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IN THE UNITED STATES DISTRICT COURT

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FOR THE DISTRICT OF DELAWARE

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EXACT SCIENCES CORPORATION,)

)

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Plaintiff,)

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C.A. No. 23-1319 (MN)

6

v.)

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7

GENEOSCOPY, INC.,)

)

8

Defendant.)

9

10

Friday, November 1, 2024

10:00 a.m.

11

Discovery Dispute Hearing

12

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844 King Street

Wilmington, Delaware

14

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BEFORE: THE HONORABLE MARYELLEN NOREIKA

United States District Court Judge

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APPEARANCES:

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MORRIS NICHOLS ARSHT & TUNNELL LLP

BY: BRIAN EGAN, ESQ.

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BY: DEREK JAMES FAHNESTOCK, ESQ.

21

-and-

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QUINN EMANUEL URQUHART & SULLIVAN LLP

BY: SANDRA HABERNY, ESQ.

23

BY: JIHONG LOU, ESQ.

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Counsel for the Plaintiff

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1 APPEARANCES CONTINUED:

2
3 ASHBY & GEDDES
4 BY: STEVEN J. BALICK, ESQ.

5 -and-

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

8 Counsel for the Defendant

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14 COURTROOM DEPUTY: All rise. The United States
15 District Court for the District of Delaware is now in
09:49:17 16 session. The Honorable Maryellen Noreika presiding.

10:02:42 17 THE COURT: All right. Good morning, everyone.
10:02:45 18 Please be seated.

10:02:50 19 Introductions, Mr. Egan.

10:02:53 20 MR. EGAN: Good morning Your Honor. Brian Egan
10:02:56 21 from Morris Nichols on behalf of the plaintiff, Exact
10:03:00 22 Sciences. Joining me at counsel table this morning is
10:03:05 23 Sandra Haberny and Jihong Lou, both from Quinn Emanuel, and
10:03:09 24 my colleague, Derek Fahnestock.

10:03:12 25 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

1 test being offered by LabCorp and provided once the coverage
2 milestone has been achieved the standard price will not be
3 lower than the reimbursement price established by CMS. And
4 describes another term about the limits on any potential
5 other advertisement of that list price. Again, depending on
6 Geneoscopy obtaining that CMS coverage which hasn't been
7 finalized or achieved yet, but Geneoscopy's submissions or
8 explanations in our opposition to the preliminary injunction
9 and everything else is the goal of getting this final price
10 crosswalked to the final price of ColoSense to CMS.

11 THE COURT: What more do you need?

12 MS. HABERNY: That leads to one of the
13 inconsistencies I was referring to. So if Your Honor looks
14 at Exhibit 4, the page ending in Bates number 481,
15 Exhibit 44 to Exact Sciences' letter, Your Honor will see
16 there, there is a paragraph starting LabCorp strategically
17 motivated and a few sentences down they reference some
18 predictions, some predicted revenue from the test and it
19 refers to footnotes. And these footnotes assume amounts
20 that are far lower per test than the \$503 that Ms. Burg
21 referenced as the CMS rate, so that would be one
22 inconsistency that we've seen and we would like to know how
23 are these numbers generated, what are they planning to do.
24 Because we have seen elsewhere that LabCorp is permitted to
25 give discounts on the test.

1 And in addition, this only references
2 reimbursement by Medicare but not private payers, so private
3 insurance payers frequently negotiate down the price of
4 tests and we have not seen anything in the documents about
5 how they will deal with private payer requests to negotiate
6 down as well as the discounts.

7 THE COURT: Okay. With that, there are
8 different numbers?

9 MS. BURG: Sure, Your Honor. Those numbers were
10 -- we felt -- in our letter, those numbers represent a
11 conservative estimate for revenue that was generated again
12 before CMS crosswalked the price of ColoSense to Cologuard
13 and it was a multiple that was created there. Based on our
14 investigation, there is no pricing plan or other documents
15 where there is any other price discussion or plan to
16 discount, so there isn't a document that further explains
17 the price that relates to the multiplication.

18 THE COURT: There must be something that
19 explains why -- I mean, \$393 a test is a pretty specific
20 number. These are not just random numbers, so there must be
21 something that explains what the basis for that footnote
22 was, right?

23 MS. BURG: Your Honor, my understanding is that
24 it is a conservative revenue estimate that was stated here
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

1 concerned with it being less than, than more than because of
2 your price erosion issue, that's what I don't understand.
3 Your argument to me is I don't believe it because there is a
4 footnote. One thing that you have pointed me to is there is
5 a footnote that says something, so the couple things you
6 pointed me to, one, the footnote, two, LabCorp can give
7 discounts, but you're not getting information from LabCorp,
8 you're just asking the defendant here. And then third, I
9 have no idea what anybody is doing with private pay. And is
10 private pay for LabCorp, is private pay for the defendant,
11 or is private pay for both?

12 MS. HABERNY: Private pay would be insurers, so
13 insurers like maybe United Healthcare or Aetna paying for
14 the test rather than Medicare, and that I think is exactly
15 what we need, we would like documents that are sufficient to
16 show the scope of the discount, the details of the discount,
17 as well as the --

18 THE COURT: Who is giving a discount because my
19 problem is you're kind of mixing the defendant and LabCorp.
20 And maybe they have, I don't know, an e-mail with LabCorp,
21 maybe they have some presentation, but they gave you the
22 agreement. What makes you think that the agreement is not
23 right?

24 MS. HABERNY: Because it does not address the
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

1 and we were not able -- our -- we are not aware of any --
2 again, under the terms of the agreement which we did provide
3 to the plaintiff, LabCorp has to come to us before they
4 discount the price. And we have not received any requests.

5 THE COURT: Who would they come to?

6 MS. BURG: Geneoscopy.

7 THE COURT: Yeah, that's a company. Who would
8 they have to come to? Who is responsible for that?

9 MS. BURG: Your Honor, I don't know if the
10 agreement specifically states that person. It's a pretty
11 small company and we have talked to the senior folks there,
12 but we're not aware of the --

13 THE COURT: Can you talk with one of them and
14 find out who it would be that would have this information if
15 LabCorp came to them.

16 MS. BURG: Your Honor, certainly we could do
17 that. But again, ColoSense isn't on the market yet so no
18 one is selling it yet and no one is offering it yet,
19 including LabCorp. So I think that the stage of the
20 discussion as least as far as Geneoscopy is aware, again, we
21 don't have total insight into what LabCorp is doing, we're
22 not aware of any discounts or plan entered into --

23 THE COURT: But someone testified to that under
24 oath so it's not just you saying we're not aware, because I
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 1 MS. BURG: Your Honor, if I may be heard for a
10:42:54 2 moment. The two patents are related patents with identical
10:42:56 3 specifications.

10:42:57 4 THE COURT: Yeah, but you didn't bring them to
10:42:59 5 the patent office at the same time. The PTAB hasn't found
10:43:03 6 on that. If the PTAB does institute on all the claims, you
10:43:08 7 can refile your motion to stay, but I am not going to stay
10:43:11 8 this case and I am not going to spend my time dealing with a
10:43:15 9 motion to stay when I don't know the full extent or scope of
10:43:22 10 important questions like how much it would impact or
10:43:26 11 simplify the issues in this case. So it's denied.

10:43:31 12 Anything else?

10:43:33 13 MS. HABERNY: No, Your Honor.

10:43:37 14 MS. BURG: No, Your Honor.

10:43:39 15 THE COURT: Okay.

10:43:40 16 COURTROOM DEPUTY: All rise. Court is
10:43:44 17 adjourned.

18 (Court adjourned at 10:43 a.m.)

19

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

22

22 /s/ Dale C. Hawkins
23 Official Court Reporter
24 U.S. District Court
25