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Memorandum

SEC Brings a Series of Enforcement Actions, Charging Issuers and Their Executives with Fraud

May 3, 2016

In March of 2016, the Securities and Exchange Commission ("SEC") initiated three enforcement actions against publicly traded companies and their executives for allegedly misleading investors regarding the progress of their product's development and/or the status of their product with regulators.¹

I. Action Against Technology Company Uni-Pixel For Allegedly Misleading Investors Regarding the Development of its Key Product and Related Business Relationships

On March 9, 2016, the SEC filed a civil suit against the technology company Uni-Pixel, Inc., as well as its chief executive officer ("CEO") and chief financial officer ("CFO")/Corporate Secretary, for allegedly making material misstatements and omissions with regard to the company's manufacturing of its key product – a touch screen technology called "UniBoss" – and related material agreements with several major technology companies.

A. The Allegations

1. Alleged Misstatements Pertaining to the Company's Manufacturing Abilities

According to the SEC's complaint, the commercial viability of Uni-Pixel's products was dependent upon the company's ability to develop "a high-volume roll-to-roll (or continuous flow) manufacturing process," which

See SEC v. Killion (Complaint) (Mar. 9, 2016); Securities and Exchange Commission Deferred Prosecution Agreement with Bernard Thomas Marren (Mar. 3, 2016); Securities and Exchange Commission Press Release, "SEC: Tech Company Misled Investors About Key Product" (Mar. 9, 2016); SEC v. AVEO Pharmaceuticals, Inc. (Complaint) (Mar. 29, 2016); Securities and Exchange Commission Press Release, "SEC: Biotech Company Misled Investors About New Drug's Status With FDA" (Mar. 29, 2016); In the Matter of Navistar International Corp., Release Nos. 10061, 77490; File No. 3-17190 (Mar. 31, 2016); SEC v. Ustian (Complaint) (Mar. 31, 2016); Securities and Exchange Commission Press Release, "SEC: Navistar International and Former CEO Misled Investors About Advanced Technology Engine" (Mar. 31, 2016).

would allow the touch sensors to be produced through a continuous process. In the spring of 2013, Uni-Pixel was still in the initial stages of developing this manufacturing process and had not yet produced any UniBoss products using a large-scale manufacturing process; it had only created several sample units by hand in "small-scale lab conditions that could not be used for commercial manufacturing." Nonetheless, during the spring of 2013, the company and its executives allegedly made several materially false and misleading statements regarding its manufacturing capabilities. In particular:

- Uni-Pixel issued a press release in which CEO Reed J. Killion stated that the company's printing and plating lines were "qualified and production ready" and that the company was "on track to meet the capacity target of sixty thousand square feet per month by the end of April."
- Uni-Pixel issued a second press release, attached to a Form 8-K filed with the SEC, in which the CEO stated that Uni-Pixel had "begun shipping initial batches of sensors to our PC maker licensee. The initial shipment quantities on the production line started at fifty moving to hundreds and then thousands over the next several months." The press release further indicated that the company "reached [its] target production equipment capacity of 60,000 square feet per month."
- In the company's earnings call for the first quarter of fiscal year 2013, Killion and the company's CFO and Corporate Secretary, Jeffrey W. Tomz, referenced the shipment of 50 units purportedly from the company's "production line" and stated that the company has had to "qualify" its manufacturing process (i.e., that it has confirmed its process as being capable of commercial manufacturing).

According to the SEC, Killion and Tomz knew that these statements were false and misleading, yet they "misled the public about the Company's manufacturing capabilities because revealing the true state of its ability to utilize its own much-publicized process would have jeopardized business and customer relationships and investment prospects." The SEC further alleged that Killion and Tomz separately ignored concerns raised by a Uni-Pixel employee regarding their alleged misrepresentations.

In November of 2013, Uni-Pixel, Killion and Tomz again issued allegedly false and misleading public statements regarding the manufacture and sale of the company's product.

- Uni-Pixel issued a press release, affixed to a Form 8-K filing, stating that the company had "received its first purchase order" from its "lead PC OEM partner for its revolutionary InTouch Sensors." The "lead PC OEM partner" referred to Dell, and "[i]n reality, Dell only ordered 1,000 Uni-Pixel Sensors at \$0.01 per unit for a total price of \$10 to review as sample products." According to the SEC, this press release misled the public "to believe that the 'lead PC OEM partner' had made a commercial purchase of Uni-Pixel's products by disclosing neither the extremely small price per unit nor the status of the order as a sample for a potential customer."
- The same press release and Form 8-K disclosed that the company "expect[ed] to ship an initial commercial run of InTouch Sensors in the fourth quarter of 2013." According to the SEC, however, "Uni-

Pixel's management did not expect that the Company would ship a commercial run of products in 2013." In fact, in December of 2013, the company's Vice President of Manufacturing allegedly advised Killion and Tomz to "remove its shipment prediction from an investor relations presentation," but they failed to withdraw or clarify their statements. Additionally, in December of 2013, Killion himself allegedly notified the company's board of directors that the company expected to ship the product commercially "no later than end of second quarter 2014," yet, according to the SEC, "Uni-Pixel failed to withdraw, correct, or clarify its claims to the public . . . nor did it inform the public about this material change in plans."

2. Alleged Material Omissions Regarding the Company's Business Agreements

According to the SEC, Uni-Pixel and its executives further misled the public by failing to disclose material terms of two agreements with major technology companies and failed to file a third agreement with the SEC.

Over the course of several months, Uni-Pixel allegedly entered into two agreements – one with Dell and one with Intel – in connection with the development, production and marketing of its UniBoss touch sensor technology. The agreement with Dell contemplated Uni-Pixel satisfying three "potential deliverables or milestones," and the agreement with Intel required Uni-Pixel to satisfy two such milestones. Pursuant to each agreement, upon the completion of each milestone, Dell or Intel would pay Uni-Pixel \$5 million, for a potential total of \$15 million or \$10 million, respectively. In Uni-Pixel's press releases announcing each of these agreements, however, Uni-Pixel did not identify Dell or Intel and failed to disclose the terms and conditions of the agreements, including their contingent nature. Instead, Uni-Pixel "touted a 'multi-million dollar' agreement" with an unnamed "Major PC Maker" and "Major Ecosystem Partner," respectively. Given its finding that each of these agreements was "a material definitive agreement that was not entered into in the ordinary course of Uni-Pixel's business and otherwise called for Uni-Pixel to acquire property, plant, or equipment for consideration exceeding 15 percent of Uni-Pixel's fixed assets," the SEC alleged that Uni-Pixel thus failed to comply with Item 1.01 of Form 8-K.

According to the SEC, Uni-Pixel also entered into an agreement with Eastman Kodak Company "in connection with a proposed joint manufacturing facility" that required Uni-Pixel to commit approximately \$12 million in operating capital. Uni-Pixel and Kodak issued a joint press release regarding this agreement, yet, the SEC alleged, "Uni-Pixel failed to timely file" the agreement as an exhibit to its Form 8-K or in a subsequent periodic report, thus violating the requirements of Item 1.01 of Form 8-K.

The SEC further alleged that Uni-Pixel failed to attach any of the three agreements as exhibits "to the Form 10-K or 10-Q covering the reporting period in which the agreement was executed or became effective," as required by Item 601(b)(10) of Regulation S-K.

According to the SEC, these omissions "were material and deprived investors of information about the only agreements from which Uni-Pixel recognized or had the future potential to recognize any significant revenues." With regard to the Dell and Intel agreements, the SEC claimed that Uni-Pixel's omissions

enabled the company "to conceal the fact that it not only missed, but also did not even have the capability to meet, contractually defined milestones required under" the agreements.

The SEC asserted that, due to their allegedly material misstatements and omissions, Uni-Pixel and its two executives violated the antifraud provisions of both the Securities Act of 1933 (the "Securities Act") and the Exchange Act of 1934 (the "Exchange Act") and that Uni-Pixel violated the reporting, books and records, and internal control provisions of the Exchange Act, aided and abetted by the company's CEO and CFO/Corporate Secretary.

B. Status of the Action

Uni-Pixel agreed to the entry of a final judgment against it, permanently enjoining the company from violating the federal securities laws. The settlement is subject to court approval. The litigation continues against Killion and Tomz.

Separately, the SEC entered into a deferred prosecution agreement with the former chairman of Uni-Pixel's board of directors, alleging that the former chairman was aware that statements in Uni-Pixel's press releases were false and misleading but "took no affirmative steps to implement any oversight of outgoing press releases or correct misleading press releases after their issuance." Under the deferred prosecution agreement, the chairman of the board is required to refrain from violating federal or state securities laws, refrain from serving as an officer or director of any issuer for five years, and cooperate with the government in its related investigations and proceedings.

II. Action Against Biotech Company AVEO Pharmaceuticals For Allegedly Misleading Investors Regarding the Status of its Lead Drug Candidate with the FDA

On March 29, 2016, the SEC initiated a lawsuit against AVEO Pharmaceuticals, Inc. and its former CEO, CFO, and chief medical officer for allegedly making materially misleading statements about the company's communications with the Food and Drug Administration ("FDA") regarding AVEO's "flagship drug candidate," tivozanib ("Tivo").

A. The Allegations

To provide context, the SEC explained that Tivo – a drug developed to treat a particularly deadly form of kidney cancer – had advanced further than any of AVEO's other drug candidates in the FDA approval process. According to the SEC, "the company had yet to have a drug approved for sale to the public," and thus, "Tivo's development, hoped-for approval by the FDA, and ultimate success were material to AVEO." According to the SEC, "investors valued AVEO's business prospects based primarily on the estimated likelihood of Tivo's success," and even AVEO itself acknowledged that the company was dependent on the drug's success.

AVEO had conducted a large-scale, randomized clinical trial of Tivo, known as TIVO-1, which tested Tivo's performance against another drug already on the market. In May of 2012, after conducting the clinical trial, AVEO representatives met with FDA staff to discuss the results from TIVO-1 and the company's anticipated filing of a New Drug Application ("NDA") for Tivo – the official application for obtaining FDA approval for the sale and marketing of pharmaceuticals. At this "pre-NDA meeting," FDA staff members expressed concerns regarding the results of TIVO-1. Specifically, the FDA staff was concerned that the results indicated that, "while Tivo seemed to be slowing the progression of the disease, patients taking Tivo were dying sooner than patients taking the other study drug." The FDA staff felt that the design of TIVO-1 and its predominantly European patient population "made it difficult to determine if patients taking Tivo were dying earlier because Tivo was toxic or because – as AVEO posited during the meeting – they were only receiving one therapy instead of two." As reflected in the official minutes of the pre-NDA meeting, the FDA staff therefore "recommended that the sponsor conduct a second adequately powered randomized trial in a population comparable to that in the US" and that it "conduct the final analysis of overall survival in the current trial."

According to the SEC, the company's chief medical officer, William Slichenmyer, attended the pre-NDA meeting and prepared a slide presentation for the company's executive committee that summarized the results of the meeting, including the specific feedback provided by the FDA, and outlined several options for AVEO to consider. This presentation was allegedly viewed by the company's CEO and CFO. The individual defendants allegedly received another slide presentation intended for AVEO's board that indicated that, at the pre-NDA meeting, the FDA staff informed AVEO that it is "[p]roblematic for FDA to approve a drug if [overall survival ("OS")] trends in the wrong direction . . . " and that it would be "in the sponsor's best interest to start another randomized trial, in a population relevant to the US."

AVEO projected that a second clinical trial would cost at least \$83 million and take approximately three years. The company began to design this second trial, called TIVO-2, including obtaining board approval for the trial. AVEO also "began running additional analyses of the existing OS data in an effort to show that the OS results were a product of some patients' having taken one drug, while others took two."

In July of 2012, approximately two months after the pre-NDA meeting, AVEO allegedly wrote to the FDA regarding its proposed design for TIVO-2 and requested a meeting with the staff. In August, the FDA responded that it "has significant concerns regarding the trial design described" in the company's meeting package, indicating that the proposed design would not adequately measure OS. Upon receipt of the FDA's response, AVEO cancelled the meeting it had requested.

In September, AVEO filed the NDA with the FDA. The NDA included the company's final OS results and additional analyses of the OS data, but "did not include data from any second trial, as no second trial had even been started. Nor did the NDA include any timetable or design for such a trial." In response to the

NDA, the FDA staff "cautioned that the OS results remained 'a significant safety concern" to be discussed at a meeting of an advisory panel of outside experts scheduled for May 2, 2013. AVEO again redesigned TIVO-2, submitted the redesign to the FDA, and received a rejection from the FDA with regard to the study's proposed design. On April 30, 2013, in advance of the May 2 meeting, the FDA staff publicly released a briefing document that disclosed prior communications between the FDA staff and AVEO, and in particular, that at the pre-NDA meeting in May of 2012, the FDA staff had recommended that AVEO conduct a second clinical trial.

According to the SEC, in the eleven months from the pre-NDA meeting to April 30, 2013, when the FDA publicly disclosed its previous recommendation to AVEO, "defendants concealed from investors that the FDA staff had recommended a second clinical trial." While AVEO informed investors that the FDA had raised concerns regarding the death rates for patients taking Tivo, AVEO and its executives allegedly concealed "the depths of the FDA staff's concerns and, in particular, the fact that the FDA staff had recommended a second full clinical trial to address those concerns" – a step that would be both costly and time-consuming. The SEC alleged that "AVEO adhered to a corporate communications strategy that emphasized AVEO's data analysis efforts, while downplaying the possibility of further, pre-approved trials." For example, the defendants allegedly made the following false and misleading statements:

- In an earnings release issued on August 2, 2012 and filed with the SEC, AVEO stated that the FDA "has expressed concern regarding the OS trend" in TIVO-1 and "has said that it will review these findings at the time of the NDA filing as well as during the review of the NDA." The press release further noted that "AVEO is conducting additional analyses" that "the company believes will directly address this issue."
- In an earnings call with investors and analysts held on the same day, Slichenmyer responded to several questions from analysts regarding communications with the FDA and the status of Tivo's FDA approval process. Slichenmyer stated that "the current data package should be sufficient to gain approval" and characterized as "unlikely" the chances that the FDA would not be persuaded by the company's additional analyses. The chief medical officer also stated twice that he "can't speculate on what the agency might be thinking on what additional actions might be necessary."
- In a Form 10-Q filed with the SEC on August 7, 2012, as well as that filed on November 8, 2012, AVEO disclosed: "The FDA has expressed concern regarding the overall survival trend in the TIVO-1 trial and has said that it will review these findings at the time of the NDA filing as well as during review of the NDA. We cannot be certain as to what type and how many clinical trials the FDA... will require us to conduct before we may successfully gain approval to market [Tivo]....[I]f the FDA... requires us to conduct additional clinical trials of [Tivo] in order to gain approval, we will incur significant additional development costs, commercialization of [Tivo] would be prevented or delayed and our business would be adversely affected."

- At three different conferences in August and September of 2012, AVEO's CFO indicated that the FDA "expressed some concern" and that the company is conducting additional analyses to provide the FDA with further information to understand the results of the clinical trial, but allegedly "did not disclose the FDA staff's recommendation that AVEO conduct a second trial, nor that AVEO was planning such a trial." Furthermore, according to the SEC, the CFO's comments misleadingly suggested that the FDA asked for an explanation of the results from TIVO-1, when "[i]n reality, the FDA staff had listened to AVEO's proffered explanation of the OS results, and had nonetheless recommended doing a second trial."
- A prospectus supplement filed with the SEC in connection with an offering of common stock incorporated by reference the company's Forms 10-Q of August 7, 2012 and November 8, 2012, as well as the Form 8-K filed on January 16, 2013.

According to the SEC, when the FDA disclosed, on April 30, 2013, that it had recommended to AVEO at the pre-NDA meeting that it conduct a second randomized trial, the company's stock price plummeted 30 percent.

Several days later, at the meeting with the advisory panel of FDA-appointed experts, the experts allegedly voted 13 to 1 that TIVO-1 "was not sufficient to support approval." The FDA followed the experts' recommendation, denying approval for Tivo.

As a result of the defendants' allegedly materially misleading statements, the SEC brought claims against each of the defendants for violations of the antifraud provisions of both the Securities Act and the Exchange Act. The SEC also brought claims against AVEO for violations of the reporting provisions of the Exchange Act.

B. Status of the Action

AVEO agreed to pay a \$4 million penalty to settle the SEC's case against it, without admitting or denying the allegations in the complaint. The settlement is subject to court approval. The SEC's case against the company's three former officers remains pending.

III. Action Against Engine Manufacturer Navistar For Allegedly Misleading Investors Regarding the Certification Status of its Engine with the EPA

On March 31, 2016, the SEC instituted administrative cease-and-desist proceedings against Navistar International Corporation and filed a complaint in district court against Navistar's former CEO for allegedly making materially misleading statements about the company's development of an engine that could meet the new Clean Air Act standards of the Environmental Protection Agency ("EPA").

A. The Allegations

By way of background, the SEC explained in its cease-and-desist order that, as a manufacturer of diesel engines, Navistar is required to "obtain a certificate of conformity . . . from the EPA each year for each model of each engine family" that the company sells. In 2001, the EPA enacted new Clean Air Act standards for engines, which became fully effective in 2010. Navistar was allegedly the only U.S. engine manufacturer that opted to develop "an exhaust-gas recirculation-only technology, known as 'EGR,' to comply with the EPA's 2010 emissions standard"; Navistar's competitors were using "a selective catalytic reduction technology, known as 'SCR." Navistar allegedly believed that the "successful development of its EGR-only technology, including meeting emissions standards, was material to Navistar's business prospects." Indeed, according to the SEC, in SEC filings and conference calls with analysts between 2010 and 2012, Navistar and its executives predicted that the technology it was developing "would provide a competitive advantage to Navistar in the big-bore engine and large truck markets."

By 2010, Navistar allegedly did not have an EGR-only engine with the requisite certificate of conformity from the EPA, nor did it have an EGR-only engine ready for production. In February of 2011, Navistar submitted an application to the EPA for certification of its EGR-only engine. According to the SEC, "Navistar did not consider the engine that the company described in the 2011 application to be a commercially competitive engine." Both before and after Navistar submitted its application to the EPA, Navistar engineers allegedly informed the company's executives "that the engine would not be drivable if installed in a truck and would not be sellable even if the EPA certified it." Nonetheless, Navistar and its then-CEO Daniel Ustian made the following allegedly misleading disclosures:

- In a March 2011 conference call with analysts, Ustian stated that the company submitted an application to the EPA for certification of its EGR-only engine, adding: "We don't plan on using this for awhile, but we are going to have it out there on the shelf that says it can be done and we can meet the standards and get all of the performance features, as well. . . . " According to the SEC, this statement falsely implied that the engine "met all of the performance features and was capable of going into production if certified."
- In an April 2011 press release in which Navistar discussed its receipt of EPA certification for other engines that Navistar considered commercially competitive, Navistar added a discussion of its recent application to the EPA regarding its EGR-only engine. Navistar stated that its submission to the EPA "once again reiterat[es] its prime technology path in meeting the [new emissions] standard through" the EGR technology. According to the SEC, by including a discussion of the 2011 application in a press release otherwise devoted to commercially viable engines that Navistar was ready to produce, "Navistar created the misleading impression" that the EGR-only engine "was commercially competitive and could be put into production if Navistar wanted to do so."

By the summer of 2011, Navistar allegedly decided not to pursue the application it had submitted to the EPA. Shortly thereafter, the company learned that the emissions credits it had previously accumulated with the

EPA, which had been allowing the company to legally sell engines with higher emissions than those required under the EPA's new standards, could be depleted by February 2012. As the SEC explained, without emissions credits or a certified engine meeting the EPA's new emissions standards, "Navistar would be required to pay non-conformance penalties ('NCPs') in order to continue to legally sell engines from its big bore heavy-duty line." In communications with the EPA staff in the fall of 2011, Navistar informed the EPA that its EGR-only engine would not be ready for certification by the time the company's remaining emissions credits are depleted. Accordingly, "the EPA promulgated an interim NCP rule in January 2012."

In the meantime, Navistar began work on another "big bore EGR-only engine" but allegedly expected that it would take at least two more years before it would be ready to certify and produce. In a meeting with the EPA staff in December of 2011, EPA staff members allegedly informed Navistar that the engine the company was developing would not meet the EPA's standards. The EPA allegedly summarized the important points of the meeting in an e-mail to Navistar, noting, among other things, that the engine Navistar described for certification does not appear to meet the EPA's certification requirements. Nonetheless, in Navistar's Form 10-K for 2011, the company noted that it planned to submit a certification application to the EPA, stating: "We believe that our engines meet [the agency's] certification requirements." The SEC alleged that "[t]his statement was materially misleading because it created the impression that Navistar was unaware of any facts indicating that its proposed submission would not meet the EPA's certification requirements."

In January of 2012, Navistar submitted a second application to the EPA for certification of its EGR-only engine. The following month, the EPA staff allegedly informed Navistar in writing that the agency's "preliminary view is that Navistar's application for a certificate of conformity raises several serious concerns [that] would need to be discussed and resolved before a decision could be made to approve" the application. The EPA proceeded to identify its concerns. Nonetheless, Navistar made disclosures allegedly creating the impression that it was making substantial progress toward EPA certification and was unaware of any EPA concerns that might impact the process. Specifically:

- In its March 2012 Form 10-Q and press release regarding the quarterly report, Navistar referred to its January 2012 application to the EPA as a "key milestone" and indicated that its submission is "under review by the EPA." The filing added: "[W]e are engaged in ongoing discussions relating to our engine certification."
- During the company's March 2012 earnings call, in response to an analyst's question regarding how long Navistar was expected to continue making NCP payments, then-CEO Ustian stated that the company submitted its application to the EPA and that the certification process typically takes "about three months," which means that "it will be about June before we get into production with that particular engine."

In the months that followed, Navistar allegedly recognized that its January 2012 application would be rejected by the EPA and withdrew the application. Navistar then submitted its third application for

certification of an EGR-only engine. In a meeting with the EPA staff regarding this application, the EPA again expressed serious concerns regarding the application. In post-meeting e-mail communications, an EPA official allegedly wrote to a Navistar executive, "As I said yesterday, based on the information provided, I believe that your engine is unlikely to receive a certificate of conformity as it is currently designed." This email was allegedly forwarded to Ustian. In spite of these communications, Navistar and Ustian made statements that allegedly created the misleading impression that the company was unaware of any concerns raised by the EPA or "of any facts that would lead it to believe that the EPA would not approve its application." In particular:

- In its June 2012 Form 10-Q, Navistar stated that, "[i]n response to certain concerns raised by the EPA, . . . we submitted a revised application to the EPA. . . . Certain issues raised by the revised application are under review by the EPA, and we are engaged in ongoing discussions relating to certification of this engine family."
- In its June 2012 earnings call, Ustian stated: "[W]e are also getting ready as soon as that certification is approved we can go into instant production within 30 days. So we have all the mechanisms in place to respond quickly once we get that certification approved." He further disclosed that the company has been "running tests" to ensure that the engine meets "all the requirements, not just of the EPA but our own requirements of performance." Additionally, in response to an analyst's question regarding the timing of the approval process, Ustian said it "shouldn't take nearly as long" as the three to four months he had mentioned on the last call.

In July of 2012, Navistar disclosed that it was withdrawing its most recent application for certification and would begin developing an engine that used SCR technology.

As a result of the conduct described in the SEC's order, the SEC alleged that Navistar violated the antifraud provisions of the Securities Act, as well as the reporting provisions of the Exchange Act. In the complaint it filed in federal court against Ustian, the SEC alleged that the former CEO violated and/or aided and abetted violations of the antifraud provisions of both the Securities Act and the Exchange Act, as well as the reporting provisions of the Exchange Act.

B. Status of the Action

Without admitting or denying the SEC's findings, Navistar settled the charges against it. The company agreed to the entry of a cease-and-desist order against it and agreed to pay a \$7.5 million penalty to the SEC. The complaint against Ustian remains pending in federal court.

IV. Significance of the SEC's Enforcement Actions

All three of the SEC's recent actions underscore the importance of a fundamental disclosure principle applicable to public companies and their management: When making public disclosures – such as those

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pertaining to the development of a product or communications with regulators regarding the product — issuers and their management must ensure that their disclosures are truthful and do not omit any material fact necessary in order to make the statements made not misleading. As the Uni-Pixel case illustrates, board members may also be implicated in circumstances where they were aware that senior management was making materially false and misleading disclosures but failed to provide proper oversight of the disclosures or to correct misleading disclosures following their issuance.

If you have any questions or would like additional information, please do not hesitate to contact **Yafit Cohn** at +1-212-455-3815 or <u>yafit.cohn@stblaw.com</u>, or any other member of the Firm's Public Company Advisory Practice.

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