09:37:55 1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF DELAWARE

3

4 EXACT SCIENCES CORPORATION,)
)
5 Plaintiff,)
) C.A. No. 23-1319(MN)
6 v.)
)
7 GENEOSCOPY, INC.,)
)
8 Defendant.)

9

10 Friday, November 1, 2024
10:00 a.m.
11 Discovery Dispute Hearing

12

844 King Street
13 Wilmington, Delaware

14

15 BEFORE: THE HONORABLE MARYELLEN NOREIKA
United States District Court Judge
16

17

APPEARANCES:
18

19 MORRIS NICHOLS ARSHT & TUNNELL LLP
BY: BRIAN EGAN, ESQ.
20 BY: DEREK JAMES FAHNESTOCK, ESQ.

21 -and-

22 QUINN EMANUEL URQUHART & SULLIVAN LLP
BY: SANDRA HABERNY, ESQ.
23 BY: JIHONG LOU, ESQ.

24

Counsel for the Plaintiff
25

NL Giken Exhibit 2007
Amazon v. NL Giken
IPR2025-00050

APPEARANCES CONTINUED:

ASHBY & GEDDES
BY: STEVEN J. BALICK, ESQ.

-and-

FOLEY HOAG LLP
BY: SARAH S. BURG, ESQ.

Counsel for the Defendant

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COURTROOM DEPUTY: All rise. The United States District Court for the District of Delaware is now in
09:49:17 session. The Honorable Maryellen Noreika presiding.
10:02:42 THE COURT: All right. Good morning, everyone.
10:02:45 Please be seated.
10:02:50 Introductions, Mr. Egan.
10:02:53 MR. EGAN: Good morning Your Honor. Brian Egan
10:02:56 from Morris Nichols on behalf of the plaintiff, Exact
10:03:00 Sciences. Joining me at counsel table this morning is
10:03:05 Sandra Haberny and Jihong Lou, both from Quinn Emanuel, and
10:03:09 my colleague, Derek Fahnestock.
10:03:12 MR. BALICK: Good morning, Your Honor. Steven

10:03:14 1 Balick from Ashby & Geddes here on behalf of Geneoscopy.
10:03:17 2 And I'm joined by Sarah Burg from Foley Hoag.
10:03:21 3 THE COURT: All right. Good morning. And
10:03:27 4 thanks for coming in. We read your letters and you say you
10:03:36 5 need more, they say you don't need more, so I figured it
10:03:40 6 would be easier if you came in and talked to me and we talk
10:03:44 7 about what you actually have so if we know that there is
10:03:46 8 more that you need.
10:03:49 9 MS. HABERNY: Thank you, Your Honor. And good
10:03:52 10 morning. So there are two categories of documents that our
10:03:58 11 requests for production are seeking. Broadly the categories
10:04:01 12 are documents sufficient to show pricing, sales, and
10:04:06 13 insurance reimbursement for ColoSense, that's the product
10:04:12 14 accused of infringing, and Geneoscopy's commercialization,
10:04:19 15 pricing and sales efforts with its partner, LabCorp.
10:04:23 16 And so Geneoscopy doesn't dispute that the
10:04:27 17 documents Exact Sciences is seeking are relevant or that
10:04:30 18 additional documents exist. That's not the issue here.
10:04:34 19 THE COURT: It's the sufficient, and what you
10:04:38 20 gave us is insufficient and they say sure it is. And what
10:04:44 21 you're now asking for is equivalent to all documents like
10:04:48 22 you would see in a normal case. So tell me, I get it, you
10:04:52 23 caught my attention, they only gave you twenty-one documents
10:04:55 24 which seems low, but what is it that you're missing?
10:05:02 25 MS. HABERNY: Right, Your Honor, we are not

10:05:04 1 seeking all documents --
10:05:05 2 THE COURT: I know. Their point is now that
10:05:07 3 you're coming back you seem to want something more than
10:05:12 4 documents sufficient.
10:05:12 5 MS. HABERNY: Right.
10:05:13 6 THE COURT: Tell me why what they gave you isn't
10:05:16 7 sufficient.
10:05:16 8 MS. HABERNY: Right. So the documents they gave
10:05:18 9 us they pointed to six of them, for example, in their
10:05:22 10 letter. Three of those documents have no information
10:05:25 11 whatsoever that's responsive to the requests. And the
10:05:29 12 remaining three are high level, so they may describe high
10:05:33 13 level goals, but they do not contain details such as the
10:05:37 14 scope of -- I apologize, Your Honor, I'm trying to protect
10:05:42 15 confidential information so I'm describing things at a high
10:05:45 16 level. But they do not describe the scope of the plans, the
10:05:49 17 details about what's been done, how certain projections --
10:05:53 18 there are projections of numbers mentioned in these
10:05:57 19 documents. We have no idea how those projections were
10:06:01 20 computed, what went into them --
10:06:03 21 THE COURT: Well, why do you need to know? You
10:06:06 22 just said in your responses sufficient to show your pricing,
10:06:10 23 or your planned pricing, or your, you know, expected sales.
10:06:16 24 Why do you need to know -- I mean, it seems like -- and if
10:06:19 25 they say, well, here, here is our pricing plan, we expect to

10:06:24 1 sell this many and now you're coming back and saying no, no,
10:06:29 2 no, no, we don't need to know what your pricing is, we need
10:06:32 3 to know how you come up with it. That seems like a
10:06:35 4 different ask.
10:06:37 5 MS. HABERNY: There is conflicting information,
10:06:38 6 because on the one hand --
10:06:40 7 THE COURT: Do you have the documents so I can
10:06:42 8 understand why you're saying it's conflicting and then I
10:06:45 9 might understand better when they say it's not.
10:06:48 10 MS. HABERNY: Yes, Your Honor, I would like to
10:06:50 11 turn them over to counsel --
10:06:52 12 THE COURT: You're showing them to me. I'm not
10:06:54 13 publishing them. Give me a copy.
10:06:59 14 MS. HABERNY: Oh, for example --
10:07:01 15 THE COURT: We are not closing the courts.
10:07:02 16 MS. HABERNY: For example, the Exhibits B, C and
10:07:05 17 D --
10:07:05 18 THE COURT: Yes. Wait. Actually I have hard
10:07:09 19 copies. It's hard for me to pull them up on the computer
10:07:13 20 because going -- you guys don't tab them in the PDF so it's
10:07:20 21 not easy to go back and forth.
10:07:22 22 Okay. B, C and D to their letter?
10:07:25 23 MS. HABERNY: Correct, Your Honor.
10:07:26 24 THE COURT: I got B.
10:07:27 25 MS. HABERNY: Right. This is an investor

10:07:29 1 presentation, it says nothing whatsoever about planned
10:07:33 2 pricing --
10:07:34 3 THE COURT: An investor presentation is highly
10:07:37 4 confidential?
10:07:37 5 MS. HABERNY: Counsel marked it confidential.
10:07:39 6 THE COURT: Is an investor presentation highly
10:07:42 7 confidential?
10:07:43 8 MS. BURG: Your Honor, there are portions of it,
10:07:47 9 they are -- they were provided to investors pursuant to a
10:07:50 10 confidentiality agreement so the investors themselves are
10:07:53 11 under an obligation of nondisclosure.
10:07:56 12 THE COURT: All right. Tell me what page you're
10:07:58 13 pointing me to.
10:07:59 14 MS. HABERNY: Well, in the entire document there
10:08:01 15 is no discussion of pricing, sales --
10:08:06 16 THE COURT: You said there were things that are
10:08:08 17 inconsistent.
10:08:09 18 MS. HABERNY: Okay. I understand, Your Honor.
10:08:10 19 THE COURT: I said to you what do you need, why
10:08:14 20 do you need the backup for their prices and now you're
10:08:20 21 pointing me to well, there is nothing about pricing. I get
10:08:23 22 it, I don't care about that, I want to know what the
10:08:26 23 conflicting stuff is.
10:08:28 24 MS. HABERNY: Right. So if Your Honor turns to,
10:08:30 25 for example, Exhibit 4 to Exact Sciences' letter.

10:08:36 1 THE COURT: Okay.

10:08:37 2 MS. HABERNY: And there is a statement on the

10:08:42 3 page that ends in Bates number 478.

10:08:47 4 THE COURT: Okay.

10:08:48 5 MS. HABERNY: And the statement says -- I don't

10:08:52 6 believe that this is confidential. "Geneoscopy is closely

10:08:55 7 collaborating with LabCorp managed care teams to develop the

10:08:59 8 ColoSense dossier presentation, strategies for coding,

10:09:05 9 pricing, medication and Medicare coverage." But they have

10:09:09 10 represented in their letter that they've already established

10:09:12 11 the Medicare coverage, so what are the strategies and are

10:09:17 12 they going to change?

10:09:19 13 THE COURT: What's the date of this document?

10:09:30 14 MS. HABERNY: I do not see a date on it.

10:09:32 15 THE COURT: What's the date of this document?

10:09:34 16 MS. BURG: Your Honor, from June 2024, so it was

10:09:37 17 prior to the CMS vote.

10:09:40 18 THE COURT: But they don't want things that are

10:09:42 19 not helpful, they want things that are current as of the

10:09:46 20 time they asked for the documents. So why are you giving

10:09:49 21 them something from June that doesn't have information?

10:09:52 22 Isn't there something more after the CMS vote?

10:09:58 23 MS. BURG: Your Honor, there really -- so the

10:10:02 24 CMS vote only occurred September 26th, so it was just very,

10:10:07 25 very recent. And so the --

10:10:09 1 THE COURT: Six weeks ago.
10:10:12 2 MS. BURG: And the vote is basically the efforts
10:10:17 3 were leading up to the CMS vote which is a preliminary
10:10:21 4 decision and they have until November to finalize the vote,
10:10:24 5 so the work in this presentation is current, we also
10:10:29 6 produced an August 2024 brand plan which is our most current
10:10:35 7 brand plan that we were able to identify.
10:10:37 8 THE COURT: All right. Where do you have what
10:10:40 9 you're planning to do with pricing for this thing?
10:10:44 10 MS. BURG: So in a number of places, including
10:10:47 11 our own brief we have explained that the plan to cross --
10:10:52 12 THE COURT: Show me the documents that you say
10:10:57 13 this -- these are the documents sufficient to show our
10:11:01 14 pricing strategy.
10:11:39 15 MS. BURG: So, for example, on -- so if you turn
10:11:42 16 one page earlier than the documents that my counsel pointed
10:11:45 17 to in the same Exhibit 4 ending in the Bates number 0477,
10:11:52 18 it's page 3 of that document, so it explains in the
10:11:56 19 paragraph that precedes the Medicare pricing and if you look
10:12:00 20 at the bottom of the sentence, the last sentence of that
10:12:02 21 paragraph that explains that we fully expect that neither
10:12:07 22 the scenarios discussed above, ColoSense Medicare pricing
10:12:12 23 will be crosswalked to ColoSense reimbursement rate of $500.
10:12:18 24 That has been the only price that Geneoscopy has requested
10:12:21 25 for ColoSense and has sought including in public documents

10:12:25 1 and presentations before CMS.
10:12:28 2 THE COURT: Is that only for Medicare or is that
10:12:31 3 for everything?
10:12:33 4 MS. BURG: So Geneoscopy does not intend to
10:12:35 5 launch ColoSense prior to getting Medicare reimbursement
10:12:39 6 from CMS and that's the price that essentially dictates any
10:12:43 7 other pricing that's discussed. We also produced the
10:12:46 8 LabCorp agreement, I believe that's Exhibit 6 to the
10:12:50 9 plaintiff's submission and that also has a section
10:12:53 10 describing pricing which is done by LabCorp which discusses
10:12:57 11 --
10:12:57 12 THE COURT: Can you point me to what you're
10:12:59 13 talking about?
10:13:00 14 MS. BURG: I believe it's Section 4.2 of that
10:13:03 15 agreement. This is a contractual agreement with LabCorp
10:13:07 16 that explains that essentially by contract -- so at 4.2,
10:13:35 17 it's a little bit -- it has a bunch of defined terms, but if
10:13:40 18 you look at page 11, the Bates number ending in 344 to
10:13:44 19 Exhibit 6 of the LabCorp agreement, the plaintiff's
10:13:49 20 submission, it's 4.2(a)(1) which describes --
10:13:57 21 THE COURT: That's 4.1, right? 4.2 starts on
10:14:02 22 page 13.
10:14:02 23 MS. BURG: Oh, sorry. Yes, sorry, 4.2 is on
10:14:09 24 page 13. It explains that LabCorp is responsible for
10:14:14 25 establishing the standard list price to be published for the

10:14:18 1 test being offered by LabCorp and provided once the coverage
10:14:22 2 milestone has been achieved the standard price will not be
10:14:26 3 lower than the reimbursement price established by CMS. And
10:14:31 4 describes another term about the limits on any potential
10:14:37 5 other advertisement of that list price. Again, depending on
10:14:43 6 Geneoscopy obtaining that CMS coverage which hasn't been
10:14:46 7 finalized or achieved yet, but Geneoscopy's submissions or
10:14:51 8 explanations in our opposition to the preliminary injunction
10:14:54 9 and everything else is the goal of getting this final price
10:14:59 10 crosswalked to the final price of ColoSense to CMS.
10:15:03 11 THE COURT: What more do you need?
10:15:05 12 MS. HABERNY: That leads to one of the
10:15:06 13 inconsistencies I was referring to. So if Your Honor looks
10:15:10 14 at Exhibit 4, the page ending in Bates number 481,
10:15:20 15 Exhibit 44 to Exact Sciences' letter, Your Honor will see
10:15:25 16 there, there is a paragraph starting LabCorp strategically
10:15:33 17 motivated and a few sentences down they reference some
10:15:39 18 predictions, some predicted revenue from the test and it
10:15:43 19 refers to footnotes. And these footnotes assume amounts
10:15:47 20 that are far lower per test than the $503 that Ms. Burg
10:15:53 21 referenced as the CMS rate, so that would be one
10:15:58 22 inconsistency that we've seen and we would like to know how
10:16:01 23 are these numbers generated, what are they planning to do.
10:16:05 24 Because we have seen elsewhere that LabCorp is permitted to
10:16:09 25 give discounts on the test.

10:16:11 1 And in addition, this only references
10:16:14 2 reimbursement by Medicare but not private payers, so private
10:16:19 3 insurance payers frequently negotiate down the price of
10:16:23 4 tests and we have not seen anything in the documents about
10:16:26 5 how they will deal with private payer requests to negotiate
10:16:30 6 down as well as the discounts.
10:16:32 7 THE COURT: Okay. With that, there are
10:16:36 8 different numbers?
10:16:37 9 MS. BURG: Sure, Your Honor. Those numbers were
10:16:40 10 -- we felt -- in our letter, those numbers represent a
10:16:45 11 conservative estimate for revenue that was generated again
10:16:50 12 before CMS crosswalked the price of ColoSense to Cologuard
10:16:58 13 and it was a multiple that was created there. Based on our
10:17:01 14 investigation, there is no pricing plan or other documents
10:17:04 15 where there is any other price discussion or plan to
10:17:08 16 discount, so there isn't a document that further explains
10:17:14 17 the price that relates to the multiplication.
10:17:19 18 THE COURT: There must be something that
10:17:20 19 explains why -- I mean, $393 a test is a pretty specific
10:17:26 20 number. These are not just random numbers, so there must be
10:17:33 21 something that explains what the basis for that footnote
10:17:36 22 was, right?
10:17:36 23 MS. BURG: Your Honor, my understanding is that
10:17:38 24 it is a conservative revenue estimate that was stated here
10:17:42 25 and we didn't identify a report that provides some other

10:17:47 1 pricing of 393. As everything that we have seen is pointed
10:17:53 2 to this 508 number as the goal to crosswalk the test and
10:17:58 3 there is no present plan at Geneoscopy to discount that
10:18:02 4 price.
10:18:02 5 THE COURT: How about at LabCorp?
10:18:05 6 MS. BURG: So LabCorp controls the pricing of
10:18:10 7 ColoSense. We are not aware of any plans by LabCorp to
10:18:15 8 discount. In that Section 4.2 that we just looked at of the
10:18:21 9 LabCorp agreement, there is a requirement that LabCorp come
10:18:26 10 very close to the Medicare price, and --
10:18:30 11 THE COURT: But there are prices and then there
10:18:33 12 are -- like the pricing include discounts or is that, you
10:18:37 13 know, they say look, this is our price, our price is the
10:18:43 14 same as the Medicare price, but if you guy, you know, 15,000
10:18:50 15 tests, we'll give you a twenty percent discount. That
10:18:56 16 impacts the price. It may not be the price. They're
10:18:59 17 offering that price, but is there a discount? And if to the
10:19:03 18 extent that that kind of thing exists, is that something
10:19:06 19 that you provided discovery on?
10:19:13 20 MS. BURG: Your Honor, we do not dispute
10:19:18 21 knowledge, not that we had limited insight into any pricing
10:19:22 22 by LabCorp just because of the nature of agreement, we are
10:19:26 23 not withholding any documents on that topic and have not
10:19:28 24 identified any documents where there is any plans to
10:19:31 25 discount or request to Geneoscopy that the price of

10:19:34 1 ColoSense be discounted in this context.
10:19:37 2 THE COURT: What about the comment that was made
10:19:39 3 about the private payers.
10:19:44 4 MS. BURG: So for private payers, we have -- so
10:19:47 5 the presentations, there are two that we are aware -- both
10:19:50 6 of which have been produced and they don't discuss pricing
10:19:54 7 to the extent those presentations are construed as private
10:19:58 8 payers. There is one from 2023 to a group of seven health
10:20:01 9 care plans and another more recently, I believe it's dated
10:20:07 10 in June of 2024, neither of which discussed pricing or
10:20:10 11 anything different than the CMS price to which we are
10:20:15 12 seeking to have ColoSense crosswalked.
10:20:20 13 THE COURT: Okay. So I don't know what you want
10:20:21 14 me to ask them to produce because she's telling me look,
10:20:25 15 we're pegging it into the CMS price. If LabCorp is going to
10:20:31 16 do a discount, that's not something we are involved in or we
10:20:35 17 know about. Like, I don't know -- let's say I'm sympathetic
10:20:39 18 to you that it seems like you have gotten kind of
10:20:44 19 shortchanged in the documents department, but I don't know
10:20:46 20 what to tell her to produce.
10:20:48 21 MS. HABERNY: Right, Your Honor.
10:20:49 22 THE COURT: Because I can't say every document
10:20:51 23 that says something, because that's too broad. And she's
10:20:55 24 telling me we don't have anything else that talks about
10:20:58 25 this. I mean, did you go subpoena LabCorp, did you ask

10:21:03 1 them?

10:21:03 2 MS. HABERNY: We did not for this proceeding,

10:21:06 3 but there must be some communication with LabCorp that can

10:21:10 4 be used to test this. It's purely attorney argument. And

10:21:13 5 we deposed a Rule 30(b)(6) witness who said I don't know 190

10:21:19 6 times in a deposition. No one can tell us this. We don't

10:21:22 7 have any documents. It's just attorney argument at this

10:21:25 8 point.

10:21:25 9 THE COURT: Well, she has a document that says

10:21:28 10 what the CMS price would be. And that they're tagging it to

10:21:35 11 I guess your product, but -- I guess I just don't know what

10:21:42 12 it is that you want.

10:21:43 13 MS. HABERNY: Well, we would request

10:21:44 14 communications with LabCorp about that and about how the

10:21:47 15 projections with lower numbers were calculated. They must

10:21:51 16 have been calculated in some way and there must be

10:21:54 17 documentation of that.

10:21:55 18 THE COURT: Yeah, but if they're old, who cares.

10:21:57 19 Right?

10:21:59 20 MS. HABERNY: We don't know that, though.

10:22:01 21 That's an attorney argument. But we have not seen any

10:22:04 22 documents that say that this projection no longer applies,

10:22:09 23 that they're not going to give discounts to arrive at those

10:22:13 24 numbers or that there is some other underlying basis for

10:22:16 25 this.

10:22:17 1 THE COURT: Is this really a LabCorp thing? I
10:22:21 2 don't understand how this works. Are they going to sell it
10:22:23 3 or it's mostly through LabCorp? I don't really understand.
10:22:26 4 MS. HABERNY: We don't have a lot of information
10:22:28 5 on that, either. And that's part of the information that we
10:22:31 6 would like, you know, what the setup is and division of
10:22:35 7 labor, the scale, you know, who they're marketing, the
10:22:39 8 efforts, all of that, we just don't have any information on
10:22:42 9 that.
10:22:42 10 THE COURT: I mean, they don't in theory have
10:22:45 11 possession, custody or control of everything LabCorp may be
10:22:49 12 doing on this, right, so what you just want a few items
10:22:54 13 where they talk about --
10:22:55 14 MS. HABERNY: Whatever they have that talks
10:22:57 15 about it, we don't have anything is the problem. They must
10:23:00 16 have discussed this with LabCorp. I can't imagine that they
10:23:04 17 went into a deal this big without any knowledge of what
10:23:07 18 LabCorp would be doing and the scale --
10:23:09 19 THE COURT: They gave you the LabCorp agreement
10:23:11 20 and the LabCorp agreement says that the reimbursement
10:23:17 21 something won't be less than something, right, so why
10:23:20 22 doesn't that tell you something?
10:23:22 23 MS. HABERNY: Well, again, because they're just
10:23:26 24 inconsistencies and we don't have explanations for them.
10:23:29 25 THE COURT: And there must be communications,

10:23:31 1 there must be --

10:23:32 2 THE COURT: How come your 30(b)(6) expert can't

10:23:36 3 explain these inconsistencies? Because if someone could get

10:23:39 4 up there and say that was what we were thinking in June and

10:23:43 5 it was a conservative estimate based on X, Y, Z, those

10:23:48 6 things don't apply anymore, maybe you would have a point,

10:23:52 7 then she's right, but this is you saying something and the

10:23:55 8 person under oath saying I have no freaking idea.

10:23:58 9 MS. BURG: Your Honor, I don't have the

10:23:59 10 transcript in front of me. I think he was asked about those

10:24:02 11 numbers and he explained it was a product of the pricing and

10:24:05 12 the numbers for the tests. I don't think he was asked

10:24:08 13 exactly what the timing was, but he was -- and I don't have

10:24:13 14 the deposition transcript in front of me, but he was very

10:24:17 15 clear that the intention was with the 508 number and that's

10:24:21 16 what's been requested and the plan Geneoscopy for ColoSense

10:24:27 17 to be sold at that crosswalk price by CMS when it launches

10:24:32 18 and gets reimbursement from CMS.

10:24:35 19 MS. HABERNY: Right, but again --

10:24:37 20 THE COURT: I guess what I'm not understanding

10:24:39 21 is if they're representing that and you're saying I just

10:24:42 22 don't believe it, that's really what your argument is, she's

10:24:46 23 saying 508, there is a document that says that 508, there is

10:24:49 24 a contract that says they don't expect that if the

10:24:53 25 reimbursements will be less than that. And you're more

10:24:57 1 concerned with it being less than, than more than because of
10:25:00 2 your price erosion issue, that's what I don't understand.
10:25:05 3 Your argument to me is I don't believe it because there is a
10:25:09 4 footnote. One thing that you have pointed me to is there is
10:25:14 5 a footnote that says something, so the couple things you
10:25:17 6 pointed me to, one, the footnote, two, LabCorp can give
10:25:23 7 discounts, but you're not getting information from LabCorp,
10:25:28 8 you're just asking the defendant here. And then third, I
10:25:33 9 have no idea what anybody is doing with private pay. And is
10:25:42 10 private pay for LabCorp, is private pay for the defendant,
10:25:46 11 or is private pay for both?
10:25:48 12 MS. HABERNY: Private pay would be insurers, so
10:25:50 13 insurers like maybe United Healthcare or Aetna paying for
10:25:54 14 the test rather than Medicare, and that I think is exactly
10:25:58 15 what we need, we would like documents that are sufficient to
10:26:02 16 show the scope of the discount, the details of the discount,
10:26:06 17 as well as the --
10:26:07 18 THE COURT: Who is giving a discount because my
10:26:09 19 problem is you're kind of mixing the defendant and LabCorp.
10:26:14 20 And maybe they have, I don't know, an e-mail with LabCorp,
10:26:20 21 maybe they have some presentation, but they gave you the
10:26:23 22 agreement. What makes you think that the agreement is not
10:26:26 23 right?
10:26:27 24 MS. HABERNY: Because it does not address the
10:26:29 25 discounts and if they do have communications with LabCorp in

10:26:33 1 e-mails, letters, steering committee minutes, PowerPoint,
10:26:37 2 something, we would like to know the scope of the discount,
10:26:39 3 how it would be applied, their plans for using that discount
10:26:43 4 as well as the plans for private payers, the reimbursement,
10:26:47 5 pricing, strategies and things surrounding that because
10:26:50 6 that's not addressed anywhere in these documents and they
10:26:53 7 must know, LabCorp must have told them some plan for this.
10:27:00 8 THE COURT: All right. So why shouldn't I order
10:27:02 9 defendant to produce correspondence, communications with
10:27:08 10 LabCorp about any discounts or any pricing for private
10:27:17 11 payers?
10:27:17 12 MS. BURG: Your Honor, so there is a couple of
10:27:21 13 things. So first, this goes well beyond the scope of the
10:27:25 14 requests that were originally served by the plaintiff and
10:27:28 15 what the parties agreed to in terms of limited expedited
10:27:33 16 discovery. This is essentially about the plaintiff not
10:27:37 17 accepting the fact that all of the documents that we have
10:27:40 18 identified that are responsive to their requests about
10:27:43 19 pricing --
10:27:44 20 THE COURT: Yeah, but I got to tell you,
10:27:46 21 twenty-one documents, it seems kind of skimpy.
10:27:49 22 MS. BURG: Well, Your Honor, the documents that
10:27:50 23 we've produced are the core documents, like --
10:27:55 24 THE COURT: I just find it hard to believe.
10:27:57 25 This is like an old document you gave me, it says something

10:28:01 1 -- that you gave them, it says something like, you know,
10:28:05 2 something may happen, will happen, but that was, you know,
10:28:10 3 before the CMS tentative approval. I just find it hard to
10:28:16 4 believe that these are the documents and there is not
10:28:20 5 something where people are looking into this more recently.
10:28:23 6 MS. BURG: Your Honor, the consistent plan of
10:28:27 7 Geneoscopy which is still working and we do not yet have
10:28:31 8 final approval of our 508 crosswalked price as well as the
10:28:37 9 inclusion of ColoSense in the NCD CMS recommendation which
10:28:43 10 is required as part of our reimbursement. We are working
10:28:48 11 very hard in our public hearings requesting the 508 price,
10:28:52 12 but to be clear, we have looked for and we are not aware of
10:28:56 13 any plan to discount any plan with --
10:28:59 14 THE COURT: You looked through communications,
10:29:03 15 e-mails, things, correspondence with LabCorp about that?
10:29:06 16 MS. BURG: Your Honor, the parties agreed that
10:29:08 17 we would not do a giant collection of --
10:29:11 18 THE COURT: Yes or no.
10:29:12 19 MS. BURG: We have not reviewed e-mails, that
10:29:15 20 would be a significant burden.
10:29:17 21 THE COURT: I'm not saying go through every
10:29:20 22 e-mail, I'm saying ask the people who are responsible for
10:29:24 23 corresponding with LabCorp, that's different than doing an
10:29:27 24 e-mail dump of ten custodians, something like that.
10:29:31 25 MS. BURG: That investigation has been conducted

10:29:33 1 and we were not able -- our -- we are not aware of any --
10:29:38 2 again, under the terms of the agreement which we did provide
10:29:41 3 to the plaintiff, LabCorp has to come to us before they
10:29:46 4 discount the price. And we have not received any requests.
10:29:49 5 THE COURT: Who would they come to?
10:29:51 6 MS. BURG: Geneoscopy.
10:29:52 7 THE COURT: Yeah, that's a company. Who would
10:29:54 8 they have to come to? Who is responsible for that?
10:29:57 9 MS. BURG: Your Honor, I don't know if the
10:29:59 10 agreement specifically states that person. It's a pretty
10:30:02 11 small company and we have talked to the senior folks there,
10:30:06 12 but we're not aware of the --
10:30:08 13 THE COURT: Can you talk with one of them and
10:30:11 14 find out who it would be that would have this information if
10:30:16 15 LabCorp came to them.
10:30:17 16 MS. BURG: Your Honor, certainly we could do
10:30:19 17 that. But again, ColoSense isn't on the market yet so no
10:30:23 18 one is selling it yet and no one is offering it yet,
10:30:28 19 including LabCorp. So I think that the stage of the
10:30:32 20 discussion as least as far as Geneoscopy is aware, again, we
10:30:37 21 don't have total insight into what LabCorp is doing, we're
10:30:41 22 not aware of any discounts or plan entered into --
10:30:45 23 THE COURT: But someone testified to that under
10:30:48 24 oath so it's not just you saying we're not aware, because I
10:30:52 25 don't know what the scope of your investigation is.

10:30:54 1 MS. BURG: So the witness did explain under oath
10:30:57 2 at the 30(b)(6) deposition which took place on Monday of
10:31:02 3 this week about the percentage discount that LabCorp is
10:31:07 4 permitted to offered under Section 4.2 of the agreement, and
10:31:12 5 that that is the extent to which there is any permissible
10:31:16 6 variation as far as Geneoscopy is aware from the 508
10:31:21 7 crosswalked price.
10:31:23 8 MS. HABERNY: We have not --
10:31:24 9 THE COURT: I don't even know what -- it just
10:31:27 10 seems like you won't accept it because you don't like the
10:31:30 11 number. That's kind of what I'm getting at. I'm not going
10:31:34 12 to make them go through all of their e-mails, so no, that's
10:31:37 13 not appropriate for this limited discovery. They're saying
10:31:43 14 the discount, nobody is selling it so there is no discount
10:31:47 15 at the moment. And to the extent a discount is allowed, the
10:31:51 16 discount is what is in the agreement. Why do you think that
10:31:56 17 a product that is not being sold that doesn't have final CMS
10:32:00 18 approval has a whole bunch of documents about how we're
10:32:05 19 going to price it? If she's saying we don't have them, I
10:32:09 20 can order her to produce them and she says we don't have
10:32:13 21 them, I just am confused.
10:32:15 22 MS. HABERNY: Well, first, Geneoscopy has been
10:32:17 23 out in public saying that it expects to start selling its
10:32:21 24 product in the second half ---
10:32:23 25 THE COURT: And has it said anything about any

10:32:25 1 price other than the $508?
10:32:27 2 MS. HABERNY: In number, no, but there is
10:32:31 3 information --
10:32:32 4 THE COURT: Tell me where it's in the documents
10:32:34 5 other than that one footnote.
10:32:36 6 MS. HABERNY: Well, the 30(b)(6) witness
10:32:38 7 testified about the discounts.
10:32:39 8 THE COURT: What did the 30(b)(6) witness say?
10:32:41 9 You guys are just like summarizing and you don't have a --
10:32:47 10 like, I don't know what the 30(b)(6) witness said. She said
10:32:49 11 that he or she explained it and --
10:32:55 12 MS. HABERNY: Right. He was testifying about
10:32:58 13 Section 4.2 of the agreement which is in Exhibit 6, and that
10:33:07 14 doesn't mention any information on discounts. He said there
10:33:10 15 was one, but didn't give information on how it would be
10:33:14 16 applied.
10:33:14 17 THE COURT: What did he say? Do you have the
10:33:17 18 deposition?
10:33:33 19 MS. HABERNY: While my colleague is finding the
10:33:36 20 testimony, I'll note that with Geneoscopy telling the public
10:33:41 21 it's going to start selling its product in the second half
10:33:44 22 of 2024, which is now, and its plans for early access
10:33:50 23 program to give away its tests for free to start, you know,
10:33:59 24 product uptake among patients, they must be making plans.
10:34:03 25 They must be deciding how they're going to apply the

10:34:07 1 discount. I mean, there has got to be something.
10:34:10 2 THE COURT: Okay. There must be, okay. That
10:34:12 3 doesn't tell me what you want me to ask them to do. There
10:34:16 4 must be is not a -- then she can't make a document. So do
10:34:23 5 you want -- I truly don't know -- is there a reason you
10:34:29 6 think something exist? Did you ask the 30(b)(6) witness,
10:34:32 7 are there documents that show this? Are there documents
10:34:35 8 other than this that show this that you can then point me to
10:34:39 9 because I truly don't know what I can order? I can't say
10:34:42 10 produce all documents. I'm not going to do that.
10:34:52 11 MS. HABERNY: Yeah, so going back to the
10:34:53 12 30(b)(6) witness, he did not provide much information at
10:34:57 13 all.
10:34:57 14 THE COURT: So what was he asked and what did he
10:34:59 15 say?
10:34:59 16 MS. HABERNY: He was asked about the
10:35:00 17 standardless price --
10:35:02 18 THE COURT: No, give me the question and answer.
10:35:04 19 MS. HABERNY: I will. There is a little bit of
10:35:06 20 back and forth in here, so I apologize for that.
10:35:09 21 "QUESTION: And that's the standardless price,
10:35:11 22 right, that does not cover private contract price between
10:35:15 23 LabCorp and entities or between Geneoscopy and other
10:35:20 24 entities, correct?
10:35:21 25 "ANSWER: I don't know.

10:35:22 1 "QUESTION: Okay. You don't know one way or the
10:35:24 2 other whether that's true or not?
10:35:26 3 "ANSWER: I'm sorry. I didn't catch that.
10:35:28 4 "QUESTION: So you don't know one way or another
10:35:31 5 whether that's true or not?
10:35:33 6 "ANSWER: I know that LabCorp is responsible for
10:35:35 7 establishing the standard list price published for the
10:35:38 8 testing offered by LabCorp which is a definition of the list
10:35:42 9 price.
10:35:47 10 "QUESTION: Right. We were talking about
10:35:49 11 standard published list price here, but then I'm asking you
10:35:52 12 about private contract price between LabCorp and another
10:35:56 13 entity or between Geneoscopy and another entity, so you
10:36:00 14 don't know whether that's possibly lower than 500 or not,
10:36:03 15 right?
10:36:03 16 "ANSWER: As previously said, we have no
10:36:05 17 intentions of pricing the test below the CMS rate.
10:36:09 18 "QUESTION: But LabCorp could potentially do
10:36:12 19 that; right?
10:36:12 20 "ANSWER: Section 204.2(a) states that
10:36:16 21 determining when to change -- when to charge less than the
10:36:19 22 standard list price for tests via following fulfillment
10:36:24 23 coverage of coverage milestone in no circumstance will the
10:36:27 24 test be publicly advertised for less than 95 percent of the
10:36:32 25 effective contract reimbursement rate with CMS by

10:36:37 1 Geneoscopy.
10:36:39 2 "QUESTION: Right. But when LabCorp negotiates
10:36:43 3 a contract with another entity, that negotiation does not
10:36:47 4 necessarily need to be public, right?
10:36:50 5 "ANSWER: I don't know. I'm not a LabCorp
10:36:52 6 employee. I didn't draft this agreement."
10:36:55 7 THE COURT: Okay. So I take your point, it was
10:36:58 8 something he didn't know, but he did know and seemed
10:37:01 9 consistent with what counsel said with respect to the list
10:37:06 10 price. My question is, I guess -- I don't even see LabCorp
10:37:11 11 mentioned in this, so why is it that you think you get stuff
10:37:16 12 with LabCorp if LabCorp is going to do the pricing, where
10:37:21 13 did you ask for that?
10:37:23 14 MS. HABERNY: It's Request for Production Number
10:37:25 15 6, which ask for agreements between LabCorp and Geneoscopy,
10:37:40 16 including any steps LabCorp has taken or plans to take to
10:37:43 17 manufacture, distribute, market, offer for sale, sell,
10:37:46 18 and/or use ColoSense or to prepare for the same.
10:37:50 19 THE COURT: And you think that means tell you
10:37:54 20 specifically what discounts on pricing they are thinking
10:37:57 21 about?
10:37:57 22 MS. HABERNY: Yes, because that would be
10:37:59 23 marketing, offer for sale, sell.
10:38:02 24 THE COURT: Okay. Did you produce those
10:38:04 25 documents? What do you do to get those because that does

10:38:08 1 seem to be -- that does seem to be including communications
10:38:13 2 with LabCorp.
10:38:13 3 MS. BURG: Again, Your Honor, I'll start with
10:38:18 4 request number 6, documents sufficient to show.
10:38:20 5 THE COURT: I get it. I'm not going to make you
10:38:23 6 produce all documents.
10:38:23 7 MS. BURG: I appreciate that, Your Honor. We
10:38:27 8 had -- we are not withholding any documents that we have
10:38:31 9 from LabCorp about their planned pricing. I think
10:38:36 10 consistent with what the 30(b)(6) witness was testifying, we
10:38:40 11 have limited insight into -- there may be other -- I mean, I
10:38:44 12 don't want to speculate, but the documents that Geneoscopy
10:38:47 13 has in its possession related to its work with LabCorp and
10:38:51 14 its plan for pricing are all tied to the 508 crosswalked CMS
10:38:57 15 price that we have been asking, which is the same as the
10:38:59 16 price of Cologuard.
10:39:02 17 THE COURT: This is what I am going to do. I'm
10:39:05 18 going to say you have to go back and talk with the people
10:39:08 19 who have communications with LabCorp and ask them is there
10:39:12 20 correspondence, are there discussions, are there documents
10:39:15 21 they have received from LabCorp, are there discussions that
10:39:18 22 they have had with LabCorp, e-mails that they've had with
10:39:21 23 LabCorp that discuss the pricing, the discounts, any
10:39:27 24 discounts they would give or the pricing for private payers
10:39:31 25 that are not available.

10:39:36 1 All right. What else do you think that I
10:39:39 2 missed?
10:39:47 3 MS. HABERNY: So we also have not received any
10:39:50 4 communications between, or any information at all about
10:39:55 5 Geneoscopy's communications and plans with private payers,
10:40:00 6 even if they're separate from LabCorp.
10:40:03 7 THE COURT: Include that if there are any.
10:40:06 8 MS. BURG: Okay. I don't believe we are
10:40:08 9 withholding that, but I will confirm that, Your Honor.
10:40:10 10 THE COURT: Some of these things I understand
10:40:12 11 they may not exist, but I want you to go back and check and
10:40:16 12 talk with people who would know.
10:40:18 13 MS. BURG: Understood, Your Honor.
10:40:47 14 MS. HABERNY: I think that's -- that covers
10:40:51 15 everything that we had for today.
10:40:53 16 THE COURT: All right. Anything else that we
10:40:54 17 need to talk about while we are here?
10:41:05 18 MS. HABERNY: So, Your Honor, there is also an
10:41:11 19 issue, we've probably could get some more of this
10:41:15 20 information including third-party discovery from LabCorp if
10:41:20 21 we had a schedule in place in the course of the regular
10:41:23 22 litigation, so I don't know if Your Honor has considered
10:41:26 23 whether to set a Rule 26 conference or if Your Honor had
10:41:29 24 given any thought to maybe a schedule for the case.
10:41:32 25 THE COURT: Yes, I don't know. I would have to

10:41:34 1 talk with my staff about that. But if it's time for us to
10:41:40 2 set a schedule, we can do that.
10:41:41 3 MS. HABERNY: Thank you.
10:41:42 4 MS. BURG: And Your Honor, we have a motion as
10:41:45 5 well to stay the case that's pending in view of the IPR.
10:41:49 6 THE COURT: Tell me what the status of the IPR
10:41:51 7 is.
10:41:51 8 MS. BURG: So, Your Honor, there are two patents
10:41:53 9 at issue that are also the subject of the preliminary
10:41:56 10 injunction proceeding. In July --
10:41:58 11 THE COURT: There are only two?
10:41:59 12 MS. BURG: There are two total patents, correct.
10:42:02 13 And IPR review has been instituted as to one of the two
10:42:06 14 patents and the other IPR is pending and we're expecting a
10:42:11 15 decision I believe in late January/February.
10:42:13 16 MS. HABERNY: February.
10:42:14 17 MS. BURG: Is about the timing of the potential
10:42:17 18 institution decision.
10:42:18 19 THE COURT: All right. I'm not going to stay it
10:42:21 20 until I know the full scope. So I'm denying that motion to
10:42:27 21 stay with leave for you to refile it once you know. But I
10:42:34 22 don't -- I'm not going to just assume because one patent was
10:42:39 23 instituted the other one will be because, you know, I can't
10:42:44 24 really make a determination as to how much it would simplify
10:42:51 25 the case.

10:42:51 MS. BURG: Your Honor, if I may be heard for a
10:42:54 moment. The two patents are related patents with identical
10:42:56 specifications.
10:42:57 THE COURT: Yeah, but you didn't bring them to
10:42:59 the patent office at the same time. The PTAB hasn't found
10:43:03 on that. If the PTAB does institute on all the claims, you
10:43:08 can refile your motion to stay, but I am not going to stay
10:43:11 this case and I am not going to spend my time dealing with a
10:43:15 motion to stay when I don't know the full extent or scope of
10:43:22 important questions like how much it would impact or
10:43:26 simplify the issues in this case. So it's denied.
10:43:31 Anything else?
10:43:33 MS. HABERNY: No, Your Honor.
10:43:37 MS. BURG: No, Your Honor.
10:43:39 THE COURT: Okay.
10:43:40 COURTROOM DEPUTY: All rise. Court is
10:43:44 adjourned.
(Court adjourned at 10:43 a.m.)

I hereby certify the foregoing is a true and accurate transcript from my stenographic notes in the proceeding.

/s/ Dale C. Hawkins
Official Court Reporter
U.S. District Court