

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEOSCOPY, INC.,

Petitioner,

v.

EXACT SCIENCES CORPORATION,

Patent Owner.

IPR2024-00459
Patent 11,634,781 B2

Record of Oral Hearing
Held: May 1, 2025

Before RYAN H. FLAX, DAVID COTTA, and
JAMIE T. WISZ, *Administrative Patent Judges*.

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The above-entitled matter came on for hearing on Thursday May 1, 2025, commencing at 1:00 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

P R O C E E D I N G S

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USHER: All rise.

JUDGE FLAX: Please be seated. Good afternoon, everyone.

MR. JONES: Good afternoon.

MS. HABERNY: Good afternoon.

JUDGE FLAX: Bear with us for just a moment while we get our computers going and your record in front of us. Okay. Okay. Before we get fully started, I did have one question for housekeeping matters for y'all. We've got one exhibit in this case, 1025, Petitioner's exhibit, which was filed Board and parties only. But I think that's a mistake. It doesn't seem to be confidential in any way. There's no motion to seal. I think maybe just the wrong button might have been hit when it was filed.

MR. JONES: Yeah, the -- we, Your Honor, we have no confidential information in any of our exhibits.

JUDGE FLAX: Okay. Yeah, I mean, it's a public article, a published thing, that we'll just switch it to general availability.

MR. JONES: Thank you.

JUDGE FLAX: Okay. Now that that's over with. So, we are here in IPR2024-00459. That is Geneoscopy, Inc. Petitioner v. Exact Sciences Corporation as Patent Owner. And it concerns U.S. Patent 11,634,781. We're here in final oral argument in this IPR. Up until now, you've had Judge Tina Hulse sitting in my chair. I am Judge Ryan Flax taking over for her. We also have Judges Wisz and Cotta on the Panel.

If the parties are ready. If y'all could introduce yourselves and anyone that you have with you, get that on the record, starting with the Petitioner.

1 MR. JONES: Your Honor, my name is Brendan Jones. I'll be arguing
2 on behalf of Geneoscopy, the Petitioner. With me here today is my partner,
3 Donald Ware, and my partner, Sarah Burg.

4 MS. BURG: Good afternoon.

5 JUDGE FLAX: Good afternoon.

6 MS. HABERNY: Good afternoon, Your Honors. My name is Sandra
7 Haberny. I'm here on behalf of the Patent Owner, Exact Sciences. Also
8 with me is Anastasia Fernands. And we have Andrew Bramhall of Quinn
9 Emanuel. Anastasia and Andrew are from Quinn Emanuel. Jihong Lou,
10 also from Quinn Emanuel. And we have four representatives from Exact
11 Sciences. We have Carly Conway, Alexandra Gorman, Savojini Adumusili,
12 and Jennifer Duke. Thank you.

13 JUDGE FLAX: Your last name, one more time, ma'am.

14 MS. HABERNY: Haberny, H-A-B --

15 JUDGE FLAX: Haberny.

16 MS. HABERNY: -- E-R-N-Y.

17 JUDGE FLAX: Thank you very much. Okay, so, I appreciate you all
18 being here in person. I prefer that very much to remote. I think that's the
19 future of our hearings. So, welcome to the future. Everyone has requested
20 60 minutes of argument, if I'm correct, and each party can reserve time for
21 rebuttal. We'll keep your time on the clock, right behind me, which is set to
22 60 minutes. We'll adjust it when y'all get up and argue based on how much
23 time you want to reserve.

24 So, Mr. Jones, you will open as a Petitioner. How much time would
25 you like to reserve for rebuttal, if any?

26 MR. JONES: Fifteen minutes, please.

1 JUDGE FLAX: Okay. You are not obligated to stop at 45 minutes.
2 It is your time, but it will count against the time you have later.

3 MR. JONES: I understand. Thank you.

4 JUDGE FLAX: And if something goes wrong up here, like I forget to
5 hit the button and you all start arguing, yell at me, please, so I can start it.
6 It's happened in the past. Okay, Mr. Jones, you can begin when you're
7 ready. We are very familiar with your record, and we have it in front of us.
8 So, as you go -- are you using the monitor for anything? MR. JONES: I
9 will be, Your Honor. I'm just --

10 JUDGE FLAX: Okay. Well, I can see it. I don't know if Judge Wisz
11 can see it, but it's not absolutely critical. We do have your demonstratives,
12 so we will be able to follow along. Which kind of goes to the point I was
13 making. As you are flipping through your slides, for the record, if you
14 would identify, please, what slide you are referring to so that we can have a
15 full and complete transcript. Also, when you are referring to evidence,
16 please identify the exhibit number, if you will. That will also help a lot with
17 the transcript. And if you're talking about any paper, like your petition, or
18 your reply, or the response, identify what it is. You don't need to say the
19 paper number. We've got that. But if you just tell us what you're talking
20 about and what page you're talking about, that would be very helpful to us
21 for the final transcript. So, when you're ready, I'll start your time and -- yes,
22 ma'am.

23 MS. HABERNY: Sorry for the interruption. Patent Owner brought
24 two boards with the claims on them, and Petitioners requested that we
25 remove them during their argument. May we approach?

26 JUDGE FLAX: Is this them?

1 MS. HABERNY: Yes, may we approach to remove them?

2 JUDGE FLAX: Sure, you can remove them. I mean, I don't know
3 that it's going to make a difference, but --

4 MS. HABERNY: It was the request.

5 JUDGE FLAX: Sure. It might make the screen easier to see, so that's
6 fine.

7 MR. JONES: Your Honors, you don't want a hard copy of the
8 demonstratives, or would that be helpful?

9 JUDGE FLAX: I don't, but we may have clerks in the room that
10 might find it helpful. I don't know if we do. Would you all like --

11 SPEAKER: Sure.

12 JUDGE FLAX: -- hard copies? Do you want a hard copy? I don't.
13 We have everything electronically, so we don't need any hard copies.

14 MR. JONES: Okay. I'm ready to go when you are.

15 JUDGE FLAX: You're going.

16 MR. JONES: Okay. Good afternoon, Your Honors. As we've
17 introduced ourselves, I'm Brendan Jones. I'm arguing on behalf of the
18 Petitioner, Geneoscopy, today. And with me here today is my partners Don
19 Ware and Sarah Burg.

20 I'm moving to slide 4 of the demonstratives. In this proceeding,
21 Geneoscopy has challenged the validity of all claims of U.S. Patent
22 11,634,781. The '781 Patent is from a family claiming priority to a
23 provisional application filed in 2009 by the Belgian company
24 OncoMethalome. The OncoMethalome patent family was acquired by Exact
25 Sciences in 2017. Acquisition acquired three years after Exact launched its
26 Cologuard product. At the time, no patents had issued from this family yet.

1 The application that actually gave rise to the '781 Patent was not filed until
2 2022 and issued in 2023. It was the first patent to issue from this family.

3 On slide 5, the challenged claims of the '781 Patent are directed to the
4 performance of two prior art fecal assays. Both assays are being performed
5 for their intended purpose, which is to detect colorectal cancer. The results
6 achieved by combining these assays is entirely predictable. Indeed, Exact
7 does not argue for unexpected results in this proceeding.

8 Independent claim 1 broadly claims a sample processing method in
9 which a fecal sample is divided into two portions and placed in two buffers,
10 one for stabilizing fecal proteins and one for stabilizing fecal DNA. The
11 '781 Patent acknowledges that both types of buffers recited in the claim were
12 known in the art and commercially available. Claim 3 is directed to the
13 performance of a routine fecal blood protein test on the first of these samples
14 and a routine DNA test on the second.

15 Moving to slide 6. The first of these routine prior art tests is an
16 immunochemical fecal occult blood test, or iFOBT, which is also known as
17 a fecal immunochemical test, or F-I-T, or FIT. The terms iFOBT and FIT
18 are used interchangeably throughout the art.

19 JUDGE FLAX: Counsel, for the purposes of this case, can you walk
20 me through the differences, the practical differences, for your case, between
21 the gFOBT test and the iFOBT test?

22 MR. JONES: Certainly. So, I'll just do it without a demonstrative.
23 So, gFOBT tests and iFOBT tests are both fecal tests that detect blood,
24 human blood, or blood in feces. They use different biochemistries in order
25 to do so. So, the gFOBT test uses a chemistry that detects heme and other
26 peroxidizing chemicals, which means that it detects not only human blood in

1 the feces but also detects other components of food. The iFOBT test, on the
2 other hand, detects -- uses antibodies that are specific for human
3 hemoglobin. So, these tests can only detect human hemoglobin and so they
4 don't suffer from specificity issues with respect to contaminating food. So,
5 for practical purposes, the iFOBT test, because it's specific for human
6 hemoglobin, doesn't require any dietary restrictions that the patient needs to
7 undergo in order to use the test. The gFOBT requires these dietary
8 restrictions to avoid cross contamination with other components in the food.

9 The other difference between the tests is more of a practical, how
10 these tests are -- how the samples are obtained in these tests. In the gFOBT
11 test, the traditional method of receiving it, if you take a wooden spatula --
12 sorry, it's going to get a little ugly here. Smear, pick up pieces of portions of
13 fecal matter, and then smear it in three places on a -- make three smears of
14 the fecal matter onto a card that is then used to detect the reaction of the
15 gFOBT. The iFOBT test, the way it works is it has a tube that contains a
16 hemoglobin stabilizing buffer in it and a cap with a probe on the end. And
17 so, the user takes the cap of the tube, pokes it into the feces and puts it into
18 the fecal into the tube. So, the feces gets mixed with the buffer. And then
19 that tube is just shipped off to a lab where automated desktop instrument just
20 reads the amount of hemoglobin in the test.

21 JUDGE FLAX: So, there's no real opportunity with the gFOBT to
22 utilize any kind of stabilizing buffer?

23 MR. JONES: Typically, gFOBT tests do not involve the use of a
24 stabilizing buffer. The iFOBT test universally involved the use of the
25 stabilizing buffer.

26 JUDGE FLAX: Okay, thank you.

1 MR. JONES: So, I'll just mention that, on slide 6, that an example of
2 one of these iFOBT tests is in the Vilkin reference, which is Exhibit 1005.

3 On slide 7. The second of these prior art tests is the fecal DNA tests.
4 These tests detect DNA biomarkers in a patient at-home collected fecal
5 sample. Such tests are disclosed in Itzkowitz and Shuber.

6 Slide 8. When both of these prior tests are performed on a fecal
7 sample that results in the performance of the challenged claims. The iFOBT
8 test and the DNA tests use different buffers to stabilize their respective at-
9 home collected fecal samples for transport to a diagnostic laboratory. When
10 both tests are performed on the sample, the sample is partitioned by the
11 patient so each portion of the sample can be preserved in its own biomarker-
12 specific buffer. This need to partition the sample also follows from the fact
13 that different portions will need to be tested using different instruments.

14 Moving to slide 9. Indeed, partitioning fecal samples by a patient
15 using different stabilizing buffers for delivery to a diagnostic laboratory had
16 been done for decades by 2009. For example, such a partitioning step can be
17 seen in this figure from a 1985 CDC laboratory manual, which the authors
18 state is adopted from a 1949 publication. This figure is from Exhibit 1026,
19 the Melvin reference. And on page 9 of the Melvin reference, it specifically
20 says that the patient should be instructed to pass a specimen into a dry
21 container under paper, then transfer a portion of the stool to vials of
22 preservative and then mix thoroughly, demonstrating that this is actually
23 what -- these steps are actually what the patient is doing in this manual.

24 JUDGE FLAX: Why are there two vials in that situation?

25 MR. JONES: So, in this case, this is from decades ago, so there's no
26 DNA tests at this time. These two preservatives are related to detecting

1 different parasites in fecal specimens. So, one preservative is for one type of
2 parasite and the other for another type of parasite.

3 Slide 10. I'd like to now focus the Panel's attention on ground 1,
4 which concerns a combination of Lenhard, Itzkowitz and Vilkin. Slide 11 so
5 Lenhard is an example of a prior art publication that describes a combined
6 performance of a fecal DNA test and the FOBT. In the Lenhard study, a
7 fecal sample was collected before a patient underwent colonoscopy or
8 surgery and received a diagnostic laboratory within 10 hours of defecation.
9 At the laboratory, a portion of the fecal sample was removed and a guaiac
10 FOBT or gFOBT test was performed, as we discussed.

11 The DNA was then isolated from the remaining portion of the sample
12 and tested for a DNA methylation biomarker called HIC1, on slide 12.
13 Now, the Patent Owner in this case argues that Lenhard does not disclose a
14 combined test but merely compares the fecal DNA test with a FOBT. This
15 is demonstrably not the case. As you can see here, looking at Table 4 from
16 Lenhard, Lenhard compares three methods for detecting colorectal cancer an
17 HIC1 DNA methylation assay alone, which is in the left columns, a FOBT
18 alone, which is in the center columns, and a combined test that includes both
19 the DNA methylation and the FOBT test, which is in the right column.
20 Lenhard repeatedly compares the combined test with each individual test
21 and in fact concludes that the combination of both assays resulted in
22 increased defecation rates -- detection rates of colorectal cancers.

23 Indeed, the improved sensitivity of the combined assays was
24 substantial, as you can see from this table. The DNA methylations test
25 sensitivity for colorectal cancer was only 42 percent and the sensitivity of
26 the FOBT was even worse at 35 percent. When both tests were used

1 together, the sensitivity of the combined test was raised by over 20
2 percentage points up to 65 percent. Lenhard never disparages the combined
3 assay, quite the contrary. Patent Owner's arguments regarding the lack of
4 motivation to combine Lenhard's DNA test with the FOBT tests are a red
5 herring. Lenhard already combines these tests and discloses the improved
6 sensitivity of the combined assay.

7 The Importance of higher sensitivity -- oh, I'm on slide 13. The
8 importance of higher sensitivity of the combined test is illustrated in Table 1,
9 which provides Lenhard's test results for individual patients who have
10 cancer. As can be seen from the results highlighted in yellow in this table,
11 many cancer patients who test positive for Lenhard's DNA methylation test
12 falsely test negative with the FOBT. The cancer in these patients would go
13 undetected and the patients themselves untreated if only the FOBT test were
14 used to test them.

15 Highlighted in blue are other patients who test positive for the FOBT
16 but falsely test negative for the DNA methylation test. The cancer in these
17 patients would go undetected and the patients untreated if only the DNA
18 methylation tests were used. These results in Lenhard therefore demonstrate
19 that the DNA test catches cancer in patients as missed by the FOBT and vice
20 versa, highlighting the importance of testing for both types of biomarkers.
21 This is also not surprising. If you have one test that detects certain instances
22 of cancer and another test that detects other instances of cancer, then of
23 course, when you perform both tests, you will catch more instances of
24 cancer than either one alone. It also illustrates the critical importance of
25 sensitivity for fecal colorectal cancer tests. Minimizing false negatives is of

1 primary importance in such assays because each false negative is a patient
2 who will likely not receive treatment and could very well die.

3 Slide 14. By the priority date, these advantages of the combined DNA
4 and FOBT assays were also reinforced in the art. So, in one example,
5 Nishikawa is a paper reporting a particular fecal DNA assay and then notes
6 that the DNA assay should provide a more sensitive and specific tool for
7 mass screening of CRC over existing assays, especially if used in
8 combination with FOBT.

9 Then we have Levin, which is on the right side of this slide. In Levin,
10 when discussing the fecal DNA tests, notes that it is worth investigating
11 whether including a gFOBT or FOBT with a DNA test at the time of testing
12 would improve sensitivity without adversely affecting specificity. Levin
13 then cites to a paper by Kutzner et al., to support the value of such a
14 combination.

15 JUDGE FLAX: Counsel, one question about Levin.

16 MR. JONES: Yes?

17 JUDGE FLAX: Is an FIT test the same as an iFOBT test? Is it just
18 using a different acronym?

19 MR. JONES: Yes. I also --

20 JUDGE FLAX: Just putting immune in a different spot?

21 MR. JONES: Oh, I'm sorry.

22 JUDGE FLAX: Is that right?

23 MR. JONES: Yes, iFOBT and FIT are interchangeable terms for the
24 same test. So, the record does get a little confused because different papers
25 refer to it as different things, but they're the exact same thing.

1 So, slide 15. So, Kutzner is a reference like Lenhard, which examines
2 a combined FOBT and fecal DNA test, which Kutzner refers to as a
3 molecular diagnosis test. Also like Lenhard, Kutzner's results show that the
4 combined FOBT and fecal DNA tests resulted in an overall sensitivity that
5 could not be achieved by any of the methods alone. Based on this, Kutzner
6 expressly suggests that the MD, which is the DNA test, and FOBT should
7 complement rather than replace each other. The scientists in Kutzner
8 therefore recognized that the combined assay's advantages outweigh the
9 associated disadvantages. I note that Exact has not identified any references
10 that expressly discourages the combined combination of these assays.

11 I'm on slide 16. While recognizing the value of Lenhard's combined
12 assay, a person of skill in the art would also recognize there are aspects of
13 the assay that are ripe for improvement. For example, Lenhard's fecal
14 sample was delivered to the laboratory within 10 hours of defecation,
15 making it impractical for at-home sample collection followed by shipment to
16 a lab. A person with skill in the art would recognize, however, that there are
17 readily available solutions to this problem. For example, Itzkowitz teaches
18 that at-home sample collection of fecal DNA assays can be facilitated using
19 a DNA stabilizing buffer, while Vilkin teaches that at-home collection for
20 FOBT can be facilitated using a hemoglobin stabilizing buffer. Vilkin also
21 teaches numerous advantages of the automated iFOBT to detect fecal blood.
22 These features were shown to improve the tests of Itzkowitz and Vilkin and
23 would have been obvious that these features could also improve the tests of
24 Lenhard in the same way.

1 Slide 17. When Itzkowitz's sample collection process and Vilkin's
2 iFOBT are incorporated into Lenhard's combined assay, the resulting
3 obvious process meets all the limitations of the challenged claim.

4 Now, I'm jumping to slide 19. As I mentioned, a person of skill in the
5 art would be motivated to use Itzkowitz's sample collection process based on
6 the express teachings in Itzkowitz and the art. As you may recall, Lenhard's
7 receipt of the fecal sample in the laboratory was within 10 hours of
8 defecation, making at-home collection impractical. Itzkowitz, on the other
9 hand, teaches that adding the DNA stabilizing buffer was shown to prevent
10 DNA degradation for several days and resulted in a better screening test.

11 Olson, an earlier Exact paper that is cited by Itzkowitz emphasizes
12 that using a stabilizing buffer mitigates loss of DNA to maximize clinical
13 sensitivity of fecal DNA assays. A person of skill in the art would therefore
14 incorporate Itzkowitz's sample collection process into Lenhard's assay in
15 order to provide a patient with the convenience of at-home collection while
16 maximizing assay sensitivity.

17 I'm moving ahead to slide 21. We've discussed this a little bit, but
18 Vilkin expressly teaches advantages of using its iFOBT over gFOBT like the
19 one that was used in Lenhard. As we discussed, gFOBT suffer from the
20 deficiency in that it's not specific for human hemoglobin which makes it so
21 there's a requirement for dietary restrictions prior to testing. iFOBT, on the
22 other hand, are hemoglobin specific, which makes it so that there aren't such
23 dietary restrictions. Vilkin expressly notes that gFOBT are faulted for low-
24 sensitivity and non-specificity for human hemoglobin and require these
25 dietary restrictions. Also, because Vilkin's iFOBT is quantitative, physicians

1 can choose an optimal hemoglobin threshold level to trigger a follow-up
2 colonoscopy.

3 Going to slide 22. The iFOBT sample collection process is also more
4 convenient than the gFOBT process which, as we mentioned, requires
5 patients to smear multiple fecal samples onto a card using a wooden spatula.
6 For example, Young, a 2007 review article states that FIT technology, which
7 is another word for iFOBT, simplifies the testing process, removes the need
8 for diet and drug restrictions, provides a preferred and more acceptable stool
9 sampling methodology such as brushes or probes rather than wooden
10 spatula, and is achievable while collecting fewer fecal samples. Young
11 concludes that iFOBT overcome most of the disadvantages presented by
12 gFOBT, are superior to gFOBT in forms of participation as well as
13 performance, and should replace gFOBT in two-step screening. Similarly,
14 these advantages are confirmed in another 2007 paper, Guittet, which
15 expressly suggests it is time to give colorectal cancer screening a new future
16 by using iFOBT instead of gFOBT.

17 Moving to slide 23. So, in short, Lenhard discloses a combined fecal
18 DNA and FOBT test with an improved ability to detect colorectal cancer
19 compared to when either assay is performed alone. The art expressly
20 suggests incorporating the known fecal colorectal cancer assay
21 improvements disclosed in Itzkowitz and Vilkin into the types of assays used
22 in Lenhard and doing so results in the fecal processing method of the
23 challenged claims.

24 The challenged claims therefore amount to the routine application of
25 known fecal analysis methods according to their intended purpose, yielding
26 expected results, and are therefore obvious. Patent Owner's response

1 attempts a scattershot attack on the strong motivations to combine that are
2 expressly and repeatedly set forth throughout the references themselves and
3 the contemporaneous literature. None of Exact's arguments rise to the level
4 of teaching away. When the art is considered as a whole, Exact's piecemeal
5 attack simply cannot overcome the extensive and express teachings of the
6 references that would motivate a person of skill in the art to arrive at the
7 method of the challenged claims.

8 So, I'm on slide 24. So, one example, in one example, Exact argues
9 that a person of skill in the art would disregard Lenhard's repeated teachings
10 regarding the better detection rates of its combined assay because in its final
11 paragraph Lenhard also proposes looking at additional DNA methylation
12 markers. Exact's argument does not hold up. The fact that in its final
13 paragraph Lenhard suggests looking for additional potential DNA
14 methylation markers does not erase the fact that in four other places Lenhard
15 highlights that the combined test is better at detecting cancer than either
16 assay alone. A reference can provide more than one motivation. And
17 Lenhard provides motivation to both use the combined test and to look for
18 additional DNA methylation biomarkers.

19 Even if a person of skill in the art believed that using the combined
20 test was not the best option, a position with which we vehemently disagree,
21 Exact's argument still fails. Exact's argument is based on an erroneous legal
22 standard. The Federal Circuit precedent does not require that the motivation
23 be the best option available, just that it be a suitable option from which the
24 prior art does not teach away. Lenhard clearly discloses that the combined
25 test is a suitable option from which it never teaches away, and this legal
26 error pervades many of Exact's motivation arguments.

1 Moving to slide 25. Exact's argument that a person of skill in the art
2 would not be motivated to combine fecal DNA tests with FOBT because of
3 reduced specificity also does not have merit. First, Exact argument ignores
4 that Lenhard already discloses the combined fecal DNA test and FOBT tests.
5 No further motivation to combine these tests is required. It also ignores that
6 while Lenhard repeatedly extols the improved sensitivity of the combined
7 test, Lenhard never even mentions reduced specificity. Lenhard never
8 disparages its specificity of the combined test with which you could
9 calculate from the tables was 89 percent. This is not surprising because a
10 person skilled in the art would be more than willing to sacrifice some
11 specificity in a fecal diagnostic assay for the significant increase in
12 sensitivity observed in Lenhard's combined assay. Exact acknowledged this
13 in a paper where he reported the results of his Cologuard clinical trial, which
14 is Imperiale, which is Exhibit 2008, where it noted sensitivity is the most
15 important characteristic for screening tests because the primary role of such
16 testing is to rule out diseases such as cancer.

17 Now, in the context of colorectal cancer screening, this preference for
18 sensitivity over specificity makes perfect sense. That's because fecal
19 colorectal cancer screening are used as part of a two-step screening process.
20 If a patient tests positive for colorectal cancer, they then have a colonoscopy
21 to confirm this positive result. Any false positives from the colorectal
22 cancer test will be caught in the second routine diagnostic procedure. On the
23 other hand, there's no safety net in place to catch false negative results.
24 Lower sensitivity means more false negatives, more undiagnosed patients
25 with cancer, and ultimately more patient deaths. This is why in Itzkowitz,
26 which is an Exact paper prepared by Exact, Exact characterized a version of

1 its test that had a similar increase in sensitivity and a loss in specificity to the
2 Lenhard's combined assay as a better screening test than its predecessor.
3 Notably, this better screening test used the exact same biomarker panel as
4 the previous version of the test. So, the improvement Exact is referring to is
5 not due to reduced assay cost and complexity.

6 This is also why in the same paper, Exact considered a later version of
7 this test that had only 82 percent specificity but showed an even higher
8 sensitivity as yet a further improved version. That a person of skill in the art
9 would not consider the 89 percent specificity of Lenhard's combined assay
10 to be acceptable is further evidenced by the fact that Exact reports a
11 specificity of below 87 percent for its commercial Cologuard product in the
12 Imperiale paper, Exhibit 2008.

13 Finally, the false positives that give rise to the 89 percent specificity
14 in the combined Lenhard test are almost exclusively from the gFOBT test
15 portion of the test. This therefore provides just further motivation to replace
16 the gFOBT with Vilkin's more specific iFOBT. Vilkin's iFOBT had a very
17 high specificity of over 95 percent, so any specificity loss associated with
18 combining it with a DNA test would be minimal.

19 I am jumping ahead to slide 28. So, in its sur-reply, Exact misreads
20 Vilkin to argue for the first time that it would be impossible to improve the
21 sensitivity of Vilkin because he already had perfect sensitivity. Exact,
22 making this argument, ignores that the experiment performed in Vilkin only
23 six patients with colorectal cancer were tested. The fact that on one day six
24 of six samples tested positive for the product -- is a product of small sample
25 size does not mean that Vilkin had perfect sensitivity as asserted by Exact.

1 On another day the Vilkin assay correctly identified as positive four of six
2 samples. On another one it was five of six.

3 In fact, a person of skill in the art would know that the Vilkin test
4 could not achieve perfect sensitivity because the assay detects fecal blood
5 and colorectal cancer tumors do not always bleed. Thus, even if the Vilkin
6 test had perfect sensitivity for human blood, it would not have perfect
7 sensitivity for cancer. Exact is also looking at this question of motivation
8 backwards with this argument. The issue here is whether a person of skilled
9 art would replace the gFOBT of Lenhard with the iFOBT of Vilkin. Vilkin's
10 relatively high sensitivity only serves to further motivate that replacement.
11 Exact makes the same mistake with regard to the Itzkowitz reference, that
12 Itzkowitz was able to increase its density by, among other things, adding
13 DNA stabilizing buffer would only motivate a person of skill in the art to
14 use the same strategy in Lenhard.

15 Exact also argues that a person skilled in the art would not be
16 motivated to combine fecal DNA tests with FOBT because Lenhard does not
17 show that adding an FOBT test improves sensitivity for adenomas. Exact's
18 argument once again has multiple flaws. First of all, Lenhard already
19 discloses the combined fecal DNA and FOBT tests, so no further motivation
20 to combine such tests is required. Second, the fact that the combined test is
21 equally sensitive for advanced adenoma does not detract from the fact that
22 the combined test is more -- is significantly better at detecting cancer. As of
23 the priority date, the primary focus of fecal tests was cancer detection. This
24 can be seen in that Levin 2008 CRC guideline paper, which is Exhibit 1013,
25 which note that at the time the fecal tests were primarily effective at
26 identifying colorectal cancer and further that detecting adenomas is not the

1 primary goal of colorectal cancer screening with these tests. Indeed, when
2 Exact themselves were evaluating versions of its own fecal DNA test in
3 Itzkowitz, it did not even bother to assess their sensitivity for adenomas.
4 They based it completely on their sensitivity for cancer.

5 Slide 30. Exact's argument concerning cost and complexity of
6 Lenhard's combined test is also unavailable -- also unavailing. Once again,
7 Exact's argument misses the point. Lenhard discloses a combined fecal
8 DNA and FOBT tests, so the question is not whether a person with skill in
9 the art would be motivated to combine these tests, but whether a person with
10 skill in the art would be motivated to incorporate the sample collection
11 process of Itzkowitz and the iFOBT of Vilkin into this combined assay. As
12 we've already discussed, the answer to that is yes. Moreover, incorporating
13 the teachings of Itzkowitz and Vilkin served to improve patient convenience
14 by facilitating the at-home sample collection in a simpler FOBT sample
15 collection device. Despite numerous prior art references discussing
16 combining fecal DNA tests with FOBT tests, none mention added cost and
17 complexity as a detriment.

18 Notably, the fact that DNA tests are significantly more expensive than
19 FOBT. So, in Young when it, in the paper Young et al., it reports that the
20 Exact fecal DNA test was \$400 each where the iFOBT and GFOBTs were
21 each under \$30 each. That does not stop the DNA tests from being
22 developed. People are willing to pay a premium for a better test.

23 Finally, I note that FOBT tests were commonplace, commercially
24 available, and relatively inexpensive, especially when compared to fecal
25 DNA test. The cost and complexity associated with simply adding such a
26 routine commercially available test to fecal DNA test was insignificant,

1 particularly when compared to the alternative of launching a research effort
2 to identify new, sensitive, and specific fecal DNA biomarkers and then
3 developing the assay to test such new biomarkers.

4 On slide 31. Exact makes an additional argument that a person of
5 skill in the art would not be motivated to separately provide preserve fecal
6 DNA in DNA stabilizing buffers in blood protein -- in blood protein, sorry.
7 Motivated to preserve separate sample -- preserve a fecal sample in DNA
8 stabilizing buffers in blood protein stabilizing buffers because there might
9 exist a buffer that stabilizes both. This argument, quite frankly, strings
10 credulity. As of the priority date, different buffers were widely used to
11 stabilize DNA and protein.

12 Notably, Geneoscopy's expert Dr. Whitney, who personally helped
13 develop and test the DNA stabilizing buffer used Itzkowitz, explained that
14 DNA stabilizing buffers were designed -- that stabilizing buffers were
15 designed to be specific for the type of biomarker being used. Indeed,
16 whereas, DNA stabilizing buffers and protein stabilizing buffers were
17 routinely used by the priority date, including in Itzkowitz and in Vilkin,
18 there is no evidence in the record that buffers suitable for stabilizing both
19 DNA and protein were known as of that date. Exact's own expert, Dr.
20 Backman, does not opine that they were. Tellingly, to this very day, Exact
21 uses two different stabilizing buffers in its Cologuard test, despite the
22 supposed convenience that would be gained by using only one.

23 Moving to slide 32. The fact is, by the priority date it had been
24 standard practice for decades to separate a fecal sample for storage and
25 transport into biomarker specific buffers, as seen in the CDC laboratory
26 manual from 1985. I'm now going to, unless Your Honors have specific

1 questions, I'd like to focus on secondary considerations, if that would be
2 okay.

3 JUDGE FLAX: It's fine with me. Do you have any questions?

4 MR. JONES: Okay.

5 JUDGE FLAX: Go ahead.

6 MR. JONES: I would now like to direct the Board's attention to the
7 issue of secondary considerations and in particular to the evidence of nexus.
8 Exact argues that the non-obviousness of the challenged claims is supported
9 by secondary considerations associated with its Cologuard product.
10 However, as the Federal Circuit has made abundantly clear, evidence of
11 secondary considerations must have a proven nexus to the claims. And it is
12 the Patent Owner, Exact, that has the burden of proving nexus. Exact has
13 not met this burden. Tellingly, in the Patent Owner response, Exact did not
14 even refer to nexus when arguing secondary considerations.

15 Slide 44. Exact argues in its sur-reply for the first time that it is
16 entitled to a presumption of nexus with respect to claim 3. Exact does not
17 argue that claim 1 is entitled to such a presumption and does not attempt to
18 show that Cologuard even embarrassed bodies any of the other 20 claims are
19 challenged. As noted, it is the Patent Owner's burden to prove that it is
20 entitled to a presumption of nexus. To do so, Exact would need to prove that
21 its Cologuard product both embodies the claimed features and is coextensive
22 with them. Exact has not met this burden.

23 At best, Exact has provided evidence that claim three broadly covers
24 Cologuard. However, as the Federal Circuit explained in Fox Factory and
25 confirmed in Teva versus Lilly, such a showing is insufficient to meet the
26 coextensiveness requirement. Rather, to meet the coextensiveness

1 requirement, what is required is the Patentee must demonstrate that the
2 product is essentially the claimed invention. This requirement, of course,
3 makes intuitive sense. An invention is very likely to be the cause of
4 secondary considerations associated with a product if that product is
5 essentially the claimed invention.

6 On the other hand, if the product includes other critical features that
7 are not claimed by the patent in question, then one cannot infer that the
8 success of the product is the result of the claimed invention rather than an
9 unclaimed feature or some combination of the two. In such a case, the
10 presumption of nexus is unavailable and a Patent Owner must prove that the
11 secondary considerations are a direct result of the unique characteristics of
12 the claimed invention.

13 Slide 45. In Fox Factory, the Federal Circuit also explained that a
14 patent claim is not coextensive with a product that includes a critical
15 unclaimed feature that is claimed by a different patent and that materially
16 affects the product's functionality. Thus, the Federal Circuit held where a
17 product embodies the claims of two patents, a presumptive nexus can be
18 appropriate only if the claims from both patents generally cover the same
19 invention. So, for example, in Fox Factory, this presumption of nexus was
20 not available when the commercial product was also covered by a related
21 patent that had claims that are substantially similar but incorporated an
22 additional feature.

23 Slide 46. On its webpage, Exact admits that Cologuard does not
24 simply embody the claims from two patents, but asserts that Cologuard
25 practices more than 60 patents unrelated to the challenge patent. That these
26 patents cover Cologuard is not simply an allegation of Geneoscopy. Exact

1 lists these patents on its website as covering Cologuard to provide notice to
2 potential infringers under the marking requirement.

3 Slide 47. These unrelated patents cover a vast array of Cologuard
4 features that materially impact Cologuard's functionality.

5 JUDGE FLAX: Counsel?

6 MR. JONES: Yes.

7 JUDGE FLAX: The first column there, identifying claimed subject
8 matter.

9 MR. JONES: Yes?

10 JUDGE FLAX: How did you come up with that list?

11 MR. JONES: Our expert reviewed each of the patents and determined
12 the general subject matter of what they covered. Our expert, as he
13 acknowledged in his deposition, he did not go through each one of these to
14 confirm that it actually covered Cologuard. He took Exact's word for it on
15 the webpage. I don't know if that would have been possible, given some of
16 the confidential aspects of Cologuard's composition.

17 JUDGE FLAX: Okay.

18 MR. JONES: Okay. That these patents cover a vast array of
19 Cologuard features that materially impacts Cologuard's functionality. These
20 patents cover a vast array of features that materially impact Cologuard's
21 functionality. They're not directed to the same invention of the challenge
22 patent. This basis alone is sufficient to preclude a presumption of nexus. It
23 cannot be presumed that any secondary consideration associated with
24 Cologuard is a product of the features of the claims of the '781 Patent rather
25 than one or more of the features claimed by these dozens of other patents.

1 Slide 48. For example, and this is, what I put up here is the Cologuard
2 physician's brochure, which is Exhibit 1081. For example, Cologuard tests a
3 Panel of 11 molecular markers selected from three independent categories of
4 biomarker type. Claim 3, on the other hand, merely recites the detection of
5 an amount of a human nucleic acid. The specific panel of DNA biomarkers
6 critical to Cologuard's success is not disclosed or claimed.

7 This case is much less like that of Teva Pharmaceuticals versus Eli
8 Lilly. In that case, the patents defined a therapeutic antibody functionally,
9 so it broadly covered commercial antibodies. However, the success of the
10 product was determined to be the specific structure of the commercial
11 antibody binding domain, which was not explicitly claimed. In our case,
12 claim 3 recites detection of an amount of human nucleic acid. It could be
13 any human nucleic acid. It doesn't even need to be cancer-specific nucleic
14 acid. But Cologuard requires an unclaimed very specific panel of 10 DNA
15 biomarkers in order to function.

16 What's more, the Cologuard test uses an algorithm to convert the
17 biomarker Panel results into a diagnosis for colorectal cancer. This step is
18 clearly important to -- critical to Cologuard because without the ability to
19 translate the results of the biomarker panel to diagnosis, Cologuard would be
20 useless and would not have achieved commercial success.

21 This Cologuard feature is also unclaimed by the '781 Patent, which
22 does not include any diagnostic step. It simply outputs an amount of a
23 human nucleic acid and an amount of a blood protein. The challenged
24 claims do not include any step where it determines whether a patient has
25 cancer.

1 I'm on slide 49. So, we also know that these unclaimed features and
2 others are significant to Cologuard's function because, like the patentee in
3 Fox Factory, Exact, itself, publicly asserted their significance.

4 So, onto slide 50. So, one example of this is when Exact published
5 the results of the Cologuard clinical trial in 2014, it expressly attributed
6 Cologuard's high sensitivity connectivity to its DNA biomarkers and the
7 algorithm component of the test.

8 Slide 51. Similarly, if you go through its webpage, Exact states that
9 its proprietary stool isolation technology proved to be a breakthrough in the
10 development of Cologuard. And Exact also emphasizes the significance of
11 its proprietary QuARTS technology for analyzing the DNA marker
12 components of the bio-panel -- of the panel.

13 Slide 52. Exact's web page also asserts the importance of its
14 unclaimed powerful mathematical algorithm, which it states is the vital
15 workhorse that translates their invisible biology into actionable information.

16 Jumping to slide 54. Lacking a presumption of nexus, Exact has also
17 not met its burden of showing that its purported evidence of secondary
18 considerations is a direct result of the unique characteristics of the claimed
19 invention. Exact claims that the unique characteristics of the challenged
20 claims that resulted in its success are diagnostic accuracy and patient uptake.
21 There is no evidence to support this claim.

22 To begin, the challenged claims do not even recite a diagnostic step,
23 let alone recite any requirement for diagnostic accuracy or patient uptake. A
24 test could achieve only 10 percent sensitivity and still meet the challenged
25 claim. A test could not detect cancer at all and still meet the challenged

1 claim. It's simply, all you need to do is determine an amount of a blood
2 protein and amount of a human nucleic acid.

3 Slide 55. As discussed before, Exact admits that Cologuard embodies
4 more than 60 unrelated patents. Exact has not shown that Cologuard's
5 success is a product of these challenged claims as opposed to any of these
6 dozens of other patents. Exact has also not accounted for how the
7 exclusivity afforded by these patents may have contributed to Cologuard's
8 commercial success.

9 I'm jumping to slide 57. Exact further failed to meet its burden of
10 proving nexus because it has failed to prove that Cologuard's success was
11 not the product of its very substantial post priority date marketing and R&D
12 investment. In a declaration from its Vice President, which is Exhibit 2023,
13 Exact admits that spent over \$290 million in research and development on
14 Cologuard after the 2009 priority date of the challenged patents. Keep in
15 mind, the method of the challenged claims was invented by
16 OncloMethylome and only acquired by Exact in 2017, so none of this R&D
17 expenditure went into developing the claimed invention.

18 Exact further admits that it spent over \$3 billion in sales and
19 marketing of Cologuard. Exact cannot prove that Cologuard's success was a
20 direct result of the unique characteristics of the challenged claim without
21 accounting for the role played by these extensive post priority date financial
22 expenditures in R& D and marketing.

23 Slide 58. Indeed, in a Forbes article published last year, Exact CEO
24 admitted to the critical role that advertising played in Cologuard's
25 commercial success. In a head-to-head study, Exact compared Cologuard
26 sales in markets without advertising to sales in markets with advertising and

1 found that direct-to-consumer marketing increased Cologuard sales by 10
2 percent per week and was 100 percent higher after only nine weeks.
3 Obviously, advertising works in this market. Exact's own studies
4 demonstrate that their extensive advertising investments played a huge role
5 in Cologuard's patient uptake and commercial success.

6 Jumping to slide 60. Perhaps most damning to Exact's nexus
7 argument is that it has already represented to the Patent Office that
8 Cologuard's success was a product of Cologuard features claimed by a
9 completely unrelated later patent that was filed in 2011, years after the
10 priority date. Specifically, during prosecution of this '278 Patent, Exact
11 asserted that Cologuard satisfied a long-felt need for a means to screen
12 colorectal cancers based on stool DNA testing and succeeded where others
13 had failed because of its use of a particular combination of markers and
14 methods for extracting the marker DNA, which are claimed in the '781
15 Patent but are not claimed in the challenge patent. Notably, the later filed
16 patent issued with claims to these features further proving that they were not
17 disclosed or claimed by the earlier challenged patent.

18 Now, I'd like to emphasize that Exact's '278 Patent which Exact
19 asserts was responsible for Cologuard's success had a priority date that is
20 years later than that of the challenged patent. This is telling because what it
21 means is that the features claimed in the '278 Patent that Exact represented
22 to the Patent Office were necessary for Cologuard's success did not exist in
23 2009, the priority date of the challenged patent. Thus, the method of the
24 challenged patent, in the context of the state of the art, when it was
25 purportedly invented by OncloMethylome in 2009, could not have been
26 responsible for Cologuard's success because Exact admits that that success

1 only hinged on components that Exact only invented years later. Moreover,
2 the challenged claims could not have solved the long-felt need for fecal
3 colorectal screening in 2009 when Exact admits that the same long-felt need
4 was only solved by a different invention in 2011.

5 Exact cannot have its cake and eat it too. It cannot be entitled to the
6 presumption of nexus for the challenged claims while also using the success
7 of Cologuard to support the non-obviousness of one of its later patents. In
8 short, Cologuard is a complex test with many components that are covered
9 by dozens of unrelated patents on which Exact spent billions of dollars
10 marketing. Exact has not demonstrated how much of Cologuard's success, if
11 any, was a direct result of the supposedly unique characteristics of the
12 challenged claim. Exact has failed to meet its burden of proving nexus, and
13 evidence of secondary considerations should be given little or no weight.

14 Do you have any, Your Honors, have any questions on?

15 JUDGE COTTA: I have one question before you conclude. Can you
16 address the testimony of Dr. Backman with respect to the direct result
17 whether the success of Cologuard is the direct result of the unique
18 characteristics of Cologuard? And I'm referring specifically to paragraph
19 155 of his second declaration where he says that that the claimed invention
20 of the '781 Patent is essential to the diagnostic accuracy and uptake, and that
21 both these criteria are necessary for both the clinical and commercial success
22 of the diagnostic product, and the addition of buffers, and the fact that the
23 sample is tested for both nucleic acid and fecal occult blood all contribute to
24 the test's diagnostic performance.

1 And I was paraphrasing a little bit there, but if you could address that
2 testimony as it relates to establishing that the objective indicia are a direct
3 result of the known characteristics of the claimed invention.

4 MR. JONES: Certainly. I'd be happy to. I don't have time to pull up
5 the exact quote, but I believe I recall that portion of his Dr. Backman's
6 declaration. So, Dr. Backman's declaration is effectively just -- unsupported
7 by any real actual evidence and just mirrors the conclusions that are
8 presented by Exact in this brief. Dr. Bachmann hasn't actually shown that,
9 for example, the addition of the FOBT test to the DNA test of Cologuard had
10 any increased diagnostic accuracy compared to the DNA tests alone. So, for
11 example in its sur-reply Exact argues that, oh, of course it did because
12 Cologuard is a better test than earlier tests, DNA-only tests in Itzkowitz, but
13 ignores that Itzkowitz used a completely different DNA biomarker panel
14 than the Cologuard test, which Exact has told to the Patent Office and quite
15 frankly to the world in its publications was, what was responsible for
16 Cologuard's diagnostic accuracy and patient uptake.

17 From a patient uptake standpoint, I also note, and I'm going to slide
18 59, that Exact's argument that the method of the challenged claims was
19 responsible for patient uptake is actually inconsistent with its admission that,
20 by its expert, that the test is no more convenient for patient use than other
21 fecal tests available at the time. So, prior art tests such as FIT tests. So, I
22 guess it's really two questions or two answers. From a diagnostic accuracy
23 standpoint, just adding a human nucleic acid and a fecal blood protein could
24 not have possibly given Cologuard its diagnostic accuracy that it gets. It
25 really required the later-invented panel of DNA biomarkers in order to
26 achieve that success. And that panel didn't actually exist in 2009. And from

1 a patient uptake there's no further value in there's no more increased patient
2 convenience for the combined test than there would have been for just the
3 FOBT alone.

4 Does that answer your question?

5 JUDGE COTTA: I think so. And with respect to that first prong you
6 are relying on Patent Owner's statements, is there any evidence that you rely
7 on?

8 MR. JONES: About the DNA test?

9 JUDGE COTTA: Yes.

10 MR. JONES: For that first prong, okay. So, for the first, I guess it's
11 mostly the Patent Owner's own statement. But of course, as you recall,
12 Patent Owner has a burden of proving nexus.

13 JUDGE COTTA: Right.

14 MR. JONES: And in this case, the Patent Owner has emphasized the
15 importance of a biomarker panel, which he also admitted was patented in the
16 2011 patent, years later. And so, it wasn't available to a skilled artisan. So, I
17 mean the whole point of secondary considerations is to look at the level --
18 what, to provide a check on what -- on how one of skill in the art would have
19 viewed the art at the time of the invention. And so, when it comes down to
20 commercial success, it's like if this invention was so great it would give rise
21 to commercial success, then someone else would have invented it if it wasn't
22 obvious. But if something was necessary for commercial success, wasn't
23 invented until years later, then that secondary consideration simply cannot
24 apply.

25 Does --

26 JUDGE COTTA: Okay. Thank you.

1 MR. JONES: Okay, I'll save what's left of my time for rebuttal.

2 Thank you, Your Honors.

3 JUDGE FLAX: Okay. On rebuttal. Okay. And same question.

4 Would you like to reserve some time at the end?

5 MS. HABERNY: Yes, Your Honor, I'd like to reserve 20 minutes,
6 please.

7 JUDGE FLAX: Okay. Okay. Whenever you're ready.

8 MS. HABERNY: Good afternoon, Your Honors. So, there are two
9 overarching problems with Geneoscopy's arguments. First is impermissible
10 burden shifting. So, Geneoscopy has the burden to prove there was a
11 motivation to combine the references it cites. Geneoscopy failed to do that
12 for several reasons that we'll go into in detail. But Geneoscopy seems to be
13 taking the position that it's existing Exact Sciences burden to prove there
14 was not a motivation to combine. And that is just not the law. It's
15 Geneoscopy's burden. If they don't meet it, that is enough to affirm
16 patentability. And they do not meet it, as we'll go into in a few minutes.

17 Second, Geneoscopy fails to consider the art as a whole. They
18 selectively read the references, and they pick and choose features and map
19 them back onto the claims, using the claims themselves as a roadmap. So,
20 what they're doing is intentionally omitting features that do not fit their
21 narrative, ignoring portions of the references that teach away or that
22 discourage the combination that would result in these claims, and simply
23 cherry picking and road-mapping them to the claims. And Mr. Andryszak,
24 could we pull up please, Geneoscopy slide 18?

25 So, this is one of Geneoscopy's slides, and you can see this for
26 yourselves. The slide looks like a roadmap. Right. So, this is them, cherry

1 picking portions of the claims out and then picking and choosing from the
2 references to map them back onto the claims. So, Geneoscopy fails to
3 explain why a person --

4 JUDGE FLAX: Here's a question. I mean, doesn't Lenhard just say,
5 put these two different types of tests together?

6 MS. HABERNY: Lenhard does include a combination in that study,
7 but I'd actually like to address that because Geneoscopy never explains why
8 a person of skill in the art would have begun with Lenhard, why that would
9 have been a starting point where there were two other tests out there with far
10 greater specificity -- I'm sorry, sensitivity. So, the Vilkin test reports --

11 JUDGE FLAX: Do they have to begin with some certain reference?
12 Doesn't the person of ordinary skill know about all these references and,
13 here's Lenhard. So, it says, do these two things together, and then you've got
14 the other references that say, here's a slightly better way to do this one and
15 here's a slightly better way to do that one?

16 MS. HABERNY: It would be illogical. So, if the motivation is
17 increased sensitivity. And the Vilkin and Itzkowitz tests came out after
18 Lenhard. Right. They're single marker class tests. And a person of skill in
19 the art were looking in the literature for ways to increase sensitivity. They
20 would find Vilkin, which reports 100 percent. They would find --

21 JUDGE FLAX: Well, your opposing counsel said it may say that, but
22 it was a very small set of test subjects, and it could be disregarded as really
23 proving that 100 percent is what the results are. Do you disagree with that?

24 MS. HABERNY: I find that actually quite amusing because that's
25 their own reference. They're relying on that data as a motivation for
26 choosing Vilkin and at the same time saying the data is unreliable. I mean,

1 it's their own reference. You know? If it's too unreliable for us to rely on to
2 say the motivation to choose that first would be there, then how is it not
3 good -- I mean, let me say that again. If it's not good enough for us to say
4 that Vilkin would have been a starting point instead of Lenhard, how is it
5 good enough for them to say, but a person skill in the arts still would have
6 been motivated to combine it with Itzkowitz. Right? It just doesn't make
7 sense.

8 JUDGE FLAX: So, going into this combination, they also have other
9 supporting evidence that says that generally in the art researchers were
10 putting these two tests together in various ways and testing the results. Why
11 is that not supportive of their position that you would try to find a way to put
12 these two things together, that they might be somehow additive or
13 synergistic in their inclusion together?

14 MS. HABERNY: Well, those references, none of those references
15 would have provided an expectation of success. They were either
16 speculative and not based on any data, or they were reporting results and
17 themselves saying nothing can be concluded from our data because it's
18 retrospective. You know, this is just not enough to support a reasonable
19 expectation that what is shown here is actually true. And then there are
20 others that are just reviews, the Levin paper, for example, questioning
21 whether or not it would be a good idea to combine either guaiac FOBT or
22 iFOBT with a protein, a DNA or RNA nucleic acid marker, and expect high
23 sensitivity and specificity. So, the art as a whole was teaching against
24 Lenhard.

25 Lenhard showed -- first of all, Lenhard did not show high sensitivity.
26 It showed 65 percent. That is horrible sensitivity. Do you know what that

1 means? It means that a third of the patients were shown to be falsely
2 negative. So, there were a third of these patients who had cancer. And it
3 wasn't just early-stage cancer. They were late-stage cancer, stage four, a lot
4 of them, stage three, stage four, huge tumors all over the body. And that test
5 missed a third of them. And then it had a specificity, which means that they
6 were calling cancer cases when the people didn't have cancer that was higher
7 than any of the two combined.

8 No one's going to look at that Lenhard paper and say, oh, that's a good
9 test. That really works. When the single-marker tests alone were giving 100
10 percent and 88 percent sensitivity, and when the authors of Lenhard
11 themselves concluded we should pursue a direction of combining DNA
12 markers. They themselves, there's got to be a reason for that. And you
13 know, part of what's taught that a person of skill in the art would have
14 recognized in that reference is that another DNA marker alone, SFRP2, had
15 a 77 percent sensitivity.

16 And so, if sensitivity is the goal. And the authors of Lenhard, they
17 were looking at prior studies and said, here's a great super sensitive DNA
18 marker. And what they were doing was biomarker discovery. They were
19 not developing a diagnostic test. They were just looking out there for DNA
20 loci, DNA promoters that have differential methylation as between cancer
21 patients and non-cancer patients. So, they themselves said, look at this 77
22 percent single-DNA marker sensitivity. Let's check out another methylated
23 promoter, HIC1, and see if that one's sensitive too.

24 They were comparing it to the, then state of the art, which was guaiac
25 FOBT. So, that's why the data came out the way it did. They were not
26 pursuing an approach of combining them. And they ended up with, even in

1 the combined test, 65 percent horrible sensitivity that was less than the DNA
2 marker alone. And ask yourselves, based on common sense, why was their
3 own conclusion that one should, or that they themselves were going to
4 continue to pursue DNA-marker-only testing when they had that data in
5 front of them? A person of skill in the art would absolutely give weight to
6 that conclusion. The people who themselves did the study rejected that
7 approach.

8 JUDGE FLAX: What is your response to the evidence that your
9 opposing counsel talked about earlier on slide 13 that indicated that this
10 increase in sensitivity to various types of cancers complemented one
11 another, where if you put the two tests together, where one might not detect
12 it, the other might detect it. So, you would expand your potential detection
13 of cancer.

14 MS. HABERNY: So, that would be true of a combination of DNA
15 markers alone. Right? Two different DNA markers, which the literature
16 contemporaneous with Lenhard and between Lenhard and the patent date
17 was showing that combining two markers is better, that combining two DNA
18 markers is better than one. And the reason behind this, the science behind
19 this, is that everybody's tumors are different. So, person A may have a
20 tumor that's methylated on promoter 1, and person B may have a tumor with
21 DNA methylated on promoter 2. Right? So, if you have multiple markers,
22 you're going to pick up the person's tumor who has methylated DNA on one
23 promoter. And the same test will pick up methylation at a different locus in
24 a different patient. That's why you would use multiple markers. And that's
25 why at between the time of Lenhard and the priority date, people were --
26 even Lenhard wanted to go in that direction. People were -- everyone was

1 going in that direction. Like, you know, we need more than one marker to
2 look for this. But the DNA is far more sensitive when you're combining
3 multiple DNA markers.

4 JUDGE FLAX: This is just for one gene, though, right?

5 MS. HABERNY: This, I'm sorry?

6 JUDGE FLAX: What we're seeing here is for one gene. Is that
7 correct?

8 MS. HABERNY: It's one gene, but some of the --

9 JUDGE FLAX: I'm sorry. This, on slide 13. I should be --

10 MS. HABERNY: Yes, so that --

11 JUDGE FLAX: I'm asking you to be clear. I'll be clear, too. Slide
12 13, it's detecting methylation on one gene which detects, it says, a variety of
13 different sorts of cancer of the GI. And then the blood test also detects a
14 bunch of different types of cancer specifically, but that they are sort of
15 complementary here. So, this is just one gene and the blood. But why does
16 that not support the fact that these two tests together might supplement one
17 another?

18 MS. HABERNY: The sensitivity, again, was just very bad. Yes, the
19 data do say that there are like, you know, a small handful of patients in
20 which one or the other did test positive. And I will add, some of them were
21 false positives. So, not all of these are true positives. Some of those FOBT
22 tests were saying positive when the patient wasn't. But that is in the data.
23 But it still resulted in a terrible sensitivity. Sixty-five percent, 1/3 of the
24 patients who had cancer, and you can even see here stage, stage four, stage
25 three. I mean, there are advanced cancers. These are cancers all over their
26 body. And this test was so bad it couldn't detect them.

1 No person of skill in the art is going to look at the literature, find these
2 tests with DNA combinations or an iFOBT in Vilkin that was done
3 consecutively with multiple collections of samples which are better, and then
4 say, but I'm going to go backwards to that really bad one and try that
5 approach. It's just not -- there's no common sense in that. It's illogical.

6 Do you have more questions?

7 JUDGE FLAX: No. Please go ahead.

8 MS. HABERNY: All right. So, like I was saying, Geneoscopy fails
9 to explain why a person of skill in the art would have chosen to start with
10 Leonardo for all the reasons that I just explained. And I'd actually like to
11 just illustrate this.

12 Slide 15. Right. So, it does defy logic because if you look, Vilkin has
13 a 100 percent sensitivity for colorectal cancer. And mind you, Geneoscopy
14 is focusing on sensitivity alone and saying specificity doesn't matter. Right.
15 So, they took a look at Vilkin and criticized the data. It's their own
16 reference, but it's right here in black and white, 100 percent, when you
17 consider all the samples. Itzkowitz --

18 JUDGE COTTA: Counsel, can I interrupt for a second?

19 MS. HABERNY: Yes.

20 JUDGE COTTA: How would you reconcile the argument that Vilkin
21 has 100 percent sensitivity for iFBOT with the argument that you just made
22 that FBOT, maybe it was the gFBOT, but FBOT is so bad that people would
23 not go backwards to that and would instead rely just on DNA?

24 MS. HABERNY: So, the combination of the FOBT that was used in
25 Lenhard is a guaiac FOBT. It's different. It's unclear how many consecutive
26 samples Lenhard used and what the methodology there was. And they

1 combined it with a DNA marker of HIC1. That resulted in a very bad
2 sensitivity. Vilkin uses an iFOBT, and I believe Your Honors had questions
3 about that in the very beginning of the hearing. The iFOBT is different. It
4 requires a buffer and according to Vilkin, it requires refrigeration and three
5 consecutive days.

6 So, it's really the methodology of Vilkin that caused this high -- 100
7 percent, near perfect sensitivity. So, what Vilkin said was the best results
8 come when you provide three different samples over three days and keep
9 them in your home refrigerator. So, that was not something very attractive
10 to the subjects in Vilkin. It had a super high sensitivity and because of that
11 methodology, three consecutive samples, keeping it in the refrigerator, that's
12 how they achieved that. That was different than what was done in Lenhard.
13 They used a guaiac FOBT.

14 But I will say that even doing what Vilkin did, if sensitivity were
15 considered in a vacuum, yes, this Vilkin data is very encouraging, but it's not
16 considered in a vacuum. The Arctic Cat and Henny Penny cases from the
17 Federal Circuit require that the art is considered as a whole every for
18 everything that it teaches. So, the only thing important here is not just
19 sensitivity, but it's also specificity and patient acceptance. And the literature
20 is replete with statements. I mean, we have slides with, you know, they're in
21 our demonstrative and in our briefing, but you know, numerous references
22 saying that patient acceptance is critical. I remember one from the CDC
23 saying the best test is one that people will actually use. Right.

24 So, Vilkin goes into detail about patient hesitancy, storing their own
25 feces in their kitchen fridge. Right. So, while Vilkin does provide the 100
26 percent sensitivity, viewed collectively with the rest of the art, there are

1 reasons why someone might want to improve on Vilkin. Right. Vilkin itself
2 wanted to improve on itself. But that would be the starting point if you're
3 going to improve a test. You say, we had a test with 100 percent sensitivity.
4 Let's improve this test. So, now we can address the patient acceptance.
5 That's the logical starting point. And Vilkin itself, in the conclusion, said,
6 we need to improve the Ziploc bag approach to keeping feces in the fridge
7 because people don't like it. Right. So, that's the test you'd improve.

8 So --

9 JUDGE FLAX: Sometimes it detected 100 percent. And that, I'm
10 looking at your same table there, am I reading it wrong that for certain
11 samples, it didn't detect 100 percent, or did it always detect 100 percent?
12 Because the last row says samples 1, 2, and 3.

13 MS. HABERNY: So, Vilkin required each subject to provide three
14 consecutive daily samples of stool.

15 JUDGE FLAX: Right. So, Monday's sample, Tuesday's sample, and
16 Wednesday's sample. That sample one would be like Monday. Sample two
17 would be Tuesday.

18 He's looking at all three as a collection.

19 MS. HABERNY: Yeah, yeah.

20 JUDGE FLAX: Okay.

21 MS. HABERNY: And the reason, the science behind this is because
22 the blood that's being detected in the iFOBT is coming from lesions in the,
23 wherever the colorectal cancer is, but they don't bleed every day and they
24 don't bleed constantly. So, you might have a day when the lesion is bleeding
25 and a day when it's not. But on balance, that's why you needed three
26 samples. This is why you cannot buy Geneoscopy's argument that three

1 samples are not required. Your Honor pointed out the exact reason, because
2 only with three samples can you achieve this sensitivity.

3 JUDGE FLAX: Okay, thank you. Thanks for clarifying.

4 MS. HABERNY: Mm-hmm. So, I also want to point out another
5 teaching in the art that Geneoscopy ignores. So, the art, numerous of the
6 references that we included in our briefing discussion decreasing
7 complexity, decreasing cost. This is discussed in detail. For example, with
8 Itzkowitz.

9 So, we have statements in Itzkowitz where they are saying, the goal of
10 this study is to reduce complexity, simplify, reduce cost, and make a test that
11 patients will accept. And this is in one of the references in their
12 combination. So, what they did in Itzkowitz was they first compared the
13 panel that was used in version one of Exact Sciences product, which did not
14 include a buffer, with the same panel of multiple genes, those used in
15 version two, that included a buffer. And they found that the buffer increased
16 the accuracy of the test. But then they concluded that ultimately a
17 combination of only two markers, vimentin and a DNA feature called DIA-
18 DY, had a sensitivity of 88 percent. So, they were looking to decrease cost
19 by reducing the number of markers. And that was what Itzkowitz was really
20 doing. Not increasing, not adding more, not combining it with other things,
21 reducing the number of things that were confined. That's what a person of
22 skill in the art would read from Itzkowitz.

23 And think about this logically. If you are using Itzkowitz for its
24 teachings as to how you might improve a CRC screening test in accuracy
25 and patient acceptance, you're not going to increase complexity with two
26 different marker types, separate containers. They say that it requires

1 separate buffers. We disagree with that. But even assuming arguendo that
2 different buffers will be required, this is all increasing complexity. No
3 person of skill in the art is going to read Itzkowitz and determine we should
4 make this more difficult. It's not this teaching.

5 And that's what Geneoscopy is doing in picking and choosing from
6 the references. You know, they need Itzkowitz to fulfill the at-home feature
7 of the claim. So, they ignore everything else that Itzkowitz says. Itzkowitz is
8 teaching away from combining multiple markers. It went from a panel of 26
9 down to two and said this is the best thing. It's just a failure to consider the
10 art as a whole.

11 So, I actually like to go into that a little bit more as well. Geneoscopy
12 has a burden to show that a person of skill in the art would separate into two
13 different collection vessels. Containers or collection vessels. Right. One
14 that's going to be used to later process the nucleic acids in the sample and a
15 separate collection vessel that's going to later be used to process a blood
16 protein. But it's Geneoscopy's burden to show why someone would be
17 motivated to do that. And this is a failure of proof on their part. So, their
18 motivation to separate into different containers is the notion, the argument
19 that two different buffers would be required: one to stabilize nucleic acid, a
20 different one to stabilize protein. And they pointed to where their expert
21 said it was common in the art to use two different buffers to stabilize, you
22 know, one buffer to stabilize nucleic acid, a different one to stabilize protein.

23 But what they didn't tell you is what their experts said in deposition.
24 And this is on our slide 25. He. He had no opinion as to whether the same
25 buffer could stabilize both. So, he --

26 JUDGE FLAX: Is there a single buffer in existence?

1 MS. HABERNY: There are, yes. And it was their -- it was
2 Geneoscopy's burden to show that a person with full understanding of the art
3 --

4 JUDGE FLAX: Is that in the record?

5 MS. HABERNY: I'm not sure if it's in the record.

6 JUDGE FLAX: If I wanted to know what that single buffer is, could I
7 find it in the record somewhere?

8 MS. HABERNY: I'm not sure that it's in the record. But what is in
9 the record is Geneoscopy's failure to meet its burden of showing that a
10 POSA wouldn't understand that.

11 JUDGE FLAX: Well, what I see in the record is that there is a test for
12 blood, and there is a test for DNA, and the evidence says that a certain buffer
13 was used for each. So, there's two there. And to my understanding that
14 there's no evidence that there was one suitable buffer for both that wouldn't
15 require using two. Where is that evidence?

16 MS. HABERNY: They never say what those buffers are, so it's so
17 vague. They refer to one of the references just simply, I think Vilkin just
18 calling it a hemoglobin buffer. We don't know what that is. Who's to say
19 that can't also stabilize protein? It's known in the art that there are buffers
20 that can stabilize both. But they never prove what these -- they're claiming
21 it's conclusory. They're claiming that these buffers stabilize only one or the
22 other. There's no evidence. That's attorney argument. They don't cite
23 anything in the art and it's their burden.

24 Again, this is where the burden shifting comes in. They're saying we
25 have to -- the burden of showing that it doesn't exist. They have the burden -
26 - or we have the burden of showing it does exist. They have the burden of

1 showing that it doesn't and that a person of skill in the art would understand
2 the only way to do this is with two different buffers. That's not in the record.
3 If a person of skill in the art does not understand that the only way to do this
4 is with two different buffers, their motivation to separate into different
5 containers fails. It's a hole. It's a hole in their proof. And it's right here that
6 their own expert doesn't have an opinion. On the next slide, slide 26. This
7 is Exhibit 2027 at lines 14918 to 15013. He doesn't have an opinion. It's
8 just, just a hole in their proof.

9 I'm not sure if Your Honors are thinking or if you'd like me to move
10 on.

11 JUDGE FLAX: No, you can keep going, please.

12 MS. HABERNY: Okay. So, another thing that Geneoscopy ignores
13 is the importance of detecting adenomas, advanced adenomas. So, advanced
14 adenomas are precancerous lesions. They are not yet cancer, but there's a
15 high likelihood that they will become cancer at some point. And there are
16 numerous references there in our briefing again saying that prevention is the
17 key, that the goal of these CRC tests should be prevention of cancer. Well,
18 how do you prevent cancer? That's by detecting the precancerous lesions
19 before they become cancer. That's detection of adenomas. And even
20 Lenhard, Levin, Shuber, and Vilkin, all of them, those are the main
21 references. They all say that.

22 So, I mean, you could show our slide 46, please.

23 JUDGE FLAX: So, detection of adenomas is a critical feature?

24 MS. HABERNY: It is a critical feature.

25 JUDGE FLAX: Is that covered by any of your other patents' claims?

26 MS. HABERNY: By our other patent claims?

1 JUDGE FLAX: Your other patents' claims. There was a list of
2 dozens of patents on one of the other slides. I'm just wondering if that's --

3 MS. HABERNY: I don't know if they, I mean, they might be. It's --
4 I'd be hesitant inside of the Patent and Trademark Office --

5 JUDGE FLAX: If you knew.

6 MS. HABERNY: -- to interpret the claims --

7 JUDGE FLAX: If you don't know --

8 MS. HABERNY: -- of them in the Office.

9 JUDGE FLAX: -- then you don't know.

10 MS. HABERNY: Yeah.

11 JUDGE FLAX: That's fine.

12 MS. HABERNY: Yeah, apologies, I don't. But if we, if we could
13 look at, yes, slide 46, here. This is a callout from Exhibit 1004 at page 3.
14 It's Table 2. This is the data from Lenhard looking at advanced adenomas.
15 He calls them adenomatous polyps, which is more difficult to pronounce.
16 But this here is data and the sensitivity is very, very poor. It only detects
17 one with the combined method. Right. So, there's no improvement using
18 the combination in detecting these adenomas. And again, prevention, even
19 Lenhard says throughout his, throughout the author's publication and it's in
20 our briefing that prevention is the goal of this. If they're not detecting
21 anything that can help prevent cancer by catching it before it becomes
22 cancer, then that's again a lack of motivation. And that's one of those
23 teachings that Geneoscopy is just selectively ignoring when trying to
24 roadmap its cherry-picked elements to the claims.

25 And if you can go to the next slide, please, 47. So, this is Shuber, the
26 other main reference. That reference already showed that their method

1 could detect greater than 95 percent sensitivity, even greater than 98 percent
2 sensitivity of adenomas. So, if your goal is to prevent cancer and you have a
3 reference here that already does that, why are you combining it with another
4 one? Ninety-eight percent, you don't get better than that. Right. There's no
5 motivation to start complicating the assays when you're already achieving
6 this goal of prevention.

7 So, can we move to Geneoscopy's slide 29, please? So, here they
8 made an argument that, you know, adenomas wouldn't really factor into this
9 person of skill in the art's understanding or motivation. And they have this
10 selective quote from the Levin reference, which is Exhibit 1013 at pages
11 1572 to 73. And here they're saying primarily, the tests are primarily
12 effective at identifying CRC, opportunity for prevention is both limited and
13 incidental, not the primary goal of CRC screening with these tests. But this
14 is a bit misleading. So, can we actually callout the document itself? So, it's
15 Exhibit 1013. This is now looking at the exhibit itself, not the slide.
16 Geneoscopy leaves off the very next paragraph. This is what they said. And
17 to frame this, this is a publication of multiple cancer organizations. It's not
18 just some research.

19 JUDGE FLAX: What page are we on in 1013, I'm sorry?

20 MS. HABERNY: It's page 1573.

21 JUDGE FLAX: Okay.

22 MS. HABERNY: And so, this is a publication not by some group of
23 five researchers in Germany. This is a publication by the biggest
24 organizations of cancer, a consortium of all the experts in cancer. And this
25 is what they said about prevention. It is the strong opinion of this expert

1 Panel that colon cancer prevention should be the primary goal of CRC
2 screening. And so --

3 JUDGE FLAX: So, this exhibit was one that the Petitioners use as
4 evidence to support that there is a reason to do the combined testing.
5 Correct?

6 MS. HABERNY: Can we pull up that portion of the exhibit as well?

7 JUDGE FLAX: So, if I'm looking at page 1578 in the second column,
8 one of the things it says is that the combined results from a standard gFOBT
9 and panel of DNA markers, and it lists three, resulted in a combined
10 sensitivity for cancer of 93 percent and specificity of 89 percent. So, when it
11 says things like that, indicating that people in the field were doing this
12 combined test and that it seemed to have pretty good results, why is that not
13 evidence that the asserted priority here, like Lenhard, is a pretty reasonable
14 reference for doing such a combination?

15 MS. HABERNY: If you'll accept my apologies. We're trying to find
16 it. So, what they are looking at there. So, I would like to also note what
17 precedes that. This says, another question worthy of consideration is
18 whether or not, so they're not concluding one way or another, they say this is
19 an open question, including a sensitive gFOBT or FIT. Right? They're not
20 saying that FIT is better than gFOBT. They're saying they're both good.
21 They both can be good. At the time of testing would improve sensitivity
22 without adversely affecting specificity. Right? So, this is another one of
23 those sentences that actually proves what Geneoscopy is doing in just not
24 considering the art as a whole. They're saying specificity doesn't matter, but
25 this reference that they cite says it does, without adversely affecting
26 specificity. Right?

1 JUDGE FLAX: What about that next sentence, though?

2 MS. HABERNY: Right. So, okay, this is referring to the Kutzner
3 article. You see the endnote 76. In a retrospective analysis. Right? So, the
4 persons of skill in the art understand that retrospective analyses, that data
5 from those cannot be used to screen patients for cancer, right? They're just
6 looking for feasibility, but they're not actually producing data that persons of
7 skill in the art rely on to go ahead and design tests. But if you -- if we take a
8 look, can we pull up Kutner, please?

9 JUDGE FLAX: So, in the abstract of Kutzner, that's Exhibit 1012, it
10 says basically what we just read, that the combined application of both
11 methods, that which are FOBT and what they're calling MD molecular
12 diagnosis, which I understand to be DNA testing, resulted in a sensitivity of
13 93 percent and an overall specificity of 98 percent, which are the numbers in
14 the Levin reference. The combined application of FOBT and MD resulted in
15 overall sensitivity which could not be achieved by any of the methods alone.
16 So, isn't that pretty good evidence that you should do the two together?

17 MS. HABERNY: Well, let's take a look at their conclusion. So, what
18 they say is our -- it got cut off, but this retrospective data, they're referring to
19 the data from their retrospective study, do not allow any conclusion on the
20 potential of this approach in diagnostic screening. They say, prospective
21 comparative studies, which include a very high number of individuals, have
22 to prove the value of the combined application of MD and FOBT. They're
23 saying you can't -- you can't conclude anything. There's no expectation that
24 this is going to work. We don't -- they don't even say, this has promise to
25 work. Like, you know, you read these scientific papers and they're like, this

1 has promise, we should pursue this direction. They're saying, you can't draw
2 any conclusion from this. It's not the right study --

3 JUDGE FLAX: Well, in the prior paragraph they say that they
4 suggest that MD and FOBT should complement rather than replace each
5 other.

6 MS. HABERNY: But they're saying here that might be hypothetical,
7 but their data don't provide an expectation of success for that.

8 JUDGE FLAX: Okay.

9 JUDGE COTTA: Counsel, before you run out of time, I wonder if
10 you could address objective indicia and in particular, how the evidence of
11 record on unclaimed features that Petitioner alleges materially impact
12 functionality affect your showing of nexus, either through the presumption
13 or by showing that the results are a direct result of the unique characteristics
14 of the claimed invention.

15 MS. HABERNY: Right. So, is Your Honor asking about the 60 other
16 patents in addition, like together with that, or just only --

17 JUDGE COTTA: In the 60 other patents, as well as the evidence
18 about markers and methods for extracting the markers that contribute to the
19 functionality and the success of the product?

20 MS. HABERNY: Yes, Your Honor. So, if we could go to Exact's
21 slide 74, please. So, I know Mr. Jones characterized what their expert did,
22 and he said that he got these descriptions of the patents from the expert. The
23 expert did not review those patents with an eye to whether they relate to
24 these claims in any way. What he did was look at the title. He didn't -- his
25 opinion --

1 JUDGE COTTA: Counsel, if I could interrupt you for a second.
2 Presumably, those patents are listed on your website as a way of marking
3 your product. And presumably, you're representing to the public that those
4 patents cover Cologuard. Am I wrong in making that assumption?

5 MS. HABERNY: Some of the patents are expired, but, yes, they
6 relate to Cologuard. So, maybe we should look at those patents closely.

7 JUDGE COTTA: Not just relate, but they cover Cologuard. Right?
8 Because that's why you're putting notice up.

9 MS. HABERNY: Well, that's the representation from what is on the -
10 - it could be different versions of Cologuard. There have been different
11 versions, but generally, that's why they're there for a marking purpose, for
12 different versions of Cologuard. But can we pull up Geneoscopy's slide that
13 lists those patents, all these patents. So, before we look at them in detail, I
14 just want to frame this properly. We put up boards with our claims, and
15 these claims cover the fundamental workflow of Cologuard. That's not in
16 dispute. Cologuard. That is how you get from beginning to feeding it, you
17 know, getting your sample analyzed and determining these amounts of
18 nucleic acid and protein. It's the fundamental workflow. There's no dispute
19 about that.

20 These patents are part of it. They're just improvements on parts of
21 this. There's no question that Cologuard practices this. This is the
22 foundation for Cologuard. Without these methods, Cologuard would not
23 function. So, stabilizing buffer, that's an improvement on what's in this
24 claim, it's like, it's literally a recited element.

25 JUDGE FLAX: So, how do you distinguish over Fox Factory?
26 Because that case only had two patents involved and it was an invention for

1 a front chainring for a bike. And one covered one way of organizing the
2 cogs and the other one included a slightly different way of doing it. And the
3 Federal Circuit said there's no nexus there because you've got two patents
4 that are covering different inventions that are part of the same product. So,
5 you've got, I don't know, 30, 40 times more patents at issue here. How do
6 you distinguish?

7 MS. HABERNY: So, in that case, they were covering different parts
8 of the product. Right. And it's similar to the like, you know, Apple phone,
9 does the swipe on, you know, does that embody the whole entire phone?
10 That wouldn't be like a case where you would say that the patent covering
11 swipe on covers the entire product. Here, this claim does cover the entire
12 product. And those other patents are directed to features that are claimed
13 here. Right? There are improvements on features that are claimed here.
14 There's nothing wrong with doing that. They're not something completely
15 separate from what's being claimed. This is not like one aspect. Our claims
16 here in the '781 Patent don't cover one aspect of Cologuard, and then a
17 completely separate aspect is covered by the other patents. There are
18 improvements on things that are in this fundamental workflow. They're
19 recited, the stabilization buffers there, DNA isolation, you're removing, over
20 here, you're removing nucleic acids, DNA markers.

21 JUDGE FLAX: Why did you focus on claim 3 in your nexus
22 argument?

23 MS. HABERNY: It's the broadest of the claims. So, it's dependent
24 from claim 1, but both claim 1, with claim 3 --

25 JUDGE FLAX: Yes.

1 MS. HABERNY: -- they're the broad -- that's the broadest that covers
2 the fundamental workflow of Cologuard.

3 JUDGE COTTA: How is the algorithm that's mentioned in the New
4 England Journal of Medicine an improvement on claim 3?

5 MS. HABERNY: Well, you're determining amounts. Right? You're
6 testing for amounts. You don't learn that in a vacuum. Right? There's data
7 processing.

8 JUDGE COTTA: Do you rely on, exclusively, on the presumption or
9 do you also argue direct results --

10 MS. HABERNY: Both. Direct.

11 JUDGE COTTA: -- to establish nexus?

12 MS. HABERNY: Yes, direct results.

13 JUDGE COTTA: How would the alleged existence of these features
14 that Petitioner says materially impact functionality? How does that relate to
15 the evidence that you have on direct results?

16 MS. HABERNY: Well, the commercial success, for example, that's a
17 direct result of this fundamental workflow in claims 1 and 3. These are the
18 features that provide Cologuard with high accuracy, with patient acceptance.
19 This is what -- this is why people -- the result of what you see in this claim,
20 in these claims, is why people use Cologuard, right? Doctors are not going
21 to prescribe Cologuard if it doesn't work. And the reason it works is this
22 fundamental workflow. So, the success of Cologuard is a direct result of
23 what you see here. And again, there's no dispute that this is the fundamental
24 workflow of Cologuard; that this is what Cologuard is and does. Right? So,
25 without the results of this specific combination of claim elements, no doctor
26 would even prescribe it because it wouldn't work. It wouldn't be accurate

1 enough, and it wouldn't -- and patients wouldn't want to use it, Right? So,
2 that's where the result of this claim method is the basis for that commercial
3 success.

4 JUDGE FLAX: So, Counsel, you're four minutes past where you
5 wanted to stop, but you had 20 minutes, so that's a long time to rebut
6 anyway. But you don't have to stop now. But I'm just giving you a heads-
7 up about where you're at in time.

8 MS. HABERNY: I would much rather answer Your Honors'
9 questions than reserve time and talk about something that Your Honors are
10 not interested in. So, if you have more questions, please ask me.

11 JUDGE FLAX: I don't think I do. Do you have any? No, we don't
12 right now.

13 MS. HABERNY: Okay, thank you very much.

14 JUDGE FLAX: So, we'll just call it 16. How about that? And you're
15 not obligated to use 16 minutes if you don't want to.

16 Okay, well, you only have 12 and a half minutes, so I'm just going to
17 give you 13, because there's no 30 second.

18 MR. JONES: That's very generous of Your Honor.

19 JUDGE FLAX: Unless there was an objection to extra 30 seconds.
20 Okay. When you're ready.

21 MR. JONES: Okay, I'm ready. So, Your Honors, in my limited time,
22 there are just a few points I would like to make. The first, I wanted to touch
23 on the idea of looking at the art as a whole, and particularly with reference to
24 Arctic Cat and Henny Penny. In those cases, the federal circuit
25 acknowledged that there can be, even if there are advantages and
26 disadvantages to a combination, that doesn't necessarily obviate the

1 motivation to combine. In those particular cases, the fact finders found that
2 the negative -- the disadvantages were severe and extreme and far
3 outweighed the advantages. That's not the case here.

4 Here the -- here, if you look at the art as a whole, all the advantages
5 and disadvantages as a whole, it's very clear that a person of skill in the art
6 would be motivated to add a DNA, fecal DNA test and FOBT. For example,
7 as we've talked about in Lenhard, they don't just suggest combining these
8 tests, they actually disclose combining these tests. And then they emphasize
9 the super detection of cancer in the combined tests without saying anything
10 about the reduction in specificity, or increased cost and convenience, or
11 anything like that.

12 Even more telling, I think, is Kutzner, where you have these scientists
13 who actually, in view of all the advantages and disadvantages, give an
14 expressed suggestion that these kinds of tests should complement rather than
15 replace each other. Now, Counsel for Exact has pointed out that Kutzner
16 also goes on to suggest a large-scale clinical trial in order to determine
17 whether or not in a large-scale diagnostic environment, that combined test
18 would be acceptable.

19 A couple things. One is, as Your Honors well know, motivation to
20 combine, obviousness requires reasonable expectation of success. It doesn't
21 require absolute knowledge of success. And then second, I'd like to also
22 note that by suggesting that they run a large-scale clinical trial where they
23 combine DNA tests and FOBT tests, that is a suggestion to combine those
24 two tests, whether it's in the clinical trial context or in the context of an
25 actual commercial product, which hopefully eventually it would lead up to.

1 In contrast, in contrast, what we have, there's simply no evidence of
2 the record that the disadvantages associated with adding an FOBT test to a
3 DNA test would in any way obviate the advantages of increased specificity.
4 Specificity, as we've discussed, is of paramount importance because that
5 means reducing false negatives and making it so that fewer patients go
6 undiagnosed and untreated. And in fact, in Cologuard's clinical trial
7 publication, Exact expressly said that sensitivity is the most important
8 characteristic of a fecal diagnostic test.

9 I just wanted to quickly touch on the Lenhard -- no, the Vilkin assays.
10 I'm on slide 27. So, this is where Exact argues that a person of skill in the
11 art would not be motivated to replace the gFOBT of Lenhard with iFOBT of
12 Vilkin because when testing the performance of the iFOBT, Vilkin collected
13 fecal samples on three consecutive days. Exact's argument once again fails
14 to consider the teachings of Vilkin as a whole. The reason for the frequency
15 of sample collections in the Vilkin experiment was based on the experiments
16 aimed at examining test reproducibility. Vilkin does not teach that when
17 used in clinical practice, samples would be collected from patients on three
18 consecutive days. Quite the contrary, Vilkin states that for certain high-risk
19 populations they will continue collecting three annual fecal tests. It also
20 notes that the frequency of testing varies from country to country, none of
21 which use three consecutive days, and that the frequent -- decision on the
22 testing frequency for screening of average risk population should be
23 optimized based on cost benefit analysis. When you read the Vilkin as a
24 whole, it does not require any specific testing frequency and certainly not
25 three consecutive days.

1 In fact, as we've seen in Young and Guittet, and actually it's also --
2 well in Young and Guittet, the art recognized that one of the advantages of
3 iFOBT over gFOBT is that iFOBT required less frequent patient testing
4 compared to gFOBT. So, frequency of iFOBT would not be a
5 discouragement of a POSA from using an iFOBT instead of gFOBT. Quite
6 the opposite.

7 The challenged claims also do not recite a testing frequency and
8 neither Lenhard nor Itzkowitz disclose any frequency of testing. So,
9 whatever frequency of testing a person of skill in the art determined was
10 optimal based on the -- optimal, we can actually be consistent with the
11 teachings of the other two references and the combination would still fall
12 within the scope of the challenged claims.

13 I'm moving away from the slide, but I'd also like to point out with
14 respect to their argument about Vilkin having the 100 percent sensitivity and
15 Lenhard having the 89 percent sensitivity and the combined sensitivity of the
16 Levin assay. I'd like to point out that what you're looking at here is a classic
17 looking at individual references in isolation, not considering their teachings
18 together. What Lenhard teaches is that a DNA test catches cancers that a
19 FOBT does not and an FOBT catches cancers that a DNA test does not. So,
20 regardless of -- that teaching is actually a general teaching that would apply
21 to DNA tests and FOBT tests. That's reflected also in Kutzner. So, the fact
22 that other tests have higher sensitivity, might have higher sensitivities in
23 isolation, wouldn't mean that someone with skill in the art wouldn't take the
24 Levin test and improve it in order to try and make a better test.

25 I also would like to note that with respect to the issue of cost and
26 complexity, with respect to the number of DNA markers versus adding an

1 iFOBT. As we've seen in -- the fact is that DNA testing is actually very
2 expensive and very complicated when it gets to the lab. For that reason you
3 saw in Itzkowitz that it did provide an advantage for them to reduce the
4 DNA test components in order to get down to two. I note that when they did
5 that, they also reduced the sensitivity of the assay down to 82 percent.
6 When you compare the complexity of actually finding new DNA markers,
7 and discovering new ways to test DNA markers and then incorporating them
8 into the assays versus taking an off-the-shelf, commercially available, well
9 established and cheap product like a FOBT, something that's accepted by the
10 market, accepted by doctors, and adding that to your assay to improve
11 sensitivity, the cost in the additional cost and the inconvenience is pretty
12 minimal. And patients have shown that -- doctors have shown or the art has
13 shown that patients are willing to accept that additional cost and complexity
14 if it gives them a better test.

15 JUDGE FLAX: So, Counsel, you have fewer than five minutes left.

16 MR. JONES: Yep.

17 JUDGE FLAX: I'd like to talk just a bit more about the objective
18 indicia non-obviousness.

19 MR. JONES: Of course.

20 JUDGE FLAX: So, I think it's kind of beyond question that these
21 claims sort of are the Cologuard kit, right? This is what you get in the mail.
22 That's it. Right? What about all those other patents? How do we know, you
23 know, the argument was made that well, we don't know if those things
24 cover, maybe they cover the exact same thing or who knows. How do we
25 know other than the labels that have been put on them that they do cover the
26 other things that are identified as so important to the success of the product?

1 MR. JONES: So, we can tell that, we know that it's critical, at least
2 one of these patents is critical to the success of the product because Exact
3 represented that to the Patent Office. So, one of these patents in that long
4 laundry list of patents of 60 patents is the '278 Patent that we've talked
5 about. So, the '278 Patent, Exact, this '278 Patent specifically covers an
6 extraction test and a test for a specific panel of biomarkers. During
7 prosecution of the '278 Patent, Exact said that this test was what allowed
8 Cologuard to satisfy a long-felt need and gave it its success where others had
9 failed. So, regardless of all those other patents in there, if nothing else, we
10 know the '278 Patent covers a critical component of Cologuard. And
11 included in what's covered is the panel of biomarkers, which Exact says in
12 their, also, in their clinical trial publication was one of the keys to the
13 specificity of Cologuard.

14 And then, Your Honor, I also like to remind you that you said the test
15 covers all of the steps of Cologuard. Well, there is that additional step of
16 actually diagnosing cancer for Cologuard. These claims end with testing for
17 an amount a nucleic acid, for amount of a human nucleic acid, and testing a
18 removed portion of fecal sample for an amount of a blood protein. That
19 human nucleic acid doesn't need to be cancer specific. It certainly doesn't
20 need to be a good one that you're able to diagnose cancer with. And just
21 knowing there is an amount of a human nucleic acid and amount of a blood
22 protein won't tell a patient whether they have cancer or not.

23 Cologuard is, the process includes a sample collection and all the
24 assays and the testing of DNA and protein. And then it needs to take its
25 complex panel of 12 biomarkers, put it into its algorithm, which Exact says
26 is the workhorse of Cologuard, and then output whether the patient has

1 cancer or not. If you don't have that last step, that last actual diagnostic of
2 cancer, Cologuard doesn't actually do anything. It's actually useless.

3 JUDGE FLAX: Is the patent you were referring to, is that the one that
4 is the 028 application in prosecution?

5 MR. JONES: I think it's 082, maybe.

6 JUDGE FLAX: It's 082, 082 you're right. Okay. Thank you for
7 clarifying that.

8 MR. JONES: I only have 50 seconds left, and that's only by the grace
9 of Your Honor. Is there anything, is there any other question I could
10 answer?

11 JUDGE FLAX: You have any questions? I don't think so.

12 MR. JONES: Thank you so much for your time. I appreciate it.

13 MS. HABERNY: Thank you, Your Honors. So, I'd like to start out
14 exactly where Mr. Jones left off with the notion of diagnosing patients. And
15 I will note that there is no evidence in the record, nothing even mildly
16 suggesting that one of those other 60 patents covers diagnosing. And if we
17 could actually, please pull up Geneoscopy slide 47. None of this says
18 diagnosing. None of it says even something remotely close to diagnosing.
19 So, if that's their one, if that's the one thing that they want to latch onto that
20 they claim is part of Cologuard but not part of these claims, there's no
21 evidence in the record that some other patent covers it.

22 JUDGE COTTA: Counsel, does --

23 a feature have to be patented in order for it to affect whether there's a
24 nexus?

25 MS. HABERNY: I think that was the argument Geneoscopy was
26 making. And what I will say is, I mean, in any product that's out there,

1 there's not going to be a patent that covers everything about it. Right?
2 There are some patents that are integral to how the product works and they,
3 you know, cover something fundamental, but no product out there. I mean,
4 a patent that would cover, a single patent that would cover every single
5 aspect of a product would be rare.

6 So, I would say, you know, the inquiry that we've been applying is
7 whether this method of claims 1 and 3 covers the fundamental workflow
8 that's responsible for the success of Cologuard. And for the reasons
9 explained previously, we believe it is. And there's nothing in the record to
10 show that there's some aspect of Cologuard that's, you know, covered by
11 some other IP that -- that would be more analogous to the Fox factory case if
12 there were like two different patents covering different aspects. And that
13 might have been where Counsel was trying to go. But none of these patents
14 claimed detecting and that was the only feature -- I mean, they don't argue,
15 they don't even argue that any of the patents claim detecting. And that was
16 the feature that they were that Geneoscopy was focusing on.

17 JUDGE FLAX: What about the one that he did mention though, in
18 response to the question, the prosecution of the 082 application. Let me
19 make sure I get that right. That's Exhibit 1086. So, looking at page 6 of
20 that, which is an amendment in response to an Office action, it says that
21 claim 1 as amended is included in applicant's product, the Cologuard
22 colorectal cancer screening test, which is the first stool DNA screening test
23 for colorectal cancer to receive FDA approval. The cited reference does not
24 teach or suggest the particular combination of NDRG4, BMP3 and KRAS
25 target human DNAs or the collected set of system components to perform

1 the steps to isolate these particular target human DNAs from human stool
2 samples. So, that's not claimed in this patent.

3 MS. HABERNY: It's improvements upon this fundamental
4 workflow. So, those DNA markers, there's a limitation that says testing for
5 an amount of nucleic acid. Yes, there it is. Element 3D, testing for an
6 amount of a human nucleic acid. That's what those biomarkers do. That's
7 just an improvement. But it's part of this fundamental workflow. And the
8 extraction, there's claim element 3C, extracting nucleic acid from the
9 remaining portion of the fecal sample. That's the extraction. It's just, it's
10 part, that's recited in this claim. That's part of the fundamental workflow.
11 You can get patents that are improvements on others. Did they show that
12 there was not a terminal disclaimer? I mean, there's all kinds of, you know,
13 reasons that they failed to show.

14 JUDGE FLAX: Is there one?

15 MS. HABERNY: We showed nexus. I'm sorry?

16 JUDGE FLAX: Is there a terminal disclaimer?

17 MS. HABERNY: I don't know. But, I mean, if they're going to claim
18 that this is some patent that covers an aspect not in these claims, you'd think
19 that's something they would look into.

20 JUDGE FLAX: The Applicant at that point, which is you, said that
21 these two things, the combination of markers and methods for extracting
22 marker DNA that were claimed there, satisfied a long-felt and unmet need.
23 So, that was objective evidence of non-obviousness. That's not claimed here
24 though, those two things.

25 MS. HABERNY: I mean, it is part of these claims. That is part of
26 these claims.

1 JUDGE FLAX: Well, where is the combination of markers in this
2 claim?

3 MS. HABERNY: Well that's what's used to test for an amount of
4 human nucleic acid in Cologuard. So, so it's a different patent, but we're
5 talking about Cologuard and what Cologuard practice is. Right? This
6 claimed method is foundational to the success of Cologuard. It practices
7 this. Without this claimed method, Cologuard would not have been
8 successful. It would not have been accurate enough, had patient acceptance,
9 and the other features --

10 JUDGE FLAX: If you were right about that --

11 MS. HABERNY: Yes.

12 JUDGE COTTA: Counsel, is your position that the patent at issue
13 and the patent, I believe that resulted in, the application resulted in the '278
14 Patent, are essentially covering the same invention?

15 MS. HABERNY: Not the same invention, but it's an improvement
16 upon the aspect of the fundamental workflow in claims 1 and 3 of the '781
17 Patent. Without this fundamental workflow, the product wouldn't work.
18 Right. So, it's an improvement on that.

19 And I apologize, Judge Flax.

20 JUDGE FLAX: So, if you're right about what you said a second ago,
21 that this is required for Cologuard to be successful. If that's true, but what if
22 it's also true that something in one of those patents there is also required for
23 Cologuard to be successful?

24 MS. HABERNY: So --

25 JUDGE FLAX: What do we do with that?

1 MS. HABERNY: So, for nexus, the patent -- this is not the
2 presumption of nexus, but for nexus, the other way of proving nexus, the
3 patent doesn't have to be the only patent responsible for the success. There
4 can be --

5 JUDGE FLAX: No, it does.

6 MS. HABERNY: No, not the only patent. It has to be instrumental to
7 the success of the -- we have a case on that. It's cited.

8 JUDGE FLAX: Fox Factory is the case and it says if two patents
9 cover the product slightly differently, and it was slightly in Fox Factory, you
10 don't get a presumption of nexus unless you've proved it otherwise
11 somehow.

12 MS. HABERNY: So, here we have the case I was thinking of. This
13 is slide 69 of our deck, and we're citing Quanergy v. Velodyne Lidar. The
14 second part of this slide says the coextensive requirement does not require
15 patentee to prove perfect correspondence between the product and a patent
16 claim.

17 JUDGE FLAX: I mean, that's another thing that Fox Factory dealt
18 with, that perfect coextensivity, that if something that's not claimed in your
19 patent now materially impacts the functionality of the product, then nexus
20 cannot be presumed. So, nothing in any of these other patents materially
21 affects the functionality, impacts the functionality.

22 MS. HABERNY: Well, presumption of nexus is not the only way to
23 prove nexus.

24 JUDGE FLAX: Right. You have to prove it otherwise.

25 MS. HABERNY: Yes, and we've proven that this is the fundamental
26 workflow. It's the basis. This is in our expert declarations. You did an

1 analysis of it. That this, without this fundamental workflow that's in the
2 claim claims, there would be no success of Cologuard. So, even if
3 Cologuard is not entitled to a presumption, we've proven nexus.

4 Do Your Honors --

5 JUDGE COTTA: Counsel, is the evidence that you're referring to for
6 the other way to prove nexus, maybe you could just summarize that for us
7 briefly. That might be helpful.

8 MS. HABERNY: The evidence, this is in --

9 JUDGE COTTA: I assume you're talking largely about Dr.
10 Backman's declaration. His second declaration.

11 MS. HABERNY: Yes, Your Honor. I'm just grabbing the
12 declaration, real quick. So, while we're looking for the exact paragraph
13 number, he did compare the Cologuard patient guide, which describes
14 Cologuard's workflow to the patent claims. This is in our Patent Owner
15 response. We cite the evidence, pages 51 through 55. So, we have the
16 collections of evidence cited there. Dr. Backman also describes in
17 paragraphs 28 through 41 what is needed to practice Cologuard. Yeah.
18 What is needed for a test to be successful. For a test to be successful. And
19 this is what he relates to the practice of the fundamental workflow. So, we
20 have it in the Patent Owner response that I just cited and also 28 to 41 of
21 Backman's declaration.

22 So, I have just a few more minutes. If Your Honor, to have nothing
23 else on objective indicia, I can move to just a few other points I wanted to
24 make?

25 Okay, so I do want to make the point that the Petitioners failed in their
26 burden of proof on dependent claims 12 and 13. And these are the claims

1 directed to RNA. So, what the Petitioner did was take the combinations
2 applied to the grounds 1 and 4, and then for grounds 2 and 5, which are
3 directed to claims 12 and 13, reciting the RNA limitations --

4 MR. JONES: Your Honor, I'd just like to object to this. This is an
5 issue that never came up earlier, and she's using her reserved time in order to
6 address a completely new issue that hasn't been addressed earlier and not
7 giving us an opportunity to respond.

8 MS. HABERNY: Well, I mean, it's in the record. If they want an
9 extra five minutes to respond, I wouldn't object to that, if Your Honors don't
10 mind.

11 JUDGE FLAX: I think I would reserve my arguments now to
12 response as to what they had in their own rebuttal. That's only fair.

13 MS. HABERNY: So, on the issue of the Kutzner reference, just a few
14 points I want to make about that. So, as they pointed out, Kutzner is what is
15 cited in the Levin authored paper, which is that big conglomeration of the
16 cancer experts. And again, I want to note that Levin did not draw a
17 conclusion from Kutzner that this is not -- that this is a closed question, that
18 this is an avenue to pursue. He said whether or not guaiac or iFOBT plus
19 DNA would increase sensitivity without adversely affecting specificity. I
20 don't think that there is evidence in the record that that was available to a
21 POSA. And so, a POSA would consider that statement in its whole. And
22 then Kutzner itself did not come to any conclusions, those authors didn't
23 come to any conclusions about their data.

24 And I do want to note that that was a 2005 paper. And four years
25 passed from Lenhard and Kutzner 2005. Four years passed, and nobody was
26 going in the direction of combining nucleic acids and protein markers.

1 Everyone was going in the direction of combining DNA with DNA, or
2 protein, multiple samples to detect protein. So, in the four years, if you just
3 look at the timeline alone, if that were enough to motivate a person of skill
4 in the art to come up with a claim like this that was so wildly successful,
5 someone would have done it, and they didn't.

6 And I would also like to note that Shuber, I mean, I'm sorry, Whitney,
7 who is the other side's, Geneoscopy's, expert, he didn't even come up with it.
8 Right. So, the Itzkowitz paper came out. Can we put up the slide of our
9 timeline? If it was so obvious, why was nobody doing it and everyone,
10 including the Lenhard authors, were going in the opposite direction?

11 And then finally, I'd like to address the Vilkin paper and just again,
12 note that even in their reply argument, Geneoscopy's only argument about
13 Vilkin and the three-day requirement is that Vilkin doesn't say what it says.
14 Right? Vilkin clearly says that three days are required for the best results.
15 And again, I just want to note if a person of skill in the art were aiming to
16 achieve that sensitivity of Vilkin, and Vilkin said the best results come from
17 three fecal samples over three days in the kitchen fridge, that's exactly what
18 a person of skill in the art would do. So, I think that Geneoscopy trying to
19 run from the language of Vilkin is telling. They have no response other than
20 to argue Vilkin doesn't actually say that.

21 And I probably don't have time to make any new arguments. So,
22 unless Your Honors have questions, I'll end there.

23 JUDGE FLAX: I don't have any. Do you have any?

24 JUDGE WISZ: I do not.

25 JUDGE FLAX: Judge Cotta, do you have any? We don't. Thank you
26 very much.

1 JUDGE COTTA: No. Thank you.

2 JUDGE FLAX: Okay, so the final hearing is now at an end. Thank
3 you all very much. I compliment both sides. You've both done a good job
4 acting as Counsel here. Good job arguing. We will count the record as
5 closed at this point. If you wouldn't mind, stay and answer any of the
6 questions that our court reporter might have as to spellings of certain things
7 or to correct anything that he may have some questions about. And we have
8 your arguments, and we will consider them and we'll render a final decision
9 in due course.

10 Thank you very much.

11 (Whereupon, the proceedings at 3:10 p.m. were concluded.)

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