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August 8, 2017

VIA ECF
Hon. Michael A. Hammer, U.S.M.J.
U.S. District Court for the District of New Jersey
Martin Luther King, Jr. Federal Building & U.S. Courthouse
50 Walnut Street
Newark, NJ 07101

Re: ***Merck & Co., Inc., et al. v. Merck KGaA, Civil Action No. 16-0266 (ES) (MAH)***

Dear Judge Hammer:

We, along with Debevoise & Plimpton LLP, represent Defendant Merck KGaA ("Defendant") in the above-referenced matter. We submit this letter jointly with Sidley Austin LLP and McCarter & English LLP, counsel for Plaintiffs Merck & Co., Inc. and Merck Sharp & Dohme Corp. ("Plaintiffs") regarding a dispute over an extension to the document production deadline.

Defendant's Request

Defendant respectfully requests that the Court extend the deadline to produce documents from August 7, 2017 to December 31, 2017, as well as extend all other dates in the case management schedule to account for this change. *See* Appendix 1, Defendant's Proposed Scheduling Order.

Defendant has gone to extraordinary lengths to complete its production of documents, but has been unable to meet the current deadline given (1) the hundreds of thousands of documents that Defendant must review to respond to Plaintiffs' very broad document requests, and (2) the onerous special procedures and requirements which Defendant must observe to comply with its obligations under EU data protection laws. Defendant has engaged over ***one hundred document reviewers*** in Europe (plus additional project managers) to complete the review and, as required by EU data protection laws, to redact all personally identifiable information. Unlike reviewing only for responsiveness and potential privilege issues, each reviewer must carefully review every word of every document to identify personal data and then apply the redactions. The process is so time-consuming that, on average, a single reviewer redacts only 6-8 documents per hour (which was confirmed by a member of the U.S. legal team who flew to Germany to personally perform redactions to better understand the process and the reasons it moves so slowly). Defendant has already expended over ***$2 million*** in costs on the review and redactions, a figure likely to double

– if not triple – before the production is completed. Defendant has explored means of speeding up the work, such as by engaging even more reviewers, but has been told that it has essentially exhausted the market of reviewers available.

It bears noting that the burdens of document discovery in this case have been dramatically one-sided. Contrasted against the extraordinary burden Defendant is facing, Plaintiffs have produced about 750 documents and have indicated that their production is now substantially complete.

The parties' counsel have met and conferred in good faith numerous times in an effort to find solutions that would enable Defendant to complete its production more quickly. Despite their best efforts, however, they have been unable to agree on any compromises that would enable Defendant to complete production before year-end. Two circumstances in particular drive the need for the extension requested.

First, Plaintiffs' discovery requests remain extraordinarily broad, even after lengthy negotiations aimed at narrowing their scope. Plaintiffs served Defendant with 75 requests for the production of documents, on a very broad range of topics. Counsel engaged in months of negotiations to narrow the scope of these requests, finally coming to agreement on the scope of the majority of requests in April 2017. But, even as narrowed, the requests are very broad. For example, they seek:

- Copies of every publication ever provided by Defendant that features the term MERCK. *See* RFP No. 31. As a large multinational company, Defendant has at least hundreds of thousands of publications directed at the United States. Even narrowed by search filters to the extent possible, there is still an enormous number of publications to review.

- Copies of all marketing and business plans for the United States, in some cases going back as far as 1995, regarding (a) the use of MERCK, (b) products or services in connection with which the parties compete, or (c) the names Defendant uses to promote or sell products or services in the United States. *See* RFP No. 50. Defendant sells literally tens of thousands of different products in the United States and has hundreds of thousands of business plans in the United States. Because the request specifically involves use of MERCK, which is part of Defendant's name, it is exceedingly difficult to reduce the size of this pool with search filters, meaning that almost all of these documents have to be reviewed manually.

- Documents sufficient to identify all advertisements in the United States that use "Merck," and a representative sample of those that use "Merck KGaA, Darmstadt, Germany." *See* RFP Nos. 35-36. Defendant has hundreds of thousands of advertisements in the United

States across multiple business lines. Even narrowed by search filters to the extent possible, the number of advertisements needing review is enormous.

- Samples of all labels and packaging, and proposed labels and packaging, for all goods or services sold or provided by Defendant in the United States featuring any term comprising or consisting of the term MERCK, or formatives of same (such as "Merck KGaA, Darmstadt, Germany"). *See* RFP No. 27. Defendant has tens of thousands of goods and services sold in the United States, each with its own label and packaging.

- Certain documents dating back to 1995 (and, on occasion, even as far back as 1890), which involves searching archives for hand-written documents that must be reviewed manually.

The response has required collection of hundreds of thousands of documents, review of which is currently ongoing.

Second, as noted, EU data protection laws require that all of these documents be painstakingly reviewed and redacted to remove all personally identifiable information. There is a limited exception for the personal data of certain individuals, such as the custodians, but even in those cases the documents generally contain names or other personally identifiable information of other individuals that must be redacted. This procedure is set out in the Protective Order, negotiated by the parties and entered by the Court on March 6, 2017. *See* dkt. entry no. 66.

Counsel has met and conferred extensively about the challenges imposed by the EU data protection laws and possible solutions. For example, Defendant has offered to produce the documents in un-redacted form for review in Europe by lawyers in Plaintiffs' counsel's European offices. Such a solution would save Defendant millions of dollars and would shave several months off the requested extension. But, unfortunately, the parties have been unable to agree on mutually acceptable parameters for this proposal or others that have been explored.

In light of the foregoing, Defendant respectfully submits that a five-month extension is reasonable and necessary considering the sheer volume of documents requested by Plaintiffs and the onerous steps necessary to ensure all personally identifiable information is redacted.[1] Plaintiffs

[1] The five-month estimate is based on Plaintiffs' representation that they will enter into an agreement with Defendant such that Defendant need not produce unresponsive family members, so long as Defendant will produce responsive family members of specifically identified documents promptly. *See* Plaintiffs' Request No. 4 below. The amount of time it will take to produce the unresponsive family members will depend on the volume requested

have failed to point to any legitimate prejudice they would suffer by entry of this extension. Plaintiffs, knowing the special challenges posed by EU data protection laws, have chosen to interpose extraordinarily broad document requests and have rejected numerous proposals aimed at narrowing the requests or otherwise expediting the production. The consequence of Plaintiffs' decisions, in addition to generating millions of dollars of extra expense for Defendant, is that the production will take much longer to complete than any of the parties would like.

Plaintiffs' Response

As this Court well knows, this litigation is merely one part of a global dispute between the parties. Defendant requests a five-month extension of time that would grind the U.S. litigation to a halt while litigation continues apace in the UK, France, Germany, India, Mexico, and Switzerland. This U.S.-only extension of time would severely prejudice Plaintiffs because it is only here, in the U.S., that Plaintiffs are plaintiffs; overseas they are defendants. By delaying compliance with its U.S. discovery obligations, Defendant is helping itself to a stay of all Plaintiffs' claims while all Defendant's claims proceed toward disposition. Defendant's awareness of the strategic implications of its extension request is revealed by its categorical refusal to extend any deadlines in any of the related litigation in connection with its five-month extension demand here in the U.S.

Because of the prejudice that Plaintiffs would suffer from a five-month delay of Defendant's document production, Plaintiffs offered all of the following items 1-6 during the parties' meet and confer. Plaintiffs estimate that items 1-6 in total would cut approximately in half the prejudice that Plaintiffs will suffer from Defendant's document delay:

1. By August 15, 2017, Defendant produces the following documents: (a) the list of domain names responsive to Plaintiffs' Interrogatory Nos. 1 and 3, (b) the list of products and services that Defendant has sold in the U.S., and (c) the sales, marketing, and other data responsive to Plaintiffs' Request For Production Nos. 46, 47, 48, and 68–74. None of these requests implicate the EU data privacy issues on which Defendant has predicated its extension request. The production of these documents without further delay is particularly important for Plaintiffs to focus and pursue their claims. During meet and confer, Defendant said that it could produce these documents by this August 15 deadline.

2. By October 13, 2017, Defendant produces all of its EU-based documents in London without redactions and all of its U.S.-based documents in the U.S.—a deadline Defendant has said it

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and the timing of the requests. Absent this agreement, Defendant requests an extension of six months to complete production of all documents in redacted form.

can meet. Defendant was the first to propose an EU production of EU documents. Plaintiffs agreed with Defendant's EU-production proposal despite that reviewing documents in London will impose substantial additional costs on Plaintiffs. Plaintiffs are willing to incur these costs to avoid the greater prejudice that will result from Defendant's demanded five-month extension of time.

3. Defendant makes its EU-based witnesses available in London for deposition, except if there is a witness with a health problem that would prevent travel to London. During meet and confer, Defendant said that it was "in favor of taking the depositions in the U.K. and U.S. and hopes all of the depositions can take place there" in light of the restrictions that German law places on the taking of depositions. For example, the German Ministry of Justice must pre-approve all requests for depositions, and only a U.S. consular officer may administer them. While Defendant now withholds this agreement, it offers no reason why the more burdensome German procedure should be required. London-based depositions will allow Plaintiffs to make up some of the time lost to Defendant's document delay. This Court has the power to order this relief notwithstanding Defendant's change of position.

4. Defendant need not produce unresponsive family members to responsive documents, on the condition that Defendant will produce such documents promptly upon request.

5. By January 31, 2018, Defendant produces its EU documents in the U.S. with the redactions required by EU data privacy law and this Court's Protective Order.

6. The parties jointly propose extensions of the other case deadlines in light of items 1-5 above.

In meet and confer, Defendant agreed that making document productions in London without redactions would comply with EU data privacy law and that it could complete such a production by October 13, 2017. The parties also agreed that this unredacted EU production would allow depositions of Defendant's witnesses to proceed in London while Defendant's production was prepared for transfer to the U.S. As Plaintiffs explained during meet and confer, Defendant's redaction process does not need to delay the remainder of the discovery schedule.

Defendant rejected Plaintiffs' offer of items 1-6 above, however, unless Plaintiffs agreed to bear responsibility for redacting Defendant's production and otherwise to assume the risk of liability associated with transferring Defendant's production to the U.S., a process that would require Plaintiffs and their U.S.-based counsel and vendors to comply with EU data security requirements and procedures in the U.S. at the risk of significant fines under EU law.[2] Defendant's

[2] Both parties agree that a transfer of EU personal data to the U.S. requires additional procedures, and creates additional potential for liability, beyond a transfer within the EU.

position is that Plaintiffs must bear the burden of Defendant's U.S. production because Defendant will have satisfied its production obligations in London and because Defendant's delay should be blamed on the breadth of Plaintiffs' document demands. For four reasons, the Court should reject Defendant's position.

First, all but a handful of Plaintiffs' document demands have been pending since August 2016. If Defendant believed Plaintiffs' document demands were disproportionate to the parties' dispute, the responsible course would have been for Defendant to raise appropriate objections in a timely manner, and to meet-and-confer about the scope of these demands. Instead, Defendant agreed to produce its documents, agreed to the Court's document-production deadline, and only now complains about the breadth of its document obligations. Even now, Defendant does not argue that Plaintiffs are not entitled to the documents they seek. Defendant's burden argument appears calculated only to deflect responsibility for its own delay.

Second, Defendant has refused to provide the concrete historical facts that would allow this Court to evaluate the credibility of its burden and diligence claims. Defendant states that it has hired 100 reviewers to process its production and estimates that the review may eventually cost millions of dollars. But Defendant has refused to say when its documents were collected, when its reviewers were retained, and when Defendant realized that it would not comply with the Court's July 31 document-production deadline. Not once before June 30 did Defendant suggest that it would be unable to comply, despite that Defendant had produced fewer than 200 documents at that point and still had hundreds of thousands of documents left to review. Yet Defendant insists that we take on faith its claim to have been acting diligently since August 2016 to comply with Plaintiffs' document demands.

Third, Defendant has never before objected to the burden of making redactions or otherwise complying with EU data privacy law, and making an unredacted production first in the EU will not materially alter Defendant's burdens. Whether or not unredacted documents are first produced in London, Defendant has an obligation to conduct a responsiveness review and to apply redactions. During meet and confer, Defendant has made clear that its responsiveness review and redactions already involve separate processes; at one point, in an effort to justify its delay, Defendant insisted that it had created a team of reviewers "dedicated solely" to applying redactions.

In light of this, Plaintiffs asked Defendant multiple times during meet and confer what additional burden this approach would impose. Defendant never provided an answer except to say that Plaintiffs' proposal would require Defendant to make an additional production. The undefined, unquantified burden of an additional production does not justify Defendant's attempt to shift the consequences of its delay or the expenses of its production onto Plaintiffs. Defendant should be ordered to take reasonable steps to reduce its delay and to bear the costs for those steps.

Below Defendant further suggests—for the first time—that requiring it to redact the documents later would somehow complicate its review of the documents for responsiveness now. But Defendant does not explain how this could be, given that Defendant has already separated out the redaction process. In any event, some adjustments to Defendant's process are more than justified by the significant reduction in delay that they would achieve.

Fourth, in addition to keeping up the progress of the case, Plaintiffs' proposal will minimize disputes about the appropriateness of Defendant's redactions. Because Plaintiffs will have access to an unredacted production, they will know whether the information underneath a redaction is necessary to the case.

No matter how this Court responds to Defendant's extension request, Plaintiffs will suffer prejudice corresponding to Defendant's document-production delay. But by permitting the parties to begin taking depositions once Defendant completes its unredacted production, Plaintiffs' proposal allows the parties to move onto expert discovery months earlier than Defendant's schedule contemplates. Plaintiffs respectfully request that the Court order items 1-6 above.

Defendant's Reply to Plaintiffs' Proposal

Plaintiffs appear to recognize that a significant extension is necessary. Indeed, under their proposed approach, document production would not finally be completed until January 31, 2018 – a month ***later*** than the deadline requested by Defendant. Specifically, Plaintiffs propose that Defendant produce their documents ***twice***: once in unredacted form in Europe in mid-October 2017, and again, at the end of January 2018, in redacted form in the U.S.

In the course of the parties' meeting and conferring, Defendant proposed producing unredacted documents in Europe ***as an alternative*** to producing redacted documents in the U.S., not as an additional interim step. The idea behind this suggestion was that Defendant could produce the documents in Europe without the redactions more quickly (and at far less cost), and Plaintiffs could then avail themselves of various options that would allow Plaintiffs themselves to transfer the documents to the United States in unredacted form. Plaintiffs rejected this proposal and advocate instead that Defendant produce the documents twice. Plaintiffs' proposal reflects their recognition that completing production of even the unredacted documents in Europe will take a few months and that the arduous redaction process necessary for production in the U.S. would take additional months beyond that.

Plaintiffs' proposal is not sensible, fair or practical. It would create even more burden for Defendant, by adding an additional interim step to an already extraordinarily burdensome process, while doing nothing to facilitate the parties completing fact discovery any sooner than they would under Defendant's proposal. The extra burden of doing an interim production in Europe would be

substantial, as Defendant's legal team would have to conduct all the QC and other production-related work twice. Plaintiffs are mistaken that this would involve just "one more round" of production-related work; to the contrary, plaintiffs' proposal would require Defendant to conduct additional rounds of review, QC and production-related work for every single production going forward. Plaintiffs' proposal should be rejected.[3] In the alternative, if Plaintiffs insist on the additional, unprecedented step of requiring Defendant to make a special interim production in Europe, all marginal costs associated with that unprecedented and unusual procedure should be shifted to Plaintiffs pursuant to Rule 26(c)(1)(B).

Defendant does not think it will be constructive to engage in a point-for-point refutation of Plaintiffs' repeated suggestion that Defendant's counsel are not credible or have failed to try to meet their obligations in good faith. Defendant respectfully suggests that it would be most productive for the parties and the Court to address the issues in a forward-looking, solution-oriented manner. Suffice it to say that we have been working diligently since receiving Plaintiffs' extraordinarily broad requests, including by negotiating for months with Plaintiffs' counsel and their predecessor counsel to narrow the scope of those requests to an achievable – though still exceptionally broad – level. Indeed, Defendant's counsel worked hard to avoid bringing disputes about discovery to the Court for resolution. However, an alternative to seeking as long an extension might be to work with the Court's assistance to narrow Plaintiffs' requests more. We would be happy to provide the Court with further detail concerning Defendant's work and efforts to negotiate with Plaintiffs' counsel and their predecessor counsel if the Court would find that useful.

Plaintiffs' reference to litigations pending in other countries is also unhelpful. Plaintiffs present an incomplete picture of what has actually occurred in the overseas litigations. For example, it is not accurate to say that Plaintiffs are not plaintiffs in the other jurisdictions, given that they asserted counterclaims in the UK, France, and Germany. In addition, Plaintiffs' discovery obligations in those other proceedings have so far been minimal (for example, in the UK case, Plaintiffs' UK counsel reviewed fewer than 5000 documents and Plaintiffs produced fewer

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[3] Plaintiffs' proposal should also be rejected because even if Defendant produces in Europe, it would be unnecessary and redundant for it to produce a second, redacted set of otherwise identical documents in the United States. Defendant has offered Plaintiffs a number of solutions so that they could access documents produced in Europe from the United States, and Plaintiffs have rejected each of them. Indeed, Plaintiffs' proffered reason for refusing these offers—that they would have to assume the risk of liability associated with transferring the production to the US—is disingenuous considering that they would still be subject to EU data protection law for processing and reviewing those documents in Europe even under their own proposed plan.

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than 500). Also, most of the overseas cases were filed long before this case, and it is therefore not surprising that some of the cases are at a more advanced stage than this case. More important, though, even if the Court were to devote the time and resources necessary to obtaining a complete and accurate understanding of the status of discovery in the various overseas litigations, doing so would have no bearing on determining a practical and feasible deadline for the completion of document production in this case.

Finally, although Defendant was willing to produce witnesses in the UK as part of a deal where Defendant would produce documents there in unredacted form *once*, Plaintiffs have offered no reason why all of Defendant's witnesses (who they have not even identified) should be forced to travel to a different country in the absence of such an agreement. In any event, the issue of whether foreign citizens must be compelled to travel to a different country for a deposition is beyond the scope of this letter, and Defendant remains open to working with Plaintiffs to schedule the dates, times and locations for depositions in a manner that is efficient, cost-effective, and responsive to any special circumstances that may apply to any particular deponents. If and when Plaintiffs identify witnesses that it would like to depose in a country outside of Germany, the parties will meet and confer on that issue at that time and present any unresolved issues to this Court.

Respectfully submitted,

s/ Stephen M. Orlofsky
STEPHEN M. ORLOFSKY

SMO:rw

cc: All counsel of record (via ECF)

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK & CO., INC., and MERCK SHARP & DOHME CORP., Plaintiffs, v. MERCK KGAA, Defendant.	Civil Action No. 2:16-cv-00266-ES-MAH *Electronically Filed* **[PROPOSED] SCHEDULING ORDER**

This matter having been presented to the Court by a joint letter (the "Letter") from Plaintiffs Merck & Co., Inc. and Merck Sharp & Dohme Corp. and Defendant Merck KGaA, raising a dispute over an extension for discovery, and the Court having considered Defendants' and Plaintiff's respective submissions in the Letter, and in light of the complexities involved in this litigation, and for good cause shown,

IT IS, on this _____ day of _____, 2017,

ORDERED that Defendant's request is **GRANTED**, and that new discovery dates are set as follows:

Discovery

1. The parties' production of documents shall be completed by **December 31, 2017**.

2. The parties need not produce unresponsive family members in the production, but must produce such family members of specifically identified documents by the opposing party upon request in a reasonable time period.

3. All other fact discovery, including depositions of fact witnesses, shall be completed by **April 1, 2018**.

4. All fact discovery disputes (other than those arising during depositions) shall be filed with the Court in a joint letter pursuant to the Court's November 7, 2016 Pretrial Scheduling Order no later than **February 28, 2018**

Experts

5. Plaintiffs' affirmative expert reports shall be delivered by **May 1, 2018.**

6. Defendant's affirmative and rebuttal expert reports shall be delivered by **June 26, 2018.**

7. Plaintiffs' rebuttal and reply expert reports shall be delivered by **July 16, 2018**.

8. All expert discovery, including completion of expert depositions, shall be completed by **August 23, 2018**.

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Honorable Michael A. Hammer, U.S.M.J.