, including in 2020 breaking a record for merger enforcement actions that had stood since 2000. While there will be pressure to be even more aggressive, the FTC's current activity levels do not leave huge amounts of room (or resources) for drastic increases. Also, as with the DOJ, any chairman President Biden might appoint, and the Bureau directors that chairman will select, will likely come from the mainstream of the Democratic antitrust community, which also suggests that FTC enforcement will not change radically. We do expect increasing scrutiny of pharmaceutical transactions, as the current Democratic commissioners' objections to FTC merger decisions have disproportionately focused on that industry, and perhaps more skepticism of vertical mergers. There's an open question as to how long it will take the FTC to switch to Democratic control. It is technically possible for Republicans to retain voting control of the agency until 2023. We do not believe that will occur, but it may take time – perhaps well into the middle of 2021 – for Democrats to take control of the FTC. However, even if Republicans remain in control of the FTC for a transition period, the FTC's independence and existing policy priorities should mean that the FTC will sustain its current high level of antitrust enforcement.

POTENTIAL HSR RULE CHANGES

In September 2020, the FTC published two documents related to potential Hart-Scott-Rodino rule (HSR Rule) changes: (i) a Notice of Proposed Rulemaking (NPRM) and (ii) Advance Notice of Proposed Rulemaking (ANPRM).

While these rules have not yet been adopted, and the timeline for adoption is unclear, if implemented, they may significantly increase the burden of the HSR Rules, particularly for investment firms. The NPRM, as drafted, would expand the definition of "person" to attempt to capture information about different investment funds that are under common management. It would also add a new exemption for acquisitions of less than 10% of the voting securities of an issuer provided that the acquirer is not a competitor, does not own more than 1% of any competitor, is not a major supplier or customer of the company and is not an

officer/director/principal/agent of the company. While this would seem to be a beneficial new exemption in addition to the existing "investment only" and "institutional investor" exemptions, in practice the new proposed exemption may be difficult to use. Moreover, the ANPRM suggests that the FTC is rethinking its approach to these exemptions on a going forward basis.

As 2021 continues, it will be important to watch these potential changes and consider their impact, especially in the context of corporate investments.

KEY TAKEAWAYS

There is little indication that antitrust enforcement will abate under a Biden administration. In pursuing actions against "Big Tech," federal and state regulators have shown unprecedented willingness to challenge already consummated deals as well as the acquisition of nascent competitors. In other sectors, enforcement by both DOJ and the FTC can be expected to be even more aggressive as well, particularly in the pharmaceutical space, though Biden appointees will likely come from the mainstream of Democratic antitrust community.

EU ANTITRUST: DEVELOPMENTS AND OUTLOOK

Despite the COVID-19 pandemic, 2020 was another active year for antitrust enforcement in Europe, with continued robust enforcement expected for the year to come.

European Commission Vice President Margrethe Vestager, having just completed her first year in her new role as Commissioner responsible for the Commission's Digital Agenda and the first year of her second five-year term as Competition Commissioner, has fully embraced Commission President Ursula von der Leyen's call to further strengthen the Commission's antitrust enforcement efforts. This has been particularly true in new and emerging markets that the Commission views as shaping European economies and society.

BIG TECH AND ABUSE OF DOMINANCE INVESTIGATIONS

After blockbuster fines against Google (in the Shopping, Android and AdSense cases) and an e-commerce sector inquiry that led to various Big Tech investigations in Vice President Vestager's first term as Competition Commissioner, the Commission's focus on Big Tech has continued in 2020 and will continue into 2021.

The Commission's Directorate General for Competition now has a number of significant ongoing investigations in the sector, several of which involve novel issues or theories of harm. These include:

Amazon Marketplace. Following an investigation initiated almost two years ago in the wake of the Commission's e-commerce sector inquiry, the Commission in November 2020 issued Amazon a statement of objections, alleging the misuse of its Marketplace's independent sellers' data. Specifically, applying a novel theory of harm, the Commission is alleging that Amazon is misusing large quantities of non-public and sensitive business data of third-party

sellers to the benefit of its own retail activities and thus leveraging its dominance in the market for the provision of marketplace services into various retail markets. These data inform strategic decisions, including product launches and targeted discounts, and allow it to focus its own offers on best-selling products (while other retailers have no such advantage).

Amazon – Buy Box. When issuing its statement of objections in the Marketplace investigation, the Commission also formally opened a separate investigation into Amazon's business practices that might artificially favor its own retail offers and offers of marketplace sellers that use Amazon's logistics and delivery services. In particular, the Commission is examining the manner in which Amazon selects sellers that appear in the "Buy Box," Amazon's direct purchase feature through which the bulk of Marketplace transactions are conducted. The Commission is concerned that Amazon may be leveraging its dominant position in marketplace services across to the logistics markets or the retail markets in which it is active.

Apple – App Store Practices. Earlier in 2020, and following complaints by Spotify and an e-book distributor, the Commission opened three formal investigations targeting Apple's App Store rules applicable to music streaming, e-books/audiobooks and apps that compete with Apple offerings. All three investigations appear to be focused on the same theory of harm, namely that Apple-imposed contract terms disadvantage app developers that compete with Apple's own apps. In particular, the Commission is concerned with Apple forcing rival app developers to use Apple's own in-app purchase system, through which it charges a 30% commission, and with Apple preventing those developers from informing users of alternative purchasing possibilities for their apps.

Apple Pay. At the same time, the Commission also opened a separate investigation into Apple's practices regarding Apple Pay. The investigation is focused on whether Apple is foreclosing rival providers of mobile payments from offering their solutions to users of iOS devices. In particular, the Commission is reviewing (i) "Apple's terms, conditions, and other measures" related to the use of Apple Pay for purchases made on merchant apps and websites accessed from iOS devices; and (ii) the alleged favouring of Apple Pay by making it the only solution with access to so-called "tap and go" technology embedded in iOS mobile devices.

While proceeding with these investigations, the Commission in parallel is also pursuing a sector inquiry of the Internet of Things (IoT) space and advancing planning for a new ex ante regulatory instrument for platforms acting as so-called digital gatekeepers:

IoT sector inquiry. In July 2020, the Commission kicked off a sector inquiry into the nascent IoT space. In doing so, it expressed concern that the IoT sector, as it grows, presents so-called "tipping risks" that might leave certain players with an unfair advantage. In that context, the ongoing inquiry is focusing on potential restrictions on data access and interoperability, as well as certain forms of favoring and practices linked to the use of proprietary standards. The sector inquiry covers products such as wearable devices (e.g., smartwatches or fitness trackers) and connected consumer devices used in the smart home context, such as refrigerators, washing machines, smart TVs, smart speakers and lighting systems. The sector inquiry is also collecting information related to services available via smart devices, such as music and video streaming services, and the voice assistants used to access

them. Based on the findings of the sector inquiry, the Commission may later initiate more targeted antitrust investigations, as it did with its e-commerce investigation.

Digital Markets Act. In December 2020, the Commission also released a legislative proposal that would create ex ante regulatory enforcement capabilities targeted at platforms that act as "gatekeepers" in the digital sector and thus have a disproportionate impact on the functioning of the internal market. The rules, if passed, would address issues such as interoperability, one-sided data access or favoring, and would apply to companies providing specific pre-defined "core platform services." The new regime would be administered by the Commission, although it remains unclear whether by the Directorate General for Competition or the Directorate General for Communications Networks, Content and Technology. It would also give the Commission powers to impose fines and remedies in the event of noncompliance. The proposal will flow through the European legislative process and is on a path that could see it adopted in or around 2023.

National Competition Authorities in Europe too have focused (and are expected to continue to focus) their enforcement efforts on Big Tech. Most notably, this has included multiple competition authorities' investigations into conduct by Amazon, the German Federal Cartel Office's investigation of Facebook's data practices as well as legislative proposals, such as in Germany and the UK, targeted at Big Tech companies.

MERGER CONTROL

With respect to merger control, boards should expect continued vigorous enforcement in Europe. In recent years, this has entailed more resources devoted to complex cases, along with longer pre-notification periods, a greater use of sophisticated quantitative tools and economic analyses, more requests for a greater range of internal documents and more wide-reaching remedies in complex cases.

If anything, the European General Court overturning the Commission's prohibition of the UK's Three/O2 mobile telephony transaction in May 2020 will only make complex merger control review more demanding and resource-intensive in complex cases in the years to come, as Commission case teams work harder to insulate future decisions from judicial scrutiny.

In 2020, the Commission also outlined a few specific initiatives in the merger control field:

Referrals. As part of an effort to close the enforcement gap for so-called "killer acquisitions" and other transactions involving nascent targets with no or limited revenues, Vice President Vestager suggested that the Commission change its approach to referrals from National Competition Authorities in Europe, to encourage referrals, even when relevant national thresholds are not met. The Commission expects this new policy could come into effect by mid-2021 and, while it remains to be seen how it will be implemented in practice, it could lead to significant legal uncertainty if the Commission were suddenly, through this loophole, able to review transactions that do not trigger review thresholds anywhere in Europe.

Market Definition. Separately, the Commission is also reviewing its 1997 Market Definition Notice to assess whether the Notice needs to be updated to better capture cases in digital markets, as well as mergers in markets where competition takes place globally. It expects to publish the results of its evaluation in 2021.

RESTRICTIVE PRACTICES

With the Vertical Block Exemption Regulation set to expire in May 2022, the Commission in September 2020 published a report on its views of the functioning of the Regulation and accompanying Vertical Guidelines. While it largely concluded that the Regulation and Guidelines had worked effectively for the past (almost) 10 years, it also noted there is a need for targeted updates to both documents as a result of the growth of online sales and new market players (such as online platforms).

Specific areas for improvement identified by the Commission include:

- tackling diverging interpretations by National Competition Authorities in Europe,
- providing further guidance on the assessment of retail parity clauses and restrictions on the use of price comparison websites, and
- when possible, reducing the burden on the businesses associated with self-assessment.

The Commission intends to publish a draft new Regulation and Guidelines in the course of 2021 for public consultation.

With regard to cartel enforcement, notwithstanding the drop in immunity and leniency applications in recent years, boards should continue to expect the Commission's rigorous pursuit of cartel activity. In particular, purchaser-side cartels have been a focus for the Commission in the last year, with the Commission fining three ethylene purchasers a total of €260 million for cartel conduct in July 2020, and with a number of other purchasing cartel investigations ongoing.

GREEN AGENDA

Throughout 2020, President von der Leyen and others on the Commission have said on several occasions that they expect competition policy to be one pillar supporting the European Green Deal. While acknowledging that competition policy cannot replace environmental laws and regulation, or green investments, the Commission does believe there is room for EU competition law to complement the proposed Green Deal legislative package.[1]

In a March 2020 speech, Commissioner Vestager signaled, for example, that State aid rules could be reviewed to better take into account sustainable objectives. Similarly, the

[1] For more information on the Green Deal and other EU environmental and sustainability developments, please see Progress Since Paris: Sustainable Policy in Europe in 2020 and Beyond, in this memo

Commission has suggested it is considering whether horizontal and vertical agreements pursuing Green Deal objectives should benefit from special treatment under the antitrust rules, or whether merger control rules should take into account sustainability objectives as relevant merger specific effects.

The Commission, in October 2020, called for contributions and views from all business sectors on ways in which the competition rules might further the Green Deal, with a conference planned to take place in early 2021 to bring together the different perspectives on this topic. The topic raises the somewhat controversial question whether harm to the climate or the environment should be included in the notion of "consumer welfare" that drives current competition law enforcement.

BREXIT

The Brexit transition period ended on December 31, 2020, and EU competition law as such has ceased to apply in the UK. In practice, this means that mergers not notified before the end of 2020 are no longer subject to the EU one-stop-shop principle, and merging companies could be faced with parallel reviews in the EU and UK. Similarly in antitrust enforcement, the Commission no longer has jurisdiction to apply Articles 101 and 102 TFEU to practices (not already under investigation) having an effect in the UK.

However, UK businesses could continue to be investigated and potentially fined by the Commission for infringements that relate to the remainder of the EU, in the same way as companies based in countries outside the EU have been to date.

OUTLOOK ON ANTITRUST ENFORCEMENT

Despite the COVID-19 crisis and its impact on the European economy, the pandemic had minimal impact on EU antitrust enforcement as the Commission has continued to advance its cases in a timely manner. In 2021, boards should expect a continuation of the vigorous enforcement and keep an eye on the various, ongoing policy debates, which could greatly influence European antitrust rules in the years to come.

ALERT MEMORANDUM

Putting Customers in Charge: Penrose Report on the State of UK Competition

15 March 2021

On 16 February 2021, John Penrose MP published an independent report on improving competition and consumer protection in the UK (**the Report**). It finds that the UK's competition and consumer regime "*has a good reputation, but not a great one*"; progress on "*cutting the costs of red tape*" has stalled; excessive regulation has left "*important industries more ponderous and less focused on their customers than they should be*"; and competition has weakened over the past 20 years, leaving consumers feeling "*ripped off*." To address these shortcomings, the Report makes a series of recommendations aimed at galvanising UK competition and consumer protection, promoting creative and light-touch regulation, and ensuring that regulation and competition are "*on the side of customers rather than of politicians, bureaucrats or company bosses*."

If you have any questions concerning this memorandum, please reach out to your regular firm contact or the following authors

LONDON

Nicholas Levy
+44 20 7614 2243
nlevy@cgsh.com

Paul Gilbert
+44 20 7614 2335
pgilbert@cgsh.com

Alexander Waksman
+44 20 7614 2333
awaksman@cgsh.com

Courtney Olden
+44 20 7614 2298
colden@cgsh.com

Ranulf Outhwaite
+44 20 7614 2228
routhwaite@cgsh.com

The Report's most significant recommendations include: (i) strengthening the CMA's powers to enforce consumer protection law; (ii) implementing measures to expedite, simplify, and introduce new forums for competition proceedings; (iii) cutting burdensome regulation and narrowing sectoral regulators' responsibilities; (iv) supporting the CMA's proposal to create a Digital Markets Unit; and (v) allowing greater scope to intervene in mergers that threaten to move operations offshore.

Context

The Report is the latest in a series of publications in the past two years addressing the UK competition and consumer protection regimes, including:

— A letter from Lord Tyrie, former Chairman of the Competition and Markets Authority (**CMA**) to the Department of Business, Energy & Industrial Strategy (**BEIS**) in February 2019, which called for the introduction of mandatory merger control filings, increased enforcement powers for the CMA, and greater focus on consumer interests.

— The Furman Report on 'Unlocking Digital Competition' in March 2019, which recommended a more flexible legal standard for intervening in acquisitions by digital platforms, and the creation of a Digital Markets Unit (**DMU**), with ex ante regulatory powers.

— The CMA's market study into digital advertising and online platforms (completed in July 2020), which supported many of the recommendations in the Furman Report, and was followed in December 2020 by advice to government from the CMA's Digital Markets Taskforce on implementing digital 'codes of conduct'.

— The CMA's report on the state of competition in the UK, which found that competition across the UK economy has declined in the last 20 years, while market concentration is higher than it was in 1998.

Drawing on these prior studies, the Report makes recommendations for how the UK competition regime can:

— Meet the challenges of the post COVID-19 economic recovery;

— Contribute to the Government's 'levelling-up' agenda;

— Increase consumer trust by tackling "*consumer rip offs and bad business practices*";[1]

— Ensure the competition regime is "*strong, swift, flexible and proportionate*";[2]

— Support UK 'disruptor' businesses; and

— Make the best use of data, technology and digital skills in the wider economy.

The following sections discuss the Report's main recommendations.

Recommendations

An expanded role for the CMA

The Report envisages a more active role for the CMA in shaping the conditions of competition in markets. The CMA's new role would include responsibility for the overall progress of competition, consumer rights, supply side-reforms and productivity improvements, with a view to the CMA becoming "*a micro-economic sibling for the Bank of England's well-established public macro-economic role.*"[3]

Under the proposals, the CMA would publish annually a wide-ranging 'State of Competition and Consumer Detriment' report addressing competition and consumer protection in all sectors of the economy and all parts of the country.

The CMA would also gain the power to determine that a business has violated consumer law – and impose fines directly – rather than having to apply to courts for cease and desist orders.

Faster and more predictable competition decisions

The Report argues that competition cases, from initial investigation by the CMA to appeals in the Competition Appeal Tribunal (**CAT**), are "*cumbersome and clunky*"[4]. It proposes a Government taskforce to redesign the CMA and CAT procedures and case management powers to achieve three core objectives:

— Expedite cases, ensuring that all but the most complicated cases are resolved within weeks or months, rather than years;

[1] Foreword to the Report.
[2] Ibid.
[3] Section 2.1 of the Report.
[4] Section 2.7 of the Report.

— Ensure that outcomes are "*as predictably simple and certain as possible*";[5] and

— Ensure that rights to a fair trial under Article 6 of the European Convention on Human Rights are properly observed.

The taskforce would include representatives from business, the legal profession, and regulators; would be led by a ministerial appointee that is independent from the CMA and the CAT; and would reconvene every five years to ensure that the three core objectives are being met (and propose further reforms if they are not).

The Report does not pre-empt the work of this taskforce, but makes four preliminary recommendations:

— The CMA should be able to accept legally-binding undertakings from parties at any stage of a merger investigation, market study, or market investigation;

— The CMA should continue to cooperate internationally with other national competition agencies;

— All appeals from decisions of sectoral regulators should be heard by the CAT (not the CMA or other Courts); and

— Firms that fail to respond properly to CMA information requests should face higher fines than the maximum currently allowed by law (£30,000 total or £15,000 per day).

Cutting red tape and promoting 'better regulation'

Alongside a strengthened competition and consumer protection regime, the Report advocates reducing the regulatory burden on businesses. It argues for 'better regulation' as a middle path between deregulation ("*which might sweep away some of the important standards we need to protect ourselves or our environment*")[6] and red tape (which "*slows businesses down, focusing them on lobbying their regulators instead of delighting their customers, and making them less creative and efficient*").[7]

The Report views this middle path as essential to realising a 'Brexit Dividend', whereby current regulations are replaced with "*lower-cost competition and consumer rules*".[8] It supports the 'better regulation' principle: that existing regulations should be removed or modernised before new regulations are introduced. And it argues that the government should treat new regulation only as a "*last resort*"[9] once lighter touch alternatives have been excluded, such as codes of conduct, self-regulation, and behavioural nudges.

More competition in the digital sector

The Report cites findings from other recent studies that some digital markets have become more concentrated: driven by network effects, some firms have large data pools to develop and personalise their services, high fixed costs, limited interoperability, and strategies that exploit consumer biases to restrict choice (so-called 'nudge and sludge' techniques).

The Report cautiously welcomes the CMA's plans to establish the DMU, as well as contemplated codes of conduct for digital firms with 'strategic market status', and 'pro-competitive interventions' to address the sources of firms' market power.

The Report warns that excessive use of the DMU's new powers could, however, increase the regulatory burden on business. To avoid 'regulatory creep', the Report recommends that the DMU should be renamed the Network & Data Monopolies Unit (**NDMU**), should only apply to individual firms that own and run so-called 'network and data monopolies,' and should use its regulatory powers only when the CMA's existing competition powers are inadequate. Any request to expand the NDMU's remit would be subject to parliamentary approval.

Despite these safeguards, the Report's ambitions for the NDMU are significant, envisaging that it would

[5] Ibid.
[6] Section 9.3 of the Report.
[7] Section 3.1 of the Report.
[8] Section 3.3 of the Report.
[9] Section 3.2 of the Report.

play an important role in "*rebuilding normal competitive markets*".[10] Further, and despite the Report's concerns about 'regulatory creep', it proposes that the NDMU should be able to make "*pro-competition interventions to reinstate normal competitive conditions wherever it's possible and proportionate*".[11] These interventions could include:

— Designing and enforcing a pro-competitive code of conduct;

— Overseeing data portability schemes so users can seamlessly switch providers;

— Allowing access to anonymised versions of important datasets, provided privacy and data protection can be ensured;

— Facilitating and encouraging new technologies that erode the power and strength of existing networks;

— Ensuring 'fair and equal access' to a monopoly network for all suppliers and customers;

— Requiring interoperability between networks; and

— Measures to make switching suppliers cheaper and more convenient. As examples, the Report identifies:

  - Open banking, which allows customer data from bank accounts to be shared with third party providers;
  - The Data Transfer Project, supported by Google, Apple, Microsoft, and Twitter, which allows customers to move their data, transaction history, and preferences seamlessly between competing products; and
  - Choice screens that prompt consumers easily to change default providers (such as online search engines) on their electronic devices.

  The Report further recommends that the CMA build on its Online Advertising Market Study by considering future market investigations into the 'price' consumers pay through their data in return for accessing digital goods and services.

More competition in regulated sectors

The Report envisages a greater role for the CMA in regulated sectors, such as electricity, gas, and water, while reducing regulatory burdens.

First, existing sectoral regulators with concurrent competition powers should strive to increase competition in their respective sectors. Each sectoral regulator should be required to publish a project plan demonstrating how they intend to achieve this objective.

Second, as these sectors return to "*normal 'pro-consumer'…markets*"[12], responsibility should be transferred to the CMA, leaving sectoral regulators with responsibility only for the core assets of 'network monopolies' such as gas pipes, electricity grids, railway tracks or water and sewage pipes. In time, the Report envisages the role of sectoral regulators being entirely subsumed by the CMA, with regulators' residual oversight of core network monopolies being handed to the NDMU.

Third, sectoral regulators should be subjected to a strengthened 'better regulation' target and their legal duties should be audited and amended. They should be left with a primary duty to achieve "*competition for the benefit of consumers first*",[13] leaving "*regulation only as a last resort*".[14]

Fourth, contracts for building and upgrading network monopoly infrastructure should be independently auctioned, thereby opening up regulated sectors to disruptors and greater competition.

Levelling-up through more competition

The Report identifies a need for more competition and consumer protection enforcement outside the South-East of England. It identifies three ways of

[10] Section 4.3 of the Report.
[11] Section 4.3 of the Report.
[12] Section 5.3 of the Report.
[13] Ibid.
[14] Ibid.

broadening local access to competition and consumer law remedies.

First, Small Claims Courts and ADR services should be made simpler, less-expensive and more accessible, to encourage consumers to hold businesses to account.

Second, businesses should be able to litigate competition law disputes in the County Courts. This reform would enable dispute resolution in respect of antitrust matters that are too small to attract the CMA's attention. The Report states that competition cases pursued in the County Courts should be dealt with quickly and inexpensively by (i) making use of strict case management powers; (ii) limiting hearings to one to two days in length; and (iii) setting low cost caps for unsuccessful parties.

Third, the Report recommends that local authority trading standards teams should be given new powers and greater resources to investigate consumer abuses. The Report recommends that trading standards teams should be subject to new statutory duties to correct for under-enforcement. Under the proposals, trading standards teams would be given new powers to conduct competition and consumer investigations.

Addressing new forms of consumer exploitation

The Report identifies three ways to improve the UK's existing consumer protection regime.

First, the CMA should address the prevalence of price discrimination (*i.e.*, where certain discounts or offers are only made available to new customers). The Report recommends that the CMA update its guidelines to include a 'fairness test'. Transactional fairness requires that businesses: (i) do not use deceptive practices such as concealing important information in the small print; (ii) do not have practices that hinder customer switching, including ensuring that switching processes are simple and convenient; and (iii) are able to explain the rationale for their pricing practices and how they benefit customers.

Second, information asymmetries between buyers and sellers prevent customers from making informed choices. The Report recommends that the CMA monitor and support the growth of digital price-comparison tools and considers measures to ensure that price comparison tools prosper.

Third, the CMA should combat the use of anti-consumer nudging (*i.e.*, where businesses use behavioural insights to disadvantage customers). The Report mentions the example of websites displaying a 'countdown' for offers or listing the number of customers currently viewing a product so as to create a sense of urgency.

Political intervention in international mergers

The Report discusses the benefits of foreign direct investment in the UK economy. It discourages political interventions in the competitive process, which should be "*as limited and controlled as possible*".[15] It endorses the current UK merger control regime, noting the CMA's "*important and valuable politically-independent power to prevent deals*",[16] as well as the narrow scope for ministerial intervention under the Enterprise Act 2002.

The Report states, however, that further political intervention in merger control may be necessary to prevent foreign companies from purchasing UK firms and taking their activities offshore. The Report recommends that ministers develop new options to block such deals, while acknowledging the difficulty in differentiating such deals from pro-competitive mergers.

Implications

The Report offers a robust defence of free markets, targeted regulation, and vibrant competition and consumer protection regimes. At the same time, it acknowledges a weakening of the consensus

[15] Section 8 of the Report.

[16] Ibid.

underlying the current system of competition and regulation, and suggests that consumer interests may have been inadequately protected.

Various considerations will determine whether the Report's recommendations are implemented. Some recommendations endorse proposals that have been made elsewhere and – tentatively – received government support. For example, the Report endorses the notion of pro-competitive regulation, as recommended by the Furman Report and the CMA.

Other recommendations will likely be more controversial, such as the proposal to reduce and ultimately eliminate the role of sectoral regulators and to allow County Courts to hear competition disputes. Likewise, the Report's proposals on 'better regulation' might depend on support from government departments.

The Report's most significant contribution, however, might come not from its specific proposals, but rather its support for competition – not burdensome regulation – as a way of enhancing the consumer interest. As the Report says, "*if competition works in favour of consumers rather than companies (or of business customers rather than their suppliers) then our post-covid, post-Brexit economy will grow faster and our society will be both happier, fairer and more just as well*." [17] This message, from a prominent Member of Parliament in a report commissioned by BEIS and HM Treasury, could prove influential as the Government considers what shape the UK competition regime should take. [18]

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[17] Section 1.2 of the Report.

[18] The Treasury's 'Build Back Better' Report, published 3 March 2021, makes a number of recommendations that are in line with the Report, including:

- Commissioning the CMA to produce regular 'State of Competition' reports on how competition is working across the economy;
- A commitment to consult on strengthening enforcement powers and penalties to deter anticompetitive behaviour;
- Hard-wiring competition principles into regulatory decision-making; and
- Easing the regulatory compliance and red tape burden on business.

2021 M&A Outlook: Cautious Optimism for Robust Dealmaking

Paul J. Shim
Partner
New York
pshim@cgsh.com

Kimberly R. Spoerri
Partner
New York
kspoerri@cgsh.com

Alix Simnock
Associate
New York
asimnock@cgsh.com

As we look back on the mergers and acquisitions landscape of 2020, clear trends emerge and paint a picture of what can be expected in 2021. Certain of these trends seemingly came from nowhere, while others have long been brewing. In either case, directors of both potential acquirors and potential targets will need to consider the implications, if any, of these trends as they approach M&A in 2021.

With more players on the prowl for attractive investments ... sellers continue to have the luxury of being picky when it comes to choosing their dance partners.

The Seller's Market Continues

Other than a relatively brief swoon following the initial outbreak of COVID-19 in the United States in the spring, 2020 largely saw the continuation of the robust seller's market we have witnessed over much of the last decade. This has played out not only in the high valuations sellers have enjoyed but also in the deal terms that sellers (particularly sellers of private companies) have been able to extract from buyers. The key contributing factor to the seller's market? Demand, of course. With more players on the prowl for attractive investments – not only private equity funds and strategic investors but also sovereign wealth funds, family offices and now SPACs (as discussed in greater detail below) – sellers continue to have the luxury of being picky when it comes to choosing their dance partners.

Private equity-backed M&A transactions accounted for 16% of overall M&A activity in the first nine months of 2020, the highest level since before the global financial crisis,[1] and private equity sponsors have been increasingly willing to get a deal done by accepting seller favorable deal terms. The advent of representation and warranty insurance (RWI) has exacerbated this trend, as premiums remain sufficiently low such that, for many buyers, procurement of RWI continues to be an attractive alternative to in-depth (and time consuming) due diligence and difficult and competitively undesirable negotiations of indemnity provisions.

SPACs – Another Competitor for Transactions Enters the Ring

2020 was the year of Zoom, Peloton and special purpose acquisition companies (SPACs). As of December 12, 2020, a total of 230 SPAC IPOs raised over $77 billion in 2020 – five times the amount of money raised by SPACs in 2019, and 20 times the amount raised in 2015. In fact, SPACs raised more money than traditional initial public offerings in 2020.[2] As discussed above, we have seen a seller-friendly market develop over the last decade, and adding SPACs to the private company toolbox as an alternative means to achieve liquidity creates more competition among potential acquirers for accretive transactions.

A SPAC is a shell company that generally raises money from public markets with the intention to later merge with a private company. The SPAC engages in an IPO shortly after its formation, attracting interest among public investors based largely on the track record and reputation of its sponsor and management team. Flush with the proceeds from its IPO, the SPAC searches for a private company with which to merge. In the early days of the SPAC evolution, SPACs typically acquired private targets for cash, much like a private equity buyout. More recent transactions have involved mergers of SPACs with target companies many times their size, more akin to a reverse IPO.

The merger between the SPAC and the private target company, which effectively results in the target company becoming a public company, is referred to as a "De-SPAC transaction." The De-SPAC transaction requires the approval of the SPAC's shareholders. In addition, SPAC shareholders may require the SPAC to redeem their shares for cash (and a small return) at any time, while retaining some exposure to future upside appreciation from the transaction via warrants that are issued by the SPAC together with its shares in the IPO.

For private companies, going public by merging with a SPAC offers two principal benefits – avoiding the unpredictability of the IPO market and speed. In a SPAC transaction, a firm exchange ratio – and thus economic value for the target company – is agreed upon up-front by the parties. Also, IPOs can take six to 12 months to complete with additional time necessary to prepare, while De-SPAC transactions can be completed within two to three months of signing, providing immediate liquidity and access to the sponsors' expertise and public company infrastructure. On the other side of the coin, the potential target must weigh the dilution resulting from the sponsors' typical 20% ownership stake and the uncertainty created by the requirement of SPAC shareholder approval and the possibility of shareholder redemption.

Nonetheless, SPACs have become a significant player in the M&A market, and the uncertainties created by COVID-19 have made SPACs a more attractive alternative than an IPO. Further, current low interest rates make locking up a significant portion of cash for the length of a SPAC far less disadvantageous to investors, and the recent history of public market "busts" for venture capital-backed companies, e.g., Uber and WeWork, has ignited even more interest in SPACs.

Of course, long-term results remain an open question. A recent Goldman Sachs report indicates that in deals completed since 2018, SPAC equities following completion of the acquisition have underperformed

[1] Refinitiv, "Records broken in global capital markets during Q3" (November 2, 2020), available here.

[2] SPACInsider, "SPAC IPO Transactions: Summary by Year" (2020), available here.

the broader market. Time will tell if this year's spate of SPACs perform and if SPACs and similar vehicles retain their current popularity.

The Impact of COVID-19 on M&A Deal Terms

Overall, we have seen M&A deal terms adapt fairly rapidly to the COVID-19 pandemic. Following a brief period of dislocation as buyers sought to walk away from or renegotiate deals entered into prior to the outbreak of COVID-19 in the United States, we have generally seen the M&A market recover with sellers implementing some standardized edits to transaction agreements to account for the pandemic. The key revised terms are (i) express inclusion of pandemics (and COVID-19 in particular) in the carve-outs to the definition of material adverse effect and (ii) wide latitude under the interim operating covenants for actions taken by targets in response to COVID-19. We expect the former to be a feature of M&A agreements going forward, but it remains to be seen how COVID-19 and future similar as yet unknown exogenous events will be treated for purposes of interim operating covenants once the tide of this current pandemic recedes.

While many lawsuits were filed earlier in the year, mostly in the Delaware Court of Chancery, by sellers seeking to force reluctant buyers to close the vast majority settled without a ruling from the bench, leaving unanswered the question – as between buyer and seller – who bears the risk of COVID-19 and, perhaps more importantly at this point, any future similar exogenous events.

In December 2020, Delaware Vice Chancellor Laster finally provided some guidance by ruling that South Korean asset manager Mirae Asset Financial Group (Buyer) was excused from closing its purchase of 15 U.S. luxury hotels from Anbang Insurance Group, Ltd. (Seller) for $5.8 billion and was permitted to terminate the agreement. Although the Buyer failed to prove a material adverse effect had occurred, the Buyer had successfully shown that the Seller's response to the COVID-19 pandemic, including furloughing staff, laying off employees and closing properties, breached the interim operating covenants. The court found that the Seller's actions in response to the pandemic were not ordinary course, i.e., not routine or consistent with its past practices in ordinary times, even though the Seller's response was consistent with actions taken by comparable companies in response to COVID-19.[3]

While sellers will likely continue to include a COVID-19 exception to interim operating covenants for some time into the future, boards of sellers should consider going forward how to prepare for the next unknown exogenous event that they may need to respond to. Sellers may consider being explicit that actions taken in response to the exogenous risks laid out in the exceptions to the material adverse effect definition (e.g., hurricanes, acts of terrorism, etc.) should be allowed under the interim operating covenants so long as they are generally in line with the responses of similarly situated companies. While this would be a major (and very seller-friendly) shift in the way that interim operating restrictions currently work – as long as the seller's market continues and with sellers able to point to the recent COVID-19 experience – buyers may have a hard time saying no.

We expect that a Biden presidency will provide fertile ground for a robust M&A market in 2021.

A Biden Presidency and M&A

With another COVID-19 stimulus package passed, providing additional support for the economy, and the Federal Reserve continuing to be hesitant to reverse low-interest policy as the U.S. economy recovers from the pandemic, inexpensive debt financing should be plentiful, encouraging more M&A. While this all sounds promising for dealmakers, if Democrats control the White House and both houses of Congress, it will enable them to pursue a broader legislative agenda that

[3] *See AB Stable VIII LLC v. MAPS Hotels and Resorts One LLC*, C.A. No. 2020-0310-JTL (Del. Ch. Nov. 30, 2020)

may hinder, or at least slow, the pace of M&A. As of printing, it seems likely that the Democrats will hold a majority in the Senate (with fifty Senate seats and the tie-breaking vote by Vice President Harris). While it is generally recognized that dealmakers would have preferred divided government (which would have ensured no major policy changes and would have in turn provided a stable environment for M&A activity), it is as yet unclear how activist Democrats will be in light of their slim majorities in the Senate and House. A Democratic-controlled legislative branch is more likely to pass additional COVID-19 stimulus packages, providing juice for the economy and indirect tailwinds for M&A, however proposed Democratic policies around tax increases as well as continuing focus from both sides of the aisle on consolidation in the technology sector and bipartisan wariness regarding foreign buyers in certain industries may serve as a countervailing drag on M&A activity. On balance, even with Democratic control of the legislative and executive branches, we expect that a Biden presidency will provide fertile ground for a robust M&A market in 2021.[4]

[4] For discussion of developments in U.S. and EU antitrust rules and enforcement, please see U.S. Antitrust: Developments and Outlook and EU Antitrust: Developments and Outlook in this memo.

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ALERT MEMORANDUM

FTC Issues Commentary on Vertical Merger Enforcement

January 11, 2021

On December 22, 2020, the US Federal Trade Commission (the "FTC") issued a Commentary on Vertical Merger Enforcement. This follows the recent issuance of revised Vertical Merger Guidelines published jointly by the FTC and Department of Justice (the "Agencies") on June 30, 2020. While the Guidelines explain the Agencies' approach to assessing the competitive effects of vertical mergers, the Commentary builds on this base by using past cases to show how these principles are implemented by the Agencies in practice. The Commentary hews closely to the Guidelines and, like the Guidelines themselves, reflects a largely middle-of-the-road approach.

In connection with the DOJ's and FTC's enforcement of Section 7 of the Clayton Act, which prohibits mergers that may substantially lessen competition, the Agencies periodically publish official guidance explaining their approach to merger review. They also publish commentary elaborating on the official guidance, such as the 2006 Commentary published to elaborate on the Agencies' approach to the 1997 Horizontal Merger Guidelines. Consistent with this practice, the FTC has issued its Commentary on Vertical Merger Enforcement to expand on the principles in the recently revised Vertical Merger Guidelines. The Commentary does not alter the Vertical Merger Guidelines, but rather is intended to "provide greater transparency to the public" about Agency practice.

As explained below, the Commentary primarily consists of summaries of specific investigations from 1994 to 2019, including those where the Commission took enforcement action and those where the Commission did not take action, to elucidate the principles described in more general terms in the Guidelines. The Commentary was issued by a 3-2 vote of the Commission. Commissioners Rohit Chopra and Rebecca Slaughter issued a joint dissenting statement criticizing the Commentary as reflecting past under-enforcement and warning parties against relying on it in the future. Commissioners Noah Phillips and Christine Wilson issuing their own statement in rejoinder harshly criticizing Commissioners Chopra and Slaughter's dissent.

If you have any questions concerning this memorandum, please reach out to your regular firm contact or the following authors.

Leah Brannon
+1 202 974 1508
lbrannon@cgsh.com

Brian Byrne
+1 202 974 1850
bbyrne@cgsh.com

Jeremy J. Calsyn
+1 202 974 1522
jcalsyn@cgsh.com

George S. Cary
+1 202 974 1920
gcary@cgsh.com

Alexis Collins
+1 202 974 1519
alcollins@cgsh.com

Daniel P. Culley
+1 202 974 1593
dculley@cgsh.com

Elaine Ewing
+1 202 974 1668
eewing@cgsh.com

David I. Gelfand
+1 202 974 1690
dgelfand@cgsh.com

D. Bruce Hoffman
+1 202 974 1784
bhoffman@cgsh.com

Mark W. Nelson
+1 202 974 1622
mnelson@cgsh.com

Kenneth Reinker
+1 202 974 1743
kreinker@cgsh.com

Vertical Mergers: Theories of Harm and Efficiencies[1]

A vertical merger combines firms that do not compete with each other, but rather operate at different levels of a single supply chain. Conventionally, many in the bar and at the Agencies, as well as antitrust economists, have believed vertical mergers to be less likely to harm competition than mergers between competitors (horizontal mergers), and enforcement against vertical mergers has therefore been relatively uncommon. Nevertheless, in some circumstances, vertical mergers may lead to a number of competitive concerns.

The Commentary lays out common theories of harm and efficiencies that the Commission has assessed in investigating vertical mergers, in each instance describing the facts and analysis in specific investigations.

— **Elimination of current horizontal competition**: The Commentary explains that a merger may have both horizontal and vertical aspects if one of the merging parties is already vertically integrated. In such situations, merger analysis must account for the loss of horizontal competition as a result of the merger.

— **Elimination of future horizontal competition**: Even when neither party is already vertically integrated a merger may have effects on horizontal competition if it was likely one party would have organically expanded to become vertically integrated but for the merger. The merger could diminish the incentive for this new entry, thus leading to horizontal effects.

— **Input foreclosures and raising rivals' costs**: Unilateral anticompetitive effects from input foreclosure is the concern raised most frequently with vertical mergers. This concern arises when a firm that supplies inputs to multiple customers acquires a new incentive to raise prices or shut off supply entirely after acquiring one of these customers. This is because by cutting off access or raising costs for a necessary input, the merged firm renders its competitors in the downstream market less competitive and the downstream part of the merged firm captures some of the diverted sales.

— **Decreased incentive to facilitate future entry**: Pre-merger, a large input supplier may have an incentive to facilitate entry by a firm that would then become its new customer, or a large customer may have an incentive to facilitate entry by a firm that would then become a new option for supply. A vertical merger could decrease this incentive because the would-be sponsor will not want to facilitate entry by a firm that will now compete directly against the sponsor.

— **Increased access to competitor CSI**: Because a seller often has access to competitively sensitive information ("CSI") of its customer, or vice versa, a vertical merger may give a firm access to its competitors' CSI. This can have both unilateral and coordinated anticompetitive effects. Unilaterally, it can decrease incentives to attempt procompetitive initiatives, mute competitive responses, or lead firms to end trade relationships to the detriment of customers. It can also facilitate establishing or maintaining tacit coordination among competitors, or remove a disruptive buyer thus facilitating tacit coordination among those who remain.

— **EDM and other efficiencies**: Vertical mergers can result in a particular kind of efficiency called "eliminating double marginalization" or "EDM," where a vertically integrated company can effectively acquire inputs at cost and pass these savings along to customers downstream. There are good reasons to think that eliminating double marginalization is less speculative than other kinds of efficiencies—including those that may result from horizontal mergers. Vertical mergers can also

[1] For a more complete analysis of the Vertical Merger Guidelines, including potential theories of harm and efficiencies arising from vertical mergers, see Cleary Gottlieb's July 2, 2020, alert memorandum *US Agencies Publish Final Revised Vertical Merger Guidelines*.

lead to other types of efficiencies like enhanced design integration between products.

Statements of FTC Commissioners

Commission Chair Joseph Simons and fellow Republican Commissioners Noah Phillips and Christine Wilson of the Federal Trade Commission voted to issue the Guidelines. Commissioners Rohit Chopra and Rebecca Slaughter voted against issuing the Guidelines and issued a statement in dissent. Commissioners Phillips and Wilson issued their own statement in rebuttal. The exchange between the two was unusually acrimonious.

— **Dissent**: The Democrat Commissioners Chopra and Slaughter explain that they voted against issuing the Commentary because it reflects "the same status quo thinking that has allowed decades of vertical consolidation to go uninvestigated and unchallenged." In particular, they object to the Commentary highlighting investigations in which the Agencies did not take enforcement action and those where Agency concerns were resolved with behavioral remedies, which they view as ineffectual.

  Commissioners Chopra and Slaughter disclaim the Commentary entirely: "We strongly caution the market against relying on the Vertical Merger Guidelines and the Vertical Merger Commentary as an indication of how the FTC will act upon past, present, and future transactions. Moving forward, we need to aggressively enforce against the harms of vertical mergers. We look forward to turning the page on the era of lax oversight and to beginning to investigate, analyze, and enforce the antitrust laws against vertical mergers with vigor."

— **Concurrence**: Commissioners Phillips and Wilson write to explain that the Commentary faithfully recounts past Agency practice—thus promoting transparency, predictability, and credibility—and point out that the dissent's objection is to that history itself and not the faithfulness of the recounting.

  They fault the dissent for lacking substance: "Any proposals for a new approach to vertical merger enforcement, which our colleagues have yet to articulate, would need to take into account and grapple with the law, economics, and the evidence in each case. Until then, vague promises of a dramatic and undefined change in enforcement ring hollow."

Analysis

The Commentary hews closely to the Guidelines. For theories of harms or efficiencies that are addressed by the Guidelines, the Commentary's discussion is similar, expanding somewhat but not breaking new ground. The Commentary, however, does elaborate on theories of harm that are not discussed in detail by the Guidelines. In particular, while the Guidelines reference only briefly that vertical mergers can have horizontal aspects as well or that they can decrease incentives to facilitate entry, the Commentary explains these theories and how they work.

The Commentary reflects a continuation of past Agency practice. As might be expected for a document that summarizes past actions, the Commentary does not announce a radical departure from past enforcement practices and priorities. Rather, it continues the Guidelines' middle-of-the-road approach to vertical merger enforcement.

The Commentary is relatively short. At 35 pages, the Commentary is about half the length of the Commentary on the Horizontal Merger Guidelines. This is not entirely surprising, as vertical merger enforcement has been less frequent than for horizontal theories of harm.

The Commentary was issued surprisingly quickly. The FTC issued the Commentary less than half a year after publishing the Guidelines. As compared to the Horizontal Merger Commentary, which was released in 2006 nearly a decade after the then-effective 1997 Guidelines, a delay this brief is surprising.

The Democrat Commissioners' dissent foreshadows increased future aggressiveness in enforcement, though the courts are likely to forestall any major

changes. The dissenting and concurring Commissioners issued strongly worded statements, reflecting continued division at the Commission. With a Democrat administration now in the White House, control of the Commission will be shifting in favor of the Democrats, either in 2023 when Commissioner Phillips' term expires, or earlier with a Republican resignation. Biden appointments at the Department of Justice will likely result in a Democrat-appointed head of the Antitrust Division much sooner. The Agencies in the new administration will likely be looking hard for vertical cases to bring to demonstrate aggressive antitrust enforcement along the lines of that sought by Commissioners Chopra and Slaughter in their dissent.

Any aggressive vertical enforcement action will not have an easy road, however. Unlike horizontal mergers, where enforcement can benefit from a share-based presumption of illegality under certain circumstances, no such presumption exists for vertical mergers. The Government's most recent vertical enforcement effort, the DOJ's challenge to *AT&T/Time Warner*, provides a reminder that more aggressive vertical enforcement may be more easily promised than accomplished.

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Goodwin Insights

March 19, 2021

Intellectual Property: Overview and Key Issues for Tax-Exempt Organizations

by Gregg Coughlin Jennifer Maimone-Medwick Ginggi N. Storer

INTRODUCTION

"Intellectual property" refers to a category of intangible property that derives from the work of the mind or intellect, such as an idea, process, creative work, symbol or name used in commerce. Even though intellectual property is intangible, it can still be owned like tangible property such as homes, cars and consumer goods. Non-profit organizations produce and own intellectual property in many forms, including organization names and logos, inventions, instructional materials, websites and brochures. Understanding the various categories of intellectual property is important for any non-profit organization to both (1) protect and benefit from its intellectual property, and (2) ensure that it is not infringing on the intellectual property rights of others. The first step in protecting a non-profit organization's intellectual property and avoiding infringing on other's intellectual property is to identify the intellectual property owned by the organization and understand what protections are available. This article provides an overview of three different categories of intellectual property — copyright, trademark and patent — and the various ways that laws in the United States protect each category of intellectual property for varying lengths of time.

COPYRIGHT

COPYRIGHT OVERVIEW

Copyright protects original works of authorship fixed in a tangible form of expression from unauthorized copying and distribution. Original works of authorship include the particular manner of an author's expression in literary, dramatic, musical and artistic works, as well as poetry, novels, movies, songs, computer software and architectural drawings. The work itself must be captured in a sufficiently permanent medium so that it can be perceived, reproduced or communicated for more than a short time. For example, a presenter giving offhand remarks at a conference would not have copyright protection for those remarks until they are recorded in a sufficiently permanent medium such as an audio recording or a written document.

Although copyright protects the particular expression of an original work, it does not protect the

idea or principle behind an original work. For example, although copyright may protect the particular string of words and sentences used in a handbook or blog post providing guidance on how a non-profit organization can integrate diversity, equity and inclusion into its mission, it would not prevent others from writing handbooks or blog posts about diversity, equity and inclusion efforts at non-profit organizations.[1]

Copyright protection in the United States exists automatically from the moment an original work of authorship is fixed in a sufficiently permanent medium, and the term of the copyright is the life of the author plus seventy years after the author's death. Registration of the copyright is not necessary, although there are benefits to copyright registration as discussed below. As a general rule, the author or creator of the work automatically owns the copyright. A copyright owner can transfer rights, but the transfer must be in writing and signed by the owner of the rights.

Work made for hire (or "work for hire") is an exception to the general rule that the author or creator of the work automatically owns the copyright in the work created. Work for hire falls into one of two categories: (1) work made by an employee as part of the employee's regular duties for his or her employer, or (2) one of nine categories of work specially ordered or commissioned for use if the parties expressly agree in a written agreement that the work shall be "made for hire."[2] The nine categories of "work for hire" are (1) a contribution to a collective work, (2) part of a motion picture or other audiovisual work, (3) a translation, (4) a supplementary work, (5) a compilation, (6) an instructional text, (7) a test, (8) answer material for a test, and (9) an atlas.[3] In situations where the "work for hire" doctrine applies, the organization that employs or engages the employee or contractor will be deemed the author and owner of the copyright in the underlying work from the moment of creation.

However, copyright works that are created by independent contractors (as opposed to employees), and that are not within the nine categories of "work for hire" listed above, will not be owned by the organization commissioning such work unless the contract between the independent contractor and organization specifically assigns to the organization ownership of the rights in the works created by the independent contractor. As a result, when non-profit organizations engage independent contractors to perform services and create work product that the organization expects to own, the contract must include appropriate language transferring ownership of any intellectual property created to the organization. It is best practice to include similar language in all employment agreements as well.

BENEFITS OF COPYRIGHT REGISTRATION

As noted above, copyright protection exists automatically from the moment an original work of authorship is fixed in a sufficiently permanent medium. However, copyright registration with the U.S. Copyright Office provides several benefits to the copyright owner in enforcing a copyright claim. For example, registration is necessary to file a copyright infringement suit, and it establishes *prima facie* evidence of the validity of the copyright when registration is made before or within five years of publication. When registration is made prior to infringement or within three months of publication, a copyright owner is generally eligible to recover statutory damages, attorneys' fees and costs. This may be helpful because proving damages in a copyright infringement case can be difficult and having a statutory right to damages and recovery of attorneys' fees can make a copyright infringement action more feasible.

Additional information about copyrights and copyright registration is available on the U.S. Copyright Office website. The U.S. Copyright Office also publishes up-to-date circulars providing additional background on fundamental concepts of copyright law and its application to various forms of copyright material, which can be found here.

TRADEMARK

TRADEMARK OVERVIEW

A trademark is a type of intellectual property which identifies and distinguishes the products or services of a particular source from the products or services of others. A trademark can be a word or group of words, name, symbol or other designation, or a combination of such designations. Trademark rights accrue upon use of the trademark in commerce even if the trademark is not registered, although (similar to copyrights) there are benefits to seeking trademark registration.

Trademark protection serves two primary purposes. First, trademark law protects consumers from confusion as to the source of goods or services. For example, donors and program beneficiaries associate the picture of a circle containing a sun-like rainbow growing out of a hand with services or programs associated with United Way. A person who sees the United Way logo on a website or handbook knows that the materials are associated with United Way without having to read anything further. Therefore, trademark law prevents other non-profit organizations from using the United Way logo on their materials without United Way's permission as such use would misguide consumers as to the producer of those materials. Second, trademark law protects the owner of the mark and the value of their brand. Trademark law is based on the principle that one cannot "reap where they have not sown" and use

confusingly similar marks to benefit from another's goodwill.

There are some marks that can never be registered as trademarks because they must be available for anyone to use. These include trademarks that are generic, merely descriptive or functional. For example, marks such as "relieving poverty" or "beautifying the community" merely designate the type of services provided rather than providing the source of the services. As a result, such marks may be considered generic and generally cannot be registered because they do not tell consumers who provides the services but rather indicate the type of services provided.

To avoid a trademark infringement claim, it may also be helpful (and sometimes necessary) for an organization to ensure that use of the mark will not create a likelihood of confusion among consumers. For a mark to be likely to cause confusion, it does not have to be identical to the other mark, it just has to be similar in sight, sound, meaning or overall consumer impression. For example, if a competitor non-profit organization operated under the slogan "We Do The Most Good," it may be considered confusingly similar to The Salvation Army's "Doing The Most Good" slogan, even though it is visually and literally distinct.

It is also worth pointing out that different organizations can use similar or even identical trademarks if they are used in connection with different good or services. For example, an airline and a faucet manufacturer can both use the trademark "Delta" without risking consumer confusion.

BENEFITS OF TRADEMARK REGISTRATION

A trademark generally does not belong to the person who creates the mark, but rather to the person or organization who uses the mark in commerce. The first person or organization to use the mark in commerce in such a way that the public can identify the goods or services associated with the mark has priority and exclusive rights in the mark.

While trademark rights are acquired not by registering the mark but by using the mark, there are still many benefits to registration. Trademark protection can be secured at three different levels: state, federal, and international. Trademark protection is country-specific and area-specific so an organization may need to register a mark in many places in order to have full protection. State registration generally is not given much weight in infringement actions because it only grants exclusive rights within all or part of the state and does not protect use of the mark outside the state of registration.

The most common form of trademark registration is at the federal level with the U.S. Patent and Trademark Office. While an organization does not need federal registration to sue for trademark infringement, there are many benefits to registering at this level. First, registration provides proof that the registering party owns the mark and provides the registering party with a nationwide right to exclusive use of the mark. This is important because common law trademark rights adhere to the first user of the mark and only exist in the geographic region where such marks are used, meaning others could legally use the same mark in another geographic area. Registration with the U.S. Patent and Trademark Office also prevents confusion and costly litigation by protecting against the situation referenced above and giving the owner the right to use the mark nationwide even in geographic regions where the mark is not yet in use. Second, after the mark has been registered for five years, it becomes incontestable and the U.S. Patent and Trademark Office can generally only cancel the mark if it is found to be generic or abandoned. Third, registration provides for federal jurisdiction in federal trademark claims. Fourth, registration with the U.S. Patent and Trademark Office can be used to obtain registration in foreign countries. And finally, registration with the U.S. Patent and Trademark Office permits the registering party to use the ® symbol next to the mark to indicate the trademark is registered when the mark is used for goods and services listed in the registration. The presence of the ® symbol next to an organization's trademark can act as a strong deterrent to would-be infringers.

In addition, it may be possible to register a trademark in other countries, using either the European Community trade mark scheme (for European countries) or the Madrid Protocol (for numerous other countries). Notably, the Madrid Protocol may allow an organization to file in the United States first and then have the mark sent to other countries where it can be registered.

Seeking federal trademark protection can confer many benefits for a non-profit organization without prohibitive cost. Additional information about trademarks and federal trademark registration can be found at the U.S. Patent and Trademark Office website.

PATENTS

PATENTS OVERVIEW

A U.S. patent is a privilege granted to an inventor to exclude others from making, using or selling an invention, or improvement to a process, for a set number of years (20 years after filing a patent application for the most common type of patent, under U.S. patent law). An invention must be new, useful and "not obvious" to be eligible for patent protection.

Similar to authors of creative works under copyright law, the inventor of an invention has the authority to file a patent application and own the resulting patent under U.S. patent law, as the default rule. Unlike copyright law, however, there is no "work for hire" doctrine. [4] As such, an organization will *not* own its employees' inventions (nor any patents covering such inventions), even if invented within the scope of the employee's duties for the organization, unless that employee has signed a written agreement (typically an employment agreement) containing appropriate language that transfers the employee's rights in such inventions to the organization. Therefore, it is critical that organizations cause their employees to sign employment agreements that have been prepared or reviewed by a lawyer who is familiar with such matters.

BENEFITS OF PATENT REGISTRATION

Unlike copyrights or trademarks, a creator of an invention does not have patent rights under U.S. law unless the U.S. Patent and Trade Office issues a patent with respect to such invention. The U.S. Patent and Trademark Office requires a complete description of the actual machine or other subject matter for which a patent is issued, and this description will be made available to the public. A patent issued by the U.S. Patent and Trademark office is generally only effective in the United States, U.S. territories and U.S. possessions, although patent protection can be sought in countries outside the United States by filing an application with the appropriate patent office in the desired country. Registering a patent gives its owner a legal monopoly over the use and production of the patented product in return for a full disclosure of the product to the public. It is worth noting that, given the strict requirements for an invention to be eligible for patent protection, filing a patent application and navigating the patent prosecution process in order to receive an issued patent can be a lengthy and expensive endeavor.

Additional information about patents is available at the U.S. Patent and Trademark Office website.

CONCLUSION

Intellectual property can be a valuable asset for non-profit organizations, but the laws protecting intellectual property can also present many traps for the unwary. Understanding the different categories of intellectual property and how each category can be protected is the first step towards protecting the intellectual property owned by your non-profit organization and ensuring that your organization is not infringing on the intellectual property of others.

[1] Another example comes from the world of music: although copyright protects the lyrics, melody and recording of the Beatles' song "All You Need Is Love," it does not prevent others from writing songs about love.

[2] 17 U.S.C. § 101 (1976); see https://www.copyright.gov/circs/circ30.pdf.

[3] Id.

[4] Patent law does recognize a "hired to invent" doctrine, but it is significantly more limited than copyright's "work for hire" doctrine.

CONTACTS:

Gregg Coughlin

Associate

617-570-1434

gcoughlin@goodwinlaw.com

Jennifer Maimone-Medwick

Counsel

+1 212 813 8891

jmaimonemedwick@goodwinlaw.com

Ginggi N. Storer

Counsel

+1 617 570 8174

gstorer@goodwinlaw.com

Alert

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Brexit & Trademarks: Important Considerations For Maintaining UK Trademark Rights Post-Brexit

by Jessica L. Rothstein Alexandra M. Vaccaro Haley Patterson

With the United Kingdom's withdrawal from the European Union, companies must reconsider the implications of doing business in the UK and the EU, including how Brexit affects the company's intellectual property rights. Included below is a summary of the effects of Brexit on trademark rights held in the EU and the UK, and steps which may be taken to maintain coverage in the UK.

As of January 1, 2021, registered EU trademark rights ("EUTM"s) no longer extend protection to the UK. However, for any EUTM registrations granted on or before December 31, 2020, the UK Intellectual Property Office ("UKIPO") is now granting an automatic extension to the UK, creating a comparable UK trademark right to that in the EUTM for any EUTM registrations granted on or before December 31, 2020. Each of these "cloned" UK registrations maintains the same filing, priority, and renewal dates as the original EUTM registration, but will be represented with a new UK registration with the UKIPO. The UKIPO will not issue a separate Certificate of Registration, and the new UK registration will require a separate renewal from the EU registration. However, the process to obtain these cloned UK registration(s) is automatic, with no additional action or costs required of the trademark owner.

Note that this automatic cloning of rights exists only for those marks registered in the EU as of December 31, 2020. For those EUTM applications *pending* as of December 31, 2020, applicants now have until *September 30, 2021* to file a new, separate UK application claiming the earlier filing date and international priority (if applicable) of the subject EUTM application.

For several years, Goodwin has encouraged its clients to file applications in the UK separate from any EU application. Accordingly, you may already own a UK application, and need not worry about any extensions and/or clones; your existing UK trademark application or registration will provide the protection you need in the UK following Brexit.

If you have any questions regarding your international portfolio or if you would like to file a UK application based on your pending EU application, our trademark team is available to assist

with insight and strategy. Of course, we would be happy to provide you with a status report of your international portfolio to identify which applications and registrations you currently own.

CONTACTS:

Jessica L. Rothstein

Partner

+1 212 459 7447

jrothstein@goodwinlaw.com

Alexandra M. Vaccaro

Attorney

+1 212 459 7081

avaccaro@goodwinlaw.com

Haley Patterson

Law Clerk

+1 650 752 3214

hpatterson@goodwinlaw.com

Goodwin Insights

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Five Tips For Life Sciences Companies To Protect Their AI Technologies

by Martin Gomez Samuel S. Stone

INTRODUCTION

Artificial intelligence (AI) has revolutionized many technology areas. As a few examples, it has already been instrumental in improving and enabling voice recognition algorithms, digital assistants, advertisement recommendation engines and financial trading applications.[1] Significant investment is being made for further development of this promising new technology, with R&D spending on AI predicted to reach $57.6 billion by the end of 2021.[2] Along with these R&D efforts, companies are also trying to protect and monetize their AI inventions, in some cases opting to seek patent protection. From 2002 to 2018, the number of AI patent applications filed with the United States Patent and Trademark Office (USPTO) more than doubled, from 30,000 to 60,000.[3]

These R&D efforts are no longer limited to software companies. Life sciences companies are making significant investments in AI technology as well. In 2019, over 60% of life sciences companies invested over $20 million into AI technologies.[4] AI and Machine Learning (ML) are being used to analyze data relating to the safety, quality and clinical effectiveness of certain treatments;[5] improve the methods of manufacturing for medical devices;[6] run in silico trials to find new drug candidates in lieu of costly in vitro trials;[7] and diagnose patients.[8]

Given that AI and ML – historically the domain of software companies – is a new frontier for life sciences companies, such companies may not be familiar with the various pitfalls and considerations that a company faces when trying to protect its AI inventions. We have assembled five helpful tips to consider:

TIP 1: MAKE SURE YOU HAVE PERMISSION TO USE THE DATA

The lifeblood of most AI technologies is the data that is used to train the AI model so that the model can “learn” from the training data and generate useful predictions or inferences when presented with new data in future applications. In the life sciences context, this training data often includes or is derived from analysis of highly sensitive patient information, such as the

patient's personally identifiable information, medical history, and even their biological materials or DNA. Life sciences companies should be careful to ensure they receive proper permission to use the data they collect for purposes of training an AI model. Failure to receive proper permission could result in significant liability and other consequences associated with noncompliance with data privacy rules and regulations. Life sciences companies should familiarize themselves with the data privacy rules applicable to the types of data they are collecting and then develop a consent form, including all proper disclosures and terms, to be signed by all patients from whom they are receiving data. Standard consent forms used to collect patient samples for clinical trials or in other clinical settings often do not address the patient's consent to use the samples to develop AI models for commercial use. The disclosures and terms will vary depending on the data collected. For example, if life sciences companies are collecting biological data from patients, the consent form should require that the samples be deidentified (e.g., identified using a unique code rather than personally identifiable information) and give the patient the option of permitting the company to use the information for research and commercial purposes while acknowledging no rights in any commercial value derived from the samples.

TIP 2: GET IP ASSIGNMENTS FROM EVERYONE CONTRIBUTING TO THE AI TECHNOLOGY

Most life sciences companies understand that an assignment of intellectual property (IP) rights is required from any individual that contributes to the company's core products and candidates. Failure to fully own and control the IP assets a company purports to own can be a big problem if discovered during diligence for a corporate transaction or enforcement proceeding. Historically, the individuals required to assign IP to life sciences companies are the scientists and engineers involved in the R&D associated with the core products and candidates. But for AI technologies, the universe of contributing individuals may be broader than expected. For example, any of the following individuals could, in certain situations, be considered the creator of an AI technology: the individuals that select the data to be acted on by an AI engine, the individuals that review the results or outputs of an AI engine, the individuals that select the ML algorithms used to train the AI model and tune the modeling parameters, and the individuals that write the source code to implement an AI engine, among others. If the IP rights are protectable by copyright (e.g., source code), then the work for hire doctrine may result in the IP rights automatically vesting in an employer. But the same is not true for independent contractors, where absent an agreement saying otherwise, copyright rights vest with the contractor. Moreover, the default rule for patent rights is that they vest with the inventor, regardless of status as an employee or contractor (again, absent an agreement to the contrary). Life sciences companies should be prudent

about getting IP assignment agreements, ideally with present-tense assignment clauses, signed by all individuals, employees or contractors, that in any way interact with or are involved with designing or developing an AI technology.

TIP 3: BE CAREFUL WHEN USING OPEN SOURCE SOFTWARE

One of the most convenient, but also most dangerous, parts about software development is there is a vast universe of software code made readily available on the internet, much of it for free under so-called "open source" licenses. Using this pre-existing and available software code is quite common and can significantly increase the efficiency of a software development project by avoiding the need to reinvent the wheel for every component and feature of a particular product, especially those that are conventional. But what is engrained in the DNA of most software companies that may not be readily apparent to life sciences companies entering the software development space for the first time is that a company must be careful about the terms on which it uses third-party software. Open source software is made available to the user under a license agreement, but unlike the more formal written and heavily negotiated license agreements a life sciences company may be familiar with (e.g., when out-licensing technology from a university), these licenses are less conspicuous and often assented to simply by making use of the software. Though they come in all shapes and flavors, open source licenses can generally be characterized into two groups: (1) permissive open source licenses, and (2) copyleft open source licenses. A permissive open source license (e.g., the MIT license) makes software code available for free to a user, but does not place significant restrictions on how the code must be used. Importantly, this means the user of code under a permissive open source license can combine the code with its own proprietary code and be under no obligation to disclose or license the combined code. Conversely, copyleft licenses (e.g., the General Public License (GPL)) also make software code available for free, but require that any modified code be licensed under the same terms. Therefore, if the copyleft licensed code is combined with proprietary code, the user may be required to make its proprietary code publicly available for free as well. Obviously, this is not a good outcome for a company desiring to keep its AI software secret. To avoid this negative outcome, companies should incorporate good hygiene around their use of open source software and implement policies and procedures to ensure that no source code is used that could jeopardize the secrecy of the company's proprietary code.

TIP 4: BE THOUGHTFUL ABOUT THE TYPE OF LEGAL PROTECTION YOU WANT FOR YOUR TECHNOLOGY

There are several legal tools available to protect the IP associated with AI technology, but each

tool has benefits and drawbacks, and some tools are better or worse suited depending on the technology and the company's business strategy. A thoughtful analysis and identification of the technology to be protected, followed by selection of the appropriate tool(s) for legal protection, is critical to maximize protection and value of AI technology. In some cases, a company may select different strategies or tools for different aspects of their technology.

Generally, there are two legal IP protection tools that a company should consider using to protect its AI inventions from external competitors: patents and trade secrets (note that a third type of IP protection, copyright, will also protect against any direct copying of the source code implementing any AI technology, but will not protect the ideas underlying the source code). Patents and trade secrets each provide different benefits and limitations. Patents require that you prepare and file a patent application for examination by government patent offices. The application is typically published (and always published if it is granted as a patent) and must describe your technology in sufficient detail to enable others to be able to practice the invention. If you are granted a patent, you have the exclusive right to exclude others from practicing the invention, even if they invented the invention completely independently from you.[9] Trade secrets, on the other hand, do not require an examination process and do not require that you publicly disclose your invention. However, trade secrets provide no protection against an independent inventor or someone that reverse engineers your invention.[10]

Life sciences companies should consider the following factors when deciding between patent and trade secret protection:

- **Likelihood of independent invention.** If it is likely a competitor will independently develop your AI invention, a patent is the best line of defense. If such independent development is unlikely, keeping the invention as a trade secret may be preferred.
- **Detectability of the invention.** Even if you obtain a patent, in order to enforce it you need to be able to identify who among your competitors is using your patented invention. Given that many software inventions are implemented within non-public servers, this can be a significant consideration for AI inventions. However, often potential infringement can be detected based on the features, performance, etc. of a publicly available product. If competitor use of your technology can be detected, patents may be a good option; otherwise keeping the invention as a trade secret may be preferred.
- **Speed of innovation.** The patent application process takes time. In some cases, it can be two to three years or more before the application is examined and granted (though this can sometimes be reduced to approximately one year if you pay for accelerated

examination). On the other hand, once a patent is granted, it comes with exclusive rights for 20 years from the application's filing date. But for some types of AI technologies, the technology is evolving so rapidly that by the time a patent application makes it way through examination, let alone by the end of a 20-year patent term, it is already obsolete. If you think an invention may become obsolete quickly, trade secret protection may be preferred.

TIP 5: IF YOU CHOOSE PATENT PROTECTION, EMPLOY STRATEGIES TO MAXIMIZE CHANCES OF SUCCESS

In the United States, inventions can be patented if they are (1) new and non-obvious over the prior art, and (2) directed to patent-eligible subject matter.[11] Even when AI-based inventions improve upon the state of the art in the life sciences and arise from substantial investments in cutting-edge R&D, their patent-eligibility is very carefully scrutinized by the USPTO. This is because AI-based inventions often intersect with subject matter that is not eligible for patenting, such as laws of nature, natural phenomena, or abstract ideas (collectively, "judicial exceptions"). [12] Inventions that are directed to these exceptions are eligible for patenting only if they amount to "significantly more" than the exceptions themselves. [13] While there are many ways to argue that an invention amounts to significantly more than a judicial exception,[14] one of the best approaches with AI-based inventions is to describe, in the patent application, the AI model's performance and the improvement(s) over the performance of conventional techniques. Ideally, model performance and comparisons to conventional techniques can be shown using statistical data such as ROC curves, measures of positive predictive value (PPV) or negative predictive value (NPV), confusion matrices, F1 scores, and other similar data. The presence of such data in the application generally goes a long way toward showing that the invention is a patent-eligible improvement over the prior art rather than an ineligible attempt to monopolize a judicial exception. Employing these techniques greatly increases the likelihood of the USPTO granting a patent for an AI-based invention.

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[1] Liana B. Baker, *Tech moguls declare era of artificial intelligence*, REUTERS (June 2, 2016, 9:06 PM), https://www.reuters.com/article/us-tech-ai-conference/tech-moguls-declare-era-of-artifical-intelligence-iduskcn0yp035.

[2] *Research Topics – AI: The next generation of intelligence*, IDC, https://www.idc.com/itexecutive/research/topics/ai (last visited Feb. 1, 2021).

[3] USPTO, INVENTING AI: TRACING THE DIFFUSION OF ARTIFICIAL INTELLIGENCE WITH U.S. PATENTS 2 (2020).

[4] Aditya Kudumala et al., *Scaling up AI Across the Life Sciences Value Chain: Enhancing R&D, Creating Efficiencies, and Increasing Impact*, DELOITTE (Nov. 4, 2020), https://www2.deloitte.com/us/en/insights/industry/life-sciences/ai-and-pharma.html.

[5] Lincoln Tsang et al., The Impact of Artificial Intelligence on Medical Innovation in the European Union and United States, 29 INTELL. PROP. & TECH. L.J., no. 8, Aug. 2017, at 3, 4.

[6] *Id*.

[7] David W. Opderbeck, *Artificial Intelligence in Pharmaceuticals, Biologics, and Medical Devices: Present and Future Regulatory Models*, 88 FORDHAM L. REV. 553, 566 (2019).

[8] Susan Y. Tull, *Patenting the Future of Medicine: The Intersection of Patent Law and Artificial Intelligence in Medicine*, 10 LANDSLIDE, no. 3, Jan./Feb. 2018, at 40, 41.

[9] *See* 35 U.S.C. § 271.

[10] Restatement (Third) of Unfair Competition § 43 (Am. Law. Inst. 1995).

[11] 35 U.S.C. § 101 *et seq*.

[12] *See Alice Corp. Pty. Ltd. v. CLS Bank Int'l* , 573 U.S. 208 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

[13] *See Alice Corp. Pty. Ltd. v. CLS Bank Int'l* , 573 U.S. 208 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

[14] *See* 2019 Revised Patent Subject Matter Eligibility Guidance, Federal Register vol. 84, no. 4 (Jan. 7, 2019).

Contributor Author
Kurt Hoppmann

CONTACTS:

Martin Gomez

Partner
+1 617 570 1836
mgomez@goodwinlaw.com

Samuel S. Stone

Associate
+1 617 570 1624
sstone@goodwinlaw.com

Alert

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Mandating COVID-19 Vaccinations Of Employees: EEOC Guidance On EEO Law Considerations

by Robert M. Hale

On December 16, 2020, the Equal Employment Opportunity Commission ("EEOC") issued guidance about how federal equal employment opportunity laws ("EEO laws") may apply to potential employer requirements that employees be vaccinated against COVID-19 (the "Guidance"). The Guidance was issued as a new Section K of the EEOC's Technical Assistance entitled "What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws." The Guidance focuses primarily on disability discrimination issues under the Americans with Disabilities Act (the "ADA"), religious discrimination issues under Title VII of the Civil Rights Act of 1964 ("Title VII") and genetic information discrimination issues under the Genetic Information Nondiscrimination Act ("GINA").

Under the Guidance, employers may generally mandate that employees be vaccinated, but any such general mandate must be subject to exceptions to address disability and religious considerations and it needs to be administered in a manner that does not interfere with rights under GINA.

DISABILITY DISCRIMINATION ISSUES

Pre-Vaccination Screening Inquiries

The ADA limits employers' rights to conduct medical examinations and to make medical inquiries that are likely to elicit information about a disability. The Guidance states that a vaccination is not a medical examination. However, it observes that screening questions that would be required in connection with administering vaccines are medical inquiries that are likely to elicit information about a disability. If an employer administers the vaccine (either directly or through a contractor) and makes such medical inquiries, it needs to show that the inquiries meet the ADA standard of being "job-related and consistent with business necessity," which would require the employer to have a reasonable belief, based on objective evidence, that an unvaccinated employee would pose a "direct threat" to the employee or others.

Voluntary Vaccination Programs

The Guidance identifies two alternatives for employers to avoid the need to justify such inquiries. One is to make a vaccination program voluntary rather than mandatory. While having a voluntary, rather than mandatory, vaccination program would avoid some of the other issues addressed below, it may not satisfy an employer's interest in promoting workplace health by maximizing the extent of employee vaccinations.

If an employer maintains a voluntary program in accordance with ADA standards for such programs, the employer cannot be penalized for asking pre-vaccination screening questions. If an employee chooses to answer pre-screening questions, the information obtained must be treated as a confidential medical record under the ADA. If the employee chooses not to answer the pre-vaccination screening questions, the employer may decline to provide the employee with the vaccine. The Guidance makes clear that the employer may not retaliate against the employee for refusing to answer the pre-vaccination screening questions.

Vaccinations by Third Parties

The second way to avoid the legally complex direct threat analysis that applies to pre-vaccination screening in an employer-administered vaccination program is to have employees vaccinated by a third party provider of vaccination services, such as a pharmacy or other health care provider, that does not have a "contract" with the employer. The rationale is that in such a case, a third party, rather than the employer, would be making the medical inquiries and obtaining the medical information.

The Guidance does not elaborate on what would be a "contract" with the employer. The Guidance does state that a contractor that makes inquiries on an employer's behalf triggers the same concerns that would exist if the employer were to make the inquiries. Although this is not addressed in the Guidance, an employer may be able to avoid the concern arising from pre-vaccination screening questions while arranging with a third party provider of vaccination services to administer the vaccination process if it makes clear that the third party will not ask questions on the employer's behalf, such as by having the third party provider agree not to provide any health information to the employer.

Verifying a Vaccination

The Guidance declares that the restrictions on medical inquiries do not affect an employer's

right to require employees to provide proof of having been vaccinated. However, it warns that if an employee does not provide such proof and the employer asks why the employee did not do so, that could elicit information about a disability, which would make the inquiry subject to the "job-related and consistent with business necessity" condition for such inquiries.

This restriction should not prevent employers from addressing an employee's failure to be vaccinated. Under other longstanding EEOC guidance, with limited exceptions, it is generally the responsibility of an employee with a disability to request a reasonable accommodation. An employer should therefore be able to take action against an employee who fails to be vaccinated and does not request a reasonable accommodation. When informing employees about a vaccination requirement, an employer could also inform employees that they may confidentially seek an exception from the vaccination requirement as a reasonable accommodation based on disability-related or religious considerations.

In addition, the Guidance advises employers to warn employees not to provide medical information in connection with their proof of having been vaccinated, so as to help ensure that employees do not disclose medical information in connection with providing verification of their vaccination.

Responding to Disability-Related Objections to Vaccination

If an employee claims a disability-related reason for not being vaccinated, his or her employer could not bar the employee from the workplace for refusing to be vaccinated unless the employee poses a "direct threat" to the employee or others. As with any reasonable accommodation request, the employer could generally first require an employee to provide documentation to support a statement that the employee is disabled and needs accommodations, unless the disability or the need for accommodation is obvious.

Assuming that the employee establishes the existence of a disability and the need for an accommodation of not being vaccinated, the employer could proceed to assess whether to consider barring the employee from the workplace based on a "direct threat." Applying the direct threat standard requires an individualized assessment based on the duration of the risk, the nature and severity of the harm, the likelihood of harm and the imminence of the harm.

If an unvaccinated employee poses a direct threat of harm to others in the workplace by potentially exposing them to COVID-19, that is not the end of the inquiry. Reasonable accommodations need to be considered through the required "interactive process" that applies

to considering any reasonable accommodation. Depending on the circumstances, reasonable accommodations may include continuing a masking requirement for an individual even if such a requirement longer applies to others, establishing special distancing requirements or permitting telework, even if others have returned to the office. The Guidance states that a person who cannot be vaccinated due to a disability cannot be excluded from the workplace unless "there is no way to provide reasonable accommodations that would eliminate or reduce this risk so that unvaccinated person does not pose a direct threat." As in other disability contexts, an employer is not obligated to provide a reasonable accommodation if doing so would be an "undue hardship." However, the undue hardship standard for ADA purposes is a rigorous one.

RELIGIOUS DISCRIMINATION ISSUES

Under Title VII, an employee may seek an exemption from a vaccination requirement due to religious considerations. The employee's objection must be based on a sincerely held religious belief, practice or observance. While the Title VII concept of a "religion" is broad, it is not so unlimited as to include all personal convictions. If an employee raises an objection to vaccination based on a claim of a religious belief and the employer has an objective basis for questioning the religious nature of the belief, the employer may request additional supporting information.

If the employer determines that the employee's refusal to be vaccinated is due to a sincerely held religious belief, that does not necessarily mean that the employee is entitled to continue working at the workplace without being vaccinated. To be legally protected, the accommodation may not impose an "undue hardship" on the employer. For Title VII purposes, unlike under the ADA, an undue hardship exists if an accommodation would impose more than a *de minimis* cost or burden on the employer. Whether an exemption from a vaccination requirement would impose more than a *de minimis* cost or burden requires an inquiry based on the individual circumstances. Even if an employer were properly to conclude that an exemption from the vaccination requirement would impose more than a *de minimis* cost or burden, the employer would then need to consider whether alternative accommodations, such as teleworking, would be a means of accommodating the employee without imposing more than a *de minimis* cost or burden.

GENETIC INFORMATION DISCRIMINATION ISSUES

Under GINA, there are restrictions on employers' inquiries that could elicit genetic information. Such inquiries could potentially be made as part of pre-screening for a vaccination. However,

as with medical inquiries, an employer can avoid such restrictions by not administering the pre-screening or vaccination process and not receiving such information.

The Guidance further notes that there are restrictions under GINA on an employer's receipt of information from an employee's health care provider. To protect employers from a claim of a violation of GINA, the Guidance advises employers that require employees to obtain vaccinations through their health care providers to direct those employees not to provide genetic information with their proof of compliance with a vaccination requirement.

CONCLUSION

Many employers are grappling with the question of whether to require employees to be vaccinated when COVID-19 vaccines are available to their employees. Some are inclined to offer voluntary programs that encourage, rather than mandate, vaccinations. Others are inclined to require vaccinations to promote the health and safety of their workers. Any employer that adopts a vaccination program should do so carefully and with the advice of employment counsel. Those that decide to mandate vaccinations need to be extra vigilant and take into account potential discrimination issues, particularly concerning disability and religious considerations, as outlined in the Guidance, in developing their approach and considering exceptions.

CONTACTS:

Robert M. Hale
Partner
+1 617 570 1252
rhale@goodwinlaw.com