



*United States Attorney
Southern District of New York*

86 Chambers Street
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March 25, 2016

BY ECF and HAND

Hon. Paul G. Gardephe
United States District Judge
40 Foley Square
New York, NY 10007

Re: *United States v. Novartis Pharmaceuticals Corp.*, No. 11 Civ. 0071 (PGG)

Dear Judge Gardephe:

The United States of America and the State of New York (collectively, “Government”) write in response to Novartis Pharmaceuticals Corp.’s (“NPC”) letter dated March 22, 2016, seeking a pre-motion conference with respect to a contemplated motion for a protective order that would prevent the Government from obtaining core discovery in this case: the records of promotional events that are at issue in this action, including the receipts, sign-in sheets, and educational materials allegedly used for these events. Notably, very little of NPC’s letter is devoted to the basis for such a motion. Instead, NPC engages in a scattershot and baseless attack on the Government’s conduct in this litigation, ranging from the propriety of the Government’s interrogatory responses to its strategy for presenting its case at trial. None of those issues is currently before the Court, however, and thus merit little response.¹ With respect to the nominal subject of NPC’s letter, not only has NPC failed to establish grounds for the issuance of a protective order, it is evident that the Government is entitled to this discovery.

A. Allegations in the Complaint and Scope of the Case

In this action, the Government alleges that NPC is liable for engaging in a nationwide kickback scheme, spanning 10 years, to induce doctors to write prescriptions for certain of its cardiovascular (“CV”) drugs. The Government alleges that NPC routinely conducted promotional events that had little to no educational value. Many events were conducted at venues that were not even conducive to an educational event, and NPC frequently provided lavish meals to attendees that were unreasonably excessive in cost (itself a kickback). Often, NPC had the same doctors attend the same events over and over again. And in some instances, the purported event did not occur at all, though doctors were still paid honoraria as if it had.

¹ To the extent NPC suggests in a footnote that the Government should be compelled to supplement its responses to NPC’s interrogatories, such a request should be denied. The interrogatories exceed the scope of Local Rule 33.3, are vague and premature, and call for the production of work product. Despite these valid objections, the Government nonetheless provided NPC with detailed information regarding the factual basis for its allegations in this case; for each of the approximately 79,000 events that the Government identified as tainted by kickbacks, it described its factual basis for doing so.

NPC claims that the Government “suddenly” expanded the scope of this case in November 2015 by identifying 79,236 events as shams in its interrogatory responses. Yet the Government never suggested that the hundreds of sham events described in the Amended Complaint comprised the entirety of the events at issue in this case. To the contrary, that pleading made clear that the total number of sham events was in the “thousands.” Am. Compl. ¶ 2. This issue was briefed extensively in connection with NPC’s motion to dismiss, and the Court approved the Government’s use of illustrative examples in its pleading, recognizing that it would not be practicable to describe therein each of the thousands of events at issue in this case. *See U.S. ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 525 (S.D.N.Y. 2014).

NPC also falsely claims that the Government “exploded” the size of this case in November 2015 by including roundtables in its list of sham events. Speaker programs and roundtables are substantially similar promotional events, at which a group of doctors is treated to a meal (often at a high-end restaurant) with the purported purpose of being educated about a particular Novartis drug. The two types of events concerned the same drugs, were organized by the same Novartis sales representatives, and were attended by the same groups of doctors. More importantly, both types of events have always been part of this case. As NPC itself is forced to admit, Ltr. at 3, a number of the illustrative events in the Amended Complaint are roundtables. Consistent with this, and notwithstanding NPC’s suggestion to the contrary, *see* Ltr. 3 & n.3, the parties’ ESI custodian protocol repeatedly includes the term “roundtable” in its search strings.

B. The Request for Event Records and the History of the Parties’ Negotiations

To avoid engaging with the merits, NPC devotes much of its pre-motion letter to mischaracterizing the history of the parties’ relevant negotiations. In response to the Government’s request for documents concerning all of its CV promotional events, NPC produced its so-called speaker program data, *i.e.*, information that had been entered in central databases regarding each of those events, such as the date, location, and title of the event. At the outset of discovery, however, the Government made clear that its request was not limited to the event data, but also sought the underlying records from the promotional events, including the sign-in sheets, printed educational materials allegedly used, and receipts for expenses incurred. At the parties’ first meet and confer regarding the scope of discovery, NPC objected to this request as overly broad to the extent it sought records for events that were not at issue in this litigation. NPC asked the Government to limit the scope of this request to a subset of events. The Government agreed to this proposal — stating it would “identify[] the specific events for which back-up materials will be produced” — as communicated in an email from AUSA C. Harwood dated March 6, 2015 (attached as Ex. A). Accordingly, on November 27, 2015, the Government identified for NPC a list of events which the Government had identified as shams, and on December 23, 2015, sent NPC an email stating that it expected the underlying records for each of those events.

Thus, when subsequently negotiating the ESI custodian protocol, the Government proceeded with the expectation that it would be obtaining event records from sources other than

the limited subset of NPC personnel who comprised the ESI custodians.² For example, the Government explicitly agreed to drop a request to run certain searches in the data of the agreed-upon custodians based upon “our understanding that, as to any events that the government identifies as a potential sham event, the parties have already agreed that Novartis will provide the Government with the backup data for such event, which will include the presentation slides and sign-in sheets.” *See* Email from AUSA J. Vargas, dated Oct. 21, 2015 (attached as Ex. B). NPC did not dispute the Government’s understanding of the existing agreement.

Importantly, the Government was not aware at the time it negotiated the ESI custodian protocol that locating the records for specific promotional events for certain time periods would require electronic searches of the files of individual custodians. Prior to January 2016, NPC did not provide the Government with any specific information regarding where such records would be located. The Government reasonably assumed that the event records would be, for various time periods, either located in a central repository or stored in hard copy form. And as we learned, this is indeed the case for a significant portion of the material from the post-2007 time period (as discussed further below).

When NPC announced in February 2016 that it would not produce any event records other than those incidentally uncovered in the course of conducting searches pursuant to the parties’ entirely separate ESI custodian protocol, the Government nonetheless sought to reach a compromise with NPC on this issue. The Government asked NPC to produce any event records that were maintained in discrete locations, such as speaker program slide decks that were maintained in NPC’s headquarters and receipts that Novartis had located in a number of CDs, along with the records for 25,000 of the approximately 79,000 sham events it had identified. NPC rejected this proposal.

The Government is not seeking the underlying records for all NPC CV promotional events or even all allegedly sham events. Rather, it is seeking only a subset of the records, and it is hard to conceive of discovery more centrally relevant to the Government’s claims in this case.

C. The Requested Discovery is Proportional to the Needs of the Case

NPC argues that the requested discovery would be “extraordinarily burdensome.” Ltr. 5. In determining whether requested discovery presents an undue burden, however, courts look to whether such discovery is “proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties’ relative access to relevant information, the parties’ resources, the importance of the discovery in resolving the issues, and

² NPC suggests that, in negotiating this protocol, the Government somehow agreed that this protocol would be the “exclusive” discovery to which it would be entitled. Ltr. 2. That is incorrect, and the parties’ joint status letter dated November 10, 2015, does not evidence any such understanding. That letter focused on the ESI custodian protocol because that had been the focus of the parties’ negotiations up to that point and represented the mechanism for conducting a significant portion of the discovery in the case. The joint status letter never purported to describe every aspect of the discovery sought by the parties, and certainly does not state that the protocol would be the exclusive discovery in this case.

whether the burden or expense of the proposed discovery outweighs its likely benefit.” Fed. R. Civ. P. 26(b)(1). In a case of this scope and magnitude, and given the likely benefits of the information sought, the burden of producing the requested discovery is more than justified.

The importance of the requested discovery to the issues to be litigated cannot be gainsaid. The requested documents go to the core issues in this case: whether educational materials were provided at these events; which doctors actually attended the events; how much money was spent on meals and honoraria; and indeed, most fundamentally, whether the underlying documentation shows that a particular event actually took place.

And this case implicates issues of enormous public concern: whether NPC defrauded federal health care programs of hundreds of millions of dollars by systematically providing inducements to doctors across the country, for a decade, in an effort to influence the drugs they prescribed to patients in their care. Accordingly, although the amount in controversy standing alone is substantial enough to justify the requested discovery, the significance of the issues raised by this litigation give this case added importance.

NPC does not dispute that the requested records are not otherwise available to the Government. But NPC nonetheless argues that, because it is already searching for records related to 6,400 of the 79,236 events that the Government identified as shams — just 8% of such events — it should not be required to produce records related to any additional events, even if such records are readily available to it. Ltr. at 4. The only justification NPC offers for this position is that these 6,400 events constitute “far more event-specific material than [the Government] could ever present to a jury,” and that there is therefore “simply no need for the Government . . . to obtain discovery relating to events[] beyond that.” *Id.* This objection is meritless. It ignores that federal courts have in place procedures to deal with trials that involve large volumes of documentary evidence, including the use of summary charts pursuant to Rule 1006. *See, e.g., United States v. Janati*, 374 F.3d 263, 273 (4th Cir. 2004) (allowing Government to introduce into evidence summary charts to prove wide-ranging fraud). In any event, a party is not limited to obtaining in discovery only those documents that it will introduce at trial. And of course, the Government cannot determine which documents it will use at trial until it has an opportunity to review them.

In essence, NPC argues that because the alleged fraud was so pervasive and widespread, NPC should be almost entirely excused from producing the relevant records from the allegedly sham events. This is, of course, not the standard that courts apply.

D. NPC Has Not Established that the Information is Not Reasonably Accessible

To resist discovery of ESI on a claim of undue burden, “the party from whom discovery is sought must show that the [ESI] is not reasonably accessible because of undue burden or cost.” Rule 26(b)(2)(B); *see also Condit v. Dunne*, 225 F.R.D. 100, 106 (S.D.N.Y. 2004). NPC has failed to meet that burden. NPC claims that it would be burdensome to obtain the records for all 79,236 events, because these documents are not “compiled in any one place.” Ltr. at 5. Yet NPC has informed the Government that, with respect to the post-2007 time period, the records for its speaker programs *are maintained in a central repository*. Thus, there should be little or

no burden associated with producing that information. NPC has also indicated to the Government that some other records, such as receipts for additional time periods and slide decks, likewise may be maintained in central locations. NPC has provided no reason why it cannot search these locations and provide such readily accessible documentation.

NPC instead attacks a strawman, asserting that it would need to search the files of more than 5,400 individual sales representatives in order to obtain the records for the 70,000 plus events. Ltr. at 5. Yet the Government is not seeking the records for all those events. The Government has limited its request to 25,000 additional events beyond those found through the ESI protocol or in central repositories. This will dramatically decrease the burden on NPC.

E. NPC's Arguments Regarding the Government's Trial Strategy Are Premature

NPC also devotes much of its letter to preemptively attacking what it believes the Government's trial strategy will be. This argument merely serves to highlight the hypocrisy of NPC's position regarding the underlying documentation. NPC argues that the Government has "no need" to obtain documentation regarding any sham event beyond the 6,400 that are part of the ESI protocol, and in the next breath decries that the Government cannot prove its case because it "plainly cannot . . . offer individualized proof for 79,236 events at trial." NPC is not raising a proper objection to the scope of discovery, but merely attempting to prevent the Government from presenting its case. NPC's attempt to scuttle the Government's case plainly fails. This will hardly be the first federal trial to involve allegations of a large-scale fraudulent scheme, and federal courts are well equipped to address the evidentiary issues that such trials present at the appropriate time. *See Janati*, 374 F.3d at 274 (noting that, when the Government has alleged thousands of potentially fraudulent transactions, it "must be given additional latitude during trial to carry its burden of proof" through the use of summary exhibits or otherwise). Further, NPC is not entitled to a preview of how the Government plans to present its case at trial at this stage in the litigation, where document discovery has not even been completed. Nor is there any need to address hypothetical evidentiary issues before they are ripe for judicial resolution.

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In sum, NPC cannot be permitted to limit its discovery obligations by using the scope of its fraud as an excuse. NPC's motion for a protective order should be denied and it should be required to produce the requested records to the Government.

Respectfully submitted,

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