McDermott Will & Emery

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McDermott International Legal Highlights

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Welcome to our latest edition of McDermott International Legal Highlights.

In this issue, we will explore a number of developments which may have significant impact on businesses across a range of sectors.

Proposed legislative changes arise in the form of Trump's first steps to revise the Dodd-Frank Act 2010. Moreover, recommended reforms to the current EU Merger Control regime are being considered in an effort to streamline and simplify the process.

We will also be considering revisions to U.S. DoJ-issued guidance to applications for leniency; and will make a thorough analysis and clarification of the impact of *Eli Lilly and Co. v. Teva Parenteral Medicines.*

We hope that these updates prove both interesting and enjoyable to read. We welcome any comments and queries; please feel free to contact your McDermott attorney or myself for any further comment or information.

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DOJ Policy Updates Signal Continuity of Antitrust Program

Mary Strimel (Washington D.C.), Stefan M. Meisner (Washington D.C.) and Ashley McMahon (Washington D.C.)

The US Department of Justice (DOJ) Antitrust Division has revised its "Frequently Asked Questions About the Antitrust Division's Leniency Program and Model Leniency Letters" (FAQs). This guidance was originally released in November 2008. The FAQs contain 34 questions and answers that include: applying for leniency; the criteria for receiving leniency under the Corporate Leniency Policy and the Leniency Policy for Individuals; conditional and final unconditional leniency letters; potential revocation of conditional leniency; and confidentiality for applicants.

Updates to FAQs

The revisions were released on January 17, and again on January 26 to correct an omitted footnote in the first release. Since the revisions come in the midst of the presidential transition, including after the new administration took office, one may assume that the FAQs had the approval from new leadership. As a first signal, the message is largely one of continuity. Though some report that the changes indicate the Division will take a narrower approach in granting immunity, this is not necessarily the case. The Division points out in its short announcement that "[m]any questions—and answers—remain unchanged from before," and that some have been "clarified" in response to 10 years of Division practice since the FAQs were first released.

Specifically

- The revisions change the wording regarding Type B leniency (available where the Division already has some evidence of a violation, but only if "[t]he corporation is the first to come forward and qualify for leniency with respect to the activity"). With respect to cooperating employees, officers and directors of a Type B leniency applicant, the wording includes a change from "the Division ordinarily provides leniency" as it would in a Type A context, to "the Division often chooses to include protection" for these persons. With this subtle change, the Division includes a caveat that it "may exercise its discretion to exclude from the protections that the leniency letter offers those current directors, officers, and employees who are determined to be highly culpable." This language raises questions in part because of the lack of definition of "highly culpable" and lack of guidance as to how the Division will exercise its discretion. However, bear in mind that it would be counterproductive for the Division to exclude from coverage an individual whose cooperation has great value for its investigation. Given the fast pace of many investigations, the Division would need to move quickly to implement any exclusion, creating a risk of potentially losing access to valuable evidence if it excludes key individuals from coverage. Company and individual counsel will need to press for clarity on individual coverage at the inception of Type B investigations
- Cooperation remains key and receives added emphasis in the revised FAQs, but cooperation has always been key to the application for leniency with the Division
- The guidance on non-antitrust crimes confirms that the Division will grant leniency for such crimes that are integral to the antitrust crime. However, as was the case before, the Leniency Program "does not protect applicants from criminal prosecution by other prosecuting agencies for offenses other than Sherman Act violations." The document makes clear that applicants should not expect to use leniency to obtain immunity from other agencies for non-antitrust crimes. This clarifies more than changes existing policy. The Division prosecutes antitrust, obstruction, mail and wire fraud crimes, but typically leaves other crimes such as securities fraud and violations of the Foreign Corrupt Practices Act (FCPA) to other parts of the DOJ. The new FAQ states that other prosecuting agencies do not typically attempt an end-run around the Leniency Program for antitrust crimes
- The revisions include a new question describing the Division's approach to the "Penalty Plus" framework under which the Division seeks enhanced penalties for companies that omit reporting certain antitrust crimes when pleading guilty to others. The Division's Penalty Plus policy has been in place for many years and is meant to punish recidivism with respect to companies that take advantage of the Leniency Program with one product but do not investigate or disclose conduct with respect to other products. With the changes, the Penalty Plus guidance is clearer. However, these incentives for thorough internal investigations by companies have always been present
- The edits also streamline the language dealing with the marker system whereby a company may investigate its own conduct. Applicants for leniency must contact the deputy assistant attorney general for criminal enforcement or the director of criminal enforcement, instead of staff in one of the Division's criminal investigative offices

Recommendations

- The Division's FAQs is an important document that provides insights into the Division's practice. The revisions to the FAQs are important changes, and they

serve to update and clarify guidance that was close to a decade old. The continuity we have seen from the Division over the years, despite the previous administration changes, is likely to continue under the current administration with respect to criminal activity. Though it is early in the days of the current administration and not all new leadership is in place, the revisions to the FAQs could be the first indication that criminal antitrust enforcement may be as usual at the DOJ.

INTERNATIONAL LEGAL HIGHLIGHTS

President Trump's Financial System Executive Order and What It Means for Dodd-Frank Compliance

Andrea S. Kramer (Chicago)

On February 3, 2017, President Trump issued an executive order setting out “Core Principles for Regulating the United States Financial System” and requiring review of existing regulations to determine whether they conform to those core principles. He also, in a memorandum to the United States Department of Labor, delayed the April effective date of a regulation imposing a fiduciary standard on certain financial professionals who advise clients, including pension funds, about investments.

These are the administration’s first steps towards revising or dismantling major portions of the 2010 Dodd-Frank Act, which President Trump criticized as a “disaster” on which he vowed to “do a big number.”

Specifically, the executive order directs the Treasury Secretary to consult with the member agencies of the Financial Stability Oversight Council (FSOC) and to issue a report with recommendations for changes to the law and the accompanying regulations to bring them into compliance with the executive order's “Core Principles.”

It is unlikely that Dodd-Frank will be repealed in its entirety, particularly since the incoming Secretary of the Treasury, Steven Mnuchin, in his confirmation hearings voiced support for the Volcker Rule, which bars banks from proprietary trading. Rather, it is expected that the target will be specific provisions viewed as burdensome and unnecessary, as well as those provisions with high compliance costs. The executive order does not in itself affect any existing rules or regulations. It is the actions taken in response to it that will determine the shape of future financial regulations. Some regulations under Dodd-Frank can be rolled back by regulation (subject, of course, to established notice and public comment requirements), but other changes, however, would require Congressional action.

Although a full repeal of Dodd-Frank is unlikely, the provisions that are most likely to be under consideration for amendment or revocation include the following:

- The Volcker Rule limitation on banks trading for their own accounts.
- The Consumer Finance Protection Bureau's oversight of consumer financial products.
- Capital requirements for banks, including concentration limits and notification requirements.
- The Federal Deposit Insurance Corporation's orderly liquidation authority with respect to institutions under its jurisdiction.
- FSOC authority to designate organizations as "systematically important financial institutions" and its authority to wind them down.

We are closely monitoring developments with respect to Dodd-Frank and financial regulations generally, and are available to discuss your questions.

INTERNATIONAL LEGAL HIGHLIGHTS

Overview of the Proposed Reforms of the EU Merger Control Regime

Mélanie Bruneau (Brussels) and Antoine de Rohan Chabot (Brussels)

In the past couple of years, the European Commission has decided to review and evaluate the functioning of different aspects of the EU merger control regime regulated by EU Regulation No. 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EU Merger Regulation), its implementing regulation and related notices and guidelines.

The process started in 2014 when the Commission adopted a White Paper titled "Towards More Effective EU Merger Control" (the White Paper), which presented the Commission's view that EU merger control worked well and that no fundamental overhaul of the system was needed. The Commission did, however, identify specific amendments to the EU Merger Regulation to make it more effective.

In the wake of the positive feedback it received during the consultation it organised following the publication of the White Paper, the Commission launched another public consultation in October 2016 on the "Evaluation of procedural and jurisdictional aspects of EU merger control", through which it is seeking feedback from stakeholders on the effectiveness of certain additional procedural and jurisdictional aspects of EU merger control. Stakeholders have until 13 January 2017 to respond.

Key Proposals in the White Paper

INTRODUCING A LIGHT AND TAILOR MADE REVIEW OF ACQUISITIONS OF NON-CONTROLLING MINORITY SHAREHOLDINGS THAT COULD HARM COMPETITION

The Commission recognised that, in some instances, acquisitions of minority shareholdings could be detrimental to competition, particularly those of competitors or vertically related companies. Competitive harm may arise, for example, from the influence acquired over a competitor's strategic decisions or access to a competitor's confidential business information.

Unlike the merger control rules in some EU Member States and countries such as Canada, Japan and the United States, the EU Merger Regulation does not allow the Commission to address competition concerns that may arise from minority shareholdings, which could, according to the Commission, constitute an enforcement gap.

For example, the Commission has prohibited the merger of Ryanair and Aer Lingus twice since 2007, as it found that the dominant position created by the merger would be harmful to the 11 million EU consumers flying annually to and from Ireland. Conversely, the Commission lacked jurisdiction to review Ryanair's near 30 per cent minority shareholding in Aer Lingus, which was subsequently reviewed by the UK Competition and Markets Authority. The UK Authority only had jurisdiction over flight routes from Ireland to the United Kingdom, and could not have reviewed the transaction in the context of the entire European Union.

As a result of this analysis, the Commission proposed in the White Paper a tailor made review system limited to certain categories of minority shareholdings. The Commission highlighted that these changes would specifically be targeted at EU-impacting transactions that give a certain degree of influence in a competitor or a vertically related company and could therefore be problematic from a competition point of view. According to the Commission, this would apply to between 20 and 30 cases per year and would leave benign transactions, notably companies' restructuring efforts or the private equity market, completely unaffected.

MAKING CASE REFERRALS BETWEEN EU MEMBER STATES AND THE EUROPEAN COMMISSION MORE BUSINESS-FRIENDLY AND EFFECTIVE

The White Paper stated the Commission's aims to reduce the administrative burden on businesses and on itself, to enhance the one-stop-shop approach, and to streamline allocation of cases to the most appropriate authority.

For pre-notification referrals to the Commission, the requirement for two separate submissions (a referral request and a subsequent notification) would be abandoned to make the process quicker and less burdensome. The Commission would have European Economic Area (EEA)-wide competence to review a transaction received via post-notification referral, with the aim of avoiding parallel reviews

by the Commission and national competition authorities (NCAs).

FOSTERING COHERENCE AND CONVERGENCE BETWEEN EU MEMBER STATES

The White Paper showed an intention from the Commission to promote enhanced cooperation between itself and NCAs, as well as amongst NCAs when reviewing a merger that does not fall under the Commission's jurisdiction, in order to avoid contradictory or divergent decisions.

The Commission acknowledged the high degree of convergence already achieved, and the White Paper supported, in principle, the idea of moving towards a system where the Commission and all NCAs would apply the same substantive EU law.

STREAMLINE AND SIMPLIFY PROCEDURES

The White Paper suggested excluding certain, non-problematic transactions from the Commission's review, such as the creation of joint ventures operating outside the EEA and those with no impact on European markets.

In addition, consideration was given to further extend the light review system based on a simple information notice to some categories of non-problematic cases currently dealt with under a simplified procedure. This would further reduce costs and administrative burdens on businesses.

The 2014 Public Consultation

Respondents to the 2014 consultation mostly agreed that the EU merger control system worked well overall and viewed favourably the White Paper's proposals in relation to the streamlining of the case referral system and the simplification of procedures.

Stakeholders were, however, more critical as regards the necessity of introducing a review of minority shareholdings, considering that

- The enforcement gap was not sufficient to call for new regulation.
- The most potentially problematic cases of minority shareholding acquisitions could be dealt with by existing rules.
- Theories of harm in relation to minority shareholdings only apply in very limited circumstances and there is not enough empirical evidence of these existing in practice.
- The proposed system would capture many more than the Commission's estimate of 20 to 30 cases per year.

The 2016 Public Consultation

According to the Commission, the 2016 consultation aims in particular to establish the effectiveness, relevance, efficiency and coherence of

- The jurisdictional thresholds set out in the EU Merger Regulation
- The simplified procedure applying to certain categories of concentrations as set out in the EU Merger Regulation, its implementing Regulation and the Commission Notice on simplified procedure
- Certain technical aspects of the procedural and investigative framework for the assessment of mergers
- The referral system as set out in the EU Merger Regulation, related provisions of its implementing regulation and the Commission notice on case referral

Of these topics, the issue of the jurisdictional thresholds set out in the EU Merger Regulation is the most interesting as, at present, it only applies to concentrations with an EU dimension, i.e., those where the undertakings concerned meet the different relevant turnover thresholds.

In the aftermath of the 2014 public consultation, a debate emerged on the effectiveness of these purely turnover-based jurisdictional thresholds. The question centred specifically on whether or not they allow the capture of all transactions that can potentially have an impact in the internal market.

This may be particularly significant for the digital economy, where services are regularly launched to build up a significant user base before a business model is determined that would result in significant revenues. Relevant business models may involve the formation of commercially valuable data inventories without generating corresponding turnover, at least in an initial period. Players in the digital economy may therefore have considerable market potential, but generate only a small turnover at the

moment when jurisdiction needs to be established for EU merger control purposes. This perceived legal gap may not only concern the digital industry, but also other industry sectors, such as pharmaceuticals.

The acquisition of companies with a low turnover is likely not to be captured under the current notification requirements of the EU Merger Regulation, even in cases where the acquired company already plays a competitive role, holds commercially valuable data, or has a considerable market potential for other reasons. It has therefore been suggested that the existing turnover-based jurisdictional thresholds of the EU Merger Regulation should be complemented by additional notification requirements based on alternative criteria, such as the transaction value.

Next steps

The Commission expects to publish the responses to the 2016 public consultation in early 2017. Depending on the results of the consultation, the Commission will assess whether or not any policy and/or legislative measures are warranted.

INTERNATIONAL LEGAL HIGHLIGHTS

Multiple Actors May Perform Steps in Method Claims for Purposes of Inducement

Mandy H. Kim (Orange County)

Addressing the issue of divided infringement, the US Court of Appeals for the Federal Circuit affirmed the district court's finding of induced infringement even though no single actor performed all steps of the asserted claims in a method patent. *Eli Lilly and Co. v. Teva Parenteral Medicines, Inc.*, Case No. 15-2067 (Fed. Cir., Jan. 12, 2017) (Prost, C.J.).

The patent at issue related to methods of administering the chemotherapy drug pemetrexed disodium (pemetrexed) after pretreatment with two common vitamins, folic acid and vitamin B12. Eli Lilly markets pemetrexed under the brand name ALIMTA®. After the patent issued in 2010, Teva and other drug makers notified Eli Lilly that they had submitted Abbreviated New Drug Applications seeking approval by the US Food and Drug Administration to market generic versions of ALIMTA®, and also filed Paragraph IV certifications declaring the patent invalid, unenforceable and not infringed. Eli Lilly brought suit against Teva and the other drug makers, alleging infringement under the Hatch-Waxman Act. The parties agreed that no single actor performed all steps of the asserted claims—rather, the steps were divided between physicians administering vitamin B12 and pemetrexed and patients administering folic acid.

During the litigation in 2013, the defendants conditionally conceded induced infringement under then-current law set forth in the Federal Circuit's *Akamai* decision (IP Update, Vol. 15, No. 9) (Akamai II). The Supreme Court of the United States, however, reversed *Akamai II*, holding that liability for inducement cannot be found without direct infringement, and remanded to the Federal Circuit to reconsider the standards for direct infringement (IP Update, Vol. 17, No. 6). This resulted in the Federal Circuit's *Akamai V* decision in 2015 (IP Update, Vol. 18, No. 12). After applying *Akamai V*, which broadened the circumstances in which others' acts may be attributed to a single actor to support direct infringement liability in cases of divided infringement, the district court found that defendants still induced infringement. Defendants appealed. Defendants also appealed the district court's finding that the asserted claims were not invalid.

The Federal Circuit affirmed, stating that under *Akamai V*, the performance of method steps is attributable to a single entity in two circumstances: (1) when that entity "directs or controls" others' performance, or (2) when the actors "form a joint enterprise." In the instant case, the question was whether physicians directed or controlled their patients' administration of folic acid. As to that question, the Court reiterated the two-prong test set forth in *Akamai V*, where directing or controlling others' performance includes circumstances in which an actor conditions participation in an activity or receipt of a benefit upon others' performance of one or more steps of a patented method, and establishes the manner or timing of that performance. The Court also noted that going forward, "other factual scenarios may arise which warrant attributing others' performance of method steps to a single actor."

Regarding the first prong, the Federal Circuit, after considering the product labeling and expert testimony, agreed with the district court's finding that physicians

condition pemetrexed treatment on folic acid pretreatment. The Court noted that for purposes of applying the test, "conditioning" was not limited to "legal obligations or technological prerequisites." Regarding the second prong, the Federal Circuit again agreed with the district court's ruling that, in view of the record evidence, physicians establish the manner and timing of patients' folic acid pretreatment. The Court cautioned, however, that its holding "does not assume that patient action is attributable to a prescribing physician solely because they have a physician-patient relationship," and stated that it "leave[s] to another day what other scenarios also satisfy the 'direction or control' requirement." Turning next to the issue of whether Eli Lilly proved the requisite intent to find liability for induced infringement, the Federal Circuit found that the evidence established that the product labeling in issue would inevitably lead some physicians to infringe which was sufficient to establish the requisite intent for inducement.

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Nihon Kai News

- Jeffrey E. Stone, a trial partner and Chairman Emeritus at McDermott in Chicago, currently serves as the chairman of the Asia Pacific Institute for the American Jewish Committee. In that role, he supervises (as a lay leader) the work that the AJC does in the Asia Pacific region, including a lot of diplomatic relations with the governments of Japan, China, India, Indonesia, Viet Nam, etc.

- On March 20, in New York, Jeffrey E. Stone moderated a panel held at the Japan Society, in which the panelists were Ambassador Reiichiro Takahashi, the Japanese Counsel General to New York, Irene Inouye, the president of the U.S.-Japan Council, David Harris, the CEO of the AJC and Ambassador Dani Dayan, the Israeli Counsel General to New York, on the subject of U.S.-Japan Relations in the Trump Era.

Moderator Jeffrey E Stone

All speakers at the Japanese Society

McDERMOTT INTERNATIONAL HIGHLIGHTS

INTERNATIONAL NEWS: FOCUS ON INTERNATIONAL DISPUTE RESOLUTION

This newsletter explores reforms to EU Merger Regulation, trade secret protections, changes to China's competition law and its health care market – as well as numerous other issues which impact on dispute resolution.

2017 INTELLECTUAL PROPERTY LAW YEAR IN REVIEW

This Special Report summarizes key IP cases from 2016, and provides a quick reference guide for in-house counsel seeking to navigate their company's patent, trademark, trade secret and copyright matters in the months ahead.

EU COMPETITION ANNUAL REVIEW 2016

This Special Report summarizes developments in EU competition during the year 2016, providing an overview of the main recent developments in EU competition rules and acts as a ready reference for complex issues of EU competition law.

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If you have questions, suggestions or comments about this newsletter, please contact us here.

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