

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

NATERA, INC.,

Plaintiff,

v.

NEOGENOMICS LABORATORIES,
INC.,

Defendant.

C.A. No. 1:23-cv-629

**PLAINTIFF NATERA, INC.'S OPPOSITION TO DEFENDANT
NEOGENOMICS' MOTION FOR ISSUANCE OF LETTERS OF REQUEST TO
EXAMINE PERSONS PURSUANT TO HAGUE EVIDENCE CONVENTION**

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
II. LEGAL STANDARD.....	2
III. ARGUMENT	4
A. NeoGenomics Cannot Show The Necessary Good Cause For Extending The Fact Discovery Deadline	4
1. The Foreign Discovery NeoGenomics Seeks Is Unlikely To Be Completed Prior To The Close Of Fact Discovery.....	5
2. NeoGenomics Cannot Show The Necessary Diligence To Extend The Fact Discovery Deadline To Permit The Discovery It Seeks	6
B. NeoGenomics' Request Is Inconsistent With Its Earlier Positions and the Court's Ruling on the Scope of Discovery.....	10
C. NeoGenomics' Vague Requests For Documents Are Unenforceable Under the Hague Convention.....	12
D. NeoGenomics' Numerous Proposed Topics of Examination Are Unduly Burdensome and Unnecessary	14
1. NeoGenomics Seeks Irrelevant Testimony	15
2. Testimony from Drs. Swanton and Jamal-Hanjani is Unnecessary and Would Be Cumulative of Natera Inventors' Testimony	17
E. Issuing the Letters of Request is Prejudicial to Natera	18
1. The Basis for NeoGenomics' Request is Unfounded.....	18
2. The Court Should Not Endorse NeoGenomics' Positions on Disputed Issues.....	23
IV. CONCLUSION.....	24

TABLE OF AUTHORITIES

	<u>Page</u>
<u>Cases</u>	
<i>In re Anschuetz & Co., GmbH</i> , 838 F.2d 1362 (5th Cir. 1988)	3
<i>B & L Drilling Elecs. v. Totco</i> , 87 F.R.D. 543 (W.D. Okla. 1978).....	9
<i>Banner Pharmacaps Inc. v. Perrigo Co.</i> , No. 1:04CV00492, 2005 WL 8165011 (M.D.N.C. July 6, 2005)	9
<i>Crouch v. Liberty Pride Corp.</i> , No. CV 15-974 (JS)(AYS), 2016 WL 4718431 (E.D.N.Y. Sept. 9, 2016)	14
<i>In re Customs & Tax Admin. Of the Kingdom of Denmark (SKAT) Tax Refund Litig.</i> , No. 18-MD-2865 (LAK), 2024 WL 3184978 (S.D.N.Y. June 26, 2024)	5
<i>Doster v. Schenk</i> , 141 F.R.D. 50 (M.D.N.C. 1991)	2
<i>Dyson, Inc. v. SharkNinja Operating LLC</i> , No. 1:14-cv-0779, 2016 WL 5720702 (N.D. Ill. Sept. 30, 2016), <i>objections overruled</i> , 2017 WL 446042 (N.D. Ill. Feb. 2, 2017)	15
<i>Eli Lilly and Co. v. Aradign Corp.</i> , 376 F.3d 1352 (Fed. Cir. 2004).....	18, 21
<i>Haarslev Inc. v. Nissen</i> , No. 5:19-CV-06128-BCW, 2022 WL 16709716 (W.D. Mo. Sept. 20, 2022)	4
<i>IOENGINE, LLC v. PayPal Holdings, Inc.</i> , No. 18-452-WCB, 2021 WL 11960830 (D. Del. Oct. 15, 2021)	4, 9, 10
<i>McMillan v. Cumberland Cnty. Bd. of Educ.</i> , 734 F. App'x 836 (4th Cir. 2018)	4
<i>MeadWestvaco Corp. v. Rexam PLC</i> , No. 1:10cv511, 2010 WL 5574325 (E.D. Va. Dec. 14, 2010), <i>aff'd</i> , 2011 WL 102675 (E.D. Va. Jan. 10, 2011)	2

<i>Metso Minerals Inc. v. Powerscreen Int’l Distrib. Ltd.</i> , No. CV 06-1446(ADS)(ETB), 2008 WL 719243 (E.D.N.Y. Mar. 18, 2008)	14
<i>Paice, LLC v. Hyundai Motor Co.</i> , No. WDQ–12–0499, 2014 WL 3385300 (D. Md. July 8, 2014)	4
<i>Quaak v. Klynveld Peat Marwick Goerdeler Bedrijfsrevisoren</i> , 361 F.3d 11 (1st Cir. 2004)	3
<i>Rio Tinto Zinc Corp. v Westinghouse Elec. Corp.</i> [1978] AC 547, 609 (UK)	13
<i>Société Nationale Industrielle Aérospatiale v. U.S. Dist. Ct. for the S. Dist. of Iowa</i> , 482 U.S. 522 (1987)	2, 3, 9, 14, 22
<i>Trovan, Ltd. v. Sokymat SA, Irori</i> , 299 F.3d 1292 (Fed. Cir. 2002)	16
<i>United States v. Al Fawwaz</i> , 116 F. Supp. 3d 194 (S.D.N.Y. 2015)	5
<i>United States v. McLellan</i> , 959 F.3d 442 (1st Cir. 2020)	5
<i>United States v. Menendez</i> , No. 23-CR-490 (SHS), 2024 WL 2214906 (S.D.N.Y. May 16, 2024)	6
<i>United States v. Rosen</i> , 240 F.R.D. 204 (E.D. Va. 2007)	2, 3, 14, 18

Other Authorities

26B C.J.S. <i>Depositions</i> § 34	3, 14
35A C.J.S. <i>Federal Civil Procedure</i> § 614	3
https://travel.state.gov/content/travel/en/legal/travel-legal-considerations/internl-judicial-asst/obtaining-evidence/Preparation-Letters-Rogatory.html	5
Restatement of Foreign Relations Law of the United States (Revised) § 437(1)(c)	3

I. INTRODUCTION

Taking advantage of the continuation of the pending case on RaDaR 1.1 and the recent addition of U.S. Patent No. 11,319,596 (“the ’596 Patent”), NeoGenomics seeks a redo—after the close of fact discovery regarding U.S. Patent No. 11,530,454 (“the ’454 Patent”)¹—of the fulsome opportunity for inventorship discovery it already exercised or had the opportunity to exercise. NeoGenomics seeks to gain an unfair strategic advantage over Natera. In doing so, NeoGenomics would have this Court relax the required level of scrutiny of the basis for NeoGenomics’ Letters of Request (“LOR”), look past the inventorship discovery already taken that applies to both presently asserted patents,² and ignore the inconsistencies in NeoGenomics’ positions over the course of this case. Notwithstanding the procedural deficiencies of its LOR, NeoGenomics belatedly seeks excessively broad and irrelevant discovery on *unasserted* claims that fails to outweigh the prejudice to Natera and burden to the English court and Drs. Mariam Jamal-Hanjani and Charles Swanton, whom NeoGenomics already recognizes are not willing participants (Doc. 352 at 6). NeoGenomics’ Motion for LOR (“Motion”) should be denied.

¹ The ’596 (Doc. 352-10) and ’454 (Doc. 1-1) Patents are, collectively, “the Asserted Patents.”

² The ’596 Patent shares the same specification, priority date, and list of inventors as the previously asserted ’454 Patent. Doc. 343 at 11

II. LEGAL STANDARD

Federal Rule of Civil Procedure 28(b) permits a deposition to be taken in a foreign country pursuant to a letter of request. The court “may” issue a letter of request “on appropriate terms after an application and notice of it.” Fed. R. Civ. P. 28(b)(2)(A). Issuance of a letter of request for discovery under the Hague Evidence Convention is neither mandatory nor exclusive. *Société Nationale Industrielle Aérospatiale v. U.S. Dist. Ct. for the S. Dist. of Iowa*, 482 U.S. 522, 522 (1987). The burden “to persuade the court that Hague Convention procedures are appropriate” is on NeoGenomics as a “proponent[] of resort to Hague Convention procedures.” *MeadWestvaco Corp. v. Rexam PLC*, 1:10-cv-511-(GBL/TRJ), 2010WL5574325, *1 (E.D. Va. Dec. 14, 2010), *aff’d*, 2011WL102675 (E.D. Va. Jan. 10, 2011). “[I]t is also settled that the decision to issue letters rogatory lies within a court’s sound discretion.” *United States v. Rosen*, 240 F.R.D. 204, 215 (E.D. Va. 2007).

Courts determining whether to grant a Letter of Request should consider “(1) the particular facts of each case, (2) the sovereign interests involved, and (3) whether the use of the Convention would provide effective discovery.” *Doster v. Schenk*, 141 F.R.D. 50, 52 (M.D.N.C. 1991) (citing *Société Nationale*, 482 U.S. at 544). A full comity analysis requires a balancing of the following five factors: (1) the importance to the litigation of the documents requested; (2) the degree of specificity of the request; (3) whether the information originated in the United States; (4) the availability of alternative means of securing the information; and (5) the extent to which noncompliance with the request

would undermine important interests of the United States or compliance with the request would undermine important interests of the foreign state. *See Société Nationale*, 482 U.S. at 544 n.28 (citing Restatement of Foreign Relations Law of the United States (Revised) § 437(1)(c) (Tent.Draft No. 7, 1986) (approved May 14, 1986) (Restatement)).

“In general, ‘[w]here the relevancy or materiality of the testimony sought is doubtful, the court should not grant the application’ for letters rogatory.” *Rosen*, 240 F.R.D. at 215 (citing 26B C.J.S. *Depositions* § 34). “Instead, letters rogatory should be issued only where ‘necessary and convenient.’” *Id.* (citing 35A C.J.S. *Federal Civil Procedure* § 614); *see also Quaak v. Klynveld Peat Marwick Goerdeler Bedrijfsrevisoren*, 361 F.3d 11, 21 (1st Cir. 2004) (“Under the best of circumstances, letters rogatory are burdensome, costly, and time-consuming.”).

In weighing a party’s petition for letters of request, the trial court must also consider any treaty reservations made by the foreign government under Article 23 of the Hague Evidence Convention. *Société Nationale*, 482 U.S. at 537, n.23 (Blackmun, J., concurring) (“An Article 23 reservation and, in fact, the Convention in general require an American court to give closer scrutiny to the evidence requested than is normal in United States discovery.”); *In re Anshuetz & Co., GmbH*, 838 F.2d 1362, 1364 (5th Cir. 1988) (“[I]t is most important that the district court should consider, with due caution, that many foreign countries, particularly civil law countries, do not subscribe to our open-ended views regarding pretrial discovery, and in some cases may even be offended by our pretrial procedures.”).

III. ARGUMENT

A. NeoGenomics Cannot Show The Necessary Good Cause For Extending The Fact Discovery Deadline

The Court should deny NeoGenomics' motion because the discovery it seeks will likely require extending the fact discovery deadline—potentially by a very significant amount. Deadlines in scheduling orders may be extended only by a showing of good cause under Fed. R. Civ. P. 16(b)(4), and NeoGenomics cannot satisfy that standard here.

“Good cause” means that the movant could not meet the deadline in the scheduling order despite diligent efforts. *McMillan v. Cumberland Cnty. Bd. of Educ.*, 734 F. App'x 836, 846 (4th Cir. 2018). “[D]iligence is the hallmark of the Rule 16(b)(4) good cause standard.” *Paice, LLC v. Hyundai Motor Co.*, No. WDQ-12-0499, 2014WL3385300, *1 (D. Md. July 8, 2014). A request for issuance of letters of request is properly denied where the movant fails to show that “the evidence sought is of such material value that the time-consuming process of obtaining [it] outweighs the negative impact on the scheduling order.” *Haarslev Inc. v. Nissen*, No. 5:19-cv-06128-BCW, 2022WL16709716, *1 (W.D. Mo. Sept. 20, 2022) (denying request where it “would result in a significant extension of both the discovery and dispositive motion deadlines”). Where there is little time remaining in the previously closed, and now reopened fact discovery period, a request for LOR is properly denied where the movant “could have exercised more diligence in pursuing [the requested deposition] earlier in the case. See *IOENGINE, LLC v. PayPal Holdings, Inc.*, No. 18-452-WCB, 2021WL11960830, *2 (D. Del. Oct. 15, 2021).

1. The Foreign Discovery NeoGenomics Seeks Is Unlikely To Be Completed Prior To The Close Of Fact Discovery

As NeoGenomics recently argued to the Court, “[a] central term of the parties’ partial settlement agreement” resolving part of this dispute was “agreeing on a case schedule that allows for trial within 6-8 months.” Doc. 341 at 8. As a result, fact discovery is scheduled to close on April 4, 2025, less than four months from the filing of this Opposition. Doc. 330 at 5. Yet, NeoGenomics waited until now (almost 1.5 years after this case commenced) to seek issuance of this LOR.

NeoGenomics’ unexcused delay means that the discovery it seeks is unlikely to be completed prior to the April 4, 2025 close of fact discovery date and will therefore likely either be barred by that deadline or will necessitate modification of the scheduling order. Issuance of a letter of request is properly denied where “[it] is unclear whether and when [the foreign] authorities might permit [the requested deposition] were this Court to request it” and “issuing the letter rogatory . . . would risk delaying [the trial].” *See In re Customs & Tax Admin. Of the Kingdom of Denmark (SKAT) Tax Refund Litig.*, No. 18-MD-2865 (LAK), 2024WL3184978, *4 (S.D.N.Y. June 26, 2024). The State Department reports that the “[e]xecution of letters rogatory may take a year or more.” <https://travel.state.gov/content/travel/en/legal/travel-legal-considerations/internl-judicial-asst/obtaining-evidence/Preparation-Letters-Rogatory.html>. Prior decisions reflect delays from letters rogatory to the English court ranging from seven months to over a year. *See, e.g., United States v. Al Fawwaz*, 116 F. Supp. 3d 194, 206–07 (S.D.N.Y. 2015) (party moved for issuance of letters rogatory to United Kingdom on July 2, 2013, and received

portion of requested material over a year later, on September 29, 2014); *United States v. McLellan*, 959 F.3d 442, 456 (1st Cir. 2020) (trial date extended seven months due to letters rogatory to the United Kingdom). These delays will only be exacerbated if either Drs. Jamal-Hanjani or Swanton seek to challenge discovery in the English court. *United States v. Menendez*, No. 23-CR-490 (SHS), 2024WL2214906, *3 (S.D.N.Y. May 16, 2024) (“Certainly, if the witnesses oppose the motion through court proceedings in London, the time until the depositions take place becomes further elongated.”).

2. NeoGenomics Cannot Show The Necessary Diligence To Extend The Fact Discovery Deadline To Permit The Discovery It Seeks

There is nothing new about NeoGenomics’ request. NeoGenomics first raised a theory of improper inventorship regarding the ’454 Patent *more than a year ago* during the Preliminary Injunction (“PI”) proceeding and had ample discovery on this issue.³ Natera produced documents showing that Natera scientists conceived of the claimed subject matter months before any interactions with Drs. Jamal-Hanjani or Swanton. *See* Doc. 144-1 at NAT-NEO-00884450 (describing experiments to identify variants in primary tumors using

³ NeoGenomics’ contention that the “earlier proceeding” of the pending case “focused primarily on the ’035 patent” (Doc. 352 at n.1) is false. Natera filed its Motion for a preliminary injunction on the then asserted ’454 and ’035 Patents (Doc. 6). NeoGenomics subsequently sought discovery on *both* patents and briefed not only its Opposition to the PI (Doc. 107), but also a Rule 37 Motion to bind Natera to an incorrect conception date specifically in connection with the ’454 Patent and discovery on inventorship (Doc. 138), which was denied (Doc. 170). That the Court did not need to reach the merits of the ’454 Patent to issue the PI based on the ’035 Patent does not negate the fact that NeoGenomics has had two periods to take discovery related to the ’454 Patent’s validity, during which it never sought foreign discovery.

whole exome or whole genome sequencing and performing targeted multiplex amplification to track those variants in cfDNA from patient plasma); Doc. 144-2 at 76-78 (discussing using ctDNA to study tumor heterogeneity); Doc. 144-3 at 12, 19, 23 (showing high sequencing depth of read using Natera's targeted multiplex amplification methods in cancer experiments); *see also* Doc. 144 (PI Reply) at 8. Natera's Rule 30(b)(6) corporate witness on Natera's projects involving Drs. Jamal-Hanjani and Swanton, Dr. Bernhard Zimmermann, testified about these technical documents and explained that Natera had conceived and developed protocols for the claimed elements of the '454 Patent by June 2014—months before meeting Drs. Jamal-Hanjani and Swanton.⁴ Doc. 144-4 (Zimmermann 10/04/23 Tr.) at 109:24-113:19, 100:24-104:12, 105:16-109:13; *see generally* Doc. 157-7 (Zimmermann Decl.).

Ignoring Dr. Zimmermann's testimony, NeoGenomics attempted to bind Natera to a later and incorrect conception date to support the timing of Dr. Jamal-Hanjani's purported contributions (Doc. 138), which was ultimately rejected by this Court (Doc. 170). As part of a parallel effort in September 2023, NeoGenomics contacted Drs. Jamal-Hanjani and Swanton to try to convince them of their purported inventive contributions based on Dr. Jamal-Hanjani's thesis and, more broadly, the TRACERx study. Doc. 144-8 at 5. In response, however, Dr. Jamal-Hanjani expressed skepticism about making any

⁴ Although NeoGenomics initially asserted affirmative defenses and counterclaims of inequitable conduct and unclean hands based on improper inventorship (Doc. 128 at 19-24 at 29-30), it later withdrew them after receiving discovery disproving its allegations (Doc. 226).

contribution to the patent, stating that “[t]hus far, even after looking at the [patent], I can’t easily ascertain if any data from my thesis or the work we did with natera resulting in the Annals of Oncology publication has contributed to the patent.” Doc. 144-8 at 4-5. More than a year later, neither Dr. Jamal-Hanjani nor Dr. Swanton have made a claim that they are inventors of the ’454 Patent and their positions are made even clearer by NeoGenomics’ recognition that they are *unwilling* to voluntarily provide testimony in the pending case (Doc. 352 at 18).

Following the PI proceeding, NeoGenomics stopped attempting to obtain foreign inventorship discovery. Instead, during the main phase of the case on RaDaR 1.0, NeoGenomics deposed multiple Natera inventors on the asserted ’035 and ’454 Patents. Regarding inventorship, NeoGenomics again deposed Dr. Zimmermann at length on the 2014-2015 project Natera conducted with Drs. Jamal-Hanjani and Swanton as well as the contributions of the Natera inventors to the claims of the ’454 Patent. Ex. 1 (Zimmermann 30(b)(1) Depo. Tr.) at 69:24-70:20, 81:23-82:14, 85:14-87:18, 88:3-90:19, 92:11-94:6, 97:6-101:3-109:11, 110:16-112:2, 113:9-125:19. Consistent with prior testimony, Dr. Zimmermann explained that Natera inventors had already conceived of performing whole exome sequencing and detecting tumor SNVs in the blood of cancer patients with cancer before Natera engaged with Drs. Jamal-Hanjani or Swanton. *Id.*, 62:20-24. Moreover, Dr. Zimmermann testified that “nobody ever determined that [Dr. Jamal-Hanjani] was an inventor, and as far as I know, neither has she thought that she is an inventor.” *Id.*, 107:19-21.

NeoGenomics' delay in seeking foreign discovery for over a year until now, as the close of fact discovery approaches, is far more egregious than delays other decisions have found sufficient to deny issuance of letters of request. For example, in *IOENGINE*, the defendant sought to depose a designee from a French company that the defendant contended was knowledgeable about potentially invalidating prior art. 2021WL11960830, *1. The defendant began corresponding with the French company and learned its designee was in France in July 2021, but waited until October 2021 to make seek a letter of request. *Id.* at *2. The court found this approximately three-month delay sufficient to deny the request. *Id.* NeoGenomics, however, began corresponding with Drs. Swanton and Jamal-Hanjani more than a year ago, far longer than the delay in *IOENGINE*.

Almost a year and a half into this case, and after fact discovery closed for the second time, NeoGenomics now seeks relief for additional documents and testimony under the Hague Convention. But NeoGenomics does not address or rebut the evidence already in the record that supports Natera's independent conception of the claimed subject matter.⁵ That failure alone is fatal to NeoGenomics' LOR.⁶ Moreover, in the absence of its own

⁵ Given that the '596 and '454 Patents share the same specification and inventors, Natera's evidence of conception and inventorship applies to both patents.

⁶ NeoGenomics cites dicta from *Banner Pharmacaps Inc. v. Perrigo Co.*, 1:04CV00492, 2005WL8165011, *2 (M.D.N.C. July 6, 2005), for the proposition that this Court should not "weigh the evidence to be elicited by deposition or determine whether the witness will be able to give the anticipated testimony." Doc. 352 at 6. That statement originates from *B & L Drilling Elecs. v. Totco*, 87 F.R.D. 543, 545 (W.D. Okla. 1978), which predates the Supreme Court's decision in *Société Nationale*. Although this Court need not weigh the evidence NeoGenomics seeks to deny its request, *Société Nationale*

diligence to pursue foreign discovery in a timely manner, NeoGenomics makes no showing of good cause that would justify its request now. Faced with extensive evidence that supports Natera's proper inventorship, NeoGenomics seeks permission from this Court for a fishing expedition and a redo of discovery without any explanation as to why it did not seek this supposedly critical discovery at any point prior during the pendency of this case.

B. NeoGenomics' Request Is Inconsistent With Its Earlier Positions and the Court's Ruling on the Scope of Discovery

NeoGenomics not only failed to pursue discovery under the Hague Convention in the earlier phases of this case, it opposed Natera's proposal for higher deposition limits, arguing that the number of depositions in the case should be restricted and follow the Local Rules' presumptive limits (Doc. 281 at 7). NeoGenomics contended that "[t]here is nothing exceptional about the facts of this case that justifies departure from the Local Rules' presumptive deposition limits. It involves two parties, two asserted patents, and a single accused product." *Id.* NeoGenomics proposed that in accordance with the "exceptional" case track in this District, the case should be limited to ten depositions and no more than four fact witness depositions.⁷ *Id.* The Court ruled that "to control the scope of discovery and to manage the proceedings efficiently and fairly," each party was permitted up to ten depositions total, including fact, non-party, and expert witnesses. Doc. 282 at 1-2.

makes clear it would be within its discretion to do so. *Société Nationale*, 482 U.S. at 544 n.28 (instructing district courts to consider "the importance to the litigation of the documents or other information requested").

⁷ NeoGenomics also proposed depositions of each fact witness on the opposition's may call or will call trial witness list to the extent not previously deposed. Doc. 281 at 7.

Although NeoGenomics listed Dr. Jamal-Hanjani and unnamed “[i]ndividuals yet to be determined” in its Initial Disclosures as potentially having information related to inventorship of the ’454 Patent (Doc. 281-1 at 9), NeoGenomics forewent foreign discovery and deposed only Natera employees, thereby reaching its fact deposition limit.

The operative facts in this case have not changed. There remain two parties, two asserted patents, and one accused product. Upon addition of the ’596 Patent, Natera served its Second Supplemental Initial Disclosures, identifying seven fact witnesses who may have relevant knowledge. Ex. 2. Should NeoGenomics depose all seven listed witnesses, as it did during the RaDaR 1.0 proceeding, the non-party depositions of Drs. Jamal-Hanjani and Swanton, that NeoGenomics is now seeking, would exceed the 10-deposition limit it previously strenuously argued and that the Court ordered.⁸ NeoGenomics offers nothing that would justify departure from its own prior restricted view of discovery or expansion of the discovery limits set forth by the Court.

NeoGenomics argues that foreign discovery “is important to support NeoGenomics’ improper inventorship defense to Natera’s claims of infringement of the ’596 patent, which Natera sought to add to the case as of November 4, 2024, as well as . . . the previously asserted ’454 patent.” Doc. 352 at 6-7. To the extent that NeoGenomics is attempting to use the ’596 Patent as a proxy for overseas inventorship discovery that it elected not take earlier (*see id.*), the Court should not reward NeoGenomics’ gamesmanship. If anything,

⁸ Consistent with the Court’s ruling, this estimate further takes into account a deposition under Rule 30(b)(6) and depositions of two expert witnesses. Doc. 281 at 2-3.

the scope of this case has narrowed compared to the RaDaR 1.0 proceeding with the two presently asserted patents sharing the same specification and list of inventors. NeoGenomics' contradictory position on the scope of discovery as the case has progressed is unreasonable and without justification.

C. NeoGenomics' Vague Requests For Documents Are Unenforceable Under the Hague Convention

Even if it were not late, NeoGenomics' LOR is procedurally defective and, thus, unenforceable. The United Kingdom has expressly rejected the use of wide-netted discovery requests in LORs served under the Hague Evidence Convention. The U.K. Reservation provides, in pertinent part:

In accordance with Article 23 Her Majesty's Government declare that the United Kingdom will not execute Letters of Request issued for the purpose of obtaining pre-trial discovery of documents. Her Majesty's Government further declare that Her Majesty's Government understand "Letters of Request issued for the purpose of obtaining pre-trial discovery of documents" for the purposes of the foregoing Declaration as including any Letter of Request which requires a person:

- a. to state what documents relevant to the proceedings to which the Letter of Request relates are, or have been, in his possession, custody or power; or
- b. to produce any documents other than particular documents specified in the Letter of Request as being documents appearing to the requested court to be, or to be likely to be, in his possession, custody or power.

Ex. 3 at 1.

The U.K. Reservation is also codified under English law as the Evidence (Proceedings In Other Jurisdictions) Act 1975 ("the 1975 Act"). Ex. 4. Consistent with

the U.K. Reservation, the 1975 Act provides that no order issued under its authority may require a person “to produce any documents other than particular documents specified in the Order as being documents appearing to the court making the order to be, or to be likely to be, in his possession, custody or power.” *Id.* at 2 (The 1975 Act, § 2(4)(b))..

Under the U.K. Reservation and the 1975 Act, an English court will not order the production of broad classes of documents (*e.g.*, “documents describing . . .”), but may order the production of specific documents that are known to exist. *See, e.g., Rio Tinto Zinc Corp. v Westinghouse Elec. Corp.* [1978] AC 547, 609 (UK) (limiting discovery to be produced by an English non-party witness in response to a letter of request, and holding that “a strict attitude is to be taken by English courts in giving effect to foreign requests for the production of documents by a non-party witness”). Ex. 5.

NeoGenomics does not even try to meet this standard. NeoGenomics does not identify a single document by date, title, or otherwise, only instead vaguely identifying “[d]ocuments which include descriptions, records, or notes of Dr. Swanton’s communications and interactions with Natera regarding the TRACERx study in the years 2014 and 2015” (Doc. 352-2 at 9) and “[d]ocuments which include descriptions, records, or notes of Dr. Jamal-Hanjani’s communications and interactions with Natera regarding the TRACERx study in the years 2014 and 2015” (Doc. 352-3 at 9).⁹ NeoGenomics’ LOR

⁹ NeoGenomics also broadly identifies “Documents” as including “descriptions, records, or notes” of Drs. Jamal-Hanjani or Swanton with Natera “regarding detection mutations in cfDNA in the years 2014 and 2015.” Doc. 352-2 at 10; Doc. 352-3 at 10.

contains exactly the kind of broad “fishing expedition” requests that English courts specifically reject. As one U.S. court explained, “[i]t is clear in Section 2(4) [of the 1975 Act] that as far as requests for the obtaining of documents is concerned the court will not allow requests for classes of documents. Particular documents sought must be individually described.” *Metso Minerals Inc. v. Powerscreen Int’l Distrib. Ltd.*, CV-06-1446-(ADS)(ETB), 2008WL719243, *4 (E.D.N.Y. Mar. 18, 2008).

NeoGenomics offers no reason to believe that either Drs. Jamal-Hanjani or Swanton would have any relevant documents from a project with Natera conducted ten years ago. With this Court’s duty as the gatekeeper to foreign discovery, the burden should not be placed on the English court to determine that NeoGenomics’ LOR is defective. *See Crouch v. Liberty Pride Corp.*, CV-15-974 (JS)(AYS), 2016WL4718431, *2 (E.D.N.Y. Sept. 9, 2016) (courts must “carefully scrutinize the application so as to reduce the burden placed on a foreign judiciary by virtue of the application”).

D. NeoGenomics’ Numerous Proposed Topics of Examination Are Unduly Burdensome and Unnecessary

The U.S. Supreme Court has recognized that “American courts, in supervising pretrial proceedings, should exercise special vigilance to protect foreign litigants from the danger that unnecessary, or unduly burdensome, discovery may place them in a disadvantageous position” and “supervise pretrial proceedings particularly closely to prevent discovery abuses.” *Societe Nationale*, 482 U.S. at 546. Courts in this district have recognized that requests for letters rogatory for testimony should be denied “[w]here the relevancy or materiality of the testimony sought is doubtful” or is “cumulative of other

testimony from witnesses available in the U.S.” *Rosen*, 240 F.R.D. at 215 (quoting 26B C.J.S. *Depositions* § 34). Thus, “the Court should weigh the likelihood that these witnesses have relevant information with the burden of testifying regarding those topics.” *Dyson, Inc. v. SharkNinja Operating LLC*, 1:14-cv-0779, 2016WL5720702, *3 (N.D. Ill. Sept. 30, 2016), *objections overruled*, 2017WL446042 (N.D. Ill. Feb. 2, 2017).

1. NeoGenomics Seeks Irrelevant Testimony

NeoGenomics contends that the “proposed Letters of Request should be issued because the proposed deponents have material information relevant to NeoGenomics’ improper inventorship defense.” Doc. 352 at 6. But this representation is belied by the nature of the testimony that NeoGenomics apparently intends to elicit. At a minimum, the scope of testimony sought from Drs. Jamal-Hanjani and Swanton is both excessive and not relevant to the issue of inventorship.

As an initial matter, NeoGenomics proposes 78 and 80 examination topics for Drs. Jamal-Hanjani and Swanton. *See generally* Docs. 252-2 and 252-3. While numerous, the vast majority of topics also seek discovery of patent claims that are not presently asserted in view of Natera’s Preliminary Infringement Contentions served on November 25, 2024 (Doc. 343-2 at 2-3) and subsequent narrowing on December 11, 2024 (Ex. 6). Pursuant to the Court’s order on case narrowing (Doc. 345, ¶2), the fourteen Asserted Claims include ’454 Patent Claims 1, 8, 10, 12, 14, 15, 22, 24, 26, 28 and ’596 Patent Claims 1, 11, 12, and 18. Ex. 6. Yet, NeoGenomics seeks irrelevant discovery on claims well beyond this scope as a means to challenge inventorship of the ’454 Patent based only on dependent

claims 3-5, 7, 17-19 and the '596 Patent based only on dependent claims 4-9 (Doc. 352 at 4), all of which are no longer at issue and conveys a misapprehension of the standard for inventorship. “[A]n inventorship analysis, like an infringement or invalidity analysis, begins as a first step with a construction of *each asserted claim* to determine the subject matter encompassed thereby. . . . The second step is then to compare the alleged contributions of each asserted co-inventor with the subject matter of the properly construed claim to then determine whether the correct inventors were named.” *Trovan, Ltd. v. Sokymat SA, Irori*, 299 F.3d 1292, 1302 (Fed. Cir. 2002) (emphasis added).

Numerous examination topics for both Drs. Jamal-Hanjani and Swanton relate to elements *only covered* by these unasserted dependent claims, rendering NeoGenomics’ purported scope of examinations both irrelevant and unduly burdensome. *See, e.g.*, Doc. 252-2 (Swanton Examination) at Topic Nos. 9-21, 34-35, 45-46, 64-66, 75-79 (relating to clonal (also called “truncal” or “ubiquitous”) variants and subclonal (also called “branch” or “heterogeneous”) variants, 22 (relating to tumor heterogeneity), 32-33, 59, 62-63, 73-74 (variants in cancer-associated genes related to Claims 4 and 7 of the '596 Patent).¹⁰

Other examination topics relate to selecting variants to track using, for example, whole exome sequencing (“WES”) or whole genome sequencing (“WGS”), which again, are irrelevant as Natera conceived of using WES or WGS in combination with its targeted

¹⁰ *See also* Doc. 252-3 (Jamal-Hanjani Examination) at Topic Nos. 7-20, 32-33, 60-61, and 71-77.

multiplex amplification method prior to meeting Drs. Jamal-Hanjani and Swanton.¹¹ *See, e.g.,* Doc. 252-2 (Swanton Examination) at Topic Nos. 7-8, 23-24, and 58-61.¹²

Finally, some examination topics have nothing to do with *any* claims and simply seek the witness's understanding of possible overlap with the disclosure in Example 13 and Dr. Jamal-Hanjani's thesis or the TRACERx study, which is unrelated to the criteria for inventorship. *See, e.g.,* Doc. 252-2 (Swanton Examination) at Topic Nos. 25-31, 36-55, and 67-72.¹³

The irrelevance of the proposed discovery counsels against issuing NeoGenomics' LOR.

2. Testimony from Drs. Swanton and Jamal-Hanjani is Unnecessary and Would Be Cumulative of Natera Inventors' Testimony

NeoGenomics argues that the evidence it seeks "cannot be obtained by alternative means." Doc. 352 at 6. But NeoGenomics has already questioned Natera inventor Dr. Zimmermann *twice* about the 2014-2015 research project between Natera and UCL as well as Natera's prior conception of the claimed subject matter. *See* Section III.A *supra*. Moreover, NeoGenomics could have, but did not, ask the other '454 Patent inventors it deposed, such as Dr. Matthew Rabinowitz and Dr. George Gemelos, about these same topics. That it did not elect to obtain such discovery does not establish that these foreign

¹¹ *See supra* Section III.A.2; *see also* Doc. 144-1 at NAT-NEO-00884450.

¹² *See also* Doc. 252-3 (Jamal-Hanjani Examination) at Topic Nos. 21-22, and 54-59.

¹³ *See also* Doc. 252-3 (Jamal-Hanjani Examination) at Topic Nos. 23-31, 34-53, and 62-70.

depositions are necessary. With respect to the '596 Patent, NeoGenomics can ask Natera inventors about inventorship and conception of the claimed subject matter. Accordingly, any testimony either Drs. Jamal-Hanjani or Swanton could offer would be unnecessary and “cumulative of other testimony from witnesses available in the U.S.,” such as Natera inventor-employees that Natera can make and has already made available. *Rosen*, 240 F.R.D. at 215.

E. Issuing the Letters of Request is Prejudicial to Natera

1. The Basis for NeoGenomics' Request is Unfounded

NeoGenomics argues that “the documents produced in this case strongly indicate that Drs. Swanton and Jamal Hanjani are inventors of claims 4-9 of the '596 patent and claims 3-5, 7, 17-19, and 21 of the '454 patent.” Doc. 352 at 7. Far from being “strong,” these documents fail to show any *inventive contribution to the claims* of the '454 and '596 Patents by Drs. Jamal-Hanjani or Swanton, and thus, cannot serve as the basis for NeoGenomics' spurious inventorship theories or justify foreign discovery from these individuals.

The basis for NeoGenomics' proposed LOR is the latest in a series of scattershot allegations concerning improper inventorship during the pendency of this litigation that reveals NeoGenomics' misunderstanding of the standard for inventorship. NeoGenomics initially argued that Dr. Jamal-Hanjani alone was omitted as an inventor of the '454 Patent due her purported contribution of the first step of WES to Claim 1. Doc. 107 at 13. But as Natera explained, Dr. Jamal-Hanjani only articulated the state of the prior art regarding

WES to Natera, which Natera already knew about, and which is not enough to establish an inventive contribution. Doc. 144 at 8; *see Eli Lilly and Co. v. Aradign Corp.*, 376 F.3d 1352, 1359 (Fed. Cir. 2004). NeoGenomics then alleged that Dr. Jamal-Hanjani contributed to experiments disclosed (but not claimed) in Example 13 of the '454 Patent and a “research plan” that generally related to analyzing cell-free DNA to detect tumor-specific SNVs. Doc. 128 at 19-24. But again, neither of these theories meets the legal requirements for inventorship for the reasons Natera described. *See* Doc. 134 at 11-13.

Despite the absence of evidence, NeoGenomics argued that Natera misappropriated Dr. Jamal-Hanjani’s work (Doc. 128 at 19) to bolster spurious accusations of inequitable conduct and unclean hands. *See id.* at 19-24. After Natera rebutted Dr. Jamal-Hanjani’s purported contributions, produced discovery showing conception by the Natera inventors alone of the claimed subject matter before interacting with Drs. Jamal-Hanjani or Swanton (Doc. 153 at 13-19), NeoGenomics eventually withdrew its claims of inequitable conduct and unclean hands (Doc. 226).

With each of NeoGenomics’ prior inventorship theories debunked, NeoGenomics has now pivoted to arguing that *both* Drs. Jamal-Hanjani and Swanton should be inventors of only certain dependent claims¹⁴ related to clonal and subclonal variants. Doc. 352 at 7-8. Again without any actual supporting evidence, NeoGenomics argues that “Natera took Drs. Swanton and Jamal-Hanjani’s work and patented it without crediting them as

¹⁴ NeoGenomics identifies Claims 4-9 of the '596 Patent and Claims 3-5, 7, 17-19, 21 of the '454 Patent. Doc. 352 at 7.

inventors.” *Id.* at 18. But NeoGenomics’ latest challenge suffers from the same deficiencies as before: NeoGenomics has not—and cannot—show that either of these individuals articulated anything more than the state of the art to Natera. In any event, Drs Swanton and Jamal-Hanjani are not alleging that they are inventors.

NeoGenomics relies on two primary documents—Dr. Jamal-Hanjani’s doctoral thesis (Doc. 352-4) and the TRACERx study published on January 28, 2016 (Doc. 352-5)—which apparently serve as the basis for NeoGenomics’ erroneous contention that Drs. Jamal-Hanjani and Swanton are inventors of various dependent claims of the ’454 and ’596 Patents. Doc. 352 at 8. NeoGenomics identifies disclosures from these documents and attempts to show their correspondence to Example 13 and various dependent claims of the Asserted Patents (Doc. 352 at 8-17), but fundamentally misses the mark. Aside from remaining silent on Natera’s prior conception of the claimed subject matter, NeoGenomics draws no distinction between the work done for a project involving Natera and the University College of London (“UCL”) between 2014-2015 and *inventive contributions* to the claims.

For example, at least as of January 2014, nine months before Natera first communicated with Drs. Swanton and Jamal-Hanjani about a possible research project,¹⁵ Natera scientists were already aware that analyzing ctDNA with its proprietary methods

¹⁵ See Doc. 153-1 at NAT-NEO-00653107-08.

could be used to study “tumor heterogeneity,”¹⁶ which is directly related to ’454 Patent Claims 7 and 21 and ’596 Patent Claim 9 that NeoGenomics alleges Drs. Jamal-Hanjani and Swanton conceived.

Moreover, to the extent that NeoGenomics alleges Drs. Jamal-Hanjani and Swanton are inventors of ’454 Patent Claims 3-5 and 17-19 and ’596 Patent Claims 5, 6, and 8, clonal and subclonal SNVs were already known in the art well before Drs. Jamal-Hanjani and Swanton communicated with Natera,¹⁷ as recognized by NeoGenomics’ own technical expert, Dr. Smith. Doc. 264-5 (Smith Decl.), ¶21. Likewise, Claims 4 and 7 of the ’596 Patent recite genes known in the art to be associated with cancer before Natera had any interaction with Drs. Jamal-Hanjani and Swanton. *See* Ex. 7 (Catalogue Of Somatic Mutations In Cancer (COSMIC))¹⁸ at 3-4, 7-8, 11-12, 15-16, 19-20, 24-25, 28-29, 32-33, 36-37, 40-41, 44-45, 48-49, 52-53, 56-57. Thus, despite NeoGenomics’ arguments to the contrary, Drs. Jamal-Hanjani and Swanton do not qualify as joint inventors by providing information *already known* in the prior art, which Natera already knew about, “because it

¹⁶ Doc. 144-2 at NAT-NEO-00574121. Tumor heterogeneity is also referred to as clonal heterogeneity within a tumor, which is confirmed by NeoGenomics’ technical expert. Doc. 264-5 (Smith Decl.), ¶¶21-22.

¹⁷ *See* Doc. 264-7 at 1 (“Somatic (cancer-only) single nucleotide variants (SNVs) are the simplest class of mutation . . . Cancers arise from a single ancestral cell that has acquired enough somatic mutations to deregulate its own proliferation and expand into a large cell population with **clonal mutations** matching the ancestral profile . . . Those mutations conferring a selective advantage preferentially expand in number, forming subpopulations with the same **subclonal mutations**.”) (emphasis added).

¹⁸ Gene names and pre-2014 references for each gene are annotated.

is not a contribution to conception.” *Eli Lilly*, 376 F.3d at 1362. That Natera conducted a project with Drs. Jamal-Hanjani and Swanton in 2014-2015 that featured clonal and subclonal SNVs, and the results of which are shown in Example 13, does not mean they made an inventive contribution to the claims.

Example 13 discloses an *application* of the claimed methods in the Asserted Patents, which were conceived by the Natera inventors prior to any contact with Drs. Jamal-Hanjani and Swanton. As Dr. Zimmermann already testified, Natera “applied our method in the collaboration. The collaboration was not the method or developing the method. We applied the method.” Doc. 144-4 (Zimmermann 10/04/23 Tr.) at 87:9-87:12. Indeed, Example 13 shows a comparison between Natera’s claimed “mmPCR/NGS assay” method and UCL’s “AmpliSeq (Swanton)” method. Doc. 1-1 (’454 Patent) at 168:31-32.

At most, the documents on which NeoGenomics relies show that Drs. Jamal-Hanjani and Swanton may have provided the true Natera inventors with some data used in an example in the specification, which was generated using the Natera inventors’ claimed method after they conceived of it. NeoGenomics’ silence on the state of the art and Natera’s prior conception is telling and reveals that none of the discovery to date connects Dr. Jamal-Hanjani or Dr. Swanton to an inventive act—that is, contributing any specific idea to the actual conception of the claims.

Careful scrutiny of NeoGenomics’ LOR makes clear that in the absence of any viable inventorship link, NeoGenomics seeks to abuse the international discovery process for a fishing expedition while frustrating the ongoing U.S. litigation with delays to the

schedule and trial date. Granting NeoGenomics' frivolous request would therefore not only be prejudicial to Natera, but would also undermine the approach taken in the English court, which already disfavors open-ended pre-trial discovery. *Societe Nationale*, 482 U.S. at 560, n.18 (Blackmun, J., concurring) ("In most common law countries, even England, one must often look hard to find the resemblances between pre-trial discovery there and pre-trial discovery in the U.S. In England, for example, although document discovery is available, depositions do not exist, interrogatories have strictly limited use, and discovery as to third parties is not generally allowed.").

2. The Court Should Not Endorse NeoGenomics' Positions on Disputed Issues

Aside from its mischaracterizations, NeoGenomics' proposed LOR is also prejudicial to Natera because it would have this Court memorialize findings on disputed issues that have not been litigated. For example, the proposed Letter states:

This Court has reviewed documentary evidence, including publications and correspondence exchanged between Dr. Swanton and Natera, which suggests that Dr. Jamal-Hanjani and Dr. Charles Swanton contributed to the subject matter claimed by the '596 and '454 patents and communicated that information to Natera.

Specifically, certain documents produced in this case suggest that Drs. Swanton and Jamal Hanjani may be considered inventors of claims 4-9 of the '596 patent and claims 3-5, 7, 17-19, and 21 of the '454 patent.

....

The evidence before this Court therefore suggests that Natera may have taken Drs. Swanton and Jamal-Hanjani's work without adding them as inventors to the '596 and '454 patents.

Doc. 352-2 at 8-9; Doc. 352-3 at 8-9. Although the Court has reviewed some evidence regarding inventorship of the '454 Patent to date, no formal ruling was issued and NeoGenomics' ask of this Court to take a position on the issue is improper. NeoGenomics' attempt to have the Court put its seal of judicial authority on NeoGenomics' disputed positions, and endorse those positions to foreign courts, should be rejected as improper and prejudicial to Natera and the foreign witnesses.¹⁹

On balance, the evidence sought through NeoGenomics' LOR is not justified and is outweighed by the prejudice to Natera and the English court's constraints on foreign discovery.

IV. CONCLUSION

For the foregoing reasons, the Court should deny NeoGenomics' Motion for issuance of letters of request to examine Dr. Jamal-Hanjani and Dr. Swanton.

¹⁹ As NeoGenomics acknowledges, "[a]ttempts to obtain testimony from Drs. Swanton and Jamal-Hanjani voluntarily have been unsuccessful." Doc. 352 at 18.

Respectfully submitted this 17th day of December, 2024.

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CERTIFICATE OF WORD COUNT

The undersigned counsel hereby certifies that this brief complies with the word count limitations of Local Rule 7.3(d).

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CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing document to be served via electronic mail on all counsel of record for Defendant.

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