

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTEGRATED DNA TECHNOLOGIES, INC.,
Petitioner

v.

TECAN GENOMICS, INC.,
Patent Owner.

IPR2024-01504
Patent 11,098,357 B1

Record of Oral Hearing
Held: January 22, 2026

Before GEORGIANNA W. BRADEN, ZHENYU YANG, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

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The above-entitled matter came on for hearing Thursday, January 22, 2026, commencing at 10:00 a.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

10:00 a.m.

JUDGE BRADEN: Good morning. We are convened for oral arguments in IPR2024-01504 which challenges claims in U.S. Patent Number 11,098,357. Welcome to the U.S. PTO's main office in Alexandria, Virginia. I'm Judge Braden, and I'm attending this hearing via video from the USPTO's Southwest Regional Outreach Office. Also appearing via video is Judge Majors. And in the room in Alexandria with you is Judge Yang.

I want to take this opportunity to address Counsel and their clients before we begin. As an inter partes review is a contested proceeding, today's hearing provides an opportunity for Counsel to orally advocate their positions on the patentability of the challenged claims as raised in the petition.

We understand that in every case that comes before us, the parties, both Petitioner and Patent Owner, have a lot at stake. The judges before you today take our role in deciding this dispute seriously. We have reviewed the briefs and the evidence, and we are prepared today with questions. These questions and your answers will help us to decide the issues in the case. In the interest of fairness and due process, we must limit our considerations to the arguments and evidence already presented in the record.

Our role as judges on the panel is to assess your arguments and evidence, and weigh those in accordance with the burdens established by our rules of procedure and precedential authority. We remind the parties that Petitioner has the ultimate burden of establishing unpatentability by preponderance of the evidence.

1 We have the briefs and the evidence available to us on our computers.
2 So if we look away or look down during the hearing, please know we are
3 consulting the documents in the record or taking notes. Please also know
4 that we are paying close attention to your arguments and carefully
5 considering the case.

6 And I apologize in advance, but when we interrupt you, we do so to
7 be able to ask you questions that may be essential to our resolution of the
8 issues or to help keep the hearing on track with time.

9 Now let's go through some housekeeping issues. Recording of any
10 PTAB hearing is prohibited. The court reporter will provide the official
11 transcript of the hearing that will become a part of the record in the
12 proceeding at a later date. To ensure that the transcript of the hearing is
13 clear, we ask that you speak directly into the microphone when talking and
14 to identify specific slide numbers, numbering and figures, and any other
15 pertinent identifying information when referring to demonstratives.

16 Please note that this proceeding is public and there may be those
17 listening on the public line. If the parties wish to discuss any confidential
18 information, please notify us before doing so, so we can wall off the public
19 line.

20 In the hearing order, which is Paper 35, each party was given 60
21 minutes total time to argue their cases. We received Petitioner's request for
22 Mr. Patrick Hynds to participate in the oral hearing under the Legal
23 Experience and Advancement Program, or LEAP, so Petitioner will receive
24 an additional 15 minutes of argument time during the oral hearing, bringing
25 their total time to 75 minutes. We remind Petitioner that the LEAP
26 practitioner must have a meaning and substantive opportunity to argue

1 during the hearing today. That said, there is no set time requirement for that
2 argument. It may be longer or shorter than the 15 minutes.

3 Petitioner will open the argument and may reserve rebuttal time,
4 which may not exceed more than half of Petitioner's total argument time.
5 Petitioner may discuss their case in chief, and how you use your time is up
6 to you. Petitioner -- I'm sorry -- Patent Owner will then respond to
7 Petitioner's argument and may reserve surrebuttal time also not to exceed
8 more than half of Patent Owner's total argument time.

9 Again, how you use your time is up to you. Please remember that
10 your arguments should be limited to only those arguments previously
11 presented in your briefs. Please make it clear which challenges and claims
12 you're addressing at all times. We ask the parties to hold any objections
13 regarding a party's argument until it is your time at the podium to note such
14 objections.

15 So, let us get started with appearances for both parties for those who
16 will be arguing today. If anyone else is attending in person or remotely with
17 you today, but will not be speaking, please identify them as well. For
18 example, please state if your client is attending.

19 Following the hearing, please confer with the court reporter to ensure
20 that no questions regarding spelling or terms or anything like that remain.
21 We'll start with appearances for Petitioner.

22 MR. FLETCHER: Good morning, Your Honors. Thomas Fletcher
23 from Williams & Connolly for the Petitioner, Integrated DNA Technologies.
24 With me at counsel table is my colleague, Patrick Hynds. We will be
25 presenting the argument for IDT today. Also present with me from my law
26 firm are Jessamyn Berniker, Kevin Hoagland-Hanson, Anna Searle, and

1 Nicholas Vincent. And finally, also present on behalf of Integrated DNA
2 Technologies is Michael Levy.

3 JUDGE BRADEN: Very good. Thank you. And now for Patent
4 Owner.

5 MS. CIPRIANO: Good morning, Your Honors. Linnea Cipriano
6 from Goodwin for Tecan Genomics, Patent Owner. With me today, also
7 from Goodwin, is Timothy Beavers, John Padro, Scott Weingaertner, and as
8 a representative of Tecan Genomics, Andreas Shields (phonetic).

9 JUDGE BRADEN: Very good. Thank you very much.
10 Judge Yang in Alexandria will maintain a clock, as you can see on the
11 bench, and she will endeavor to give each party a five-minute warning
12 during their opening argument and near the end of any reserved rebuttal
13 time. As you can see, the hearing room has a timer that is set up for each
14 party with the requested time allotment. The light on the clock changes to
15 yellow when you are nearing the end of your time, whether opening or
16 rebuttal. And when the light is red, you have run out of time and you should
17 stop talking.

18 Petitioner, do you wish to reserve any rebuttal time?

19 MR. FLETCHER: Yes, Your Honor. We'd like to reserve 25 minutes
20 for rebuttal.

21 JUDGE BRADEN: Thank you. Patent Owner, do you wish to
22 reserve any surrebuttal time? And I'll ask you that again before it's your turn
23 again at the podium to make sure it doesn't change it. But this way, we can
24 set up the clock.

25 MS. CIPRIANO: Understood. At this time, I'd like to reserve 15
26 minutes for surrebuttal.

1 JUDGE BRADEN: Very good. Thank you.

2 Are there any questions or issues the parties would like to raise before
3 we begin, starting with Petitioner?

4 MR. FLETCHER: No, Your Honor.

5 JUDGE BRADEN: Patent Owner?

6 MS. CIPRIANO: No, Your Honor.

7 JUDGE BRADEN: Very good. Petitioner, you may begin your
8 argument when ready.

9 MR. FLETCHER: Good morning, Your Honors. Thomas Fletcher,
10 again, at the podium for Petitioner, Integrated DNA Technologies. And,
11 again, with me is my colleague, Patrick Hynds.
12 I'd like to begin with a brief overview of the claims that are the focus of this
13 proceeding, Claims 1 and 2 of the '357 Patent. Claim 1, shown here on
14 Slide 2, begins in its preamble, stating that it is a method for detecting
15 duplicate sequencing reads. That is what this patent is about.

16 And the first limitation of the method is about how the nucleic acids
17 are prepared. The nucleic acids are ligated to an adapter with particular
18 features. Following the ligation, those nucleic acids are amplified by a step
19 like PCR to create many, many copies of these nucleic acid fragments.

20 After the amplification step, those nucleic acids are sequenced on a,
21 for example, next generation sequencing machine. And this portion of the
22 claim produces a large amount of sequencing data. And that data is then
23 processed in the final limitation of Claim 1 to identify sequence reads with
24 identical identifier and target sequences as duplicates. That's Claim 1. And
25 then in Claim 2, we remove any duplicate reads from the sequencing reads.

1 And these two claims have been the focus of the parties' briefing and will be
2 the focus of our presentation today.

3 Now, it is possible to conceive of these claims and these limitations
4 by separating them into the physical limitations on the left of Slide 3, and
5 what Tecan's expert, Dr. Bustamante, called the, quote, "computer-aided
6 limitations" of Claim 1 and Claim 2 on the right of Slide 3.

7 And as the trial record in this case has developed, the focus of the case
8 has been on the computer-aided limitations. On Slide 4, I'd like to introduce
9 IDT's expert, Dr. Peter Sims, from Columbia University. He, in support of
10 our petition, documented extensively how the prior art teaches the physical
11 limitations of these claims regarding the first three portions of the claim: the
12 ligating, the amplifying, and the sequencing.

13 And as the record has developed, the fact that the prior art references
14 teach the physical limitations has gone un rebutted, and the focus of this
15 proceeding has become the computer-aided limitations.

16 What's very interesting about that is that, as Dr. Bustamante, Tecan's expert,
17 has explained, computer-aided analysis of sequencing data was well known
18 by the priority date. What we've shown here on Slide 5 is an excerpt from
19 his declaration. This is his affirmative testimony going through the well-
20 known workflow that people in the field use to analyze sequencing data.
21 And among those processes within this workflow he called out duplicate
22 identification. This was already a known step in the DNA sequencing
23 workflow as of the priority date.

24 And the patent admits this too. In the various examples within the patent, it
25 states that standard software is used for duplicate identification and removal.
26 The patent specification doesn't teach any new duplicate identification or

1 removal software. So, what has become the focus of this proceeding is also
2 the portion of the claim that the patent and the expert concede is already well
3 known within the field.

4 So over the course of this morning's affirmative presentation, we will
5 start with claim construction and go through what we perceive to be the two
6 remaining live claim construction disputes. This portion of our presentation
7 will be given by my colleague, Mr. Hynds. I will then return to the podium
8 to discuss the anticipation arguments and related obviousness argument
9 grounded in the Bielas reference. In our papers, this was one of the later
10 grounds. But as the record has developed, this is an anticipation argument.
11 This has become the focus of the briefing. And then I will speak to the
12 obviousness grounds based on the combination of Iafrate and Kivioja.
13 Unless Your Honors have any questions about this introduction, I'd now like
14 to turn the podium over to my colleague to address the claim construction
15 issues.

16 MR. HYNDS: Good morning, Your Honors. Patrick Hynds on
17 behalf of Integrated DNA Technologies. As my colleague, Mr. Fletcher,
18 mentioned, I will be addressing the remaining claim construction disputes in
19 this proceeding.

20 The sole limitation subject to a claim construction dispute is the
21 computer-aided limitation. The computer-aided limitation sets forth the
22 requirements for the identification of duplicate sequencing reads. It says,
23 "identifying sequence reads with identical identifier and target sequences as
24 duplicates." I will first address the meaning of the term duplicates, and then
25 I'll address what is required --

1 JUDGE BRADEN: Mr. Hynds, we can go ahead and skip the
2 duplicates part. Let's get to the good stuff.

3 MR. HYNDS: Yes, Your Honor. All right. So the good stuff -- the
4 parties disagree about the meaning or what is required for the duplicate
5 identification. What we agree on is that there are two data inputs. There is
6 an identifier sequence, and there is a target sequence. Both of those need to
7 be used in the process of identifying duplicates. But is there any temporal
8 requirement in this limitation that dictates when those two data inputs need
9 to be used in the duplicate identification process? IDT says no. This is a
10 straightforward claim. You have your two data inputs. At some point in the
11 process you must use those two data inputs to identify duplicates.

12 Tecan, on the other hand, says no. Tecan asked the Board to layer on
13 two additional limitations to the computer-aided limitation. First, Tecan
14 asked the Board to read in the identification process occurs through a step
15 that uses both the identifier and at least a portion of the target sequence.
16 Through its step requirement, Tecan seeks to impose simultaneity, that is,
17 that both data inputs must be used at the exact same time. Tecan then asked
18 the Board to read in that only a portion of the target sequence need be used
19 to -- in the identification of duplicates.

20 I want to be clear about IDT's claim construction position. Tecan
21 characterizes in Paper 34 at page 3, which you can see on Slide 13 here,
22 IDT's position as not caring about how the identifier sequence and the target
23 sequence are used in the identification of duplicates. To the extent this
24 argument is characterizing IDT's position as saying you could use only one
25 of the data inputs in the identification of duplicates, that is incorrect. IDT

1 agrees, both data inputs must be used. What IDT does not agree with is that
2 both data inputs must be used simultaneously.

3 So the dispute, to be clear, is whether simultaneity is required in the
4 claim language. But Tecan's position, its simultaneity requirement, I will
5 discuss is unsupported by the plain language, the patent specification, the
6 prior -- the prosecution history, and the intrinsic record.

7 If we start with just the plain meaning of the claim, as I've said, it
8 requires identifying sequence reads with identical identifier and target
9 sequences. Your two data inputs use those to identify duplicates. Nowhere
10 in the claim is there a limitation that dictates when in the process of
11 identifying duplicates that you need to use those two data inputs.

12 Tecan's position, on the other hand, imposes simultaneity, and on
13 Slide 16 here, we've depicted what that would look like. You have your
14 identifier sequence and your target sequence put together as a single data
15 input. You match it up to another sequencing read and ask, do those two
16 pieces of data match? If yes, they're duplicates.

17 Tecan looks for support in the language of the claim for its
18 simultaneity requirement, but it's not there. Tecan argues that each of the
19 steps of the claim method include the specific elements necessary for that
20 step, and the identifying step is no different. Our interpretation of Tecan's
21 argument is that they're saying the steps that precede the computer-aided
22 limitation support the simultaneity requirement. But that's not the case.

23 If we take the amplifying step as just an example, which the patent
24 says can occur via PCR, which is shown here on Slide 18, the Board knows
25 well that PCR occurs through a multi-step process. You first denature two
26 fragments of DNA at a specific temperature. At yet another temperature-

1 dependent step, you anneal primers to the fragments of DNA. At yet another
2 temperature-dependent step you generate complementary sequences. And
3 you repeat that process over and over again until you've sufficiently
4 amplified your product.

5 JUDGE BRADEN: But, Counsel, would you agree that PCR, even if
6 you argue that it's a multi-step process, it is a single process, and you never
7 take that Eppendorf tube out of your PCR machine in order to run these
8 different steps, do you?

9 MR. HYNDS: That's true, Your Honor. It is a single step process.
10 And in the colloquial sense, the identification step is also a single step
11 process. It is the step of identifying duplicates. But the dispute is whether
12 or not the data inputs have to be used simultaneously, which IDT contends is
13 unsupported by the claim language, the rest of the intrinsic record, and the
14 extrinsic record.

15 Recently, the Federal Circuit in *Apple v. Gesture Technology* has
16 rejected the addition of a temporal limitation that was unsupported by the
17 plain and ordinary meaning of the claim language, and the Board should
18 do -- the Board should do so here as well.

19 If we look to the patent specification, the patent specification also
20 supports IDT's position. In other words, that all you need to use is the two
21 data inputs without regard or without a temporal limitation, dictating when
22 those two data inputs are used.

23 Example 1 starts with duplicate sequencing reads being identified by their
24 genomic start positions. So you take your litany of target sequence reads.
25 You match them up to a reference genome. You identify a genomic start

1 position. Example 1 then directs the POSA to then look to the identifier
2 sequences. Do all of those match?

3 And in a third step in the process, you then identify duplicates, or in
4 the language of the specification, the sequences were considered to have
5 come from the same initial DNA ligation event.

6 So, a three-step process is described in Example 1, not a simultaneous
7 one, and Tecan's attempt to run away from Example 1 is unconvincing.
8 IDT's position is that Example 1 is covered and Example 5 is covered. Both
9 are covered by the meaning of the -- the plain meaning of the identification
10 step or the computer-aided limitation.

11 Example 1 is what the patent points to for the identification of true
12 duplicates. The only figure associated with any of the examples is Figure 5.
13 Figure 5 provides data for the process. So Example 1 was core to the
14 patent's meaning.

15 In attempting to convince the Board to impose a simultaneity
16 requirement, Tecan spends most of its effort on the prosecution history.
17 Specifically, Tecan relies on three statements in the prosecution history, but
18 none of them provide the support that Tecan seeks.

19 If we start with the active step language. Samuels do not --

20 JUDGE BRADEN: And I'll note we're on Slide 24, correct;
21 Mr. Hynds?

22 MR. HYNDS: Yes, Your Honor, Slide 24. My apologies.

23 JUDGE BRADEN: Thank you.

24 MR. HYNDS: Yeah. So Slide 24 -- the excerpt is from Petitioner's
25 Exhibit 1018. The active step language says that Samuels, et al, do not teach
26 the active step of identifying duplicate sequencing reads as a sequencing

1 read comprising the same identifier site and nucleic acid fragment. But the
2 active step refers to the fact that applicant argued in prosecution that
3 Samuels didn't teach an identification of -- a step of identifying duplicates at
4 all. So the active step refers to, hey, our process has a process of identifying
5 duplicates. Samuels doesn't.

6 If we then look to the used in combination language, the used in
7 combination language at least equally supports the proposition that the
8 identifier sequence and the target sequence are both used as data inputs
9 without regard to when they're used in the process of the identification of
10 duplicates.

11 And if we look to Petitioner's Exhibit 1018.0799, the first full
12 paragraph on that page is where the used in combination language comes
13 from. It's in the second to last sentence. The very beginning of that
14 paragraph says that, "McCloskey et al. disclosed a method of identifying
15 redundant sequences based solely on two or more sequence reads sharing an
16 identical barcode and batch stamp."

17 What the applicant was doing was distinguishing the fact that McCloskey
18 only taught using an identifier sequence to identify duplicates, not that
19 McCloskey taught the process of identifying duplicates using the identifier
20 sequence and target sequence, but in the wrong order.

21 The same is true for the used in conjunction language. Again, the
22 applicants were distinguishing the fact that McCloskey only taught the use
23 of a barcode and the identification of duplicate sequencing reads. Used in
24 conjunction, at least again, just like the used in combination language
25 equally supports the proposition, IDT's position, that all you need are your

1 two data inputs. You have to use them to identify duplicates, but there is no
2 temporal limitation in the claims.

3 Finally, it's telling here that Tecan never raised a prosecution history
4 disclaimer argument. There's nothing clear and unmistakable about the
5 language and the prosecution history. At best, Tecan can rely on the
6 prosecution history for support. But in the face of the plain language of the
7 claim, the patent specification and the context of the statements that Tecan
8 points to in the prosecution history, it cannot bear the weight that Tecan asks
9 it to bear. So the intrinsic record supports IDT's claim construction position
10 that no simultaneity requirement is in the plain language of the claim.

11 What about the extrinsic record? Well, the extrinsic record, including
12 Dr. Bustamante, Tecan's own expert, supports IDT's position that no
13 simultaneity is required. Asked if a comparison or the data analysis process
14 can be split into two components, such that first identifiers are compared,
15 then target sequences are compared, is that still a single step?
16 Dr. Bustamante testifies, you could start with a string comparison that would
17 begin with a character comparison. In other words, you could go nucleotide
18 by nucleotide or base by base through your identifier sequence and your
19 target sequence and ask, do these match? Do these match? Do these match?
20 Not at all a simultaneous process in the identification of duplicates.

21 In fact, Dr. Bustamante testified that all you need in the end is to have
22 identical identifiers and identical target sequences in order to identify
23 sequence reads as duplicates. That's exactly IDT's position. You need the
24 two data inputs, but there's no simultaneity requirement, no temporal
25 limitation, in the computer-aided limitation.

1 And if there were any doubt, asked again, if my workflow or the data
2 analysis process compares the identifiers first, then clusters them based on
3 that, then compares the target sequences, is that still a single step?

4 Dr. Bustamante testified, I would say so.

5 So, to recap, the claim language supports IDT's claim construction
6 position, the specification does, the prosecution history does, and
7 Dr. Bustamante's testimony does. The only thing that Tecan can point to is
8 the prosecution history. But as we discussed, the prosecution history is, at
9 best, ambiguous and actually supportive of IDT's position. And when -- as
10 the Federal Circuit said in *AquaTex*, where the prosecution history neither
11 supports nor discredits a particular meaning of the term, it should not be
12 given much weight, and the Board should not give the prosecution history
13 much weight here.

14 Unless the Board has any further questions about the simultaneity
15 requirement, I'd like to move on to talk about the portion of requirement.

16 [For] Tecan's second limitation, it asked the Board to layer on to this
17 claim that only a portion of the target sequence need be used in the
18 identification of duplicates. Perhaps obviously, it's IDT's position that that's
19 unsupported by the claim language itself. Again, the computer-aided
20 limitation says identifying sequence reads with identical identifier and target
21 sequences as duplicates, a portion of is simply read into the claim. It's not
22 there.

23 Tecan, for support for its position, says at Paper 34, pages 9 to 11, that
24 the target sequence could be longer than the sequencing read, and thus, you
25 will only need a portion of the target sequence. But if we walk through the
26 claim language, that position is unsupported by the language itself.

1 Again, this is a method for detecting duplicate sequencing reads.
2 Sequencing reads are defined in the sequencing limitation as including the
3 identifier and target sequence. So, the target sequence is part of the
4 sequencing read. And in the computer-aided limitation --

5 JUDGE BRADEN: So, Counselor, is it Petitioner's position that
6 target sequences means one base pair or the entire target sequence? Where
7 does Petitioner fall out on that?

8 MR. HYNDS: Yeah. It's the entire target sequence, Your Honor,
9 that -- it's anything that's -- so the duplicate sequencing read -- the target
10 sequence is part of, as the claim language says, part of the sequencing read --

11 JUDGE BRADEN: So the entire target sequence?

12 MR. HYNDS: So it must be the entire target sequence as the claim
13 term defines the term. Right?

14 JUDGE BRADEN: Thank you.

15 MR. HYNDS: So, if the sequencing read includes the target
16 sequence. So whatever is read. And I think Your Honor might be pointing
17 to Tecan's argument about Example 5 where there is the target -- or the read
18 was 50 base pairs long. The read incorporated both the identifier and the
19 target sequence under the claim's terms.

20 The claim term that -- or sorry -- the claim here says that you're detecting
21 duplicate sequencing reads. That includes the target sequence.

22 So, in the context of Example 5, read in view of the claim language,
23 the sequencing read was just those 50 base pairs. It didn't matter that there
24 was a latter 150 base pairs that were unsequenced. They were never
25 sequenced. They can't be used in the data analysis process. And that's all
26 the computer-aided limitation is about.

1 Finally, and this I think goes to, Judge Braden, your question as well,
2 it's our understanding that Tecan's position, according to the expert
3 testimony from Dr. Bustamante, that a single base, by definition, could be a
4 portion of the target sequence. But that would render absurd results. You
5 could end up with one base pair and identifying the target sequences as
6 duplicates. But we agreed, the parties agreed, that duplicates means 100%
7 identity between the identifier sequence and the target sequence; so you need
8 to use the entire target sequence there in order to find your duplicate. Not a
9 single base or 3, 5, 10, 15 -- the entire target sequence.

10 Unless the Board has any further questions, I'll turn it back over to
11 Mr. Fletcher to address anticipation and obviousness.

12 JUDGE BRADEN: Thank you very much for your arguments,
13 Mr. Hynds.

14 MR. HYNDS: Thank you, Your Honor.

15 MR. FLETCHER: So, we'd now like to turn back --

16 JUDGE BRADEN: Counsel, I know that you were going to go
17 straight into your anticipation on Bielas, but could you just answer a quick
18 question for me?

19 Regarding the need to have the entire target sequence, how does that
20 impact your challenge that's based on Kivioja, which uses the five prime
21 mapped position? Does that mean that the Iafrate and Kivioja reference
22 challenge is off the table now, or how does that impact it?

23 MR. FLETCHER: It is not off the table. I think this goes to how you
24 interpret the use of the target sequence. But let me skip ahead to that.

1 So, when this genomic alignment happens, there is broad agreement
2 between the parties that the target sequence is used. Dr. Bustamante
3 explained that. Dr. Sims explained that as well.
4 The target sequence is used and mapped to the genome, and the data at that
5 point get annotated with the genomic coordinates of the sequence. And as
6 Dr. Bustamante testified during his deposition when I asked him -- and this
7 is in the record, at Exhibit 1124, page 91 -- "sequences with the same
8 genomic coordinates are nearly, if not always, identical because they have
9 been aligned to the genome." And it's a sort of -- I apologize. I have a bit of
10 a math background. I come to it thinking about transitivity. And so the
11 sequence has been compared to the genome. And then the genomic
12 coordinates are provided for two different sequences. And then the
13 coordinates get compared to each other.

14 And so, if A equals B and B equals C, then A equals C. And that's the
15 way in which Kivioja teaches the identifying of duplicates with the same
16 target sequence even though genomic coordinates are used.

17 JUDGE BRADEN: Very good. Thank you, Counselor.

18 MR. FLETCHER: Certainly. So I'll flip back to Bielas for a moment.
19 So, I'm now on Slide 33 where we have reproduced Figure 3B from Bielas
20 with Dr. Sims's annotations. And as Dr. Sims explained in his declaration,
21 the Bielas method of Example 3 teaches the methods that are claimed in the
22 '357 Patent. And the annotations in the Figure 3B shown on Slide 33 are
23 intended to help the Board, Your Honors, walk through how Bielas maps
24 onto the claims.
25 So what we have at the top in the right hand corner of Slide 33 is our
26 original gene fragment that is being focused on for purposes of Example 3B.

1 As the Bielas reference then explains, it is ligated into the vector with the
2 adapters, it is amplified and sequenced, and that all happens in the box at the
3 top of Figure 3B. And that takes care of all the physical limitations of the
4 claims, and that has not been disputed by any of the parties.

5 The focus of the proceedings have then come to the data processing
6 that is reflected on the remainder of Figure 3B on the right. And in Bielas's
7 example that it's using to describe how its process works, we see a
8 representation of four different sequences that have come off the sequencing
9 machine. They all have been grouped into this family of four sequences
10 because they have the same identifiers, which are the boxes on the left and
11 the right of the sequences. And within this grouping of four sequences,
12 Bielas then compares the target sequences. That's what's reflected as
13 happening in this grouping. And from these four sequences, Bielas creates a
14 final consensus sequence.

15 There's been a lot of discussion, and we'll go through it all, about what
16 is a consensus sequence? But as reflected here, and as described by
17 Dr. Sims, what Bielas has done is compared all of these sequences and
18 decided to keep the sequence with the black diamond, and it has rejected the
19 white triangle that shows up in one of the four sequences.

20 Critically, as shown in this implementation of Bielas, three of the
21 sequences were entirely identical, and those three identical sequences have
22 now been reduced to one. At one point in the proceedings, there was a
23 discussion about whether the fact that there is this second different sequence
24 takes this method off the table. The parties have agreed it does not. The fact
25 that this is a comprising claim means that it does not matter that in Bielas's
26 method some sequences that were perfect duplicates, and one sequence that

1 was a close but not quite duplicate, were combined together into one. That
2 fact does not matter anymore.

3 So, that's what Dr. Sims explained about Bielas. When we got to take
4 Dr. Bustamante's deposition, it's clear that there is, I think, substantial
5 agreement about how this method works. He agrees that these sequences
6 have all been grouped by their identifiers. The identifier sequences have
7 been used to cluster the sequences for the data analysis. That's what he was
8 testifying to in Exhibit 1124 at page 164. That's what's shown on Slide 34.

9 Now Dr. Bustamante also agrees that in this Bielas method, the target
10 sequences get compared next. The Bielas method compares the inserts
11 between the identifiers. Those are the target sequences. It compares them
12 all and then outputs the final sequence that's shown on the bottom. And as
13 Dr. Bustamante agreed, shown here on Slide 36 in his deposition on
14 page 166, "the final product of the method is a single pair of sequences."
15 That's what Bielas generates.

16 So it started with a fragment. It ligated adapters, amplified it. It used
17 the identifier sequences to group them. It then compared the target
18 sequences, and it put out a single sequence.

19 So, the focus of the briefing has been on the fact that this happened in
20 two data processing steps. First, the sequences were clustered by their
21 identifiers, and then the target sequences were compared. Under IDT's
22 claim construction, that fact does not matter. Even under Tecan's claim
23 construction, that fact does not matter because, as Dr. Bustamante testified
24 in his deposition, the comparison is still a single step because of how it can
25 be broken apart.

1 If you take a look at data, you can look at it string by string, nucleotide by
2 nucleotide, piece by piece. In Dr. Bustamante's mind, it is all a single data
3 processing step.

4 Now, in our papers we emphasize the *Hewlett-Packard v. Mustek* case
5 to make the point that it does not matter what the reference uses in terms of
6 words to describe what it is doing. That's one of the points of the case
7 throughout the Federal Circuit's precedent. It doesn't matter that the Bielas
8 reference doesn't use the word duplicate. What matters is what Bielas
9 teaches and what the method in Bielas does.

10 And so, even though that sequence at the bottom of Figure 3B is not
11 described as having been deduplicated, instead, the reference used the word
12 deconvoluted. That doesn't matter. What matters is what is being taught,
13 what the person of ordinary skill in the art understands.

14 There's also been a debate in the papers about whether it matters that
15 the algorithm Bielas uses is a consensus sequence algorithm rather than
16 some other algorithm. As Dr. Bustamante testified in his deposition, "those
17 get to the same place. They are the same thing." And emphasized here on
18 Slide 39, middle portion one of his answers, he says, "there are multiple
19 ways that this can be accomplished." He was refusing to agree that the
20 patent is limited to any particular sequence algorithm.

21 He says, "you start with a pair, define those as identical, add another
22 sequence that is identical to that, you would arrive at the same conclusion
23 regarding duplication that would also have the same consensus sequence."
24 So, even though you could assign different names to these types of
25 algorithms, the output is the same. They all satisfy the requirement of

1 having identified duplicates with the same target sequence and identifier
2 sequence.

3 JUDGE BRADEN: So, Counsel, can we take a step back? This is
4 going to Slide 37 and talking about whether Bielas, the identifying and
5 deduplication, this occurs in a single step. Can you expand on that a little
6 bit?

7 When I look at the claims, it talks about identifying sequence reads
8 with identical identifier and target sequence. Does that mean that it is
9 identifying these sequences with the identifier and the target sequences at the
10 same time, or in the same "step"?

11 MR. FLETCHER: I apologize, Your Honor, can you please repeat the
12 question. Or I -- maybe I start over and try and explain, if that would help.

13 JUDGE BRADEN: Well, I'm wondering about the single step part.
14 Is this -- if I look at the testimony and look at what you have on Slide 37, is
15 this single step, does that mean it's occurring at the same time or just
16 occurring near in the same time, one after the other, by the data processing?
17 What is actually happening here in your single step?

18 MR. FLETCHER: Yeah. So, again, IDT's position is you simply
19 have to use both pieces of information. But you could take a break in
20 between. I think what's happening in Bielas is, it's a way of organizing the
21 data. So, first they're grouped, and then they're compared; so it's happening
22 rapidly in sequence on the computer.

23 But the way Tecan has focused on it -- they've said, you need to, as my
24 colleague Mr. Hynds showed, build one long string of text and compare that
25 entire string to the other ones. You don't get to break that string into chunks
26 and do a more efficient, smaller pairwise comparison.

1 But I think Dr. Bustamante, he has this background in computer
2 science. We asked him, is it still a single step even if you break the
3 comparisons up? And that's what the question I posed to him was, "would
4 there still be a single step even though there are N comparisons being made
5 one after the next?" And he says, "yes, it is all part of the single identifier
6 step. You could break it down as far as you would like. It is still that single
7 process by which you're comparing these pieces of data."

8 I hope that's -- clarified it.

9 JUDGE BRADEN: Yes. Thank you, Counselor, I believe I
10 understand your position.

11 MR. FLETCHER: Okay. So, just briefly, with respect to Slide 40 as
12 the Petitioner with the burden of proof, this is part of our obviousness
13 ground on Bielas. So, the Bielas reference didn't use an eight base pair
14 identifier. It had a different number of nucleotides in its identifier.

15 So with respect to Claim 9, we argued that the claim would have been
16 obvious because the length of the identifier is a readily changed variable that
17 the POSA could work with. And I don't understand Tecan to have disputed
18 that point in any meaningful way, and Dr. Bustamante, for his part, agreed.

19 The length of the identifier is a feature that the person of ordinary skill
20 in the art could vary. They would recognize there is a tradeoff between the
21 length of your identifier and the complexity of your sample. They would
22 select an appropriate identifier length for the complexity of the sample. As
23 he testified, that was recognized in 2012. Because you have a fixed amount
24 of real estate, you have to decide how much to use for the barcode.

25 So now briefly turning to Iafrate and Kivioja, I think we already
26 covered the most exciting part of it, but I'll start at the top at the beginning.

1 These are two references. The Iafrate reference is a patent from
2 Massachusetts General Hospital. This is the patent that Integrated DNA
3 Technologies licensed to create its products in this space. This is the
4 anchored multiplex PCR patent that is discussed in Dr. Sims's declarations.
5 And we have on the right of Slide 42 the Kivioja reference. This is a
6 scientific paper talking about ways to improve DNA sequencing.

7 So why would the POSA have looked at Iafrate? Well, Iafrate is
8 teaching how to use better methods for preparing DNA samples for working
9 with patients with urgent health needs. And it teaches methods for enriching
10 target sequences prior to sequencing. It teaches that these will have research
11 and clinical applications. The POSA would have wanted to use Iafrate's
12 NGS methods. And, as Dr. Sims explained, these can be used for
13 diagnosing and treating cancer. That's part of what's described in the patent.
14 And the POSA would have wanted to make those methods as accurate as
15 possible.

16 And I am going through this material because Tecan has alleged that
17 the allegations for the obviousness combination were too conclusory, were
18 too flimsy to justify invalidating these claims as obvious. And I think the
19 record here is quite the opposite. Dr. Sims provided a substantial
20 explanation for why these two references point to each other and belong
21 together.

22 And as Dr. Sims explained, the problem with Iafrate's method is
23 because it depends on several rounds of PCR, it can introduce inaccuracies.
24 That is a known problem with PCR and why people in the field were doing
25 all of this barcode work that we see reflected in a stack of references in the
26 record.

1 And so because the person with ordinary skill in the art would have
2 wanted to address the possibility that Iafrate's methods could introduce
3 inaccuracies, the POSA would have wanted to improve upon them.

4 Now, the Iafrate adapter already has all of the features of the claims of
5 the '357 Patent, except for that unique identifier. It hadn't yet incorporated
6 the molecular barcode identifier. But that is what Kivioja teaches.

7 And as Kivioja explains on its very first page, the use of these
8 barcodes, the use of this method, can improve accuracy of almost any next
9 generation sequencing method. In my now almost 20 years of practicing
10 patent law, I don't think I have had such a good direct, in the reference,
11 teaching to combine as this one.

12 Kivioja says, from the very beginning, use our methods to improve
13 other methods. And so that there's no mistake, we asked Dr. Bustamante,
14 "do you address the motivation to combine these references?"
15 Dr. Bustamante testified, "I do not." So I think the record is clear in this trial
16 that the person of ordinary skill in the art would have had reason to combine
17 Kivioja and Iafrate.

18 Dr. Sims then explained how the POSA could combine these
19 teachings. In fact, some of the sequencing -- DNA sequences contained
20 within the adapters between the two references are identical, and Dr. Sims
21 explained how the unique identifier shown in yellow on Slide 50 from the
22 excerpt of Kivioja could be added easily to the adapter used in Iafrate.

23 So, we now get -- having finished the physical limitations -- to the
24 computer-aided limitations. What does Kivioja teach about how to identify
25 duplicates and how to do this? This is where we started the discussion.

1 Kivioja uses those molecular barcodes that are shown in the excerpt of
2 Figure 1 from Kivioja here on the left of Slide 51. And those unique
3 identifiers are the little circular dots shown in the figure that have been
4 appended at the top of the method. The nucleic acids have been amplified.
5 The sequencing results have come out, and Kivioja is now processing the
6 sequencing data.

7 As Dr. Bustamante testified, Kivioja's method for identifying
8 duplicates uses both the molecular barcode and the genomic coordinates as
9 we discussed earlier.

10 And then -- we already covered that -- skipping ahead to Slide 54.
11 How does the algorithm work? It is shown here, at the bottom of
12 Figure 1A, the algorithm has grouped the sequences based on the sequence
13 content, the green portion, which in Kivioja's method is the genomic
14 coordinates, and it's used to identify a sequence represented by the colored
15 dot. And it has, as Dr. Sims said, collapsed them. As Dr. Bustamante
16 testified, it deals with them. But, critically -- and we'll use the example on
17 the left -- we have many green sequences with two unique identifiers, blue
18 and pink.

19 And as Kivioja explains, we have all this sequencing data, but at the
20 end of the day, that's really only two sequences, and that's what's reflected in
21 the left hand side when it says "two UMIs." As Dr. Sims explained, this is
22 deduplication. This is the identification of duplicates.

23 So, now I'd like with my last few minutes to end with a point that we
24 raised in our reply, emphasize that we started this portion of these
25 proceedings with three petitions. But when it came time for the Patent
26 Owner response to be filed, the Patent Owner, Tecan, disclaimed two of the

1 patents. And so those were gone, and the Board entered adverse judgment
2 on those two patents.

3 So, what happens? That's not controlling, but it's IDT's position that
4 this is informative and something that is important for you all not to lose
5 sight of. When Tecan obtained these patents, it had to terminally disclaim
6 the '357 Patent over the '399 Patent. It has now, in fact, disclaimed, the '399
7 Patent, and that is an informative fact.

8 And in its surreply at page 22, Tecan says nothing to distinguish the '399
9 Patent and the '357 Patent. It simply says, as we all agree, this fact is not
10 controlling, but it does nothing to dispute the fact that it is interesting and
11 informative, and it should inform the Board's analysis of whether the claims
12 of the '357 Patent are valid.

13 And I'd like to stress it was not for lack of space. Tecan had over 600
14 words left in its surreply. If it had anything to say about the difference
15 between the '357 Patent and the '399 Patent, it could have. We invited it to
16 do so in our reply brief. The fact that it didn't address it should also be
17 telling and factor into this Board's analysis on the merits of whether the '357
18 Patent's claims are anticipated or obvious over the references we have
19 brought to the Board's attention.

20 Unless the Board has any other questions, at this time I'd like to
21 reserve the remaining time for rebuttal.

22 JUDGE BRADEN: Thank you very much, Counselor. I see no
23 questions from my colleagues so you have your remainder time for rebuttal.

24 And now we'll hear from Patent Owner when they are ready.

25 MS. CIPRIANO: Your Honors, are you ready? I'm ready when you
26 are.

1 JUDGE BRADEN: Counselor, can you please confirm the amount of
2 time that you would like for surrebuttal?

3 MS. CIPRIANO: 45 minutes on affirmative argument is perfect. 15
4 minutes for surrebuttal, please.

5 JUDGE BRADEN: Very good. Thank you. And you may begin
6 when you are ready.

7 MS. CIPRIANO: Thank you. So, good morning. Again, this is
8 Linnea Cipriano for Patent Owner Tecan Genomics.

9 At the outset, I'd like to address the last point that opposing counsel
10 addressed. And I think that it would be improper for this panel to consider
11 Tecan's decision to reduce the burden on the parties and the Board by
12 simplifying this case to a single patent that -- that had no bearing on the
13 substance of the issues in front of us today and should not be considered any
14 kind of substantive decision by Tecan or a decision by the Board. And that's
15 reaffirmed by the Federal Circuit's decisions in the *Softview* case.

16 So stepping away and looking at the merits of the proceeding, as
17 you've just heard, there are three main issues in dispute between the parties.

18 The first is claim construction. It is Tecan's position that the
19 prosecution history of the '357 Patent makes clear that the challenged claims
20 require the identifier and the target sequence to be used in combination in a
21 step of identifying duplicates. This construction is further supported by the
22 specification and supported by the testimony of Dr. Bustamante, the only
23 expert to provide testimony on this issue.

24 The second issue is whether the combination -- and I will be
25 addressing the points in a slightly different order than my colleague. The

1 second issue is whether the combination of Kivioja and Iafrate render the
2 challenged claims obvious. And that's Ground 1 of the petition.

3 Under Tecan's construction of the challenged claims, the answer must
4 be no. Kivioja discloses a process where the target sequence is used to map
5 the reads, but is not used in the step of identifying duplicates. Kivioja
6 further does not disclose the additional requirement of Claim 2 that
7 duplicates be removed from the data set.

8 Finally, the petition does not provide sufficient explanation regarding
9 the motivation to combine the adapters in Iafrate and Kivioja.

10 Finally, the parties dispute whether Bielas discloses all elements of
11 the challenged claims. The answer here is similarly, no. Bielas teaches that
12 sequencing reads are grouped based on having matching cypher pairs.
13 That's it. There is no disclosure of a target sequence ever being used with
14 those cypher pairs to group sequences. Therefore, Bielas cannot anticipate
15 or render obvious the challenged claims.

16 So let's start with claim construction. And I've put up Slide 4 to
17 reorient us to the claim language and to the disputed constructions.

18 As Petitioner explained, there are two aspects of the construction of
19 this term that the parties dispute. First is whether the identifier and the target
20 sequence must be used in a step to identify duplicates and second is whether
21 the entire target sequence must be used in this process. And I'd like to talk
22 through each of these, in turn.

23 So Petitioner's argument largely discounts the prosecution history,
24 which would be error here. On Slide 5, I've put a few quotes from the
25 Federal Circuit. "As the Federal Circuit has instructed, the prosecution
26 history is usually the best source for understanding the claims. It contains

1 express representations from the applicant, and it's particularly important
2 where the applicant limited the invention, making the claim scope narrower
3 than it whether -- otherwise would be." That is precisely the case here.

4 The patent specification broadly -- we can take a step back and look at
5 the specification of the '357. The patent specification broadly describes the
6 use of unique molecular identifiers to identify duplicates in a sample, and the
7 claims reflected that breadth when they were originally filed. During
8 prosecution, however, the examiner rejected the claims based on prior art
9 that overlapped with portions of the subject matter, and applicants then
10 narrowed the claim to avoid the prior art.

11 If we look more specifically at what occurred during prosecution, this
12 is -- I put on Slide 6 an excerpt. This is actually prosecution of the parent
13 application of the '357 Patent but where similar claim limitations were
14 introduced. The examiner -- prior to this amendment, the examiner rejected
15 the then pending claims in an office action, and this office action starts at
16 Exhibit 1018 starting at page 773. "The examiner rejected the claims as
17 obvious in light of Samuels" -- "the combination of Samuels and
18 McCloskey."

19 At page 780 of Exhibit 1018, "the examiner asserted that Samuels taught
20 most limitations of the then pending claims, and the claims would have been
21 obvious in light of Samuels in combination with McCloskey."

22 In response to that office action, applicants amended the claims as
23 shown on Slide 6, modifying the duplicate identification limitation to make
24 it an express identification step, changing detecting to identifying.

25 With this amendment applicants distinguished both Samuels and
26 McCloskey, and my -- opposing counsel parsed apart the distinguishing of

1 Samuels versus McCloskey. I want to make sure that the Board highlights
2 that this was an obviousness rejection. So you cannot look at simply the
3 references in isolation, but must look at them as the examiner was seeing
4 them in combination here. But when --

5 JUDGE BRADEN: So, Counsel, how is it that this amendment that
6 was in the parent that -- I believe it was the '399 Patent -- this amendment
7 here for an obviousness rejection, how does this inform us that the identifier
8 site and the nucleic acid fragment have to be used simultaneously together in
9 order to identify a duplicate sequencing read?

10 MS. CIPRIANO: So, really, it is the comments that were made in
11 connection with this amendment that inform that analysis. And, if I may, I
12 put some of those statements on Slide 7.

13 And so when discussing Samuels, applicant stated that Samuels did
14 not teach an active step of identifying duplicates. And as I'll discuss a bit
15 later, Samuels is virtually the same method that you see in Bielas that
16 Petitioner -- on which Petitioner relies. And the Patent Owner said Samuels
17 didn't teach this method of identifying duplicates.

18 The applicant went on to distinguish McCloskey, stating that the
19 claimed invention uses the identifier and the target sequence in combination.
20 Now, when looking at the two references together, Samuels -- and I can go
21 to Slide 22 just for reference -- Samuels was a reference that grouped the
22 reads by barcodes, by identifiers, and then looked at the sequence for
23 mutations. This is the --

24 JUDGE BRADEN: So please clarify that, Counselor, because I
25 thought that I understood Petitioner to say that Samuels only used this

1 barcode tag, that it did not use the sequence in order to aid in deduplication.

2 Did I mishear?

3 MS. CIPRIANO: But --

4 JUDGE BRADEN: Please clarify.

5 MS. CIPRIANO: Yeah. Sure.

6 The McCloskey reference -- and that's what I was going to get to just
7 in a moment to clarify that exact point -- the McCloskey reference only uses
8 barcodes. So I think that's what the reference that my opposing counsel was
9 referencing when he said "only using the barcode," but I'm sure he can
10 correct me if I'm incorrect there.

11 JUDGE BRADEN: But Samuels uses both an identifier and nucleic
12 acid fragment sequence; is that correct?

13 MS. CIPRIANO: So, Samuels used the identifier. I think that he
14 called it a barcode in Samuels -- to group the sequences and then looked for
15 mutations in the sequence. It was a method of detecting mutations. So,
16 that's the context that we need to read the prosecution history in.

17 So, if we go back to --

18 JUDGE BRADEN: I'm sorry. Could you repeat that, please?

19 MS. CIPRIANO: Sure. I was pointing out that Samuels used an
20 identifier and looked at mutations, and the examiner was combining that
21 reference with McCloskey that used a barcode. And, really, McCloskey was
22 used for the length of the barcode there in examiner's --

23 JUDGE BRADEN: And so the argument is that because Samuels'
24 fragments or sequences are not identical, they do not read on the claim; is
25 that correct?

26 MS. CIPRIANO: I'm sorry. I don't think I understand your question.

1 JUDGE BRADEN: That's okay. Please proceed, Counselor.

2 MS. CIPRIANO: Okay. So, going back to Slide 7. So applicant,
3 when discussing McCloskey, was stating that in the claimed invention, the
4 claimed invention uses the identifier and the target sequence in combination.
5 So, yes, McCloskey uses only barcodes, but Samuels used the barcodes in a
6 different way. And applicant made note that this combination of the target
7 sequence and the identifier was an improvement, provided improvement
8 over the McCloskey method.

9 So, the examiner later allowed the claims to issue in the '399 Patent
10 that are not at issue in this proceeding. But the prosecution history
11 continued when the continuation application that led to the '357 Patent was
12 filed. And I have a later amendment, or later comments, from the
13 prosecution history on Slide 8.

14 So the examiner continued to raise the same prior art against the
15 pending claims and issued another 103 rejection based on Samuels and
16 McCloskey. And to overcome this rejection, applicants again distinguished
17 McCloskey and explained that in contrast, the claimed invention uses the
18 fragment sequence in conjunction with the identifier to identify duplicates.

19 So, contrary to what Petitioner argues, there is no ambiguity here.
20 The applicant made clear that a critical aspect of the claimed invention is
21 that the identifier and the target sequence must be used together to identify
22 duplicates.

23 JUDGE BRADEN: And when you say together, you mean
24 simultaneously, not consecutively?

25 MS. CIPRIANO: No. No. I do not, Your Honor. And let me make
26 that point very clear. So, Petitioner takes issue with Tecan's proposal and

1 argues a simultaneity requirement. And that's not Tecan's position at all.
2 Tecan is not saying that the identifying step needs to be one single thought
3 or one single stroke of a computer program. But it does need to be a step in
4 the method that is directed to identifying duplicates. And just like, as you
5 noted, the PCR step of an amplification, that is a multi-step process, but it is
6 all directed to identifying a duplicate.

7 And here, there's no -- we're not trying to say that there is a temporal
8 requirement that the identifier needs to be compared before the sequence or
9 anything like that. It's Tecan's position that the sequence and the identifier
10 just must be used together in the step for identifying duplicates and not in
11 steps that achieve different purposes, or that are used to create different
12 types of data.

13 JUDGE YANG: So, Counselor, I have a question on that. So, if you
14 use the identifier to say these identifiers are identical and group all these
15 sequence reads together, and then you look into the sequence of interest and
16 look for identical ones, would that be a single step or different steps?

17 MS. CIPRIANO: If the identifier sequence is used to group the
18 sequences and then the sequences themselves are used to identify duplicates,
19 yes, that would be a step of identifying duplicates.

20 JUDGE YANG: Okay, thanks.

21 MS. CIPRIANO: But I will note that for this proceeding, the Board
22 need not answer the question of whether the target sequence and the
23 identifier must be used simultaneously, because the prior art cited in the
24 petition does not use a multi-step process for identifying duplicates.

25 The cited prior art never uses the target sequence and the identifier in
26 combination. Kivioja uses the target sequence in a step to map the reads and

1 generate a different data set that is then used in their analysis. But it only
2 uses the identifier to identify duplicates.

3 In Bielas, the identifier, the cypher pairs, are -- that's the only data that is
4 ever used in a grouping of reads. Thus, the question of a multi-step process
5 is largely irrelevant to the issues before the Board.

6 Petitioner attempts to argue in its papers that the specification does not
7 support Tecan's interpretation of the claim, but that is incorrect. Example 5
8 describes the precise embodiment of the claims as they should be read.

9 Example 5 -- and I have that on Slide 9 -- Example 5 describes an
10 embodiment that shows how an identifier and a target sequence can be used
11 in combination to identify duplicates. So, in Example 5, a library was
12 created using adapters illustrated at the top of column 20, and that's on the
13 left-hand side of Slide 9.

14 And these adapters contain an index site for multiplexing, a sequence
15 primer binding site, and an identifier site made up of mixtures of random
16 nucleotides. So, these identifiers were added to fragments in the library, and
17 the library was sequenced. And after sequencing, Example 5 describes two
18 analysis steps.

19 First, six bases of the index read were used to separate the reads into
20 sample types. So that's going to be the indexing or the multiplexing step.
21 And second, the first 50 bases of the target sequence read were compared to
22 identify duplicates, and duplicates were removed from the data set.

23 Importantly, based on the structure of the adapters, the first 50 bases
24 of the target sequence read used for the duplicate identification would
25 necessarily include both the identifier site and the target sequence, or the
26 first part of the target sequence. Therefore, the comparison described in

1 Example 5 is a comparison of both the identifier and the target sequence to
2 identify and remove duplicate reads.

3 Petitioners only really focus on Example 1. But based on the
4 prosecution history, the claims do not extend to Example 1, because
5 Example 1 does not use the target sequence and the identifier together.
6 Applicants narrowed their invention during prosecution, resulting in a focus
7 on the embodiment, as Example 5.

8 And I'll note that no one is arguing that examples two, three, and four
9 should be covered by these claims. Two, three, and four are examples. As I
10 was saying, the patent is broader than the claims that ultimately issued.
11 Two, three, and four are examples that only use an identifier to identify
12 duplicates.

13 So, the only expert testimony on this issue was from Dr. Bustamante,
14 and I have some of his testimony on Slide 10. And contrary to IDT's
15 representation, Dr. Bustamante's testimony supports Tecan's interpretation of
16 the claims.

17 Dr. Bustamante provided testimony explaining that his interpretation
18 of Example 5 matches Tecan's construction of the claims and aligns with
19 how a person of ordinary skill would have read the patent and the
20 prosecution history. Taken together, the intrinsic and extrinsic records
21 support a construction that requires that these pieces of information be used
22 in the identifier step together.

23 JUDGE BRADEN: Okay. So I just want to make sure I understand
24 Patent Owner's position, because when I was reading this, it appeared that
25 you were going fishing for duplicate reads, and the bait you're using is this
26 identifier with at least a portion of the nucleic acid target sequence. That's

1 your bait. But then it seemed like Petitioner is saying, no, no, when you go
2 fishing for these duplicate sequence, the initial fishing that you get a group
3 of fish based off of your bait is the identifier. You've got, then, that set of
4 fish. You now go fishing again with your nucleic acid target sequence. Two
5 different things.

6 How am I supposed to read this? What am I fishing with?

7 MS. CIPRIANO: So, I think, based on Tecan's read of the claims and
8 the way that they're used and discussed in the prosecution history, in your
9 example, fishing for the identifier or using the identifier to compare
10 sequences and then using the target sequence to compare sequences, that
11 would be a fulsome identification step.

12 JUDGE BRADEN: Thank you very much.

13 MS. CIPRIANO: I would like to just add on, Tecan's distinguishing
14 interpretation here. The issue that -- what would not fall into an identifying
15 step -- the identifying step of the claims is a fishing expedition where you
16 look for the identifiers or you look for the sequence, one or the other, and
17 then you do something else with that data, and you convert it into to
18 something that is not the sequence of the identifier or not the sequence of the
19 target sequence and use that instead in the identifying step.

20 JUDGE BRADEN: Thank you very much, Counselor.

21 MS. CIPRIANO: So, moving on to the argument about a portion of
22 the target sequence. So, the other aspect of the term that the parties dispute
23 is whether reference to the target sequence requires a comparison of the
24 entire target sequence.

25 Now, I think some of this is the parties talking past each other a little
26 bit. And I'll just -- I want to clarify that it's Tecan's read of the record of the

1 patent that the target sequence and the read are not necessarily coextensive,
2 and that's truly where Tecan's construction come from.

3 So, if the Board finds that the read sequence and the target sequence
4 are coextensive and should always be coextensive, then I don't think we
5 have a dispute. But let me explain why Tecan thinks it's important that a
6 portion of the read -- the construction is proper under a portion of the target
7 sequence.

8 So here, I've put Figure 4 on Slide 11. And Figure 4, I think,
9 illustrates -- helps to illustrate this concept of the -- the sequence read being
10 different than the target sequence. And so, when sequencing fragments, the
11 sequence reads start at a prime or binding site and extend into the target
12 sequence. But these reads, as the patent indicates, vary in length and are
13 typically shorter than the entire fragment or the entire target sequence that's
14 being looked at. And this is illustrated in the read one sequence error -- or
15 arrow, excuse me, of Figure 4 and indicating that this extends the
16 target -- through the target sequence, but it doesn't necessarily cover the
17 entire thing.

18 And in many instances, as reflected in the various examples in the
19 specification, there -- for example, Example 5, there is no definition in
20 Example 5 of what the target sequence is, but there is a definition of how
21 many sequences were actually used or how many base pairs were used in the
22 comparison step. Only the first 50 base pairs were used there. And we think
23 that that's evidence that the read length may be need to be used, but the read
24 length and the target sequence are not necessarily coextensive.

1 So, just in the realities of gene sequencing and the variability in read
2 length, the only reasonable interpretation is that at least a portion of the
3 target sequence needs to be used in the comparison to identify duplicates.

4 Unless there are questions on claim construction, I'd like to move on
5 to the substantive points.

6 So, turning now to the substantive arguments, I'd like to address the
7 combination -- Ground 1 first, the combination of Kivioja and Iafrate.

8 Now, you heard from Petitioner that the computer-aided -- I'm sure
9 I'm not quoting him perfectly accurately, but I think I heard that the
10 computer-aided analysis was well known in the art, but this is a wildly
11 overbroad claim. The -- yes, computers were used to analyze sequencing
12 data, but we're talking about a very specific method of analyzing that data.
13 And that was not disclosed in the prior art.

14 So, based on the proper construction of the claims, none of Petitioner's
15 arguments regarding Kivioja hold water. So let's start with Petitioner's
16 arguments of Kivioja. And I've put an excerpt on Slide 13.

17 So for the identifying duplicates limitation, Petitioner relies solely on
18 the Kivioja reference. And I note that just because there's no -- there's no
19 dispute that Iafrate does not contribute to Petitioner's argument regarding
20 this limitation. And this is the -- this is the disclosure that Petitioner points
21 to for this limitation of -- that the mapped reads with the same gene position
22 and label were collected to one UMI.

23 Now, there is no real dispute that Kivioja does not use the actual
24 target sequence in this step. Petitioner argues that Kivioja's use of the target
25 sequence in the prior step to arrive at the gene and position data is sufficient
26 to meet the claims. Such an interpretation, though, ignores the requirement

1 that the actual target sequence be used in the process of identifying
2 duplicates, and importantly, the gene and position data is different
3 information, a different data set from the target sequence. And I'd like to
4 spend a moment to talk about that and just to confirm that point.

5 So, on Slide 14, I have an excerpt of Dr. Bustamante's declaration.
6 So, as we all know, the target sequence is going to be a chain of As, Cs, Ts,
7 and Gs reflecting the nucleic acids that are in the target sequence. As
8 Dr. Bustamante explained, however, the gene and position data are
9 coordinates on a known genome that denote where matching or closely
10 matching sequences appear. There can be no dispute that this data provides
11 different information than the actual sequence data.

12 So, if we compare the Kivioja method to the claimed method, the
13 differences are stark, and I've illustrated -- tried to illustrate that on Slide 15.
14 I have Kivioja's method -- a rough estimate of the Kivioja's method at the
15 top of Slide 15 and the '357 Patent method at the bottom.

16 Now, in both methods, there is no dispute that identifiers are included
17 in the adapters and the fragments are sequenced. Kivioja then takes the
18 sequence data, puts it in a different computer program, maps the sequence
19 against a known genome, and generates a separate data set of the gene and
20 position data of each read. Kivioja then uses that data to make a comparison
21 and identify duplicates.

22 So, this is not a -- and then just to fill out -- the challenged claims
23 attach adapters with identifiers, sequence those reads, but use directly that
24 sequence data and -- take the sequence data and move it directly to the
25 comparison step and don't use it to generate different data. This is not --

1 JUDGE BRADEN: So, Counselor, what are we supposed to do with
2 the fact that you've got comprising language in your claim, and Kivioja still
3 does -- it has an identifier, and at some point, it has target sequence that it
4 uses then to deduplicate? The fact that you've got other steps in
5 there -- you've got other things in there -- what do we do with that? How
6 does that not meet the claims as Petitioner argues?

7 MS. CIPRIANO: So, as the Federal Circuit has -- yes, comprising
8 claim is -- comprising transition opens the claim to other steps. However, it
9 does not negate the fact that the claim limitations need to be met, and the
10 claim limitation requires that the target sequence and the identifier be used
11 together.

12 In Kivioja, those two pieces of data are never used together in a step
13 to identify duplicates, whether that's multi steps or not. The target sequence
14 data is used to generate different data, and that different data is used as a
15 surrogate for the sequence data in the actual identifying step.

16 Now, Petitioner points to Figure 1 as an illustration in his
17 papers -- points to Figure 1 as an illustration of the target sequence is used.
18 But I'll just note that that representation is a little off base. As explained in
19 the caption of Figure 1, and I've put that on Slide 16, Figure 1 is merely an
20 illustration of the different ways UMIs, or unique molecular identifiers, can
21 be used and the results of that use. There was no disclosure in Figure 1 of
22 the process or the analysis steps used to arrive at the results that are
23 illustrated, and a person of ordinary skill in the art would not have
24 understood Figure 1 to provide any separate information from the method
25 described in the rest of the paper, which is how we just spoke about.

1 Therefore, Petitioner has not met its burden of showing that Kivioja
2 discloses the duplicate identification step as properly understood, and it
3 cannot show that any challenged claim is obvious under Ground 1.

4 I'd like to look specifically at Claim 2, also in Ground 1, and point out
5 that Petitioner has also failed to show that Kivioja discloses the additional
6 element of Claim 2 that requires that duplicate reads be removed. So,
7 Petitioner relies on the differences between Figure 3B and Figure 3C in its
8 papers. But I'd like to point out that these figures actually show that no data
9 has been removed from Kivioja's data set.

10 So, Figure 3, walking through them a little bit -- I put them on
11 Slide 17 -- Figure 3C shows the number of UMI families detected in the
12 data, which Petitioner identifies as the deduplicated data. Figure 3B,
13 however, plots the total number of reads without deduplicating, illustrating
14 that not only was all the data kept, but it was plotted and reported.

15 Additionally, as included in the excerpt at the bottom of Slide 17,
16 Kivioja expressly states that the copy number of each UMI was recorded and
17 they report average copy numbers in the paper. So, contrary to Petitioner's
18 positions, Kivioja does not remove duplicates from its data. It keeps them,
19 and it uses them in its counting analysis. Therefore, the combination of
20 Kivioja and Iafrate cannot render obvious Claim 2.

21 And I'd like to just take one -- make one final point about Ground 1,
22 and that's with respect to Petitioner's motivation to combine arguments. So,
23 Petitioner's obviousness argument suggests that a person of ordinary skill
24 would have started with the adopter of Iafrate and combined it with Kivioja,
25 the adopter of Kivioja, to arrive at the challenged claims.

1 But the Petitioner -- the petition does not provide sufficient
2 explanation of why a person of ordinary skill in the art would pick and
3 choose these individual elements and combine an adopter to arrive at the
4 challenged claims.

5 Petitioner's motivation to combine arguments rely on -- largely rely on
6 a single sweeping statement that you heard opposing counsel talk about, that
7 Kivioja's method can be widely employed, but the Board has rejected
8 motivation to combine arguments based on similar broad statements. For
9 example, in the *Johns Manville* case cited in our papers. So, Petitioner's
10 arguments are legally insufficient and should not succeed.

11 So, moving on, unless there are questions on Kivioja, I can move on
12 to the Grounds 2 and 3. So, the dispute between the parties in Grounds 2
13 and 3, again, revolve around the identifying duplicate step of the claim
14 method.

15 And I'll note, as an initial matter, and I think opposing counsel
16 admitted that Bielas never mentions a step of identifying duplicate reads.
17 Now, while -- Bielas is truly directed to identifying mutations. So, while
18 that fact alone is not determinative -- we have to look at what Bielas actually
19 does -- it would be the lens through which a person of ordinary skill would
20 have read and understood Bielas.

21 So, I've put Figure 3B on Slide 20, and this is really the -- the figure that the
22 parties' papers focus on. And Petitioner points to Figure 3B as evidence that
23 both the target sequence and the cypher pairs are used to identify duplicates,
24 but neither the figure nor its description explain any instance where these
25 pieces of information are used together to identify the duplicate sequence

1 reads. And I'd like to look a little bit at the -- the text of Bielas when it
2 describes this process.

3 So on -- and I have a couple of excerpts from Bielas on Slide 21. And
4 if we look on page -- so Bielas fails -- really, focuses on the cypher pairs
5 to -- to when it talks about the grouping of reads in every instance. So on
6 page 6, for example, at the top of Slide 21, it states, all sequencing reads
7 having identical cypher pairs were grouped into families, period. On,
8 page 27, it talks about the unique cypher tags are used to computationally
9 deconvolute the sequencing data. Again, it's only talking about the identical
10 cypher pairs.

11 On page 31, it's repeating the language that all sequencing reads with
12 identical cypher pairs and their reverse complements were grouped into
13 families. Only the cypher pairs were used. There is no mention in Bielas of
14 using the target sequence in the process of sorting reads into families, which
15 is the process necessary for Petitioner's argument. There's also no
16 disclosure --

17 JUDGE YANG: Counselor, I have a question.

18 MS. CIPRIANO: Uh-huh.

19 JUDGE YANG: So, looking at Figure 3B of Bielas, it looks as if for
20 the cypher family two -- it looks as, to me, at least, the -- the code -- the
21 identifiers on both sides are identical among all these sequences. And yet,
22 one of them has this empty triangle. So why wouldn't that be -- why would
23 that be excluded in the final -- at the bottom of the deconvoluted data set?

24 MS. CIPRIANO: So, my understanding of Bielas is that the final -- at
25 the bottom of the figure is the consensus sequence that Bielas generates.

1 JUDGE YANG: So, it's not by excluding the triangle -- the one with
2 the triangle -- the one with the mutation or whatever you call it?

3 MS. CIPRIANO: Well, in the figure, yes. The difference between the
4 bottom and the grouping at the top is the lack of the triangle. But there's no
5 disclosure in Bielas of how that is done other than deconvolute, which is a
6 rather vague term.

7 So, Petitioner looks to Examples 1 and 3 of Bielas to support its
8 arguments that Bielas meets the challenged claims. And if we look at
9 Slide 23, so Petitioner points to Example 1 in Bielas. But the Example 1
10 does not support Petitioner's arguments. Petitioner points to the statement
11 that unique cypher tags were used to computationally deconvolute, as we
12 were just discussing the sequencing data, as evidence that this and, I believe,
13 opposing counsel referred to these as interchangeable, but the evidence in
14 the record in this case does not support such a conclusion.

15 Deconvolute does not have an established meaning in the art as
16 established in the record. And when we asked at deposition about this
17 term -- and I've put some of Dr. Sims' deposition testimony on
18 Slide 23 -- when we asked Dr. Sims about this testimony, he admitted that
19 deconvolute can mean different things in different contexts, and there is
20 nothing in Bielas that supports Dr. Sims's interpretation that this step
21 involves deduplication.

22 And even if we accept Dr. Sims's unsupported position that
23 deconvolute is the same thing as deduplicate, Bielas explicitly states that the
24 unique cypher tags are used for the deconvolution and not the target
25 sequence. There is no mention of using the target sequence at all in this
26 process.

1 So, turning back to Slide 22, if we look at Example 3 -- Petitioner
2 relies on Example 3 of Bielas to support its point -- Example 3 similarly,
3 does not support Petitioner's argument. And as I mentioned before,
4 Example 3 describes a method that is very similar to that disclosed in
5 Samuels, cited during prosecution.

6 So Samuels described a method of distinguishing PCR errors from
7 nucleotide polymorphisms present in the original sample utilizing molecular
8 barcoding. The reads were grouped by barcode and then analyzed to
9 identify mutations. And Example 3 describes a very -- Example 3 of Bielas
10 describes a very similar method of identifying mutation.

11 Applicants overcame examiners' rejection based on Samuels by
12 narrowing the duplicate identification step, as I've discussed. And applicants
13 expressly stated during prosecution that the claimed methods were unlike the
14 method of Samuels because the claimed methods identified duplicates.

15 Your Honors, I see Judge Braden is no longer on the screen.

16 JUDGE BRADEN: I'm here. I'm listening.

17 MS. CIPRIANO: Okay. Good. That's just to make sure that I did --

18 JUDGE BRADEN: But thank you.

19 MS. CIPRIANO: Yes.

20 JUDGE BRADEN: I did not notice that, apparently, in Alexandria
21 the screen went out. But, no, I am here and listening.

22 MS. CIPRIANO: Okay. Great. Just wanted to confirm that. Thank
23 you very much.

24 JUDGE BRADEN: So my question for you -- and maybe this follows
25 up on Judge Yang's question is in Figure 3B and of Bielas, if there is no use
26 of the sequence, how do we get rid of that sequence that has the open

1 triangle, if we're only using the cypher group to group -- the cypher
2 sequence to group? How are we getting this consensus sequence if we're not
3 using the sequences?

4 MS. CIPRIANO: So, certainly, the sequence needs to be used to
5 generate a consensus sequence. The issue here is that Bielas does not
6 provide any information about how that consensus sequence is done. And if
7 we look at Slide --

8 IT TECHNICIAN: Excuse me. We lost one of the judges.

9 MS. CIPRIANO: We're fine.

10 JUDGE BRADEN: I'm here.

11 IT TECHNICIAN: Okay.

12 JUDGE BRADEN: My video is just out. So, I don't know if you
13 want to get IT to fix the video, but I'm here and fully engaged.

14 MS. CIPRIANO: If you can hear me, I think we're good from my
15 perspective.

16 JUDGE BRADEN: Yes.

17 MS. CIPRIANO: And so I just -- I will note that Bielas does not
18 provide any information about how the consensus sequence is generated.
19 And as Dr. Bustamante testified, as shown on Slide 24, there are many ways
20 to create a consensus sequence. It does not necessarily include a process
21 that compares the sequences to each other. They could be compared to a
22 reference sequence. There are many ways that a consensus sequence can be
23 generated. But Bielas doesn't say how it generates the consensus sequence.
24 So any conclusion that this disclosure in Bielas necessarily meets the
25 identifying duplicates limitation here would be nothing more than
26 speculation.

1 So, I hope that answers your question about how the sequence is used.
2 It is clearly used in some manner. It is just -- the record does not indicate
3 how that sequence is used, and it certainly is not supportive of using it in the
4 specific way that that is required by the claims.

5 JUDGE BRADEN: Very good. And Counselor, you only have just
6 under four minutes in your main portion before you come back for
7 surrebuttal, but when you do come back for surrebuttal, we do need to see if
8 you can address the issue of the terminal disclaimer and whether when a
9 parent patent is subject to a terminal disclaimer and it's disclaimed, what
10 happens to the child patent.

11 When the '399 was issued, I believe -- or I'm sorry -- when the '357
12 Patent -- in order to be issued, I believe it had a terminal disclaimer tied to
13 the '399 Patent. So, when you disclaim the '399 Patent, does that impact the
14 '357 Patents and the enforceability of its claims? If you could address that
15 when you come back on surrebuttal, we would very much appreciate it.

16 MS. CIPRIANO: Happy to, Your Honor.

17 JUDGE BRADEN: But you still have three minutes left.

18 MS. CIPRIANO: So, unless there are questions on the substantive
19 arguments, I will save that point for surrebuttal, and I'll confer with my team
20 as my colleagues go up.

21 JUDGE BRADEN: Very good. Thank you.

22 MS. CIPRIANO: Thank you.

23 JUDGE BRADEN: And we're going to take a moment right now to
24 see if IT can get the video back up and running in Alexandria. If they can't,
25 that's fine. But let's see if they can.

26 (Pause.)

1 JUDGE BRADEN: Thank you all for your patience. We're now
2 getting Judge Majors to rejoin.

3 MR. FLETCHER: Your Honor, while Judge Majors is joining, I just
4 wanted to confirm the time we have for rebuttal. It's shown here, 18.

5 JUDGE YANG: You have 28.

6 MR. FLETCHER: Thank you. I don't believe we're going to use all
7 28, but just in case.

8 (Off-microphone comments.)

9 JUDGE BRADEN: Very good. It looks like we're here and ready to
10 go.

11 Petitioner, you may begin your rebuttal arguments when you are
12 ready.

13 MR. FLETCHER: Thank you, Your Honors. I'd like to share the
14 rebuttal time with my colleague, Mr. Hynds. We propose to split up the
15 rebuttal. He'll come up here to address the claim construction points that
16 Tecan presented and any questions Your Honors have about the claim
17 construction portion, and I will return to speak about the grounds. If that's
18 all right, I'll turn it over to Mr. Hynds.

19 JUDGE BRADEN: Very good. Thank you, Counselor.

20 MR. HYNDS: Thank you, Your Honors.
21 I just want to make a few quick points on rebuttal. When opposing counsel
22 stood up and said what would support their claim construction position on
23 what is required for the identification of duplicates, what I did not
24 hear -- what we did not hear was that the plain and ordinary meaning of the
25 claim language supported their position.

1 As this Board knows, since Phillips and all of its
2 progeny -- sorry -- that is the most important evidence of the meaning of the
3 claim. So, the computer-aided limitation, again, IDT's position, it sets forth,
4 it's straightforward, two data inputs. That's all that's required. You must use
5 those data inputs in the step of identification of duplicates, but no temporal
6 limitation. And, again, as Your Honors pointed out, this is drafted as a
7 comprising claim, which I think is important to keep in mind.

8 Also, just as a quick clarification, which opposing counsel kindly
9 clarified as well -- Judge Braden, to your question about what I was saying
10 about the prosecution history and only relying on a barcode, I was
11 distinguishing only McCloskey there or what the applicants were
12 distinguishing below, was that McCloskey was only using a barcode.

13 But on Samuels' point, I think Judge Braden, you also mentioned this,
14 and -- and you're correct that what -- what the applicant said during
15 prosecution was that Samuels isn't even identifying duplicates. That's how
16 they distinguish Samuels. It's not that there was a step of using both the
17 identifier sequence and the target sequence. That wasn't a point of
18 distinguishing. It was just Samuels doesn't teach identifying duplicates.
19 McCloskey teaches only identifying duplicates on the basis of using a
20 barcode.

21 On -- it seems like presentation might not be -- scoot over here now. Can
22 you guys see the presentation, Your Honors?

23 JUDGE BRADEN: We have --

24 JUDGE YANG: They have the slides. They can --

25 MR. HYND: Okay. Wonderful. So, I just wanted to point to
26 Tecan's Slide 11, the argument about a portion of the target sequence.

1 Figure 4 is discussed in only one place in the patent, and that is only in the
2 identification of the figures. That's at column 3, lines 30 through 33. It
3 doesn't provide us any detail about what Figure 4 is saying. Dr. Bustamante
4 never testified to anything about what Figure 4 is saying. I don't think that
5 we can read too much into the fact that the lines underneath are only
6 covering a portion of the target sequence. They're arrows. They may well
7 be signifying that the read is continuing through the target sequence.

8 But, in any event, I just want to be clear that our position, IDT's
9 position, is that within the meaning of the claim language, the target
10 sequence is whatever is read. That's what must be used. Not a portion of it.
11 If the target sequence is -- sorry -- yeah, the target sequence is just whatever
12 is read. That is part of the sequencing read, which is defined in the
13 sequencing limitation, and that is mandated to be used in the identification of
14 duplicates and the identifying limitation, or what we've been calling the
15 computer-aided limitation.

16 JUDGE BRADEN: So, Counsel, to clarify that, if the sequence read
17 is 50 base pairs, then the target sequence that -- in Petitioner's position that
18 must be used is that 50 base pair?

19 MR. HYNDS: That's correct. If we're talking about the Example 5,
20 that 50 base pairs included also the identifier sequence. So, it would be -- I
21 think that was eight base pairs or six base pairs. It would be 50 minus
22 whatever the identifier sequence was. But yes, whatever is read, that's the
23 target sequence, that's the portion that must be used in the identification of
24 duplicates.

25 JUDGE BRADEN: Thank you, Counselor.

1 JUDGE YANG: I just want to follow up on that. That is, even if the
2 target sequence itself is, say, a 100 base pair. If the read itself, say, is 42,
3 plus the 8 for identifier, you would call that the -- would satisfy the claim
4 limitation?

5 MR. HYNDS: So, Judge Yang, if I'm understanding it correctly,
6 it's -- you're asking that, could it be longer than the 50 base pairs, if the read
7 was 100 base pairs long?

8 JUDGE YANG: No. I'm saying, if the sequence, the target sequence,
9 is 100 base pairs, and you just said the identifier is eight, and we say the
10 read -- the entire read including the identifier is 50, and if those 50 are
11 identical, then that would satisfy the limitation -- even though the target
12 sequence itself is longer than the read?

13 MR. HYNDS: Right. So, I think that the difference we're seeing here
14 is that how we define the target sequence. So, if we define the target
15 sequence, Judge Yang, the way that you're saying it is, whatever the nucleic
16 acid fragment is, for example, then we're just talking about what is read, and
17 you're correct.

18 Like, what IDT's position is, is that the target sequence, as defined in
19 Claim 1, is whatever is read. So what we would call the target sequence is
20 that 50 base pairs, not the 100 base pairs. That's the nucleic acid fragment
21 between the adapters that were added.

22 JUDGE YANG: Okay. Thank you.

23 MR. HYNDS: All righty. If there are no further questions from Your
24 Honors on the claim construction issues, I will turn it over to Mr. Fletcher.

25 JUDGE BRADEN: Thank you, Counselor.

1 MR. FLETCHER: So now, Your Honors, turning to the grounds that
2 were discussed today, Kivioja plus Iafrate and Bielas.
3 I believe I heard opposing counsel say that only Dr. Bustamante spoke about
4 how the Kivioja data analysis work, and that's not correct. We discussed it
5 in our petition on pages 37 to 38, and Dr. Sims testified about it in his
6 declaration, Exhibit 1079, paragraphs 256 to 260.
7 We heard from -- or I heard, at least, opposing counsel argue that Kivioja
8 only uses the identifiers, and that's not correct either. I'd like to direct Your
9 Honors to -- in Kivioja Figure 1A, and I'd like to get that slide up. Bear with
10 me a moment. Thank you.

11 So, again, this really only comes through if you have a copy of
12 Kivioja in color, but I'm referring now to Slide 51. And in Kivioja,
13 Example -- Exhibit 1012 in Figure 1A, we see, for example, at the bottom in
14 that -- of the bottom of the figure, Figure 1A, there are sequences that have
15 the pink identifier and in some instances, the pink identifier was attached to
16 the green fragment, and in some instances, it was attached to the blue
17 fragment.

18 Nevertheless, the Kivioja method has managed to disambiguate those
19 fragments. The green plus pink have ended up on the left, and the blue plus
20 pink have ended up on the right in different UMI groupings. So it is not
21 correct that Kivioja only uses the identifier sequences.

22 Turning to Petitioner -- sorry -- Patent Owner's Slide 15 --
23 Mr. Hynds, if you could pull up Slide 17 in our deck. Petitioner's Slide 15,
24 the comparison between the Kivioja method and the '357 Patent's method.

25 Counsel described the differences between these methods as stark, and
26 I take issue with that adjective. The differences between these methods are,

1 frankly, not stark at all. This is a comprising claim, as Your Honors pointed
2 out; so the fact that the '357 Patent does not claim the genomic alignment
3 that is done in Kivioja does not matter. So, take out the fourth and fifth
4 columns of the comparison. And then what we see in the data analysis in the
5 sixth column of the comparison is that the information Kivioja was using
6 was the genomic coordinates, whereas the information that the '357 Patent is
7 using is the target sequence. But those are effectively the same things.

8 As I pointed out in the opening in response to Your Honor's question, as
9 Dr. Bustamante testified, the sequences that share the same genomic
10 coordinates are nearly, if not always, identical, and there was no refutation
11 of that from Counsel during the prior portion of the argument. So, while --

12 JUDGE BRADEN: But, Counselor, and I don't want to put -- I don't
13 want to put words in Patent Owner's, Counselor, but the way I understood
14 the explanation of that, and I believe the reference was to Patent Owner's
15 Slide 14, was that even -- even if the alignment means that these positions
16 would have the same sequence, that's not relevant, because that's not what's
17 being used in the comparisons in Kivioja. It's the location. It's the genomic
18 position and not the sequence itself. Can you speak to that, please?

19 MR. FLETCHER: And Your Honor, here, I think we're seeing these
20 additional limitations or restrictions being placed on the claimant aren't
21 appropriate. The Kivioja method used the targeted sequences. There's no
22 question about that. That's how the genomic coordinates got generated.
23 And when the genomic coordinates are then compared, two sequences with
24 the same target sequences are being flagged as duplicates, although the data
25 that is used were the genomic coordinates.

1 JUDGE BRADEN: So, it's inherent that they would have had to have
2 used the target sequence in order to determine the genomic position in order
3 to be able to use that UMI?

4 MR. FLETCHER: I think I agree, Your Honor, but I'd like to just
5 focus on the word inherent. That is a bit of a third rail word in patent law. I
6 don't believe anybody disputes that the target sequence is what is being used
7 for the genomic alignment. So everybody agrees that that's how one
8 generates the genomic alignment.

9 And just briefly, at the end of Patent Owner's slide deck, and they
10 didn't get to this in their opening, there was a comment on inherency. And I
11 just think that's a misplaced concept. We're not making any inherency
12 arguments in this proceeding. I think the more apt case to be discussing is
13 actually one that we cited in our papers, the *Mustek* case. And it makes clear
14 at 340 F.3d 1326 that a reference can anticipate or render obvious if it
15 sometimes performs the claimed method or claimed -- is the claimed
16 apparatus, even if it is not always that.

17 Inherency is about limitations that nobody in the reference recognizes.
18 And if they always, always, always happen, then we will read them in
19 because they are inherently there, even though they are not spoken to. That's
20 not this case. This case is about what the reference teaches about its method
21 and the fact that it used the target sequence to generate the genomic
22 alignment to do the deduplication.

23 But so, as we see in Petitioner's Slide -- sorry, Patent Owner's
24 Slide 15, these two methods are in fact extremely similar, so similar that the
25 combination of Iafrate and Kivioja renders them obvious.

1 Now, I just want to say one further point on genomic alignment. It
2 feels to me almost like it's being trotted out as though it's something wildly
3 different, and I would like to stress that it's not. It is a core part of the DNA
4 sequence analysis workflow. It is so integrated into what is normally done
5 that in all of the patent's examples, there is genomic alignment. So, even in
6 Example 5 that Patent Owner has alleged the claims are limited to, the patent
7 describes using genomic alignment as part of the data analysis. That's at
8 column 20, line 64.

9 As my colleague Mr. Hynds explained earlier, that was also a key
10 piece of Example 1, and the patent teaches its method of identifying quote,
11 unquote, true duplicates. It teaches using the genomic coordinates as the
12 stand-in for the target sequences.

13 The last thing I want to say at this time about Kivioja is there is also a
14 little bit of a discussion or suggestion that Kivioja does not remove
15 sequences, but that is exactly what Kivioja's UMIs represent. Kivioja takes
16 its sequencing data, and using its sequencing data, generates a second
17 collection of sequencing information, the UMIs.
18 And as we all have sight seen from Patent Owner's presentation, that is a
19 smaller data set that contains fewer sequences. And as Figure 1A
20 showed -- sorry to make you go back, Mr. Hynds, thank you -- where there
21 were numerous pink plus green or blue plus green sequences in the sequence
22 information, when we get to the UMIs, there are only two.

23 The fact that Kivioja, I guess, does not throw away its prior database
24 does not matter. The point is, it has created a set of UMIs and those UMIs
25 represent deduplicated sequences. And that is something that Dr. Sims

1 explained as well, for example, in his deposition, Exhibit 2016, pages 113
2 and 14.

3 So, moving now to Bielas. Judge Yang, you asked about the triangle
4 and what Bielas teaches about the sequence analysis. Dr. Sims explained
5 this in his declaration, Exhibit 1079. One place in particular he spoke about
6 the data analysis is paragraph 470, where he points to Bielas's invocation of
7 the Illumina ELAN software that comes with the Illumina data sequencer.

8 But Bielas does speak to how it's doing the sequence analysis. And
9 the point of Bielas, what Bielas was really trying to be sensitive to, was
10 finding these point mutations and trying to determine whether a point
11 mutation was real, it was there in the original fragment, or whether it is
12 something that was introduced by the PCR.

13 And so, as shown in Figure 3B that I have up on Slide 33 of
14 Petitioner's deck, in this example, the black diamond point mutation is in the
15 original fragment. Of course, if you're doing the experiment, you don't
16 know that until you see the sequencing data.

17 And so the point of Bielas is to generate the sequencing data, obtain
18 the sequencing data, and because the consensus sequence spits out the black
19 diamond across the board, that is preserved as a true mutation, whereas the
20 white triangle is recognized as being an artifact. It is not present in the
21 original fragment because it shows up in just that one of the four sequences.

22 So, that is what Bielas teaches about its use of the target sequences to
23 determine what the true deduplicated sequence should be.

24 Finally, Your Honors invited Patent Owner to comment on the effect
25 of the terminal disclaimer as we --

1 JUDGE BRADEN: Before you get to the terminal disclaimer, if you
2 wouldn't mind using a little bit of your time to tell me what's the difference
3 between Bielas and Samuels?

4 MR. FLETCHER: Bielas and Samuels. Okay. Well, I think there are
5 several, but I'll focus on what happened in the prosecution history.

6 The argument that was being made in the prosecution history that has
7 been discussed in the record today was that Samuels was looking for
8 differences. And so, it was trying to find different sequences rather than
9 finding sequences that were the same. And so the key feature here is, at the
10 end of the day, Bielas is making that one true sequence, whereas Samuels
11 was going out of its way to try and find, here are all my different sequences.

12 You know, if I were the examiner, I'm not sure I would have
13 considered that to be a true distinction, but that is what Tecan argued at the
14 time to distinguish Samuels' and Bielas's data processing.

15 JUDGE BRADEN: Okay. Thank you. And then if you'd please
16 move on to the terminal disclaimer.

17 MR. FLETCHER: No. Your Honors, as I emphasized in my reply
18 brief, as I emphasized in my opening argument, I think it's an important fact.
19 I think it is an important fact that if we were still prosecuting these patents,
20 there's no question that the '357 Patent should not issue. Now, it has issued.
21 So, as *Softview* makes clear, we still have to go through the real work of
22 looking at whether its claims are anticipated or obviousness -- obvious over
23 the prior art. And to be very clear, I am not suggesting that you short circuit
24 that analysis. You have to do it. That's what the *Softview* case stands for.
25 But it is still relevant. It is still meaningful and important that there has been

1 no distinction offered between these patents. And because we haven't heard
2 about it yet, and I suppose I'll hear about it for the first time on surrebuttal --

3 JUDGE YANG: I'll give you a preview of the question we have. So
4 we hear you that we need you to do independent analysis on the
5 patentability, but our question is not about the patentability. If we
6 understand you all correctly, the current -- the '357 Patent, when it was
7 issued, it was -- it had a terminal disclaimer over the no -- no longer existing
8 '399 Patent? Is that correct?

9 MR. FLETCHER: That is correct, factually.

10 JUDGE YANG: So, when it was disclaimed, that disclaimer said the
11 term of the '357 Patent would not go longer than the term of the '399 Patent.
12 Is that correct?

13 MR. FLETCHER: That is almost correct, Your Honor. I wish it were
14 that clear.

15 JUDGE YANG: Okay.

16 MR. FLETCHER: I would have filed a motion much earlier.
17 There's additional caveats and carve-outs in the phrasing of the terminal
18 disclaimer that I think opposing counsel may point to. But, you know,
19 applying my duty of candor that I encourage you to find as well, the terminal
20 disclaimer has various exceptions, and so I think that is --

21 JUDGE YANG: Okay.

22 MR. FLETCHER: -- an important thing to notice.
23 My point is simply it is relevant, and it is something that you should have in
24 your minds when looking at the record that we have assembled about how
25 similar these claims are to the prior art, how the prior art teaches these
26 methods, how the prior art renders these methods obvious. And if we hear

1 for the first time a technical distinction, I would be appreciative of the
2 chance to speak to it in surrebuttal, if I may.

3 JUDGE YANG: Noted.

4 MR. FLETCHER: Thank you, Your Honors.

5 JUDGE BRADEN: Patent Owner, whenever you are ready for your
6 surrebuttal, you may begin.

7 MS. CIPRIANO: If you just want to take -- disconnect that, I'm not
8 going to use any slides. I don't think that --

9 Okay. Your Honors, thank you very much for your attention. I want
10 to make one point on the substance before I get into the term of disclaimer
11 issues. First, to speak a little bit about, and maybe clarify, the fishing
12 hypothetical and the idea of talking about identifying duplicates with the
13 fishing.

14 And I think that the important point is the references at issue here, in
15 Bielas, they fish with the identifier only, and then they do something else
16 with the sequence. In Kivioja, they fish once with the identifier, and then
17 they fish with something else. They don't ever fish with the sequence. They
18 do something else with the sequence before they get to the fishing for
19 duplicates.

20 So here, I just wanted to make the point that we don't have references
21 in the record that fish for both the identifier and the target sequence for
22 identifying duplicates.

23 On the point of terminal disclaimers, and certainly we would be happy
24 to provide a more fulsome briefing if that's helpful to the Board, but we do
25 think that the trialed patent, that is the '357, must be considered on its own in
26 this proceeding.

1 And one -- well, I have a case from the District of New Jersey that
2 considered the Federal Circuit precedent on this, not exactly this point, but
3 on the disclaimer -- but on a parent patent that expired due to failure to pay
4 maintenance fees. And the District of New Jersey considered the Federal
5 Circuit precedent and found that that was not sufficient to execute the
6 terminal disclaimer on the trial patent based upon on the reasoning behind
7 the terminal disclaimer, the purpose of a terminal disclaimer during
8 prosecution.

9 We're not seeking to extend the life beyond what was
10 normally -- what was the natural life of the patent, but instead, limit the
11 patent term to the invention to the amount of time that is allowed. And that
12 case is the *Hoffman* -- the District of New Jersey case is the
13 *Hoffmann-La Roche v. Orchid Chemicals*. And that's case number --
14 apologies, the internet cut out on me. I'll give you the citation in just a
15 moment. That's Case Number 2:10CV04540.

16 And again, we can brief this issue, if that is helpful to the Board going
17 forward.

18 JUDGE BRADEN: Thank you, Counselor.

19 MS. CIPRIANO: And unless the Board has questions, I'm going to
20 give up the rest of my time.

21 JUDGE BRADEN: Do I have any questions from either of my
22 colleagues?

23 JUDGE MAJORS: No. Thank you.

24 JUDGE BRADEN: Very good. What we are going to do in view of
25 the terminal disclaimer and the adverse judgment, what we're going to do is
26 we're going to allot five pages of post-hearing briefing explaining the

1 situation and explaining why the '357 Patent is either still enforceable or is
2 not enforceable in view of the disclaimer of the 35 -- or the '399 Patent.
3 This will be due on Wednesday, February 11th, and an order stating this
4 same information will come out either today or tomorrow.

5 Do I have any questions from Petitioner?

6 MR. FLETCHER: No, Your Honor.

7 JUDGE BRADEN: Any questions from Patent Owner?

8 MS. CIPRIANO: Yes, Your Honor. On the briefing, this is
9 simultaneous briefing on February 11th?

10 JUDGE BRADEN: Yes.

11 MS. CIPRIANO: Thank you. No further questions. Thank you.

12 JUDGE BRADEN: Very good. Thank you all for appearing today
13 and for answering our many questions. Your answers have helped the panel.

14 We would like to especially thank our LEAP practitioner, Patrick
15 Hynds, for appearing today to participate in the oral hearing. PTAB benefits
16 from your participation, so we're very appreciative to you for your
17 willingness to take part, to your law firm and the client for allowing you this
18 opportunity. We hope that you gained valuable experience from your
19 participation today.

20 We will take this case under advisement and issue a decision in due
21 course. This hearing is now adjourned. After a 20-minute break, we will
22 reconvene for oral argument in IPR2025-0015 and IPR2025-00016. Thank
23 you all.

24 (Whereupon, the above-entitled matter went off the record at
25 12:11 p.m.)

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