UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of:	
CERTAIN PHOTODYNAMIC THERAPY SYSTEMS, COMPONENTS THEREOF, AND PHARMACEUTICAL PRODUCTS USED IN COMBINATION WITH THE SAME	Inv. No. 337-TA-1411

[redacted]

Washington, D.C.
Thursday, December 19, 2024

Deposition of MARK BALDYGA, a witness herein, called for examination in the above-entitled matter, pursuant to notice, the witness being duly sworn by Barbara J. Moore, a Notary Public in and for the District of Columbia, taken at the offices of POLSINELLI 1401 I Street, Washington, D.C. commencing at 9:40 a.m., and the proceedings being taken down by Stenotype by BARBARA MOORE, CRR, RMR, and transcribed under her direction.

IPR2024-01312
Biofrontera Inc. et al v. Sun Pharmaceutical et al
Sun Pharmaceutical's Exhibit 2039
EX2039, Page 1

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APPEARANCES:

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* * * * *

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PROCEEDINGS

****

MARK BALDYGA,

having been called as a witness and having been first duly sworn, was examined and testified as follows:

EXAMINATION BY
ATTORNEY HABBAZ:

Q. Good morning. My name is Raymond Habbaz with the law firm of Desmarais, LLP, on behalf of Sun Pharma. With me is my colleague Tuhin Ganguly. Could the witness introduce themselves for the record.

A. My name is Mark Baldyga.

Q. What is your current address?

A. 10507 Gooseberry Court, Trinity, Florida, 34655.

Q. Mr. Baldyga, have you been deposed before?

A. I have not.

Q. To review some of the ground rules for a deposition, I'm going to ask you to ask you a

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series of questions. I expect you'll provide answers to those questions.
Does that make sense?
A. It does.
Q. If you need any clarifications from my questions in order to answer it, please ask. If you answer my question, I'll assume you understood it.
Does that make sense?
A. It does.
Q. If your counsel objects to any of my questions, you'll still have to answer the question. The objection is for the record.
Does that make sense?
A. It does.
Q. I'd like to go around an hour or maybe a little more than an hour for each set of questions, but if you need a break at any time, just let us know. If there's a question pending, we'd just ask that you answer the question before we take a break. Okay?
A. Okay.

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Q. And you've been doing a good job of this. If you can give verbal answers instead of just nodding so that the court reporter can take it down.
A. Okay.
Q. It shouldn't be a problem.
And Mr. Baldyga, you understand that you're providing testimony today under oath just like if you were in court; right?
A. Right.
Q. Is there any reason you cannot give truthful and accurate testimony today?
A. No.
(Exhibit 1 was marked for identification.)
Q. You've been handed what's been marked as Exhibit 1. Exhibit 1 is Sun Pharmaceuticals first 30(b)(6) notice of deposition to Biofrontera.
Do you see that?
A. I do.
Q. Have you seen this document before?

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A. I'm unsure.
Q. Let's start here first. You're aware there are a number of entities with the name Biofrontera in them in this case?
A. Yes.
Q. I'm going to refer to all of those entities as Biofrontera. Will you understand if I do that?
A. I will.
Q. Okay. If in your answers you need to clarify which Biofrontera entity you're talking about, please do so. Otherwise, we'll assume Biofrontera is all entities. Is that fair?
A. That's fair.
Q. And if you turn in the document to around page 8, do you see the topics there? Do you see the topics?
A. I see the topics.
ATTORNEY HABBAZ: Counsel, for the record we understand that Mr. Baldyga is prepared to testify as to topics 15, 17, 21 as to marketing, 22, 25, 26, 32, 37 to

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46, 55, 56, 63, 64, and 66 and 72. Do I have that right?
(Discussion held off the record.)
ATTORNEY PETERSON: Twenty-two the parties agreed to drop, so he will not be testifying on that. Forty-two the parties also agreed to drop. The exhibit was served on both sides in the usual agreement it was dropped. And 67 we also dropped.
ATTORNEY HABBAZ: Okay.
ATTORNEY PETERSON: The other ones, subject to our objection he's prepared to testify.
ATTORNEY HABBAZ: Okay. We can circle back to 67. We can do that later.
BY ATTORNEY HABBAZ:
Q. Mr. Baldyga, looking over the topics generally that you've been assigned to, are you prepared to testify on behalf of Biofrontera on those topics subject to your counsel's objection?

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A. I'm prepared.

(Exhibit 2 was marked for identification.)

Q. You've been handed what's been marked as Exhibit 2. Exhibit 2 is Biofrontera's notice of deposition to you, Mr. Baldyga.

Do you see that?

A. I see it.

Q. And have you seen this document before?

A. Yes.

Q. You understand that you're also here to give sworn testimony in your personal capacity as well, yes?

A. Yes.

ATTORNEY HABBAZ: Going to go off the record.

(Discussion held off the record.)

So we can go back on the record.

Q. Mr. Baldyga, without getting into the substance of any conversations you've had with your

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lawyers, how did you prepare for today's deposition?

A. Can you repeat that.

Q. Without getting into the substance of your conversations with your attorneys, how did you prepare for today's deposition?

A. We met face-to-face and prepared.

Q. Okay. And did you speak to anyone other than attorneys?

A. Can you clarify the question.

Q. Sure. In order to prepare for today's deposition, did you meet with any of Biofrontera employees?

A. I did not meet with any other Biofrontera employees.

Q. Did you meet with anyone else other than the lawyers in this law firm?

A. I did not.

Q. How long did you prepare for, please?

A. One working day.

Q. Okay. Did you review any documents during your preparation?

A. Yes.

Q. Generally what sort of documents did you review?

A. Can you specify?

Q. Sure. In preparing for your deposition today, what sort of documents did you review in order to be Biofrontera's corporate representative?

A. PDFs, PowerPoint, Excel spreadsheets.

Q. Okay. And did any of those documents help you recall things that happened in the past that you had forgotten?

A. Yes.

Q. Okay. And any specific documents come to mind for that?

A. Nothing specific.

Q. Okay. And Mr. Baldyga, just to switch gears for a second, do you have a college degree?

A. Yes.

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Q. What did you study?

A. Political science.

Q. Do you have any other degrees?

A. No.

Q. And so you don't hold any degrees in computer science or physics; correct?

A. I do not.

Q. And you're not an electrical engineer; correct?

A. Correct.

Q. You don't have a medical degree; correct?

A. Correct.

Q. And you don't have a degree in economics?

A. I do not.

Q. You are not a lawyer, right?

A. Right.

Q. You understand that Sun Pharma has accused Biofrontera by infringing two of its patents by selling the RHODO-LED XL the United States? Have you read those two Sun Pharma

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patents?
A. No.
Q. No?
A. No.
Q. Have you looked at them at all?
A. No.
Q. Fair to say that you have no opinion as to whether those patents are infringed; correct?
A. Correct.
Q. And have you known what's known as prior art to the Sun Pharma patent?
A. Can you repeat the question.
Q. Have you reviewed what's known as prior art to the Sun Pharma patent?
A. No.
Q. Fair to say you have no opinion as to whether the Sun Pharma patents are valid; right?
A. Repeat the question.
Q. Is it fair to say that you have no opinion as to whether the Sun Pharma patents are a valid patent?
A. I don't have -- I don't have an

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opinion.
Q. Okay. Before this lawsuit was filed, were you aware that Sun Pharma had patents covering five patentable LED devices?
A. No.
Q. Are you currently employed by Biofrontera, Inc.?
A. Yes.
Q. When did you join Biofrontera, Inc.?
A. Well, we became Biofrontera, Inc., in 2021. I joined Biofrontera in 2016.
Q. Okay. Can you walk me through what roles you have had at Biofrontera.
A. Sure. Okay. So I started as a regional sales manager, and I was promoted to national sales director. I was promoted to vice president of sales and marketing, and I was also given additional responsibilities for market access.
Q. Okay. And how long have you -- when were you promoted to vice president of sales and marketing?

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A. March of 2022.
Q. Okay. And what does it mean that you have additional responsibilities for market access?
A. I oversee market access.
Q. What is market access?
A. Market access is ensuring that your product has reimbursement status with payers.
Q. When you started in 2016, which entity -- you said you joined Biofrontera, which entity was that?
A. Biofrontera.
Q. Would it have been the AG, the parent company, likely?
A. It could have been. But yes, the German, so yes, that we were Biofrontera.
Q. Before you were promoted to vice president of sales and marketing in 2022, were you aware of the RhodoLED XL?
A. Yes.
Q. When were you first aware of the RhodoLED XL?

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A. If I recall, we were -- the XL was approved sometime in 2020, and that's when I recall.
Q. Okay. And so you had no awareness of the Rhodo-LED XL before it was approved; is that right?
A. I had awareness.
Q. And when did you first become -- under what circumstances would you have been aware of the XL?
A. Just through general discussions.
Q. Okay. About how long before it was approved were those discussions?
A. Yeah.
Q. Okay. What was your involvement, if any, in the development of the product that became the RhodoLED XL?
A. I didn't have involvement.
Q. And what are your responsibilities now as vice president of sales and marketing?
A. Excuse me?
Q. What are your responsibilities now

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in your current role?
A. I oversee the sales team, and I also oversee the marketing team.
Q. Okay. And who do you report to?
A. Hermann Luebbert, our CEO.
Q. Do you have direct reports?
A. Yes.
Q. Who are they generally?
A. I have the regional sales managers, and I have our director of marketing.
Q. Is your compensation tied to the success of the RhodoLED XL in any way?
A. In any way -- I'm tied to our -- what's the word I'm trying to think of? Our revenue and the XL is part of our revenue, so the answer is yes.
Q. If the RhodoLED XL is a significant commercial success for the company in the coming years, does your compensation increase significantly in your view?
ATTORNEY PETERSON: Objection. Form.

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THE WITNESS: I have no idea.
BY ATTORNEY HABBAZ:
Q. Okay. Is your compensation tied to the outcome of this lawsuit?
A. No.
Q. Have you been asked to testify at trial?
A. No.
(Exhibit 3 was marked for identification.)
Q. You're being handed what's been marked as Exhibit 3. Exhibit 3, first of all, start because this is the first type of exhibit. Are you familiar with what Bates numbers are?
A. No.
Q. Do you see on the first page on the bottom right there's a footer with some letters and numbers.
A. I see that.
Q. We call that a Bates number. It's how it was made available in this litigation by Biofrontera so that we can keep track of documents.

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It's sequential page numbers on the bottom, so I'll be referring to those for the record.
A. Okay.
[redacted]
Q. If you turn to the second page ending in -115, do you see where it says "the RhodoLED XL trifold"?

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A. I see that.
Q. What's a trifold?
A. Trifold is a promotional piece that I believe it's folded in a manner so it's three piece or three sections.
Q. Okay. And who is the intended audience of the trifold?
A. Prospects and customers.
Q. Okay. And by "prospects and customers," are those healthcare professionals who might be interested in the device?
A. Correct.
[redacted]

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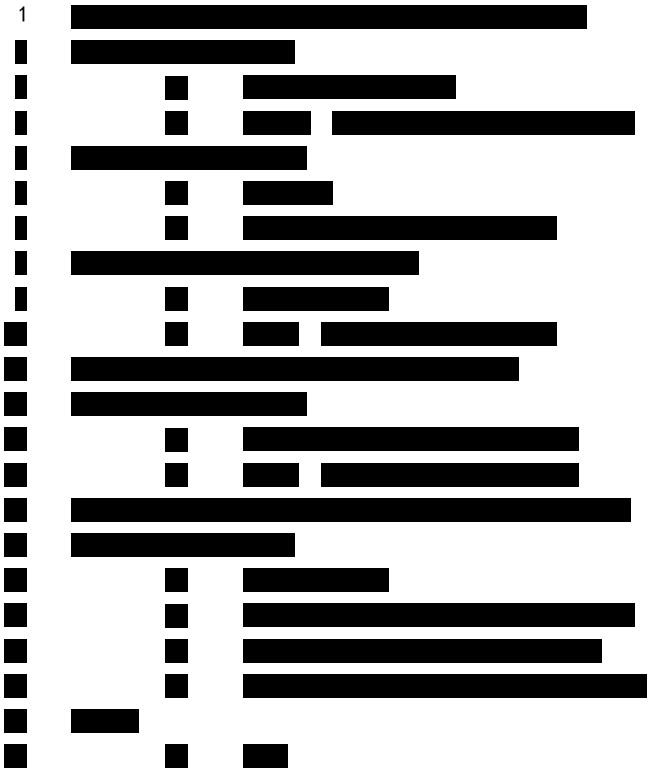

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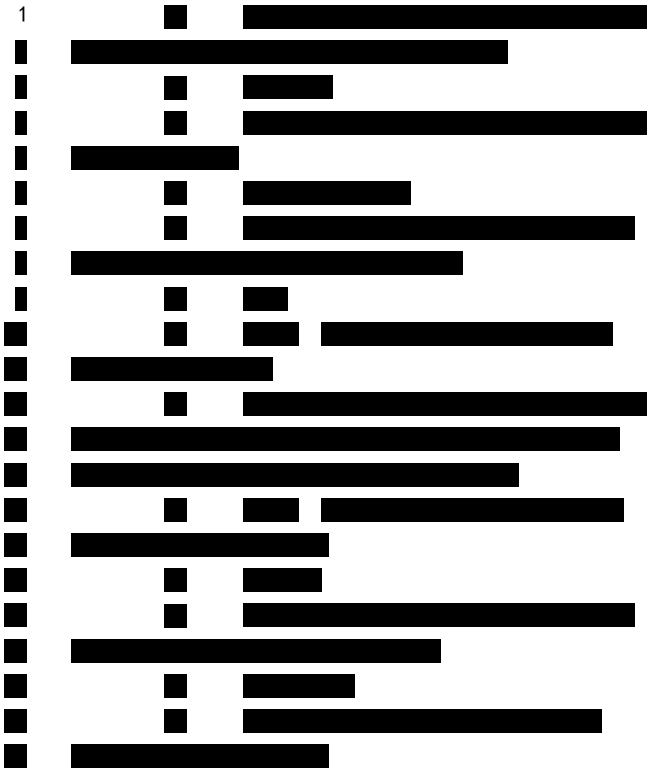

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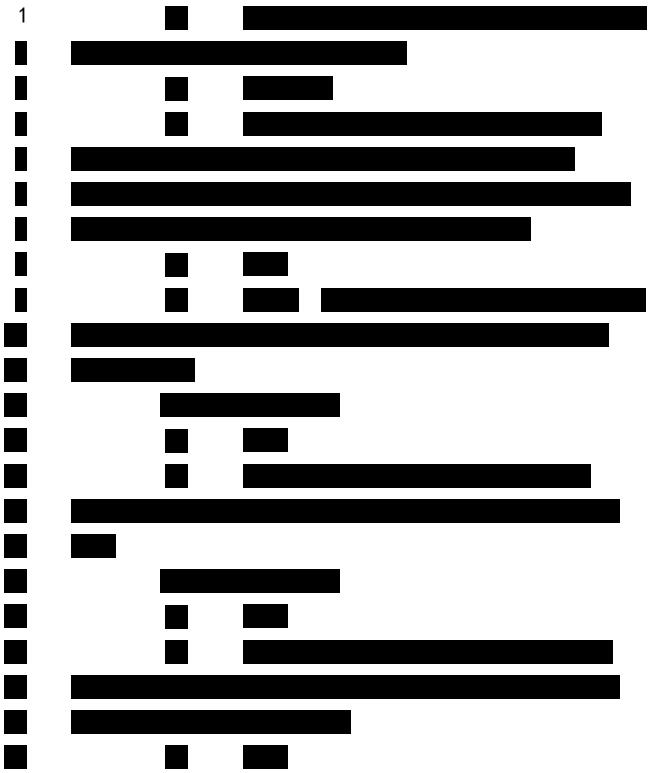

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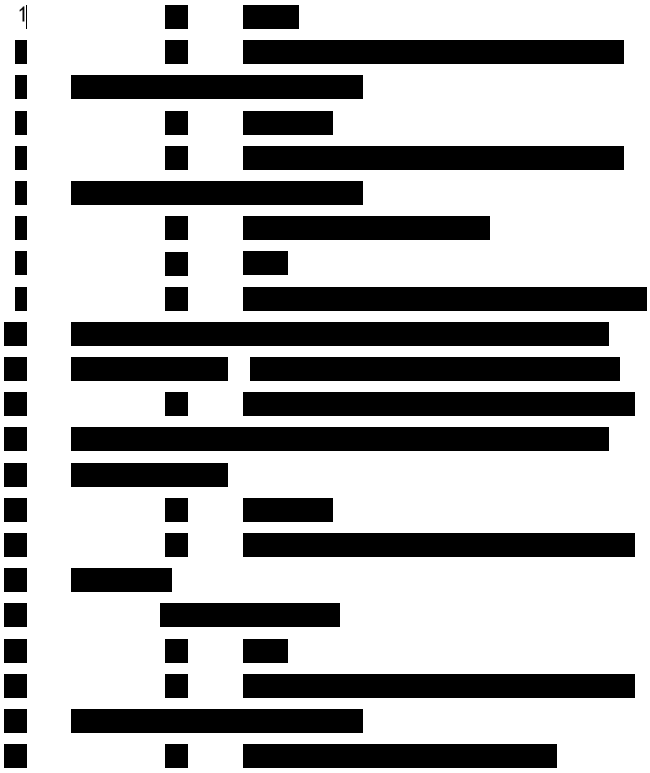

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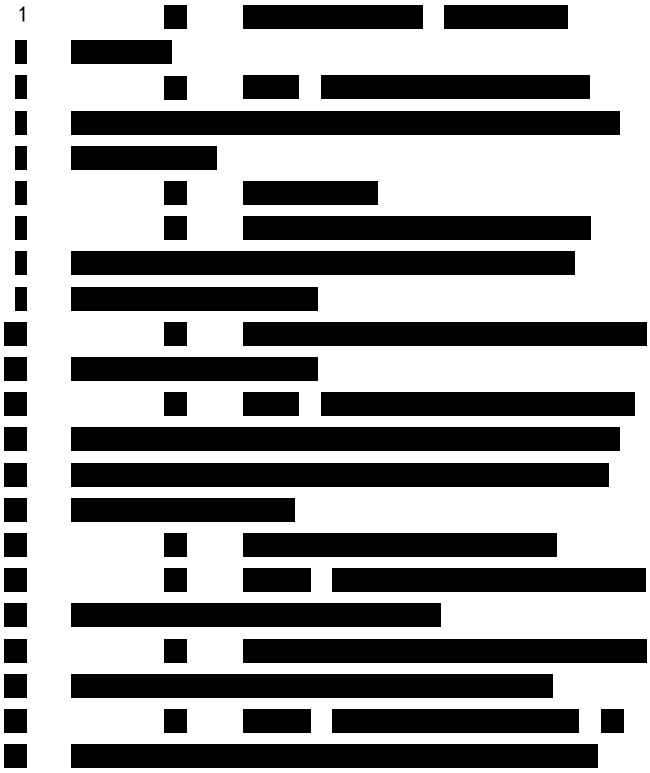

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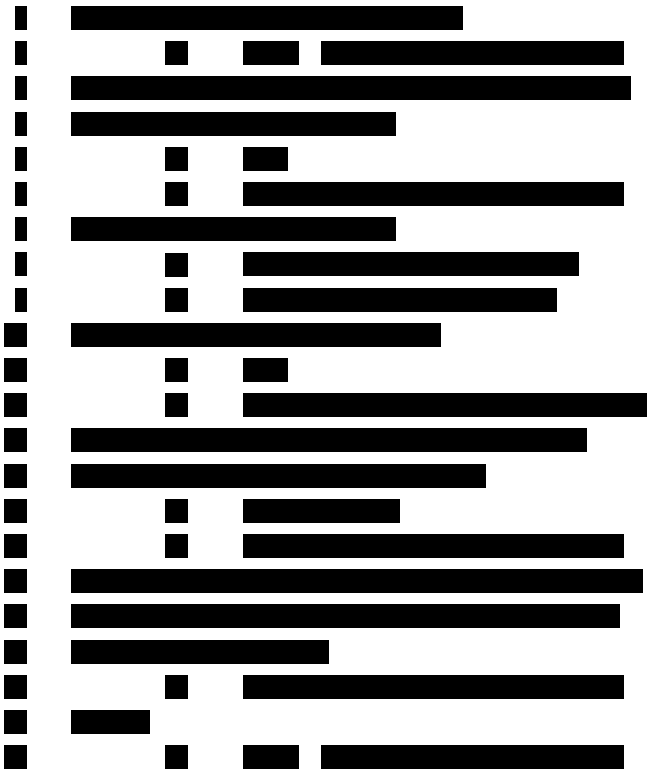

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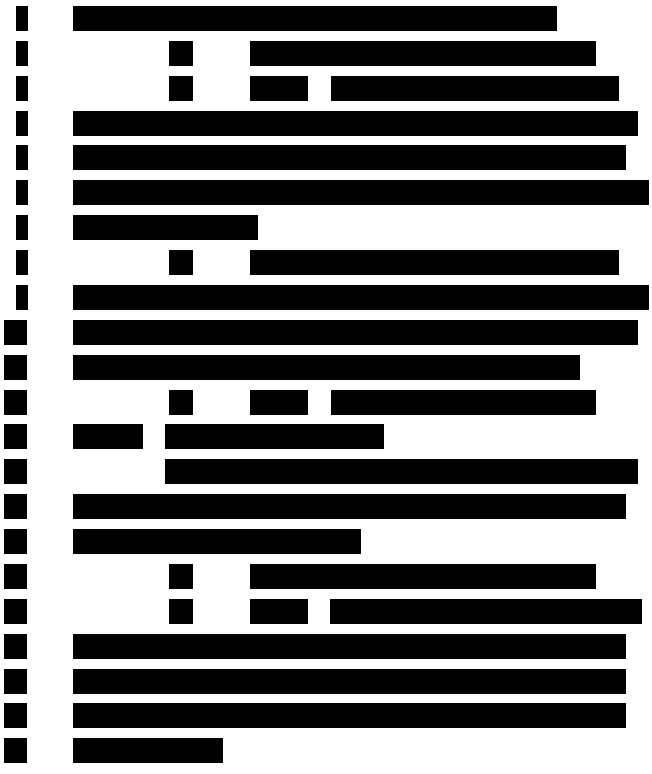

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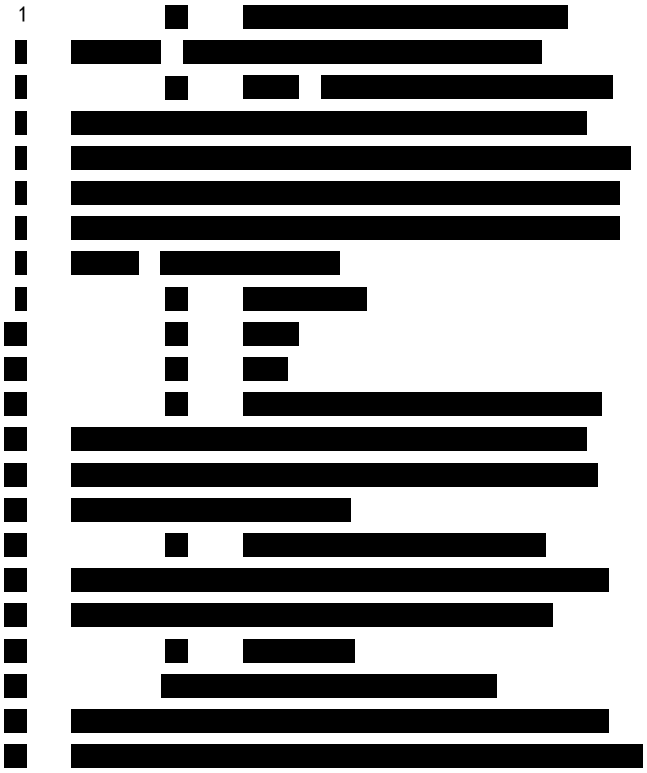

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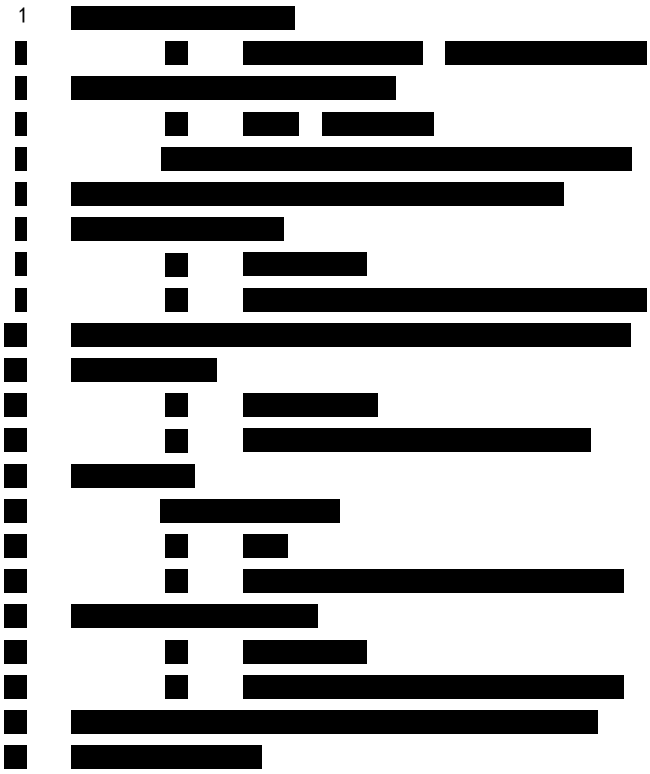

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Q. You've been handed what's been marked as Exhibit 4. Exhibit 4 is a document that's been used in this litigation with Biofrontera with Bates BF_1411_ITC 00121065.

Do you see that?

A. I do.

Q. And I'll represent to you that the document was provided to us with a file name that included RhodoLED XL trifold.

A. Okay.

Q. Do you know if this is an example for the trifold brochure for the RhodoLED XL?

A. Yes.

Q. And you can see Exhibit 4 includes some of the same graphics that we spoke about in connection with Exhibit 3; right?

A. Yes.

(Exhibit 5 was marked for identification.)

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Q. You're being handed what's been marked as Exhibit 5. Document bearing Bates number Sun-ITC 0168513.

Do you see that?

A. Yes.

Q. Are you familiar with this document?

A. Yes.

Q. What is it?

A. It's a promotional piece.

Q. And what is it promoting?

A. Treatment for actinic keratosis with PDT.

Q. Is it a Biofrontera promotional material for the XL and Ameluz?

A. Yes.

Q. Who is the intended audience of Exhibit 5?

A. If I recall correctly, this is a patient, patient audience.

Q. Okay. And so this is -- Exhibit 5 is a brochure from Biofrontera advertising the

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RhodoLED XL and Ameluz indications; right?
A. Correct.
Q. If you turn to pages 6 and 7, Bates ending in -516. The brochure includes on the right how Ameluz and RhodoLED XL work together.
Do you see that?
A. Yes.
Q. And if you look on the bottom left, do you see that? It says "Ameluz" in red.
A. This logo?
Q. Yes.
A. I see that.
Q. And Biofrontera tells patients that Ameluz includes animo-levulinic acid.
Do you see that?
A. Yes.
Q. And so looking at the graphic on the right, again, on page 7, Biofrontera tells patients that Ameluz and RhodoLED XL work together where, if you look at the third sentence on the top right, the red light of the RhodoLED or RhodoLED XL illuminates these cells and activates the agents.

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Do you see that?
A. I see that.
Q. And so Biofrontera is telling patients that the RhodoLED XL together with the Ameluz can be used to treat actinic keratosis; right?
A. To clarify, this is written up, we're not telling you that.
Q. Sorry, what's the distinction you're trying to draw?
A. Telling is a spoken word.
Q. So Biofrontera is communicating to patients that the RhodoLED XL together with Ameluz can be used to photodynamically treat actinic keratosis; correct?
A. Right.
Q. In that communication, Biofrontera includes a graphic of the 55 panels of the RhodoLED XL in a curved arrangement; right?
A. Yes.
Q. And the pages here are illuminating a treatment surface of the patient's skin,

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presumably. Is that fair?
A. That's fair.
Q. Turn to the next page ending in -517.
A. (Witness complies with request.)
Q. Biofrontera's brochure for patients for the RhodoLED XL includes another photo of the device; correct?
A. Yes.
Q. I should say several photos of the device; right?
A. I see three.
Q. Okay. And if you look, the photo of the device on the left, again, you can see the arrangement of groups of LEDs on the panel. Right?
A. I can see those.
Q. Okay. There are, for each panel, three groups of LEDs. Fair?
A. I'm not sure.
Q. Do you see that there's a top group, a center group and a bottom group of LEDs on the panel?

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A. I see those.
Q. Okay. And based on the graphics shown here, the top group of LEDs are spaced closer together compared to the center group. Right?
A. Correct.
Q. And the bottom group of LEDs are also spaced closer together compared to the center group; correct?
A. Correct.
Q. Okay.
(Exhibit 6 was marked for identification.)
Q. You're being handed what's been marked as Exhibit 6. Exhibit 6 is a document produced by Biofrontera in this litigation with Bates number BF_1411_ITC 00038818.
Do you see that?
A. Yes.
Q. And you are listed here on the first page; right?
A. Yes.
Q. What is Exhibit 6?

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A. It's a PowerPoint presentation.
Q. What is the purpose of the PowerPoint presentation?
A. To inform.
Q. And can you give me any specificity as to what this particular PowerPoint presentation is intended to inform?
A. I'm unsure what our target audience for this piece was.
Q. I can represent that the file name for this document as it was given to us by Biofrontera includes Pariser, P-a-r-i-s-e-r, September 2024.
A. Okay. That's Dr. Pariser.
Q. Does that tell you any more information about what the purpose of this presentation was?
A. It does.
Q. Okay. And so what was the purpose of the presentation in Exhibit 6?
A. We presented at a Pariser Dermatology partner meeting.

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Q. Okay. And when you say "a partner meeting," is that partners in the dermatology practice?
A. Correct.
Q. Okay. And are those -- is Pariser a preexisting customer of Biofrontera's?
A. They are a customer.
Q. Okay. And have they purchased RhodoLED XL?
A. Clarify.
Q. Has the Pariser partner group purchased from Biofrontera a RhodoLED XL?
A. They're evaluating the XL. So they have not purchased.
Q. Okay. And evaluating, is that the process by which they pay a monthly fee to have access to the device for a period of time?
A. Yes.
Q. Okay. When did they start the evaluation?
A. I would recall September or October of 2024.

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Q. Okay. So possibly given the file name of September 2024, so I assume that this presentation was given in September of 2024 or thereabouts.
A. Yes.
Q. Okay. And so part of the purpose of Exhibit 6 was to encourage a customer of Biofrontera to evaluate and possibly purchase the RhodoLED XL device. Is that fair?
A. It's one of the reasons we would do this presentation.
Q. Okay. And on the evaluation period, during the time that a customer is evaluating the RhodoLED XL device, can the healthcare professionals in that practice use the device to photodynamically treat a patient with Ameluz?
A. Yes.
Q. Are you aware of whether this particular customer has done so?
A. Yes.
Q. And sorry, just to clarify, yes, the customer has used the RhodoLED XL with Ameluz to

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photodynamically treat a patient?
A. Yes.
Q. Just to clarify one thing, when you say "customer," Biofrontera, I assume, has also made its devices available for clinical studies as well; right?
A. Correct.
Q. So when we say "customers" here, that is not a use of the device to support a clinical study; right?
A. If I understand your question correctly, yes. The customer is purchasing Ameluz from us, and they are using the XL.
Q. Right. And Biofrontera is not intending to collect clinical data from that customer in order to support a clinical trial, for instance?
A. Correct.
Q. Okay. And where is the customer that Exhibit 6 was given to, where are they located?
A. Pariser Dermatology is in the

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Virginia Beach area of Virginia.
Q. And so Exhibit 6, do you consider Exhibit 6 to be part of a successful campaign to induce a customer to purchase and use the RhodoLED XL?
A. I wouldn't say "successful."
Q. Why is that?
A. I don't believe we've been successful.
Q. With the customer that purchased -- with Pariser, you don't think you've been successful in getting them to use the RhodoLED XL?
A. You'd have to define successful.
Q. How do you define successful as RhodoLED XL's marketing?
A. Success is achieving our goals, and we have not achieved our goals.
Q. What was your goal -- just focusing on this customer, Pariser, what was your goal in connection with Pariser?
A. To inform them about our therapy.
Q. Did you succeed in your goal here?

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A. In informing them, yes.
Q. Was it another goal to induce Pariser to evaluate and use the RhodoLED XL?
A. What does "induce" mean?
Q. Get them to do it, I would say.
A. Can't get anyone to do anything. I can ask them to do it. I can encourage them, but I can't get them to do anything.
Q. I'm not trying to -- I just need a clear answer.
One of your goals in presenting to Pariser was to get them to purchase your device; true?
A. Yes.
Q. And after presenting to Pariser, they, in fact -- when I say "purchase," that includes giving money in order to make use of the device. Is that fair? I know you have evaluations in industry sales.
A. Correct.
Q. But when we say "evaluate," they are getting money in order to use the device; right?
A. Correct.

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Q. And so following the presentation in Exhibit 6, Pariser has given Biofrontera money in order to use the device for a certain period of time; right?
A. Yes.
Q. And they've gone and used that device to treat patients; right?
A. Yes.
Q. Okay. And so let's look at the presentation. If you go to slide ending in -24, this is one of those slides that Biofrontera presented to its customer about the RhodoLED XL.
A. Where do you see it numbered?
Q. On the bottom. Do you see the --
A. Okay, I do.
Q. On page -824.
A. Yes.
Q. Okay. This is one of the slides that was presented to Pariser, a Biofrontera customer, about the RhodoLED XL; correct?
A. Correct.
Q. Okay. And this slide includes

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various features of the RhodoLED XL. Fair?
A. Fair.
Q. One of those features that was presented to customers was the wavelength of 635 nanometers; right?
A. Right.
Q. And another one of the features that was advertised with the customer was that the RhodoLED XL includes five panels with this particular LED arrangement that we see here; right?
A. Right.
Q. And those panels in a uniformed light, that's also one of the points you communicated to the customer; right?
A. Right.
Q. If we look on the bottom, one of the graphics shown to the customer is an illustration of the five panels illuminating a full patient head. Is that fair?
A. Again.
Q. This is, again, in that CR curved configuration; right?

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A. Right.
Q. And you noticed the customer that this allows for a full face or I assume full scalp illumination treatment; is that fair?
A. Yes.
ATTORNEY PETERSON: Objection to form.
Q. These are all accurate descriptions of the RhodoLED XL device; right?
A. To the best of my knowledge; right.
Q. To the right side we also have the points that there are 37 joules per square centimeter energy delivery; right?
A. Yes.
Q. You also provide the total illumination area when five panels are used in a curved configuration; correct?
A. Correct.
Q. And you also have a treatment distance listed here; correct?
A. Right.
Q. In this presentation -- did you

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present this slide?
A. I did not.
Q. Okay. Who presented this slide?
A. If I recall, this was John Lyons.
Q. Do you recall any questions from Pariser about the features of the RhodoLED XL?
A. I don't recall any.
Q. Okay. Do you know why these particular features are being emphasized in the presentation to Biofrontera customers about the XL device?
A. I don't -- emphasize, I wouldn't use that word.
Q. Okay. Do you know why these features were selected for presentation?
A. No.
Q. Okay. Biofrontera has another device called the RhodoLED; right?
A. Right.
Q. I've been calling it the original. Is that fair?
A. There's many. That's fine

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Q. What do you use?
A. BF RhodoLED, other lamp, it's fine.
Q. Okay. The RhodoLED XL differs in the features it can offer compared to the original lamp; right?
A. Right.
Q. And one of the differences are that it has five panels with 25 LEDs; right?
A. Right.
Q. And it has a different LED arrangement of the panel; right?
A. Right.
Q. And unlike the XL, the original device cannot be arranged for a full face illumination with five panels in the curved configuration; right?
A. Correct.
Q. And the treatment area and the illumination area for the XL is larger than the original device also; correct?
A. Correct.
Q. And those are some of the features

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being selected for use in this specification; right?
ATTORNEY PETERSON: Objection to form.
A. There isn't any comparison to the original lamp in this presentation.
Q. Right. My question was totally different. The features that we just went over that are different from the original RhodoLED are used on this slide to promote the XL. Fair?
A. Those features are used to promote this XL.
Q. How are the five panels of the RhodoLED XL connected?
A. Can you clarify?
Q. Sure. Are you aware of how the five panels are held together or held to each other?
A. My opinion would be by hinges.
Q. Okay. And where are those hinges located on the device?
A. On the side.
Q. On the side of what?

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A. I'm not sure.
Q. So when you say "side," do you mean on the side of the panel?
A. That would be my understanding.
Q. Okay. And looking at each panel, the top edge and the bottom edge of each panel is shorter than the side edges of the panel. Right?
A. I'm not sure. I'm just not.
Q. It's not meant to be a trick question.
A. I'm not giving a trick answer. I'm just not sure. It's nothing I've thought about.
Q. Okay. When you've seen this device in person, you sell the device, you promote the device?
A. Right.
Q. The panels are not in a square shape; right?
A. Yes.
Q. They are angular shape; fair?
A. Fair.
Q. The top side of the panel, of each

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panel is shorter than the long side on the side of each panel; right?
A. I'm not sure.
Q. Okay.
A. A rectangle, right. That is a rectangular shape, that would be correct.
Q. And a rectangle has a short side and a long side.
A. Yes.
Q. And the short side here is the top and bottom of the panel; right?
A. That would be correct.
Q. And the long side is the side?
A. Correct.
Q. During treatment -- well, let's start here.
The healthcare professionals could choose to use all five panels in treating patients; right? It can all be turned on?
A. Correct.
Q. The panels can also be turned off; is that right?

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A. Right.
Q. And so during a treatment -- let's start here.
When treating a patient with all five panels turned on, during that treatment the healthcare professionals can turn off one of those panels; correct?
A. During treatment, I'm not sure.
Q. Okay. They could pause the treatment; right?
A. Right.
Q. And they can turn off the panel at that point; right?
A. I'm not sure.
ATTORNEY HABBAZ: Okay. Do you want to take a break?
ATTORNEY PETERSON: Sure.
(Recess taken from 10:37 a.m. to 10:50 a.m.)
BY ATTORNEY HABBAZ:
Q. Welcome back.
A. Thank you.

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Q. Did you discuss the substance of your testimony with your counsel?
A. The substance, no.
Q. What's your understanding as to why Biofrontera decided to develop the RhodoLED XL?
A. My understanding is we want to further PDT along in the marketplace.
Q. Okay. How does the RhodoLED XL further develop the PDT?
A. In my opinion?
Q. Yes.
A. In my opinion, it gives healthcare providers an opportunity to use this device to treat PDT.
Q. Okay. Why is the XL necessary for that goal if you have the original RhodoLED?
A. I would put that in the opinion of the person who would purchase that.
Q. Okay. But speaking as Biofrontera's corporate representative, could you explain why the company chose to develop the RhodoLED XL device when it already had the original RhodoLED?

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A. So we still sell the original device, so we offer both of those devices. And it's a good opportunity for healthcare providers to choose what they want to use.

Q. Okay. But what is the choice you're providing to those healthcare providers? What is different about the XL that could cause one to purchase the XL over the original?

A. Okay. There's a couple things. One is the price. It is more expensive than the original lamp. The second thing is it does have some features that the original device does not have.

Q. Okay.

A. That could be appealing to an office.

Q. Okay. I'm a little bit confused as to the answers you gave. How does the price fit into what's appealing about the XL to the healthcare professional?

A. Exactly. It doesn't.

Q. Okay. So --

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A. To clarify, I believe you asked me what was the difference. One of the differences is it's a different price.

Q. Okay.

A. Maybe I misunderstood your question.

Q. The question was -- and I'll ask it again -- what is different about the XL that causes a healthcare provider to purchase the XL instead of purchasing the original?

A. Yeah. So it's not the price. The features that are different than our original device.

Q. Okay. And that's the justification for the higher price, those different features?

A. One of them.

Q. Okay. What's the justification, if you had to convince a customer or a potential customer about Biofrontera, why they should spend more money on the XL device as opposed to the original? What are the points that you raised?

A. In my words, I wouldn't position it that way. I wouldn't say spend more money. I would not do that. It's got a longer extension cord than the original device. That is a big deal. It does have the panels that our smaller device doesn't have, so there are some features that are different.

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Q. Okay. And what do you find convincing when selling the XL device about the panels, about the differences between the panels in the XL from the original?

A. I wouldn't use the word "convincing."

Q. Okay.

A. I wouldn't.

Q. Okay. What are the features specific to -- let's not talk about the extension cord. Focusing in on delivering treatment to patients and on the panels themselves --

A. Uh-huh.

Q. -- what are the features of the panels as compared to the original device that you think are part of the justification for the higher price of the XL?

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A. So I'll answer it that the difference between the XL and the original lamp is the XL has five panels, the original lamp has one panel.

Q. Does the XL provide the same level of performance in terms of light delivered to patients as compared to the original?

A. I'm not sure.

Q. Okay. Does it provide a better treatment to patients compared to the original?

A. I'm not sure.

Q. Okay. Do you know what the advantage of having five panels over one panel is?

A. From what point of view?

Q. From a healthcare provider's point of view.

A. I don't.

Q. Okay. So it's your -- you don't know one way or another as the corporate representative of Biofrontera and with your experience in sales and marketing why a healthcare professional would prefer the five-panel device

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over the one-panel device that Biofrontera sells?
A. I do, and there's not one answer. It's not a general statement.
Q. Can you give me an answer as for -- for why a -- I'll strike that. We'll try to make this simpler.
A. Sure.
Q. In your understanding -- and you can give me multiple answers -- why would a healthcare professional prefer the RhodoLED XL, the five-panel device over the original RhodoLED, the one panel?
A. One of the features, some providers see a benefit of having five panels over one panel. One of the features.
Q. What is your understanding of what the benefit of five panels are?
A. My benefit or from a provider's point of view?
Q. From the provider's point of view.
A. Feedback that I received is they like having the five panels versus the one panel.
Q. And why is that?

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A. When treating a patient.
Q. Can you give me anything more as to why they think having five panels is a benefit?
A. One of the benefits is you can treat a patient's full face with one treatment. On our original lamp, you cannot do that.
Q. Okay. When going from the one-panel device to the five-panel device, in your understanding, is the change in the patient's skin in terms of the treatment received, is that about the same?
Does that question make sense?
A. No.
Q. So what I'm trying to get at is you're going from a one-panel device to a five-panel device, and it's -- as a potential customer one of the questions I might have is, okay, I understand I have a larger treatment area.
A. Uh-huh.
Q. Can you tell me that the uniformity of the light, the intensity of the light, the changes, the physiological changes in the skin,

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it's going to stay the same, it's just a larger area as compared to the original with the five panels?
Does that make sense?
A. I believe your question makes sense.
Q. Okay. So what I'm trying to get at is, does Biofrontera communicate to healthcare professionals that there are advantages to the five-panel device in the larger treatment area while maintaining the characteristics of the light and the changes that the light makes on the patient?
A. So if I understand your question correctly, utilizing the five-panel versus the original lamp, does it offer PDT treatment to the patient.
Q. Yes.
A. It does.
Q. And does it offer a similar level of treatment as compared to the original?
A. Similar level. I don't understand.
Q. Like the change in the skin, the

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effectiveness of the treatment.
A. So if we're talking efficacy, no.
Q. Okay. Why do you say that?
A. My understanding is and my recollection is we don't have studies specifically on the XL versus our original lamp talking about efficacy.
Q. Okay. Do you know if it's the same level of efficacy?
A. I don't.
Q. Okay. And so going back to where we started here, what was the motivation for Biofrontera to develop and then sell the RhodoLED XL in view of the original RhodoLED?
A. I'm not sure of their motivation.
Q. Okay.
A. Yeah.
Q. And if a sales representative asks you how do I convince or how do I educate a potential customer on why they should select the XL and not the original device, what are the features that you emphasize or what are the questions that

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you --
A. So nothing different than we've already shared.
Q. Can you summarize?
A. So we summarize that yes, there is a longer extension cord. Yes, we have established that there is a different price between the two, and yet there is different features of this XL versus the smaller lamp or the original lamp, we should say.
Q. And we reviewed those features earlier in, I believe it was Exhibit 6 -- yes, Exhibit 6; is that right?
A. Okay, 6.
Q. I think on slide ending in -824; right?
A. Right.
Q. And those are the features you're referring to or some of the features you're referring to?
A. Some of the features.
[redacted]

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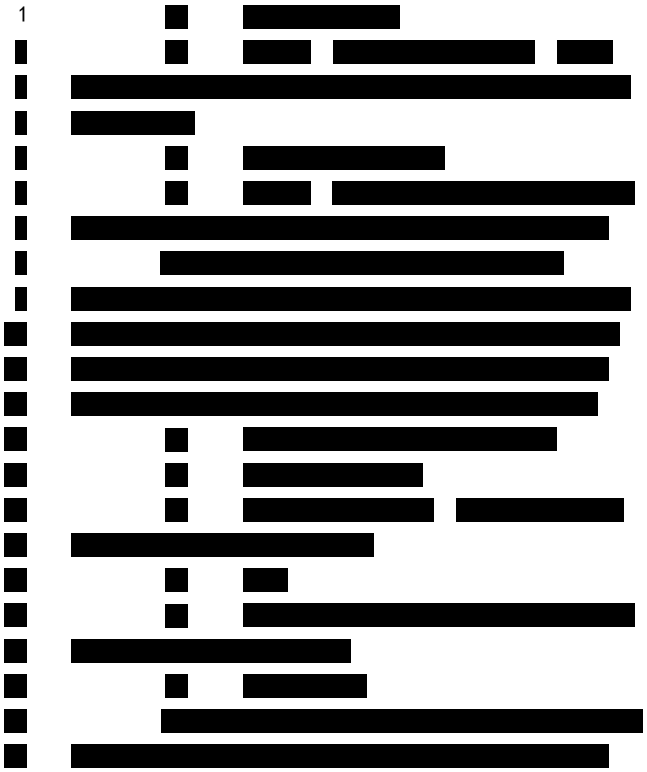

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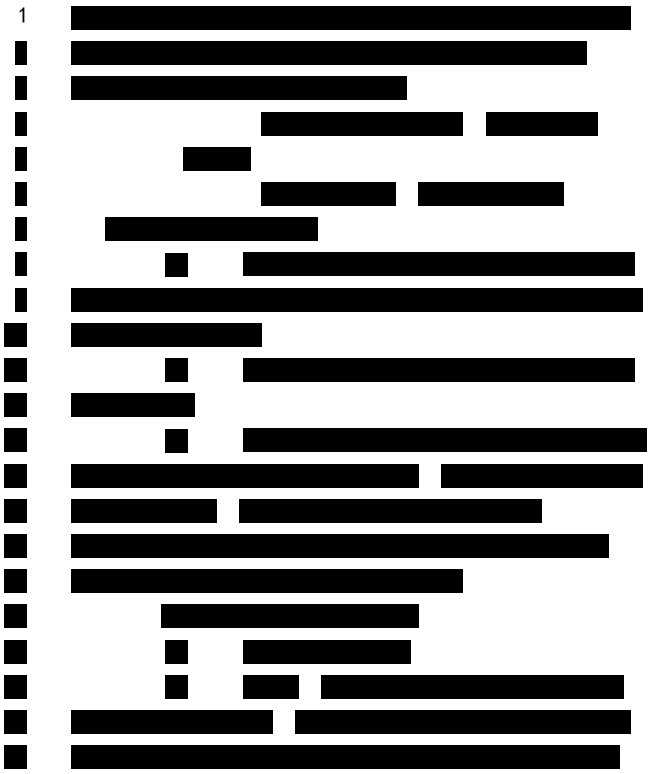

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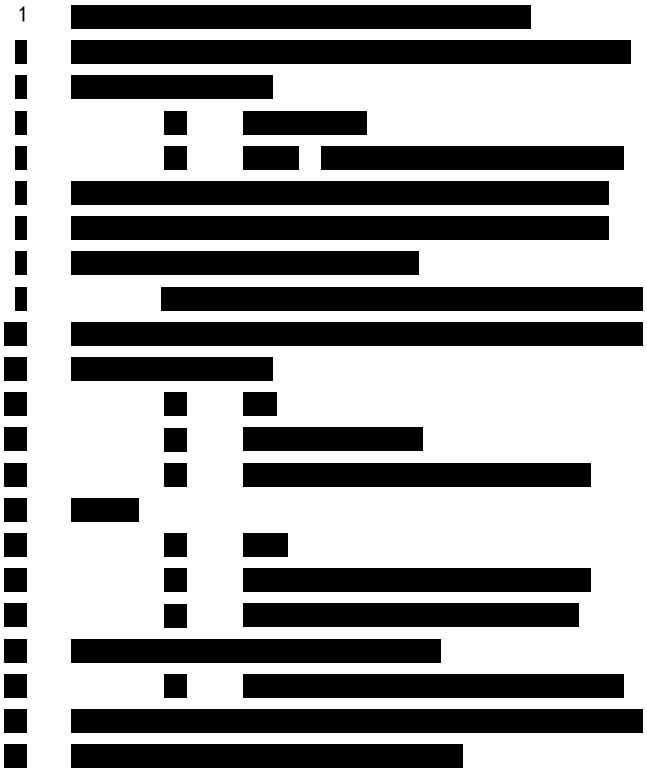

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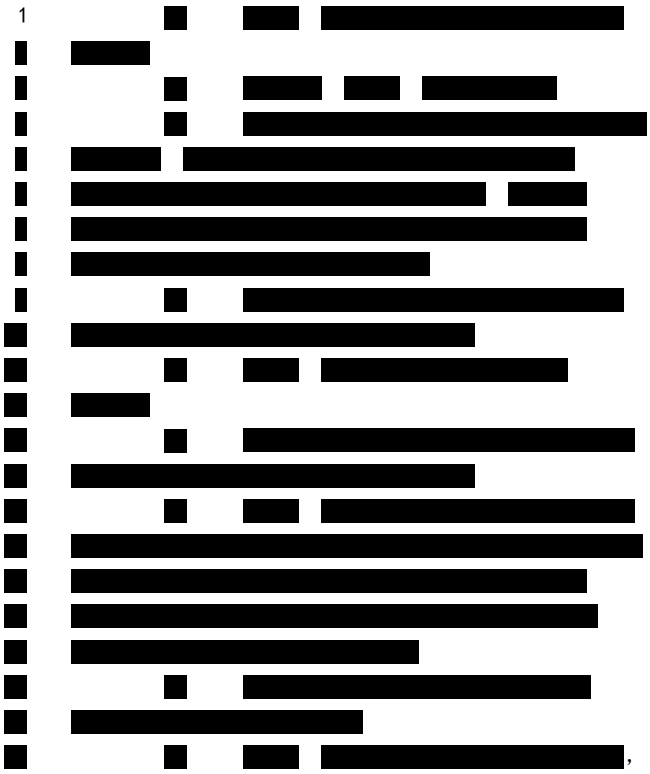

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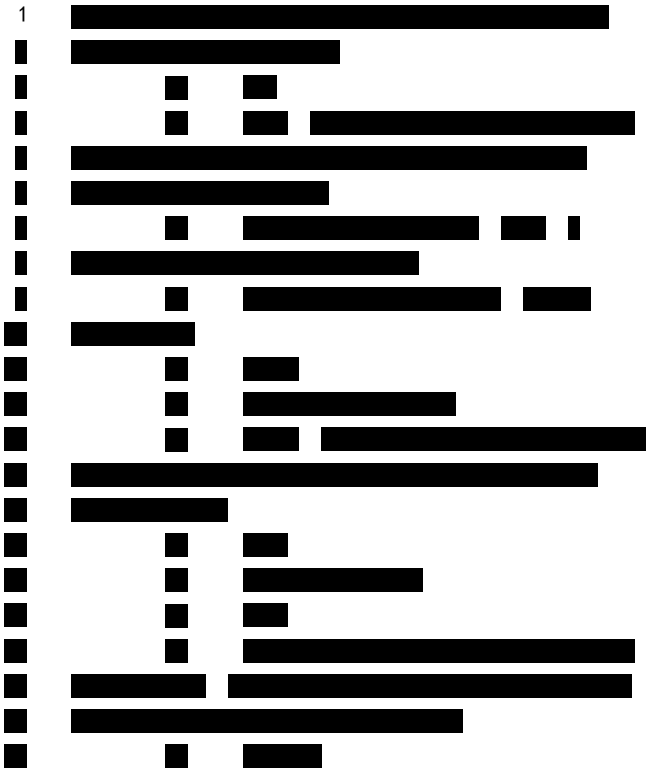

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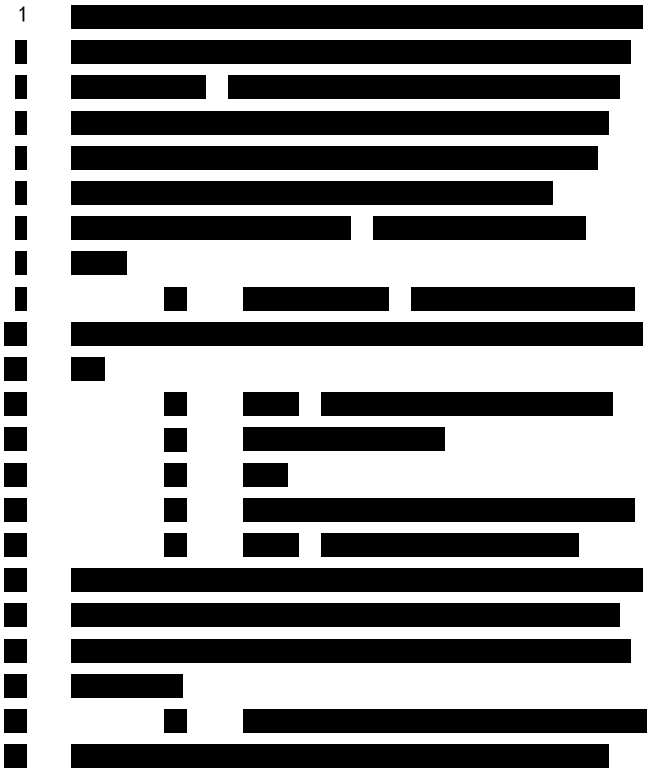

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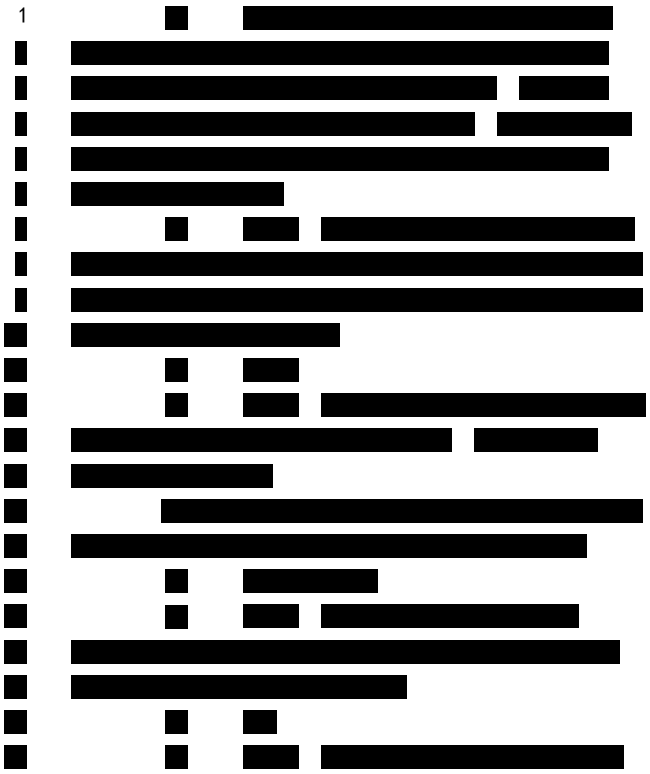

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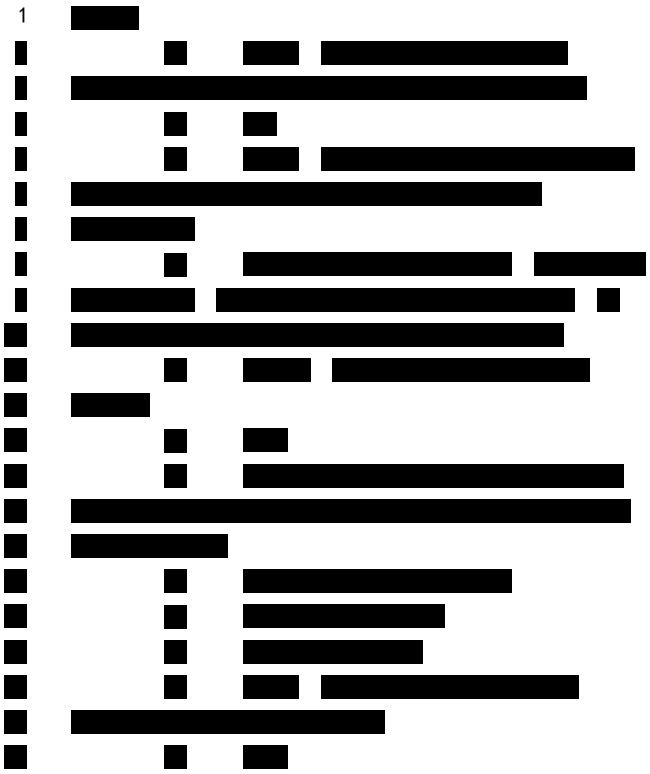

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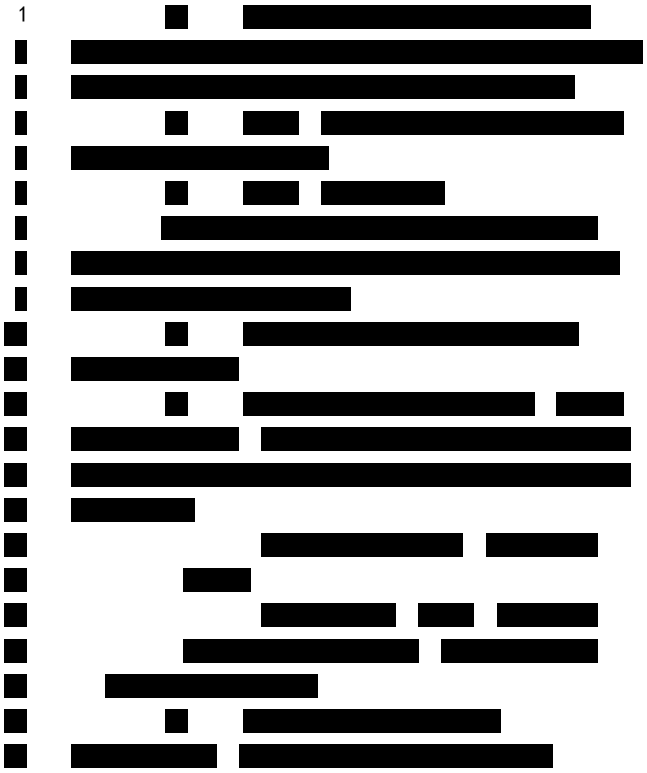

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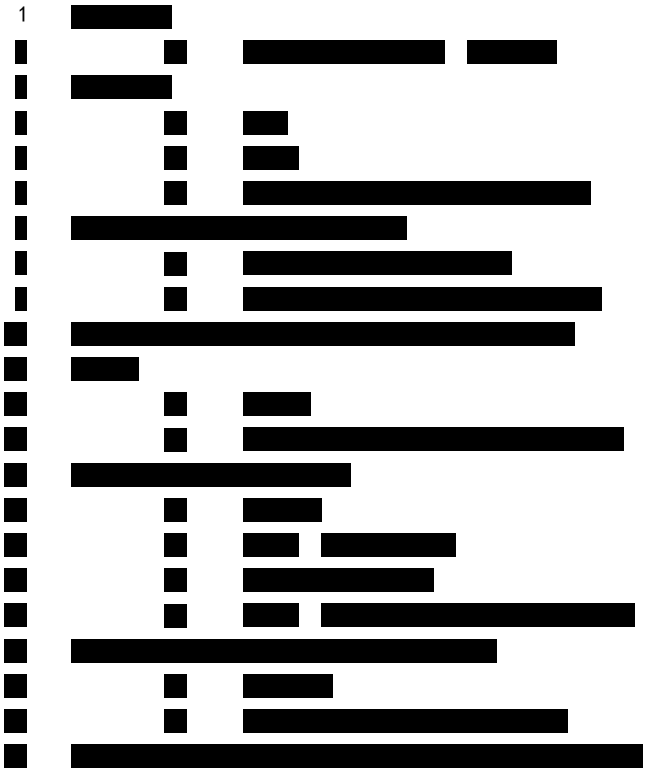

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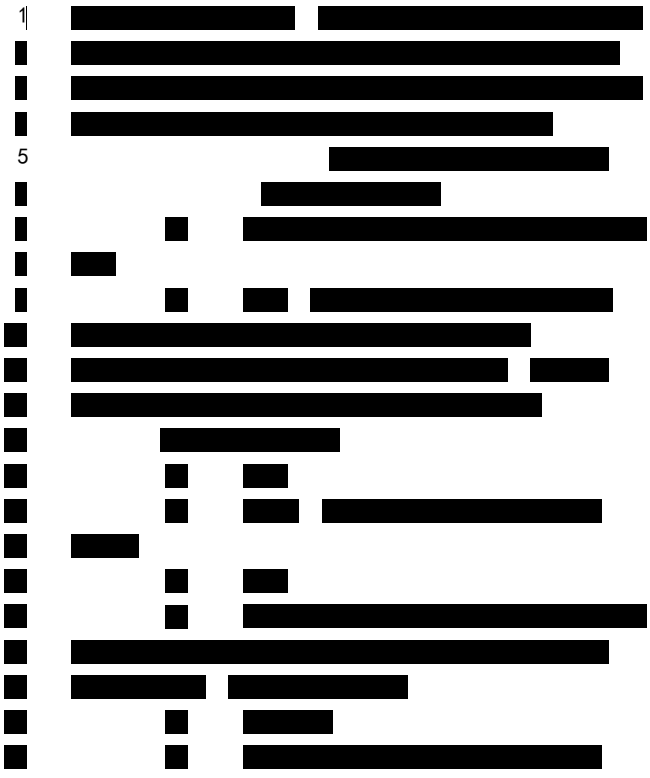

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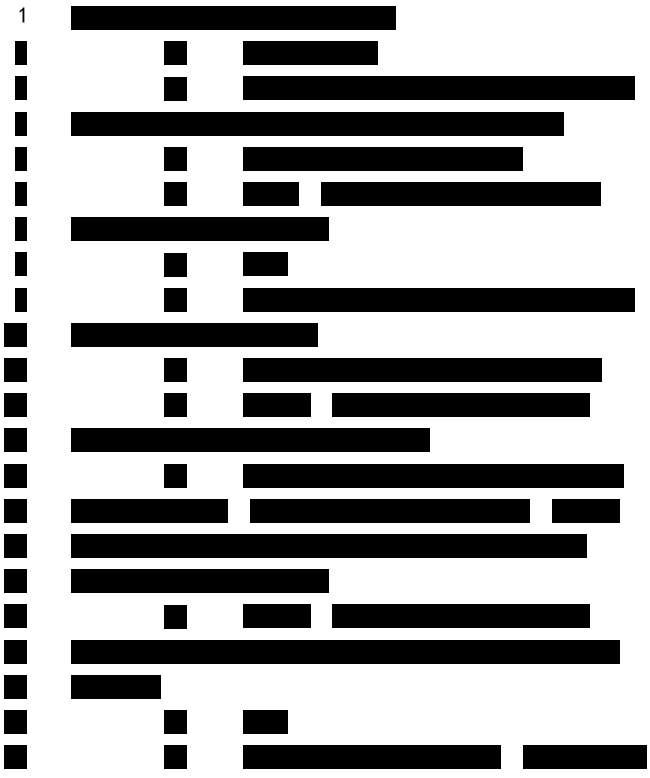

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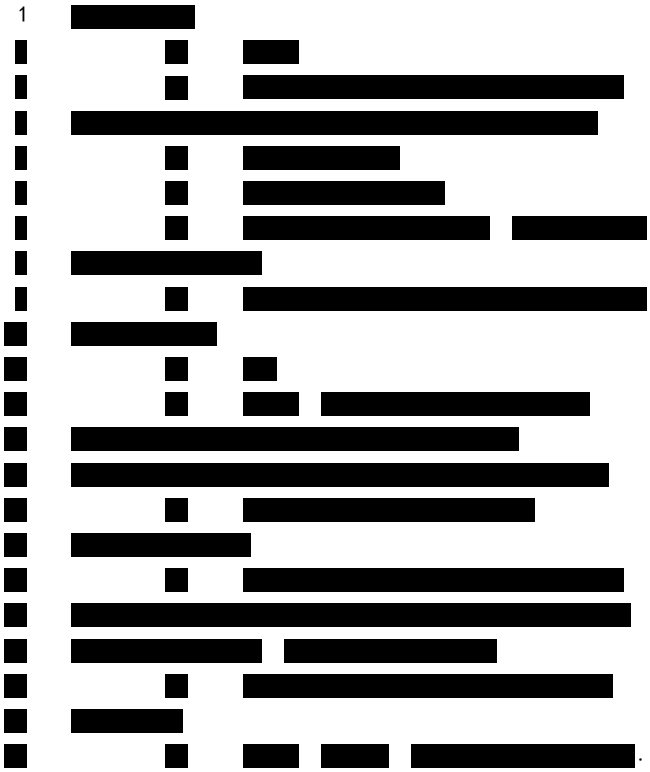

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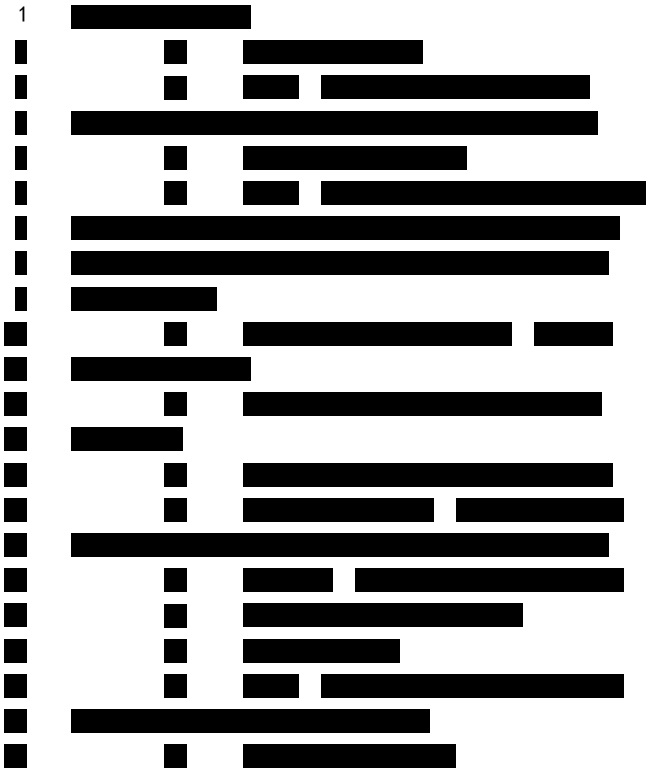

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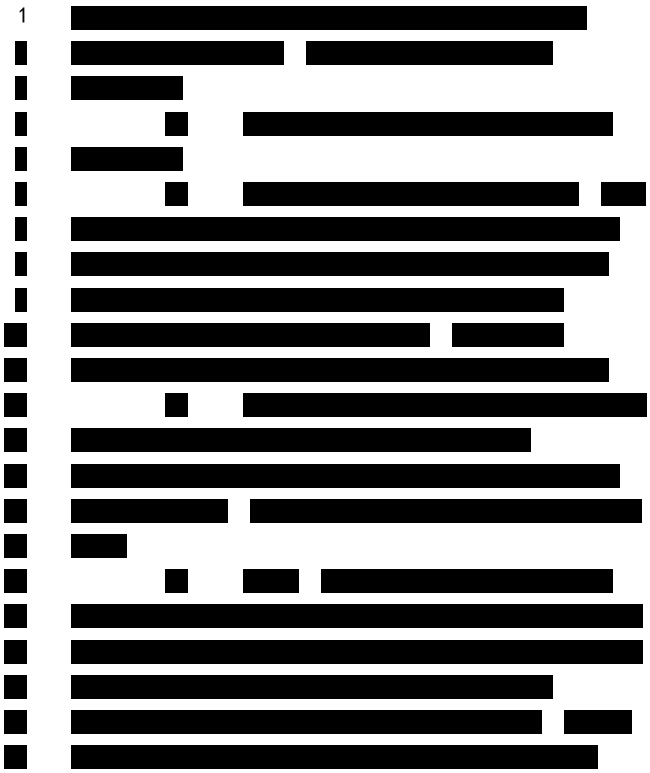

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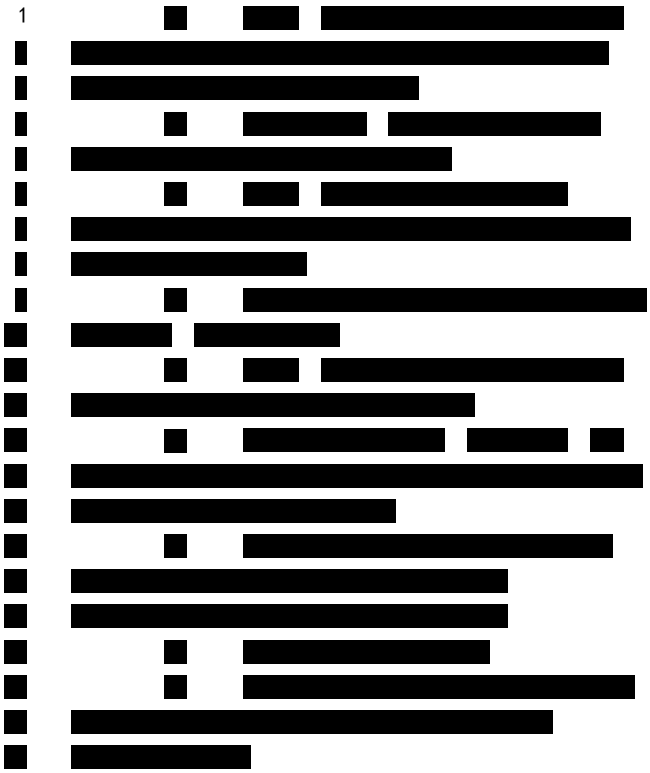

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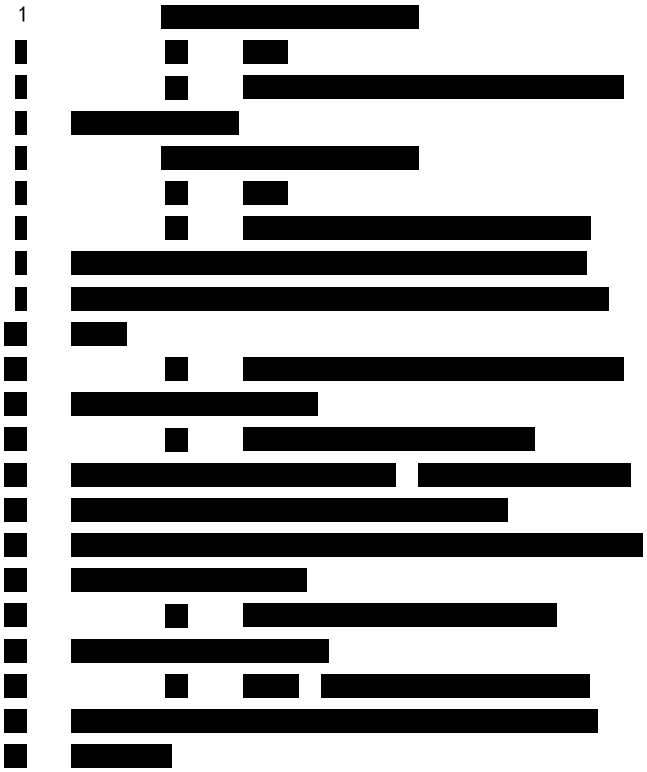

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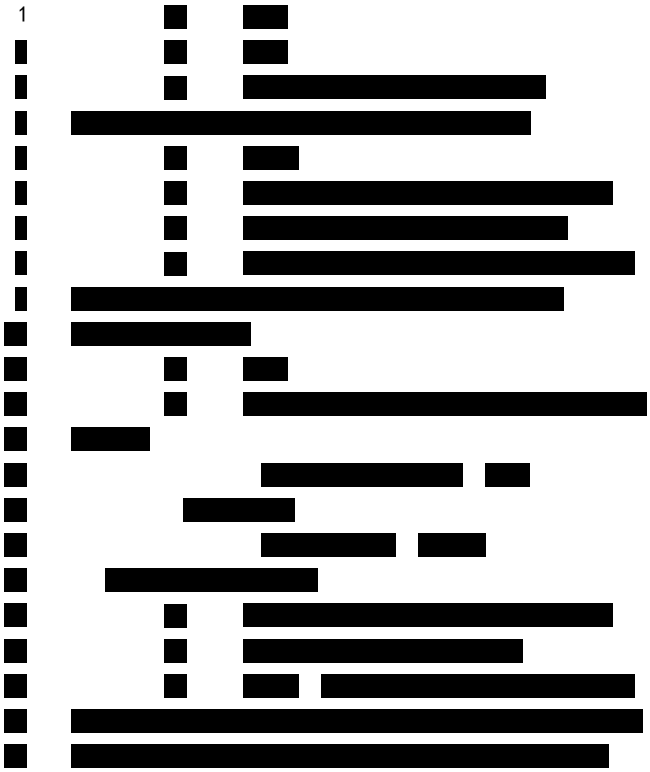

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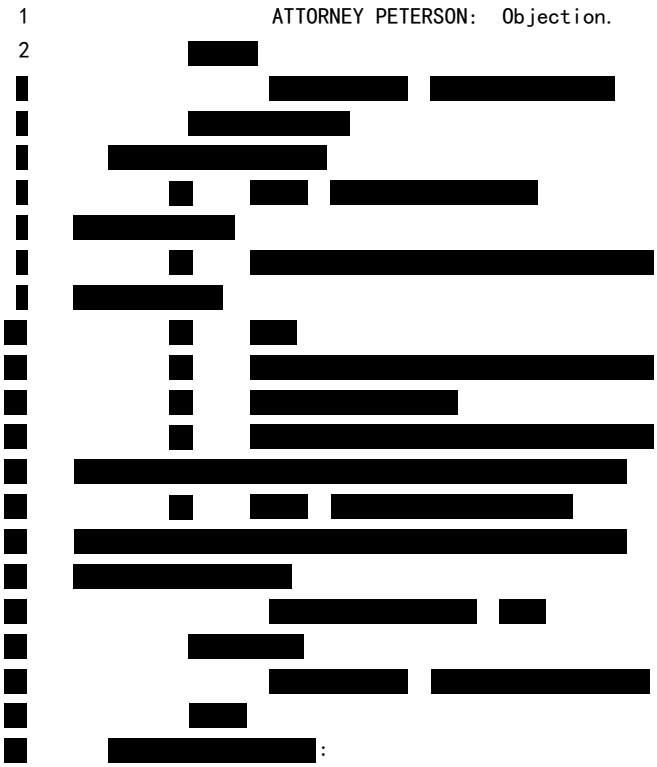
ATTORNEY PETERSON: Objection.



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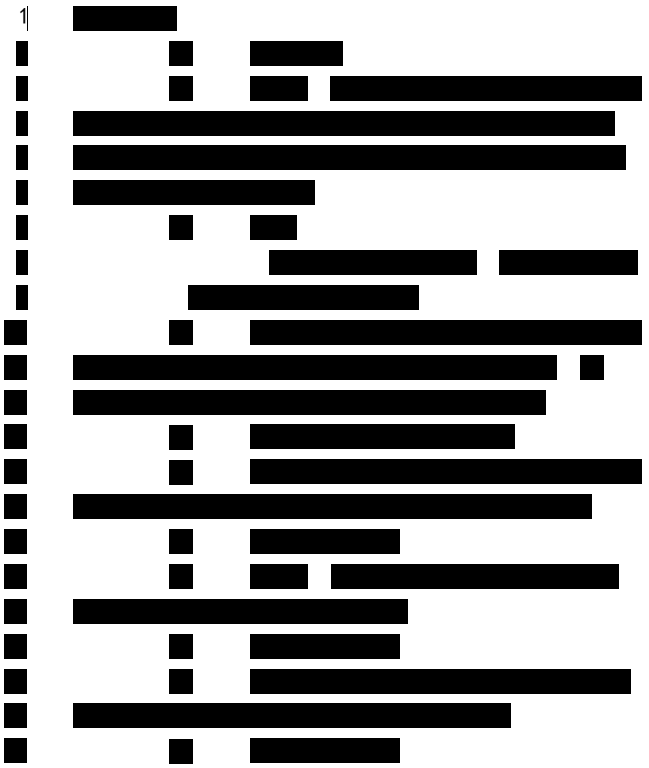

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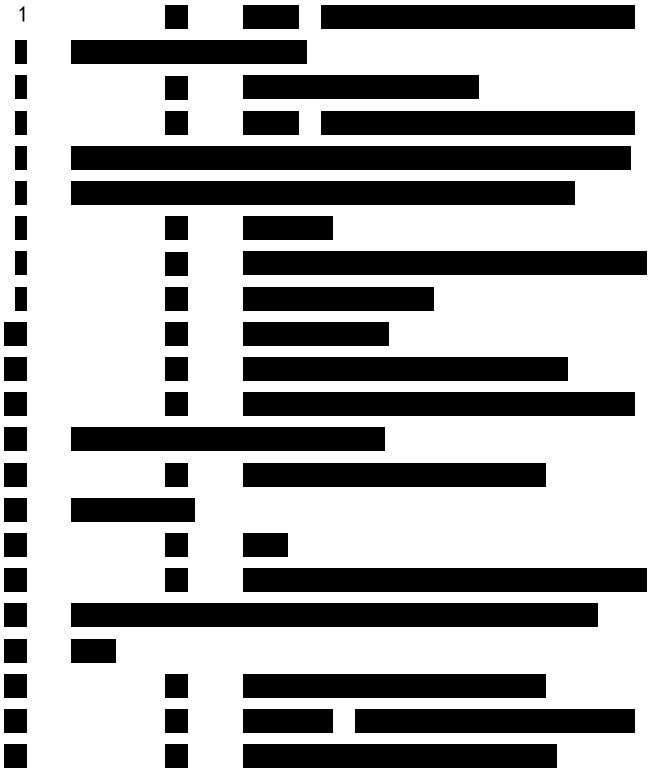

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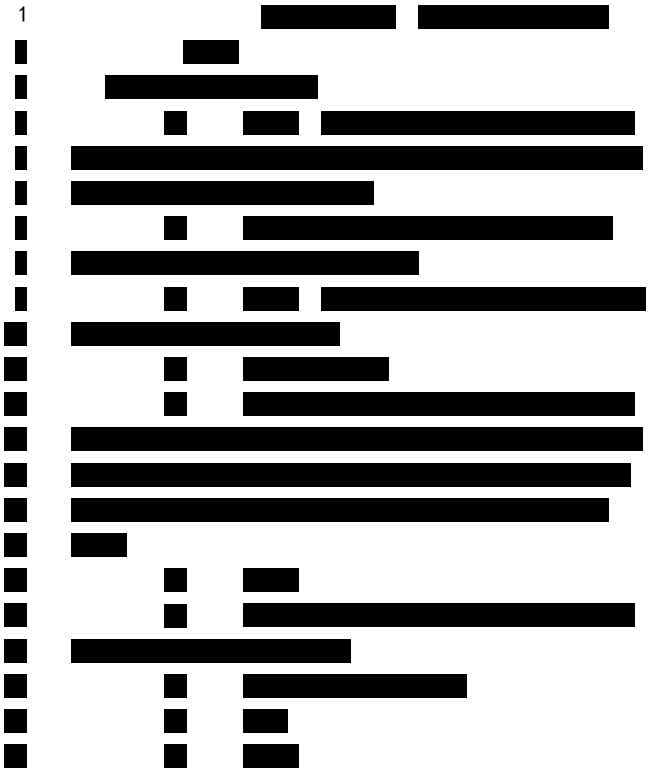

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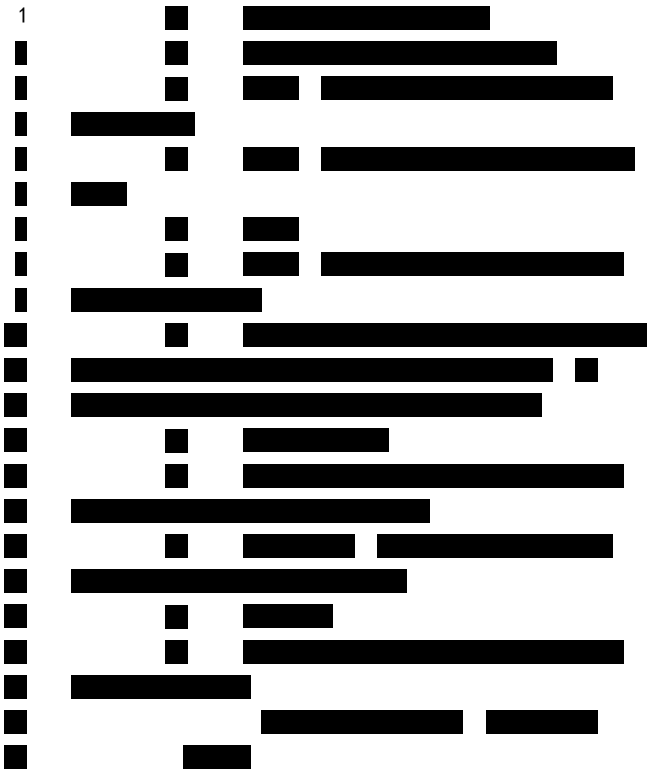

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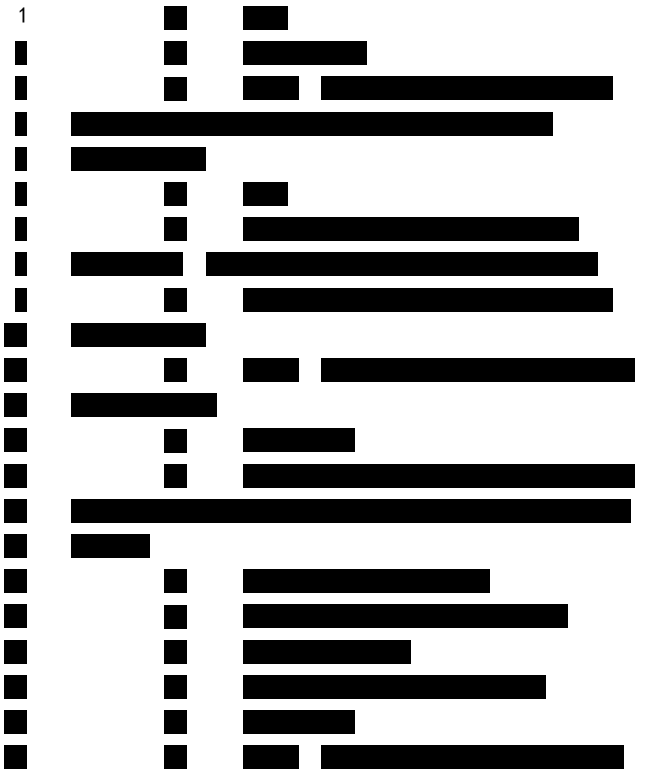

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Q. Well, do you know what the average selling price is for the original RhodoLED?

A. We sell the new -- we sell it new. We also sell it refurbished, and the refurbished will fluctuate. So I don't know the average.

Q. Okay.

A. If you're putting them all together.

Q. Okay. New, what's the price?

A. $7,500.

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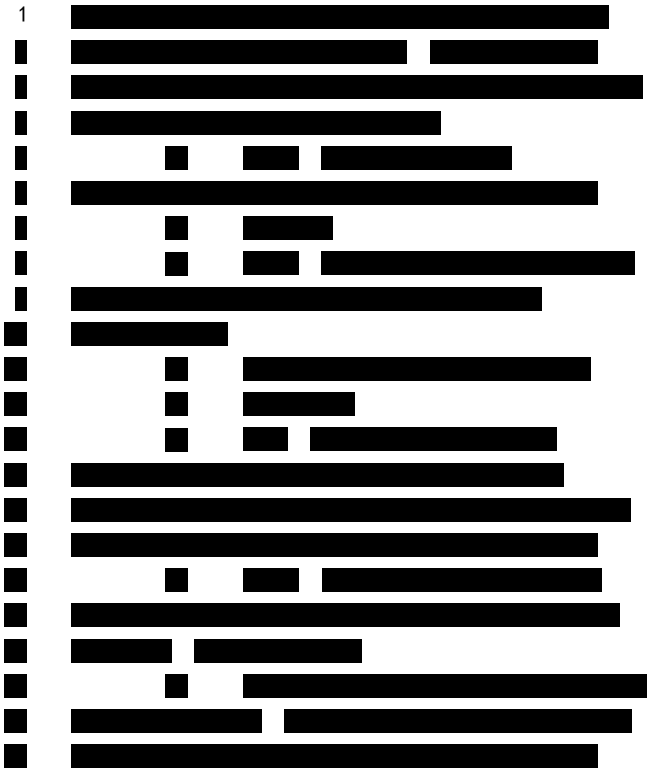

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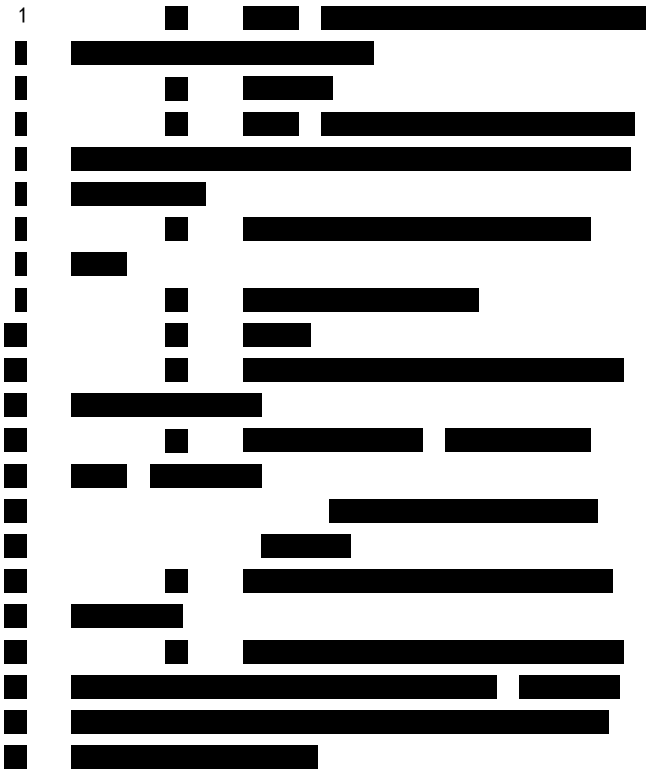

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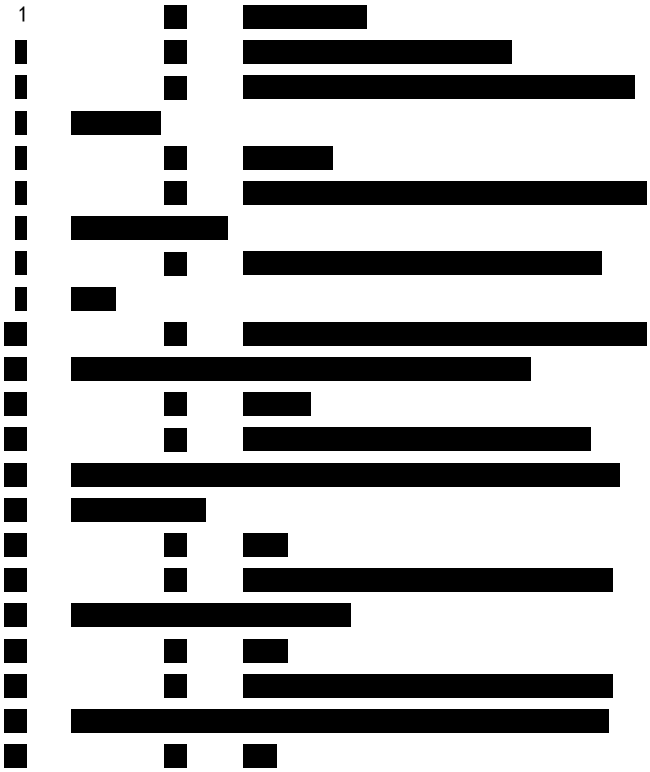

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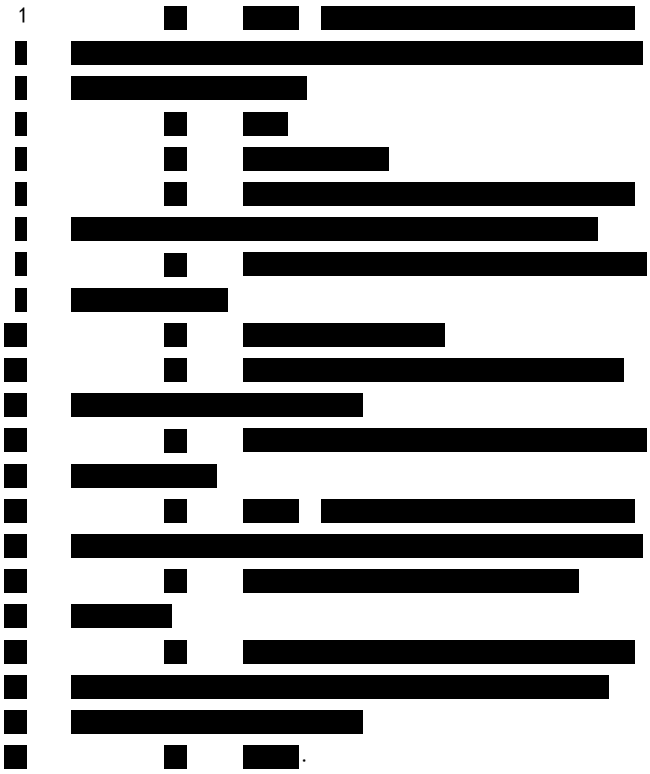

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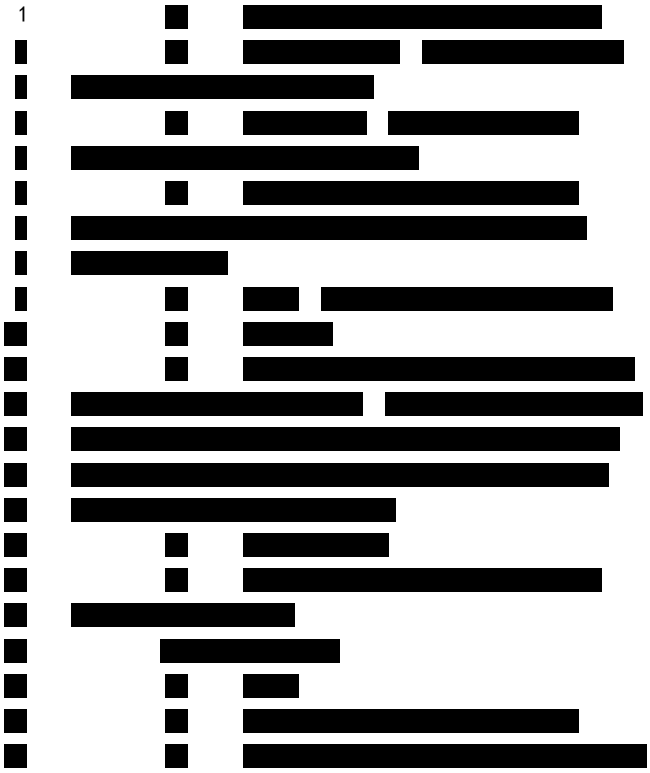

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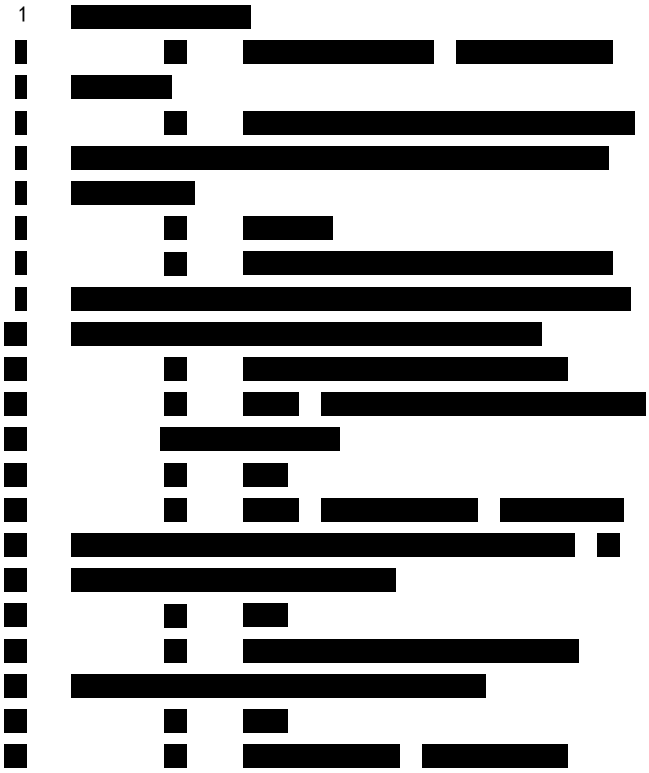

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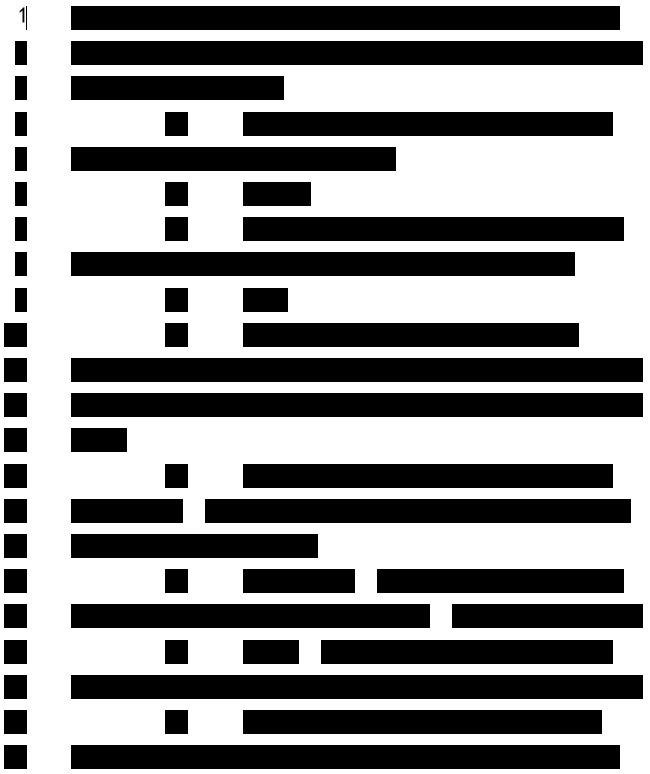

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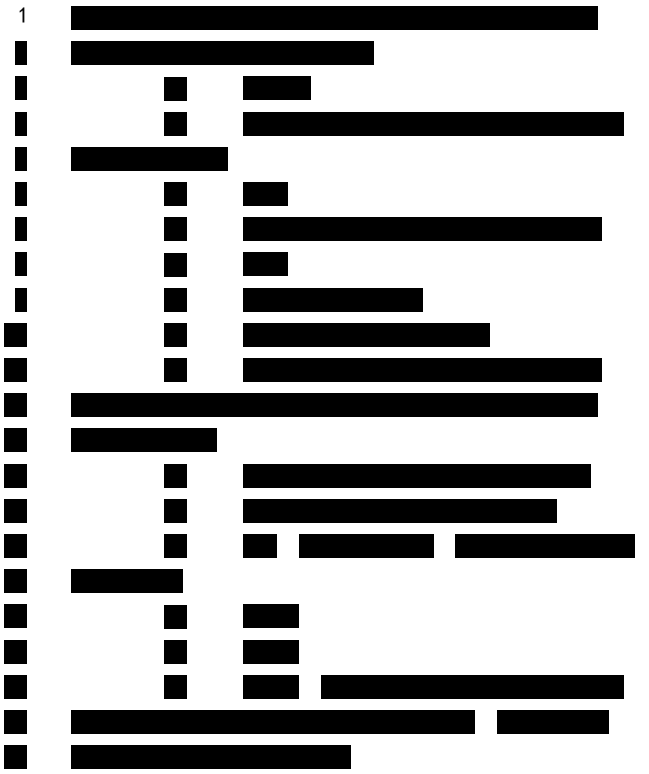

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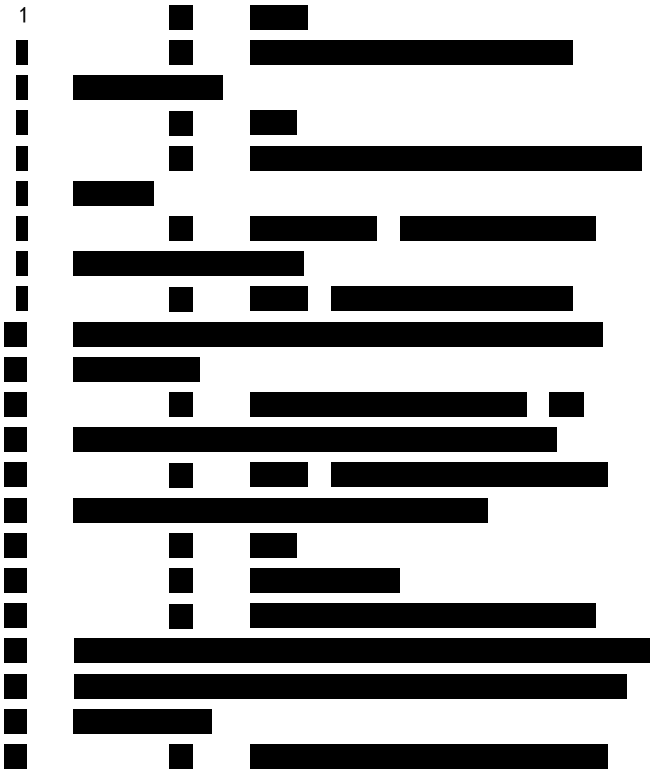

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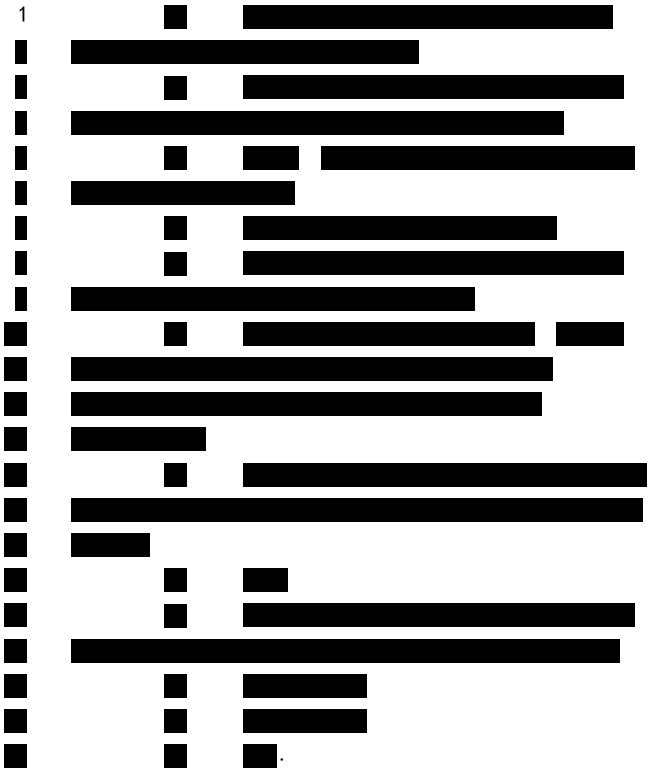

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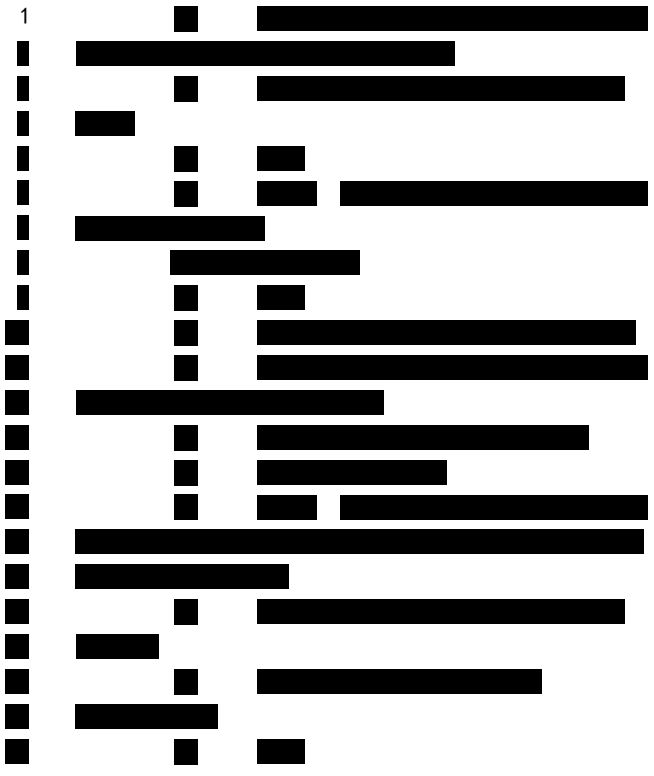

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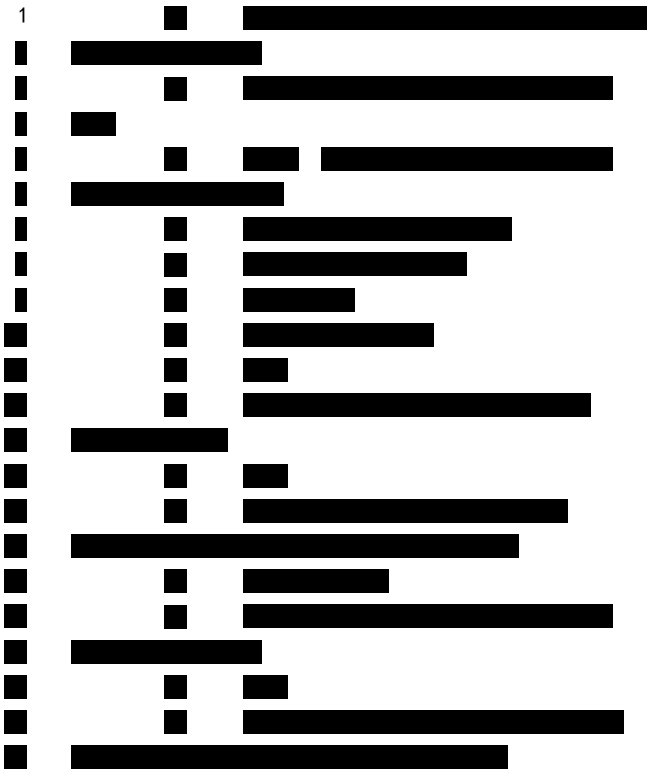

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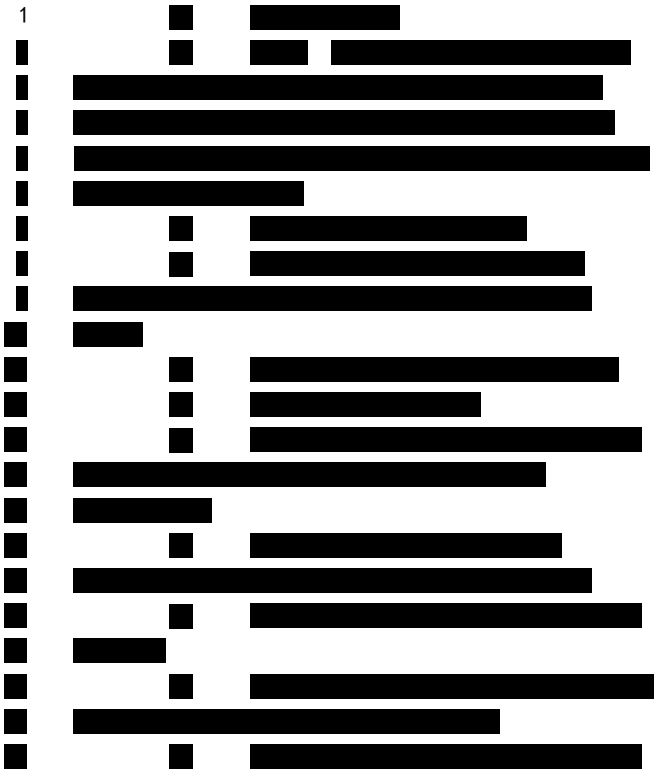

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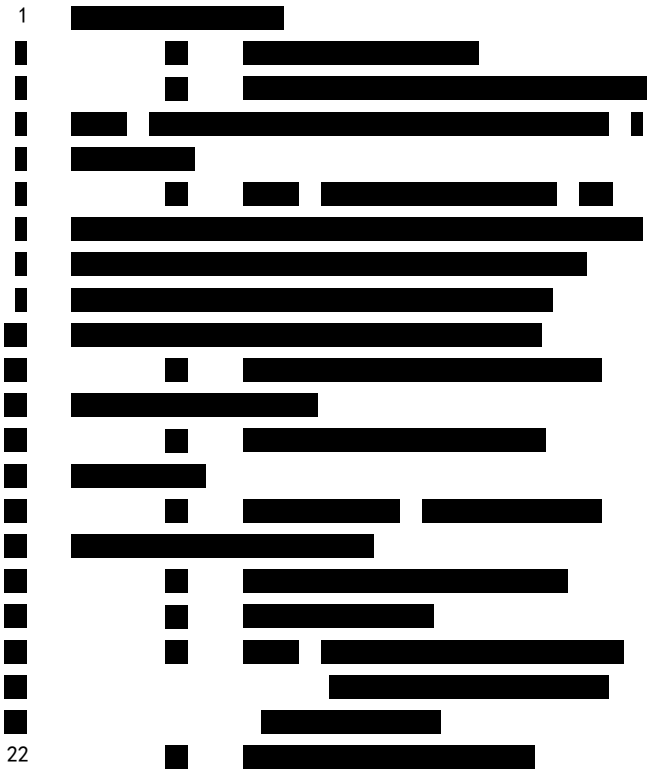

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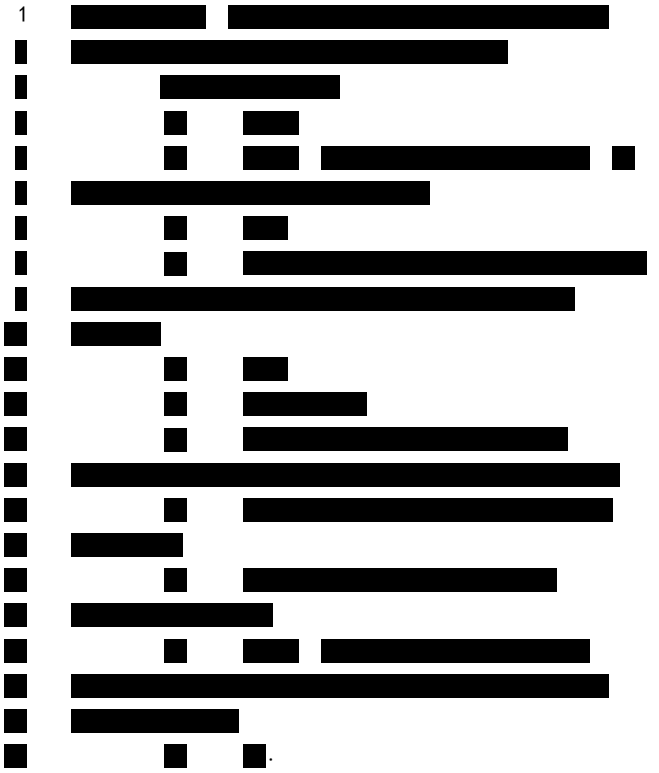

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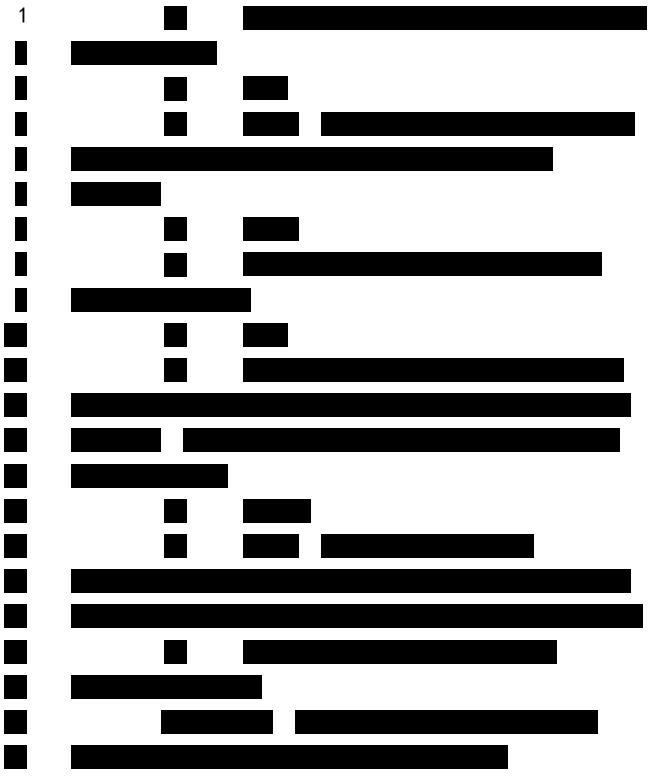

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Q. For example, what's the market price of the RhodoLED XL currently?

A. 18,500.

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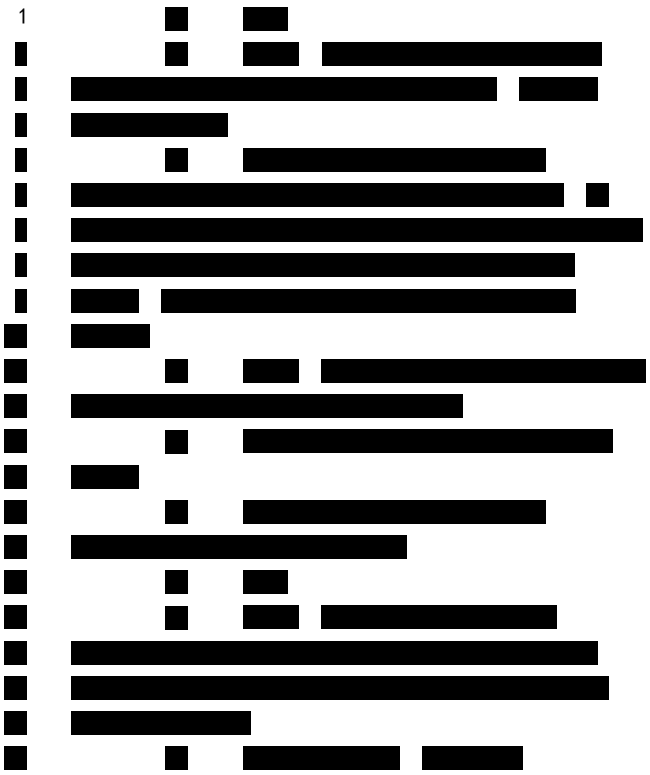

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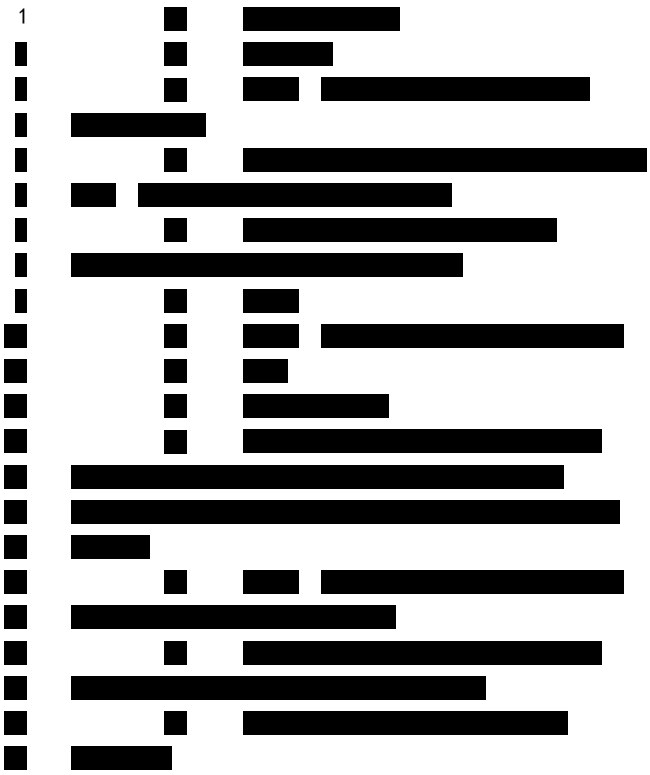

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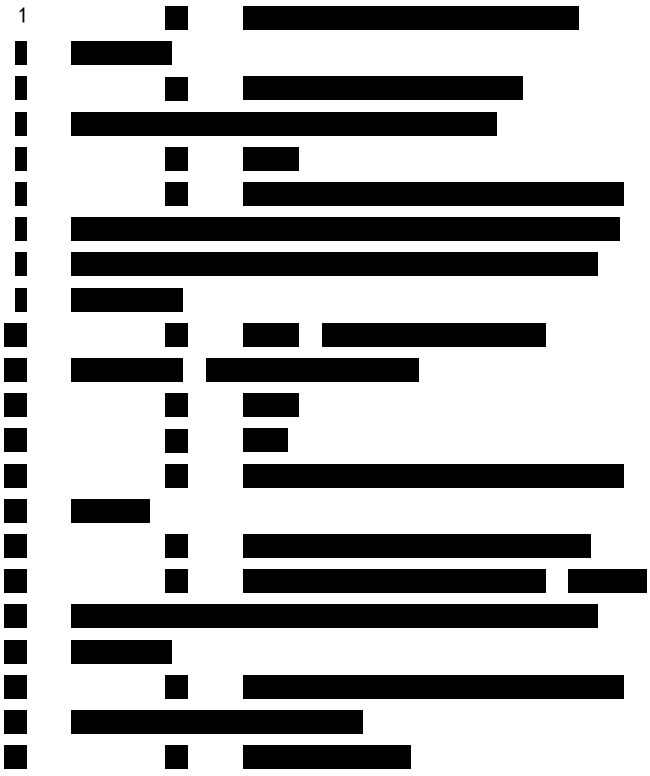

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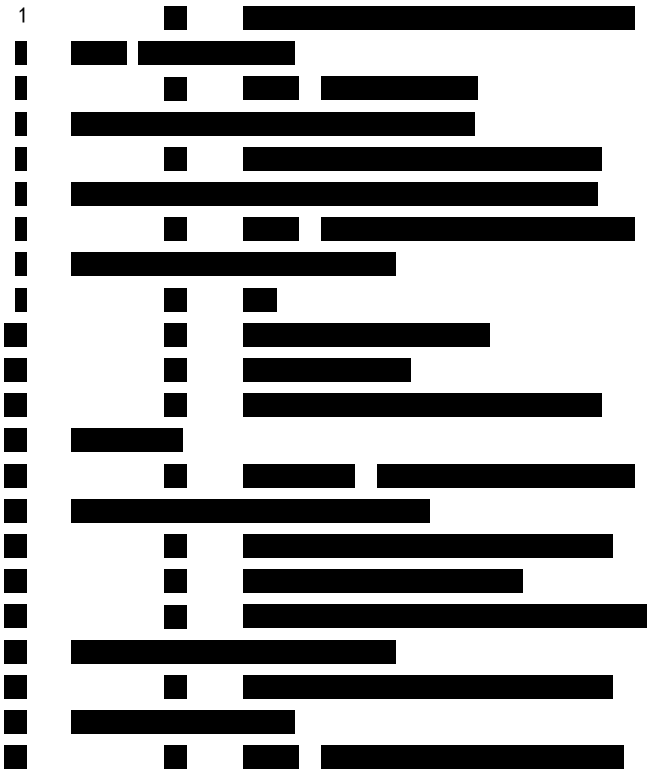

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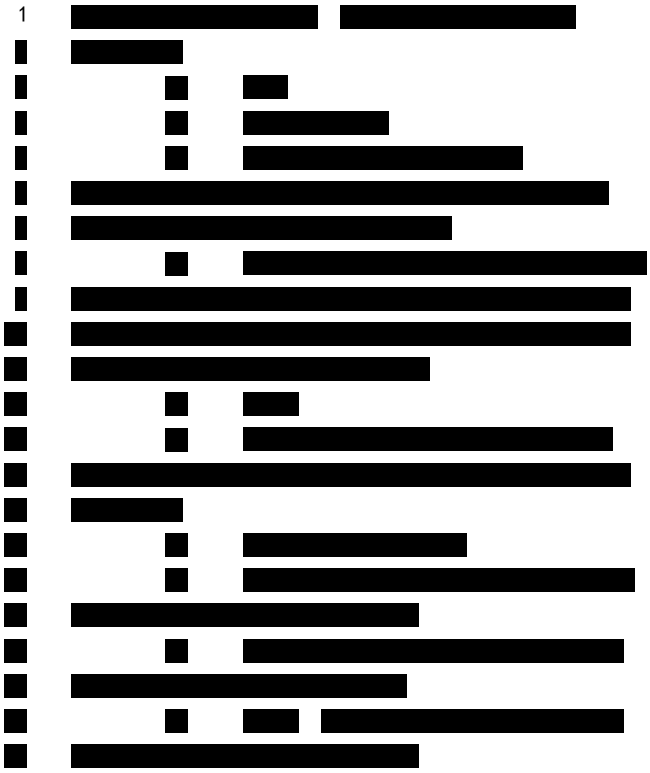

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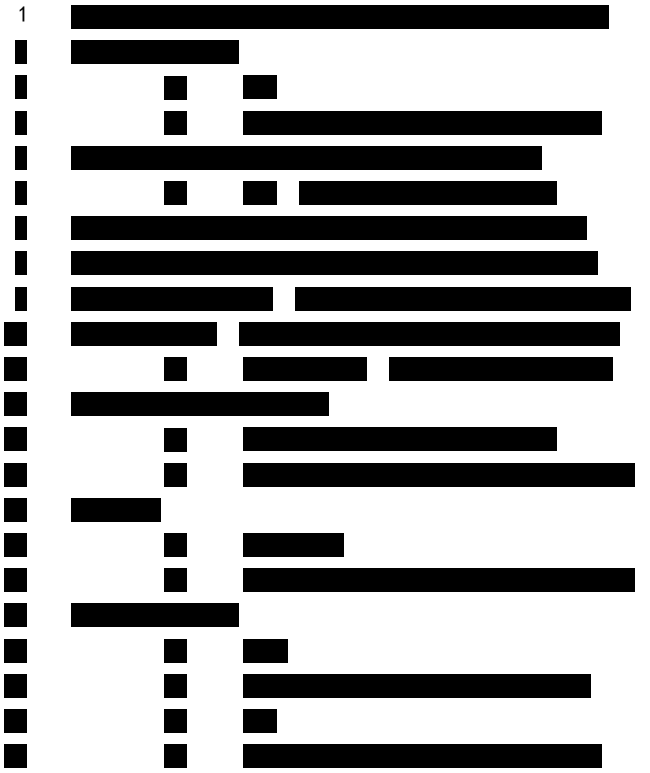

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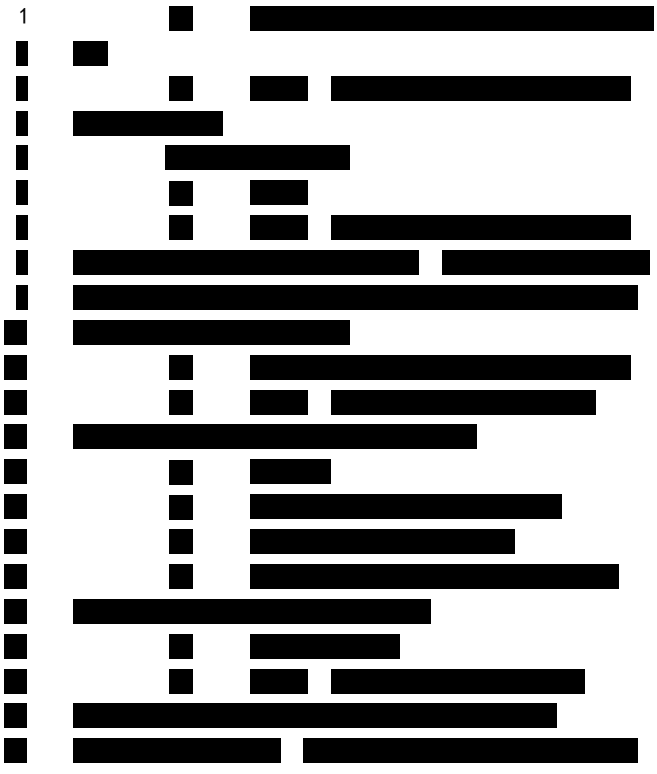

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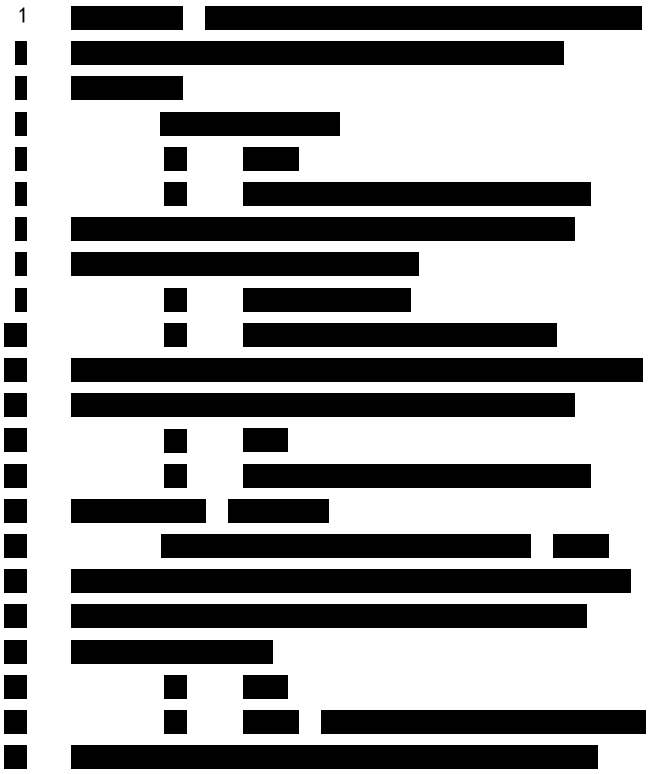

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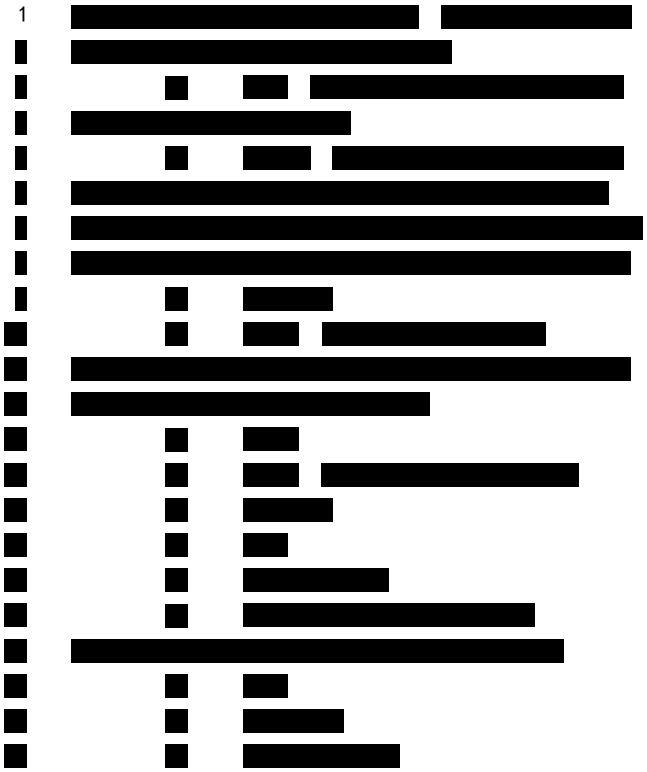

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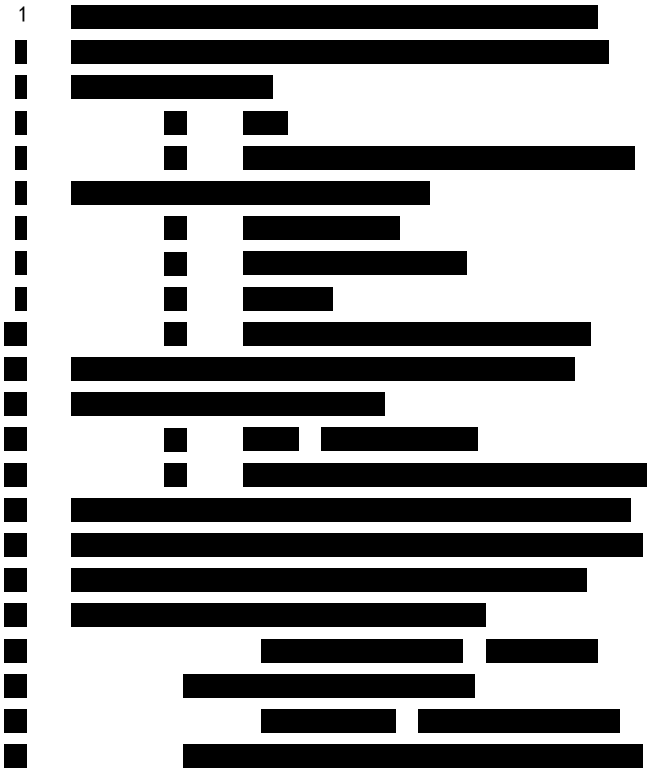

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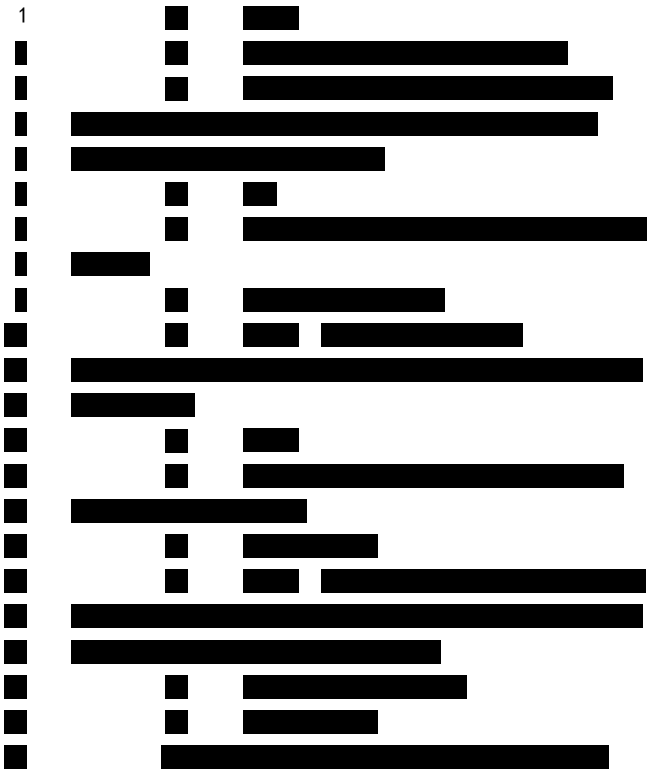

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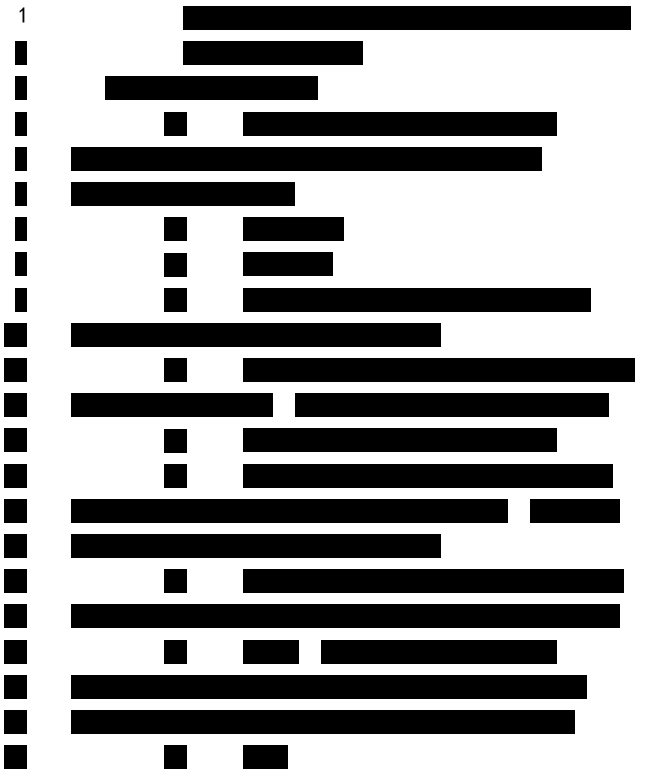

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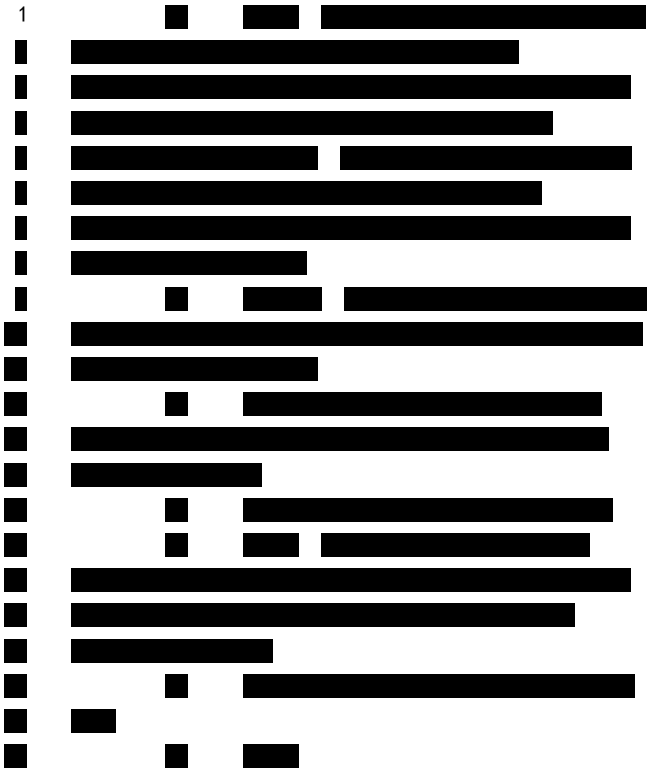

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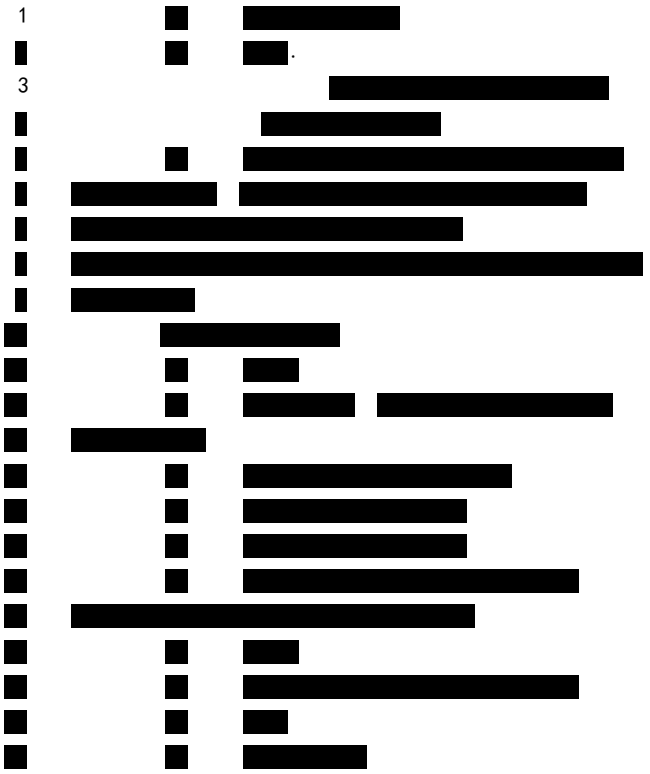

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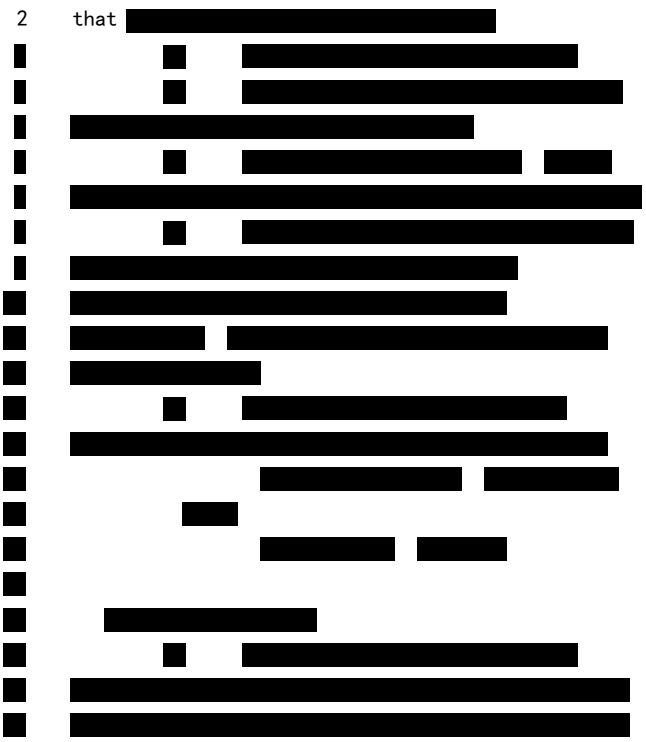
A. These are prospects and customers that



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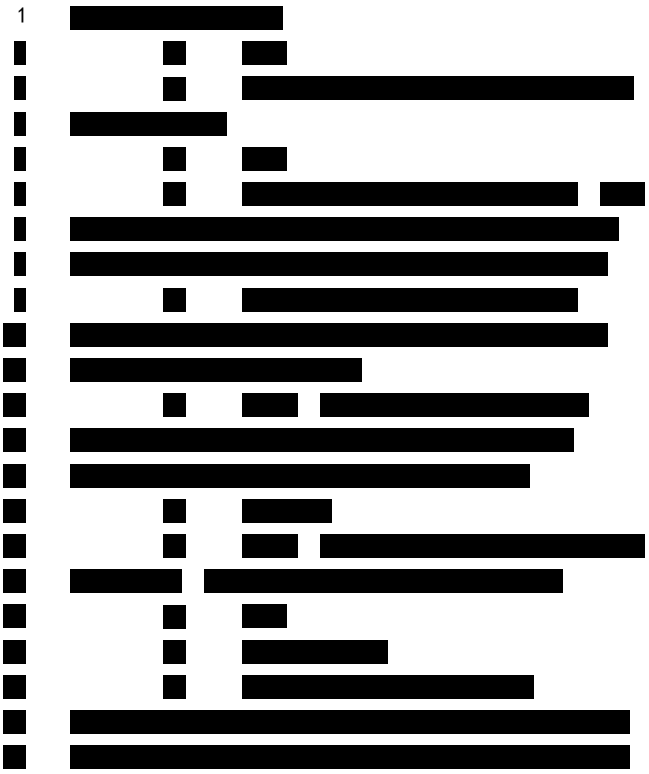

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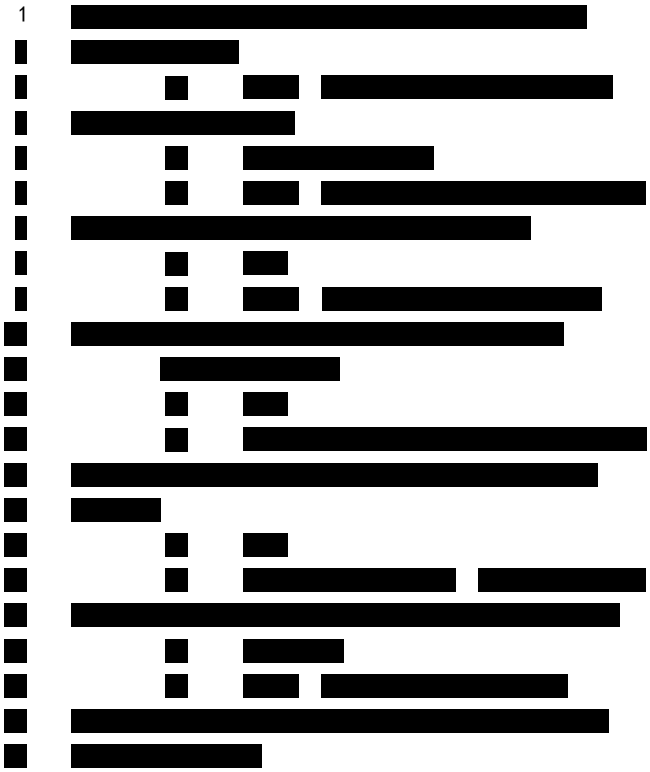

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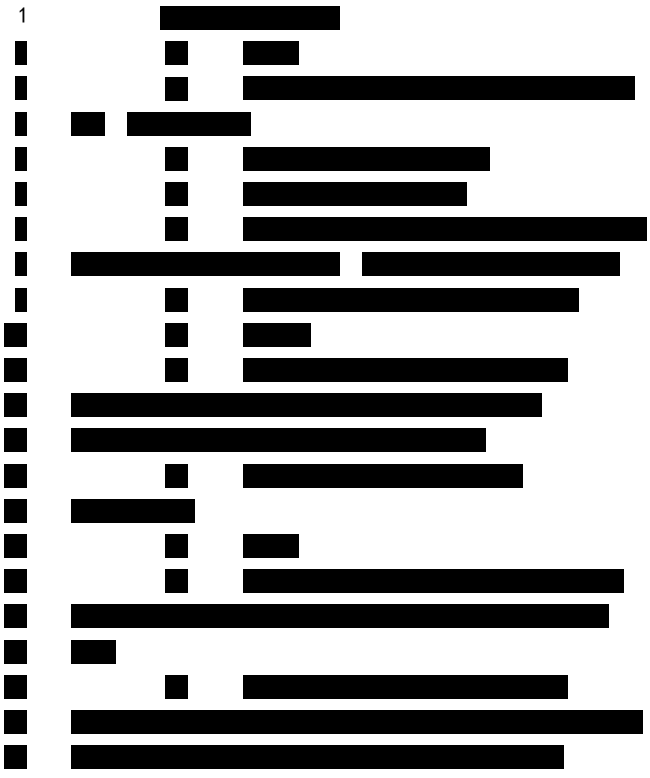

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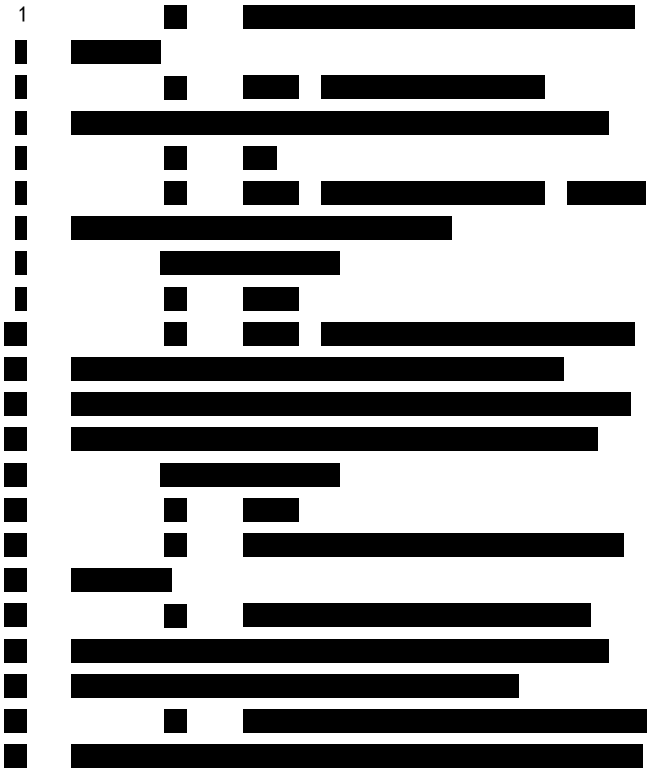

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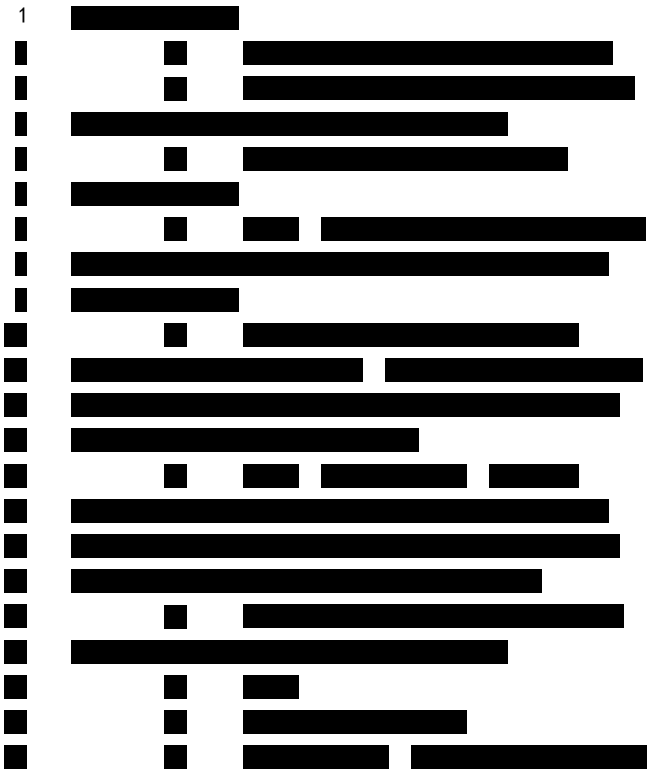

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[redacted]

Q. Okay. And so can you tell me one way or another if there are advantages for healthcare professionals using the RhodoLED XL as compared to the BLU-U device?

A. No.

Q. Okay. In terms of the competitive landscape for the RhodoLED XL, what other devices are out there that the XL competes with?

A. Many.

Q. What are they?

A. There's a variety of different lights that will promote that they do PDT. Approved or unapproved?

Q. Let's focus on that. How many devices besides the RhodoLED XL are approved for PDT in the U.S.?

A. I'm only aware of two.

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Q. Who are those?

A. Well, there's three devices: Our two devices and the BLU-U.

Q. And that's the Sun Pharma device?

A. Correct.

Q. There are other devices on the market that are not approved for -- by the FDA for use in PDT; correct?

A. Correct.

Q. Okay.

ATTORNEY HABBAZ: I think we should break.

(Recess taken from 12:27 p.m. to 1:10 p.m.)

BY ATTORNEY HABBAZ:

Q. Welcome back, Mr. Baldyga.

A. Thank you.

Q. Over the break, did you discuss the substance of your testimony with counsel?

A. No.

(Exhibit 10 was marked for identification.)

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[redacted]

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[redacted]

Q. What do you consider a good outcome for the RhodoLED XL?

A. One of the considerations is the placement of a lamp.

Q. Okay.

A. Another consideration is providing the training so they can properly utilize the device.

Q. Okay. And so one commercial success

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for the RhodoLED XL is placement in healthcare professional provider offices. Is that fair?

A. Yes.

Q. And another is the training by Biofrontera employees to the healthcare professional for how to use the XL properly; correct?

A. Correct.

Q. And using the XL properly there, does that mean following the instructions in the user manual for the XL?

A. Yes.

[redacted]

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[redacted]

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[redacted]

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[redacted]

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Q. And what is that, who is that?
A. It's our employees that work in our headquarter office. They're not field-based.
Q. And then the MSL, do you know that is?
A. I do.
Q. What is that?
A. It stands for a medical science liaison.
Q. Okay. What's a medical science liaison?
A. By my definition, it is someone that typically has a PharmD degree, and they represent our company from a science point of view.
Q. Are they employees of Biofrontera?
A. Yes.
Q. Okay. If doctors have a question about using the device in a way that differs from the user manual, are they directed to the MSL?
A. Yes.
Q. Why is that?
A. The promotion is always done

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on-label. And if there's any questions that are not unlabled, approved, then they would go to medical.
Q. And "unlabeled" here means in accordance with the user manual?
A. Yes.
[redacted]

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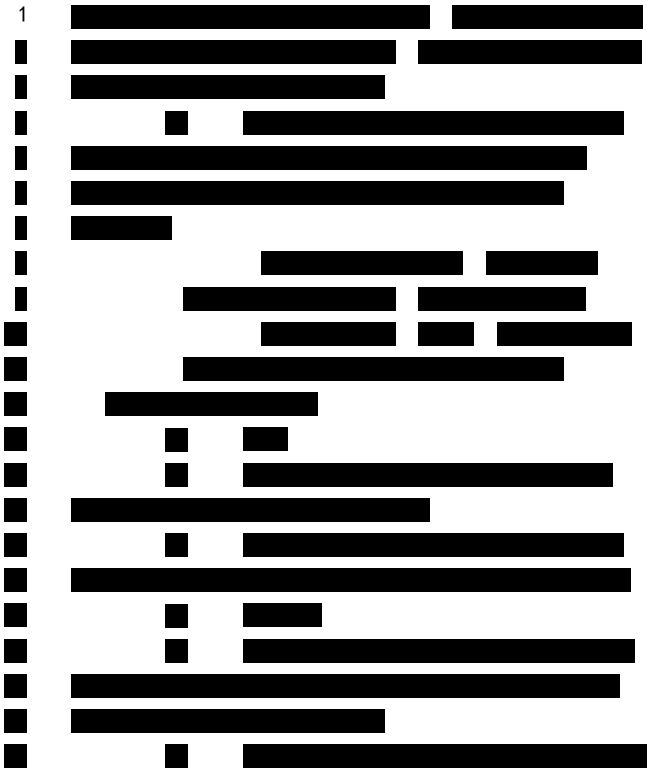

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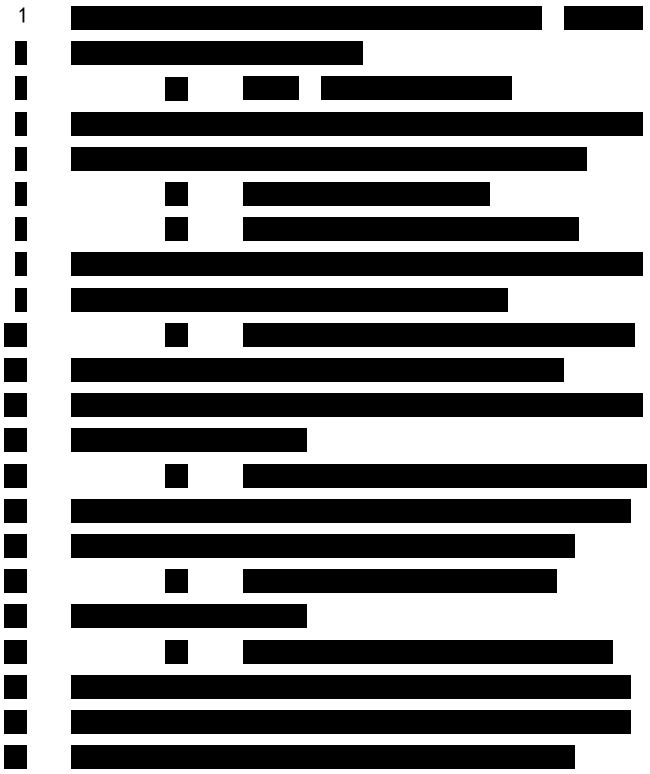

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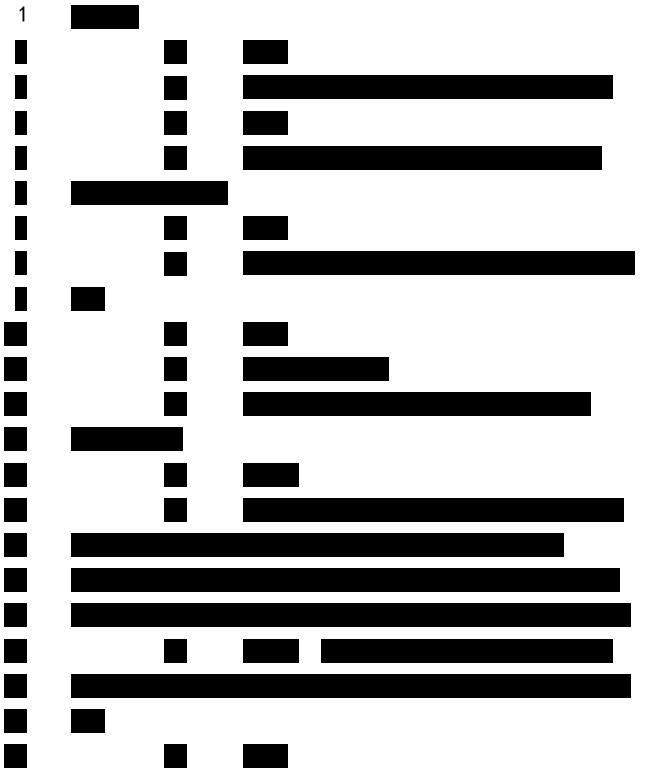

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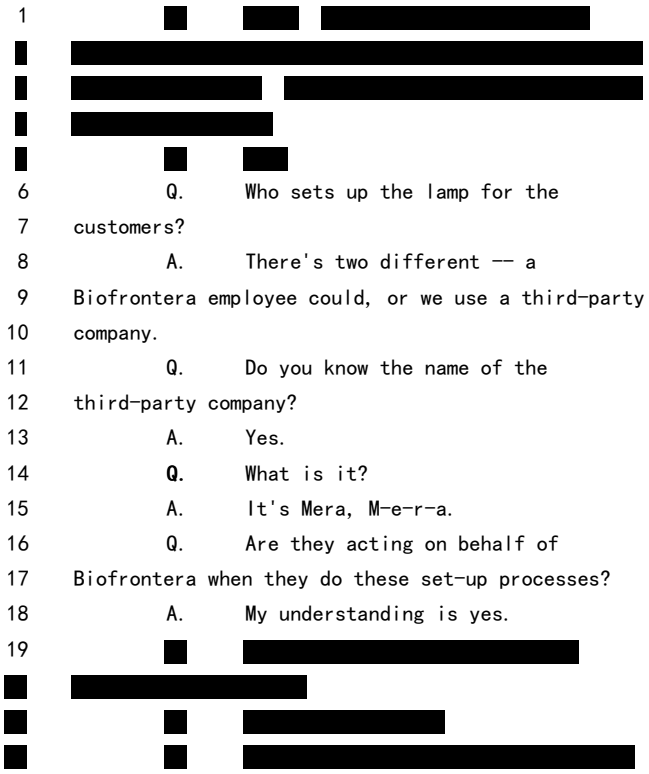

Q. Who sets up the lamp for the customers?
A. There's two different -- a Biofrontera employee could, or we use a third-party company.
Q. Do you know the name of the third-party company?
A. Yes.
Q. What is it?
A. It's Mera, M-e-r-a.
Q. Are they acting on behalf of Biofrontera when they do these set-up processes?
A. My understanding is yes.

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Q. Okay. I should ask, what's included in setting up? Is that simply unlocking it and plugging it in?

A. And removal of the packaging.

Q. Okay. And then the in-service, what's included there?

A. So in-service, to the specifications of the manual, the territory manager will train the customer on that.

Q. Okay. And that's the user manual

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for the XL?

A. Yes.

Q. Okay. And that happens with every sale of the XL device?

A. It does.

Q. Okay. And does Biofrontera expect all users of the XL device to follow all instructions in the user manual?

A. Yes.

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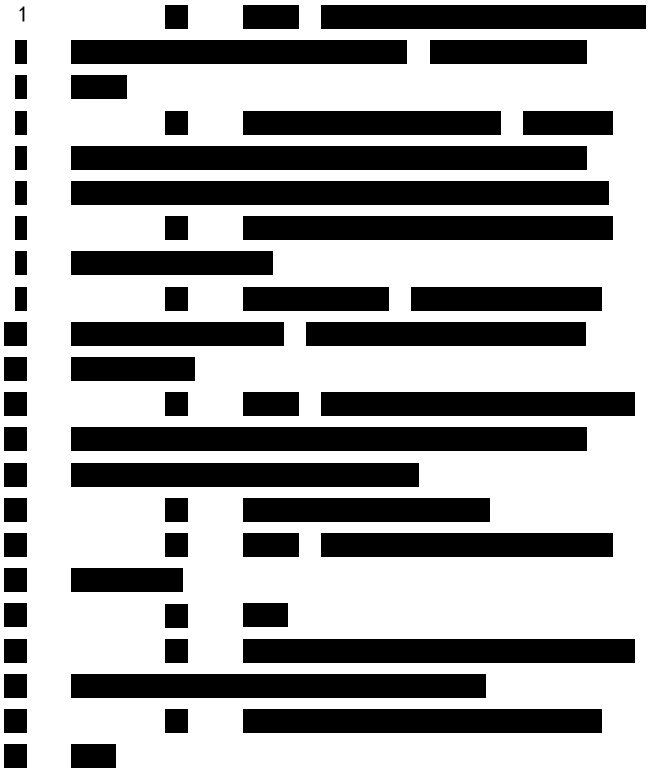

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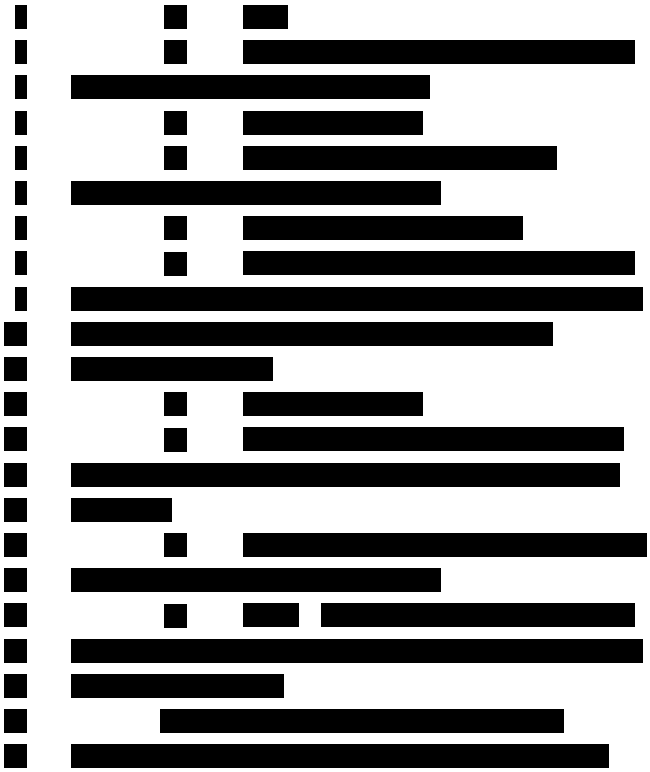

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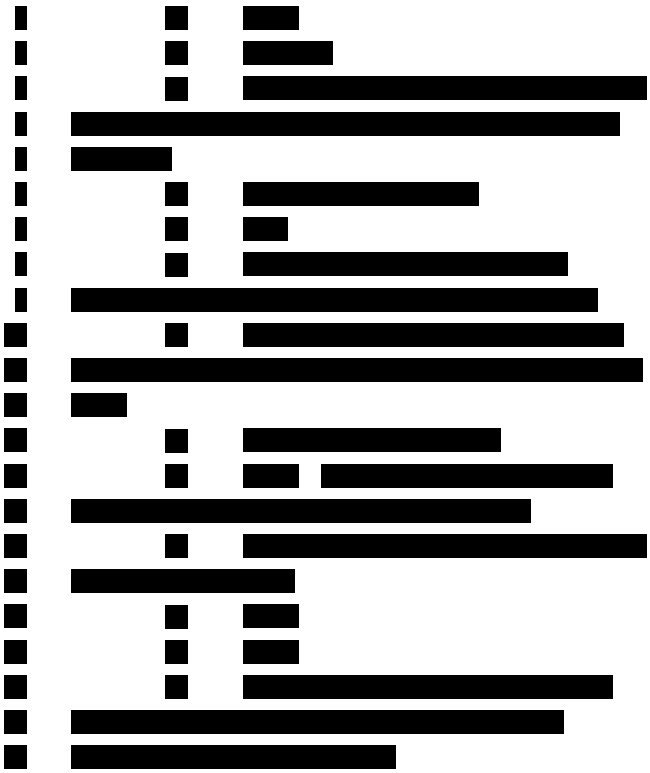

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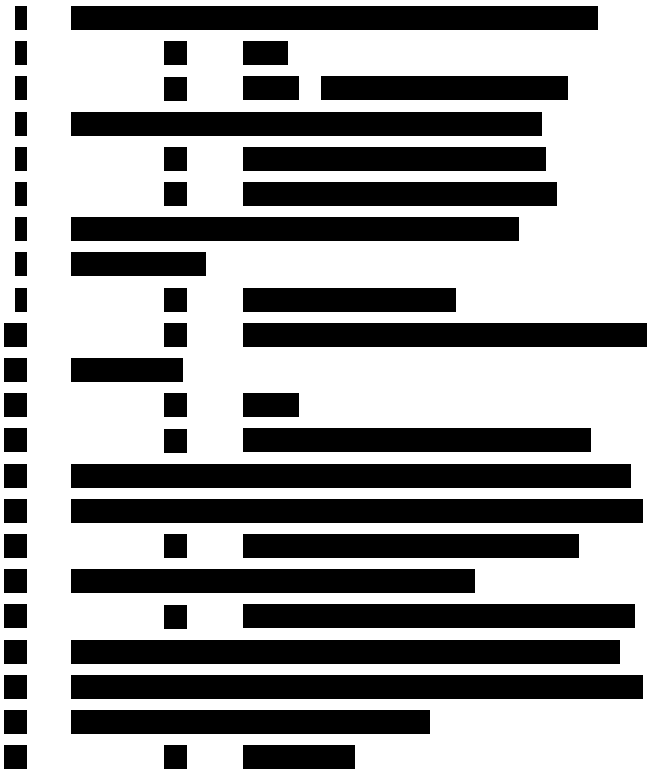

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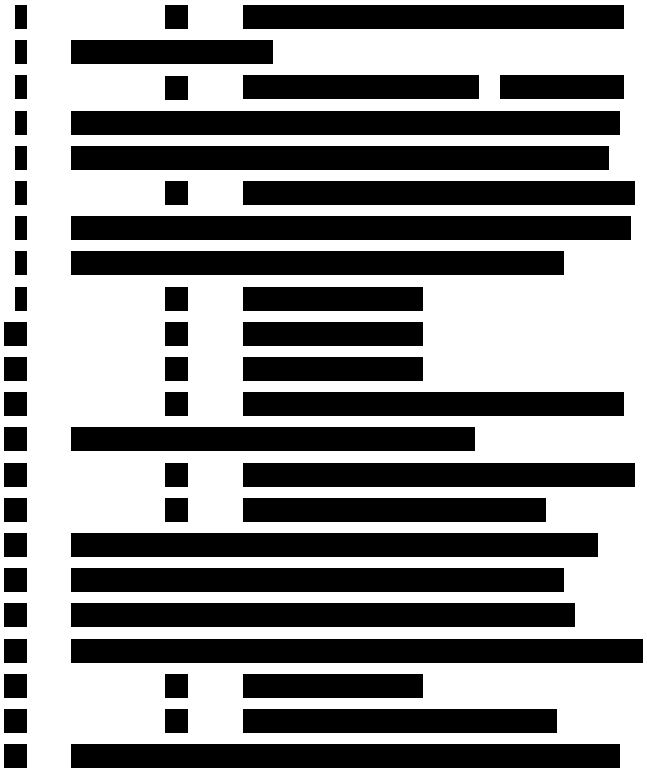

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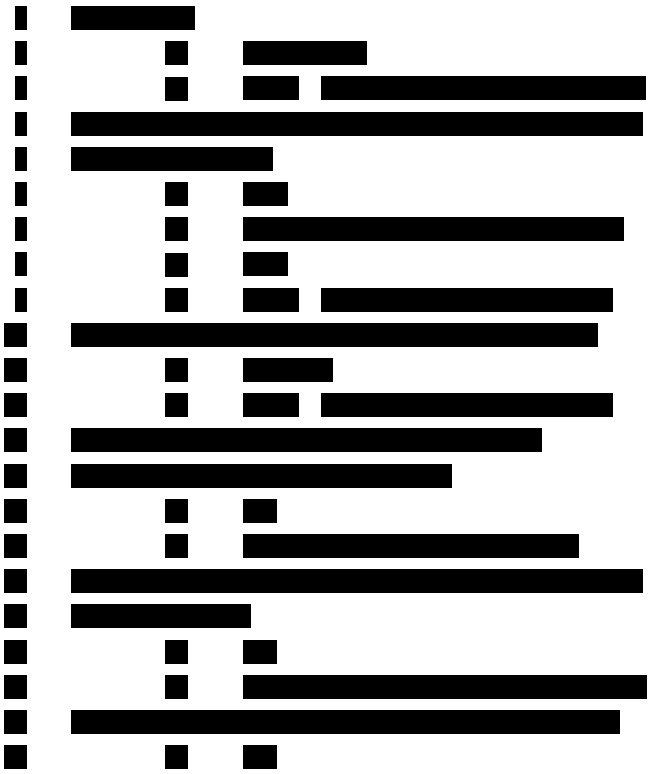

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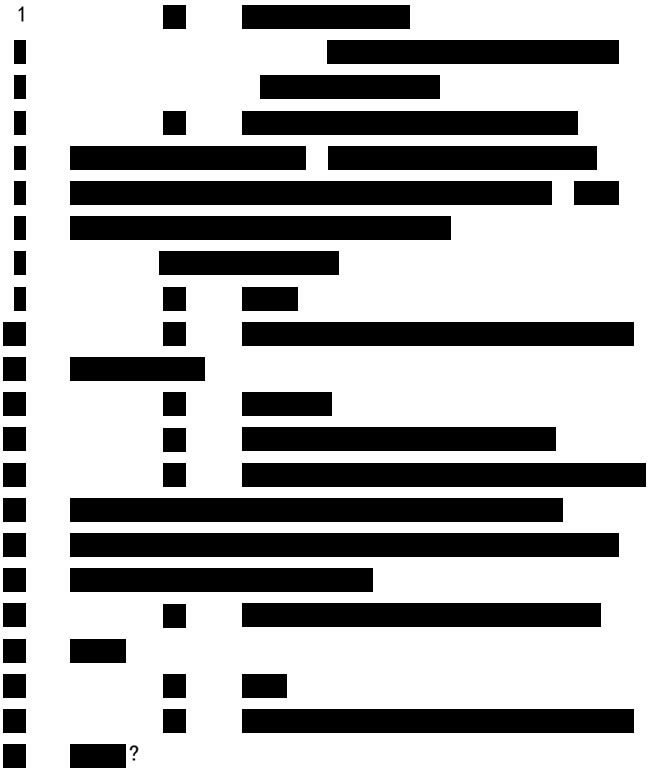

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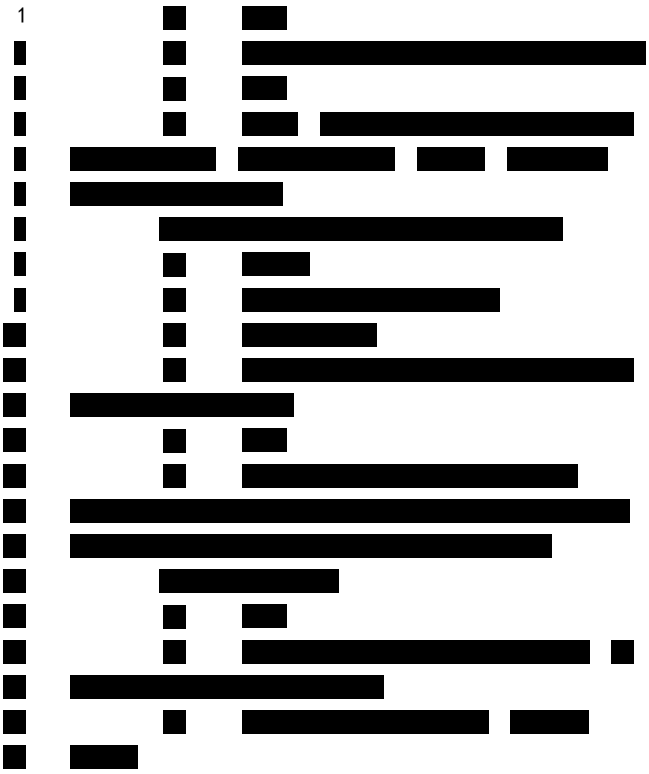

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Q. Okay. Would you consider the original RhodoLED device a successful product?

A. Eventually.

Q. Eventually. And so later in its life it became a commercially successful product?

A. Yes.

Q. And the next generation of the XL?

A. Right.

Q. You can set that aside.

A. Sure.

(Exhibit 12 was marked for identification.)

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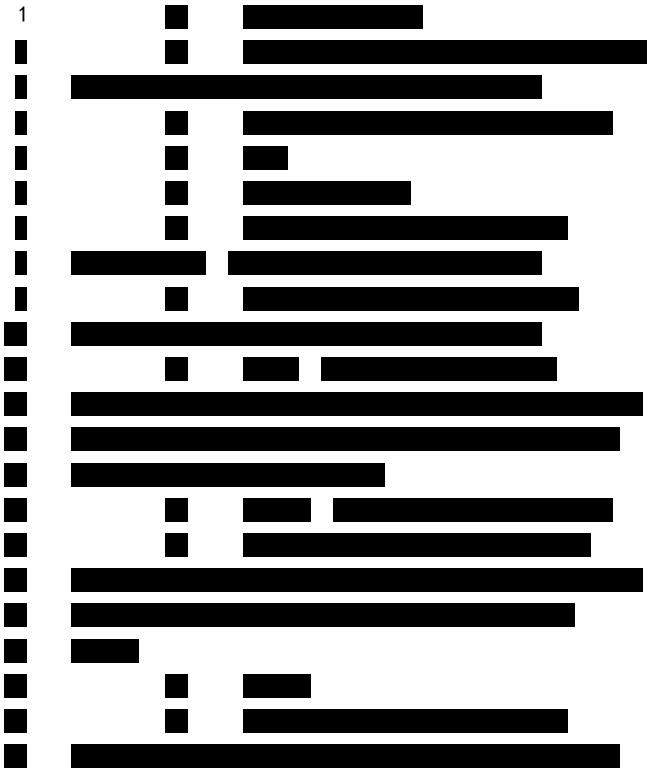

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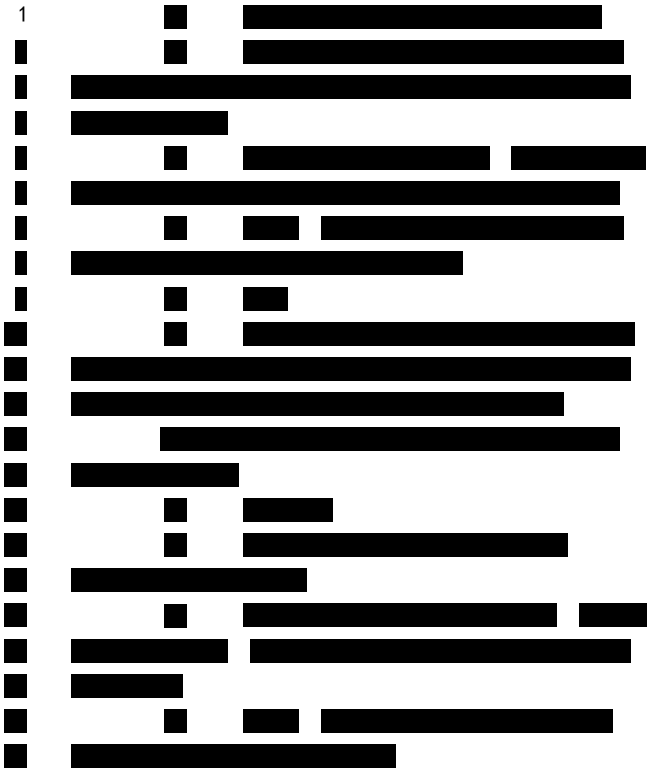

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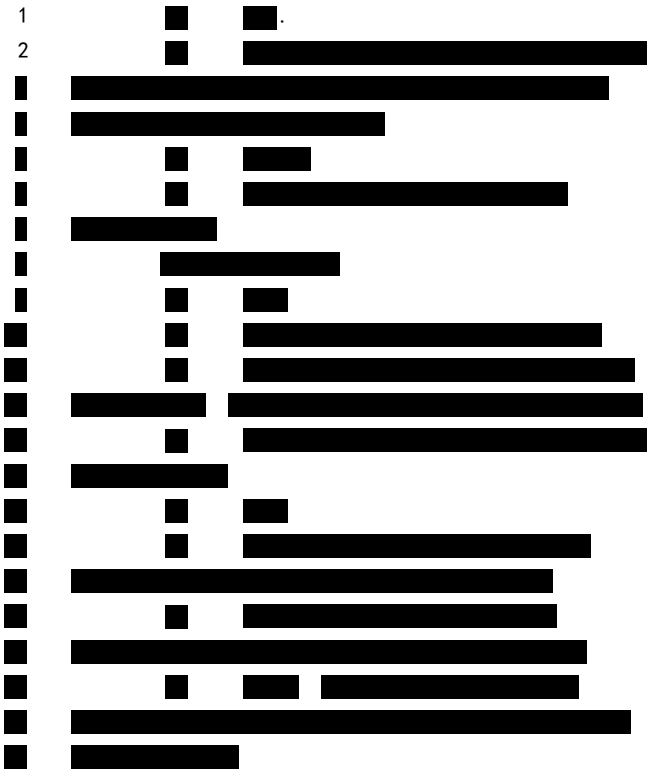

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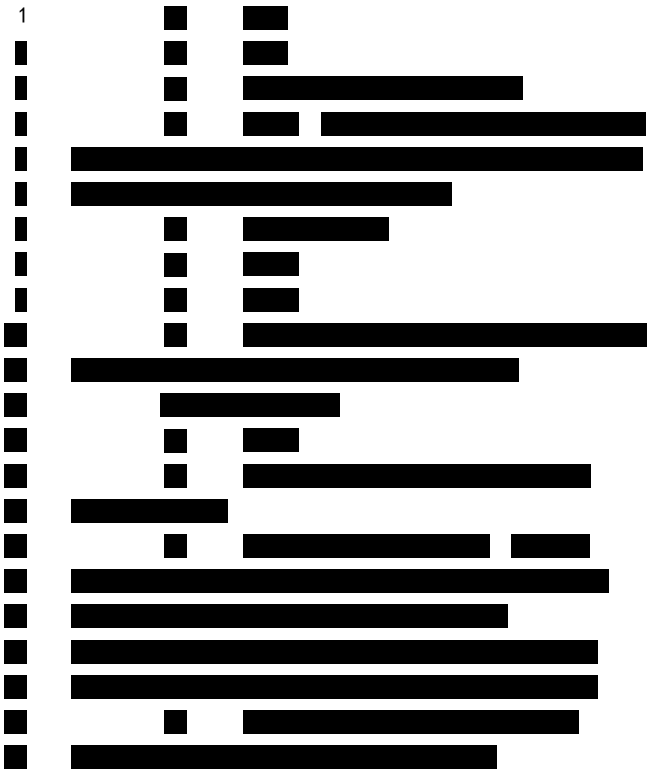

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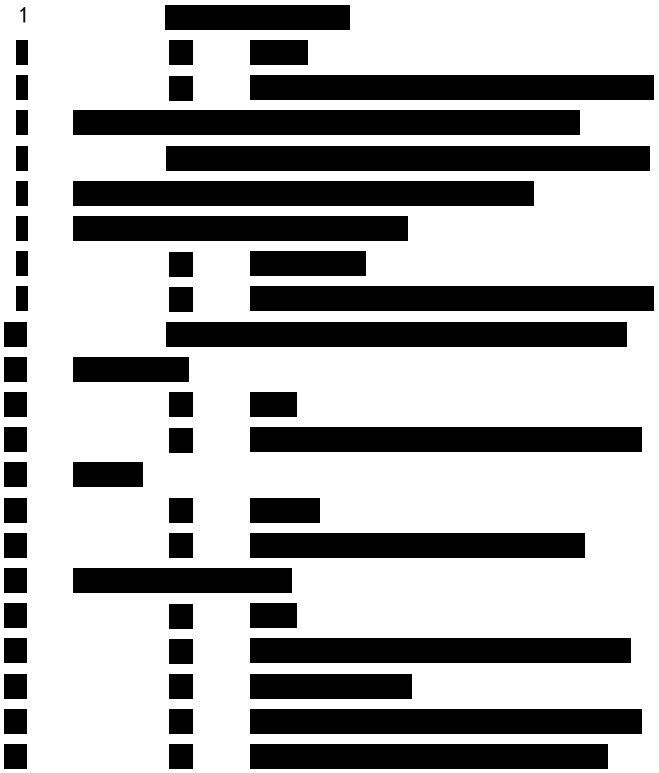

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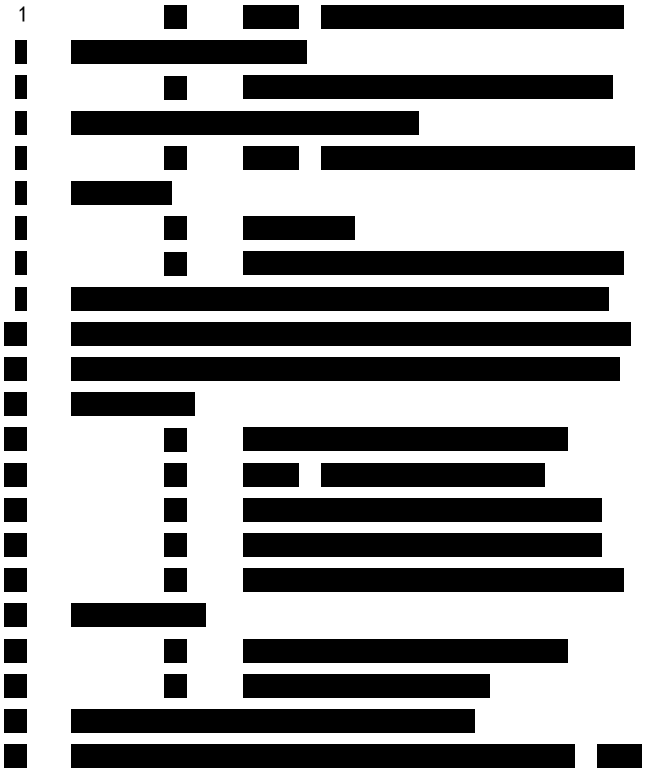

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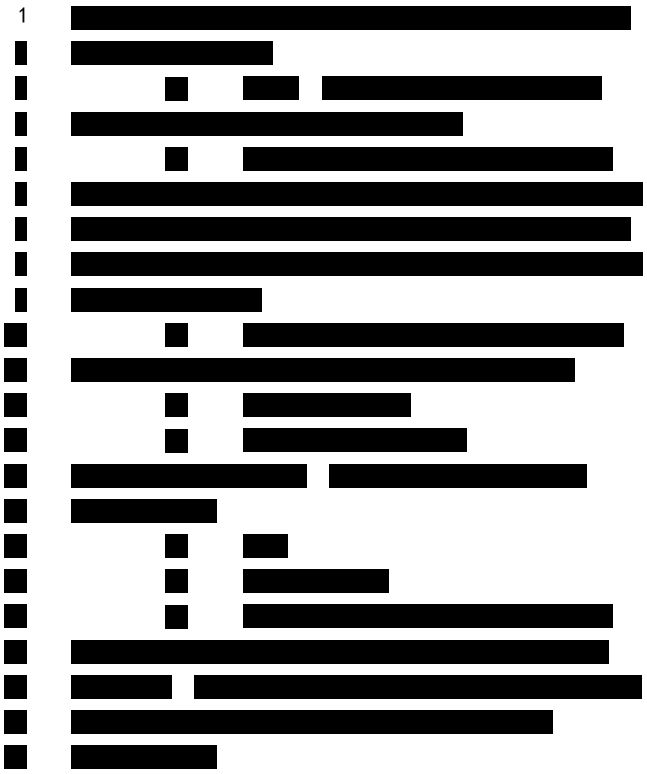

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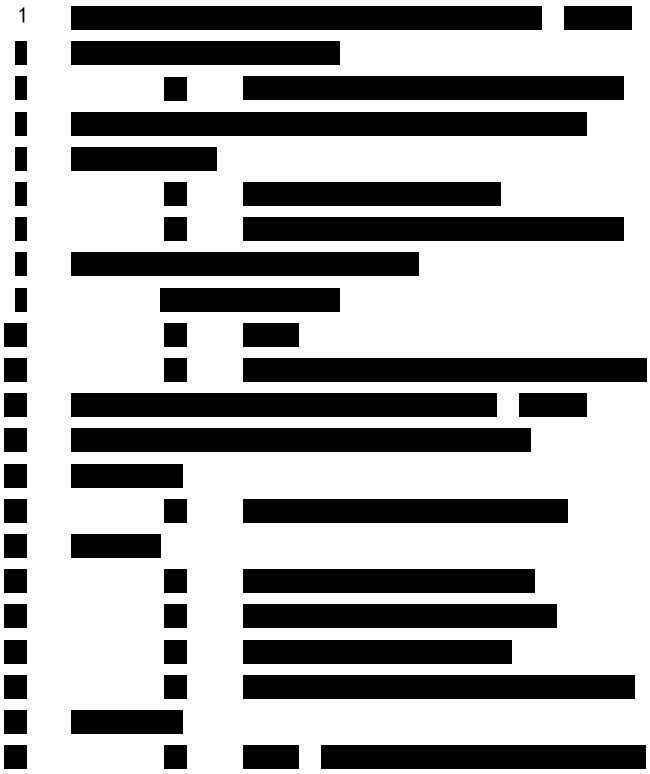

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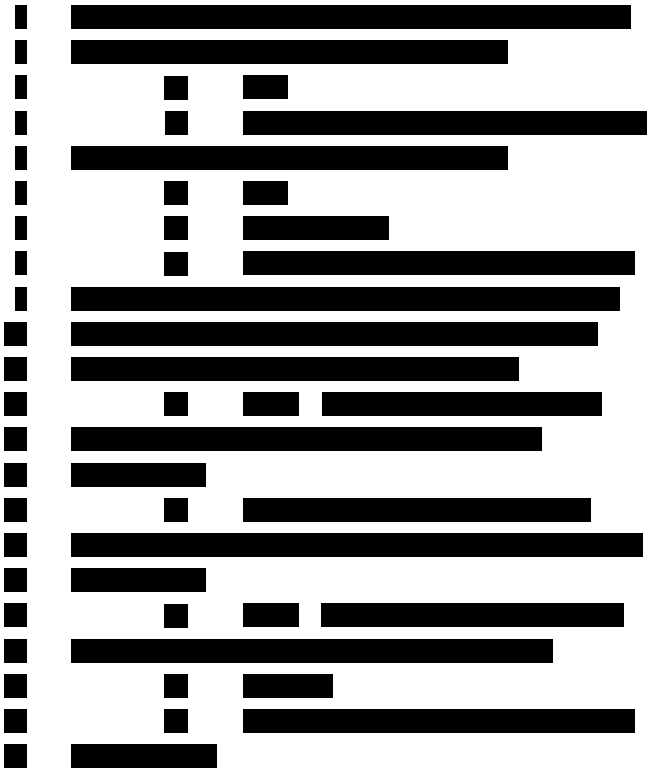

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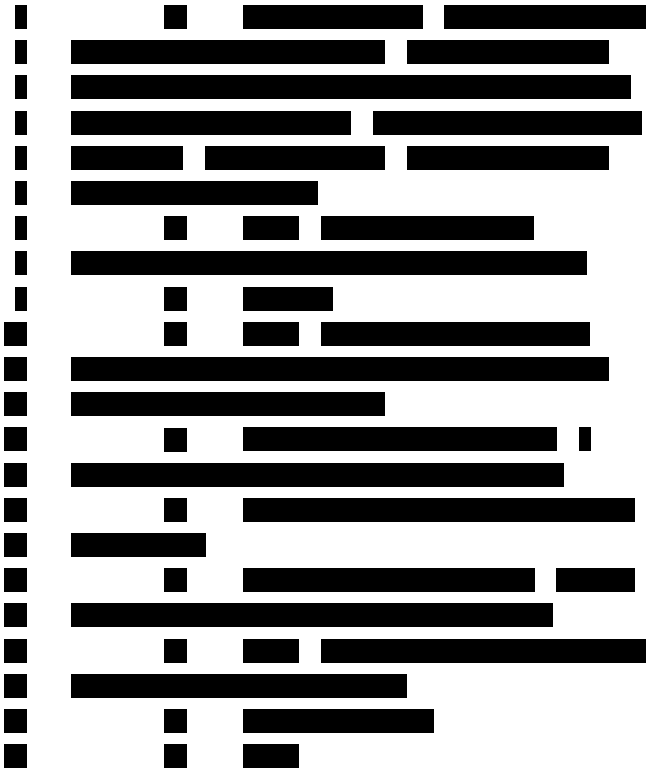

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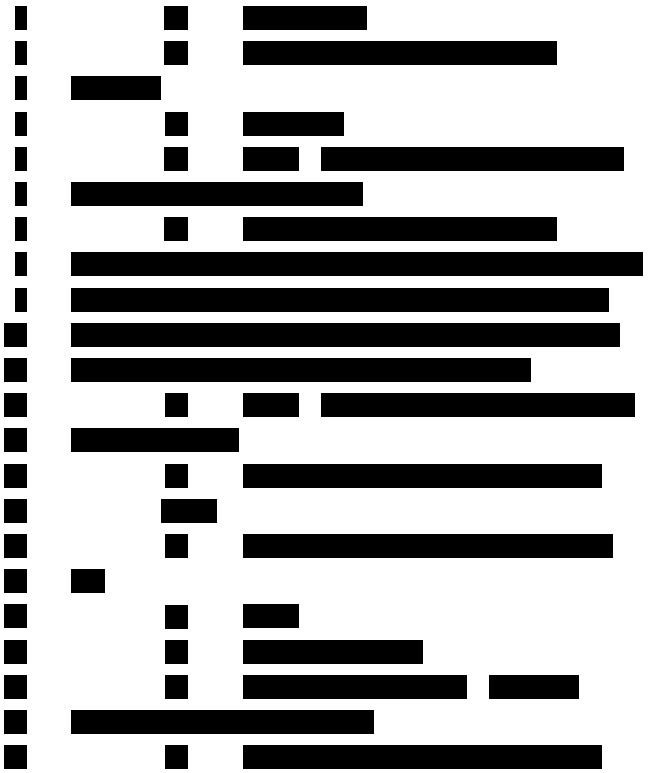

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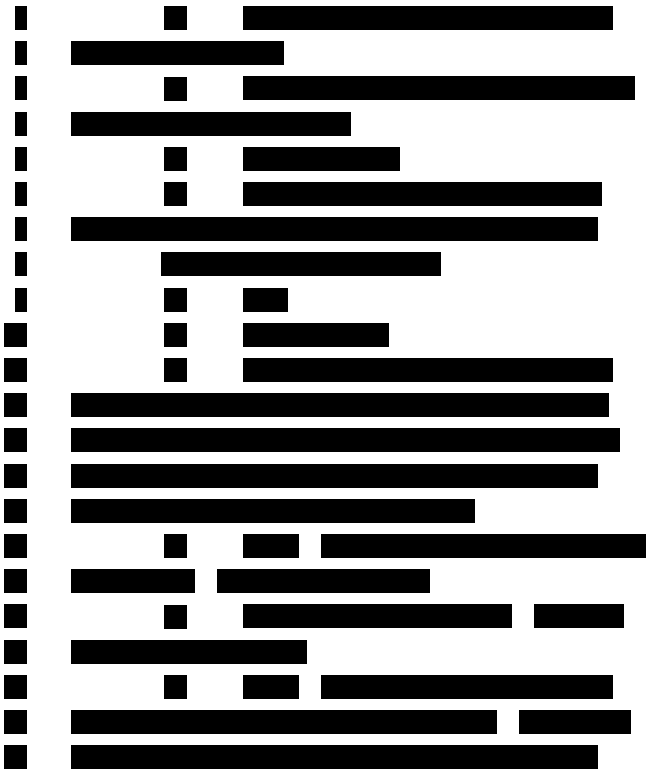

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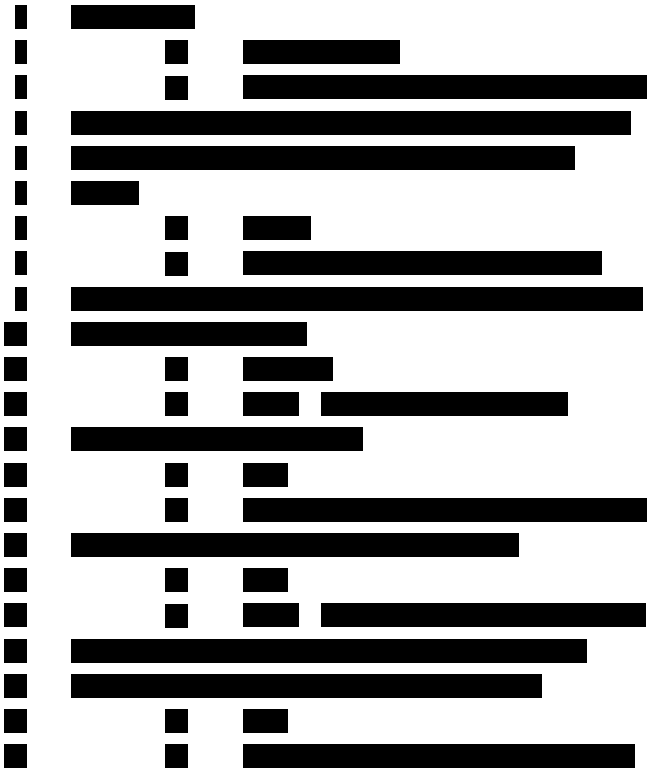

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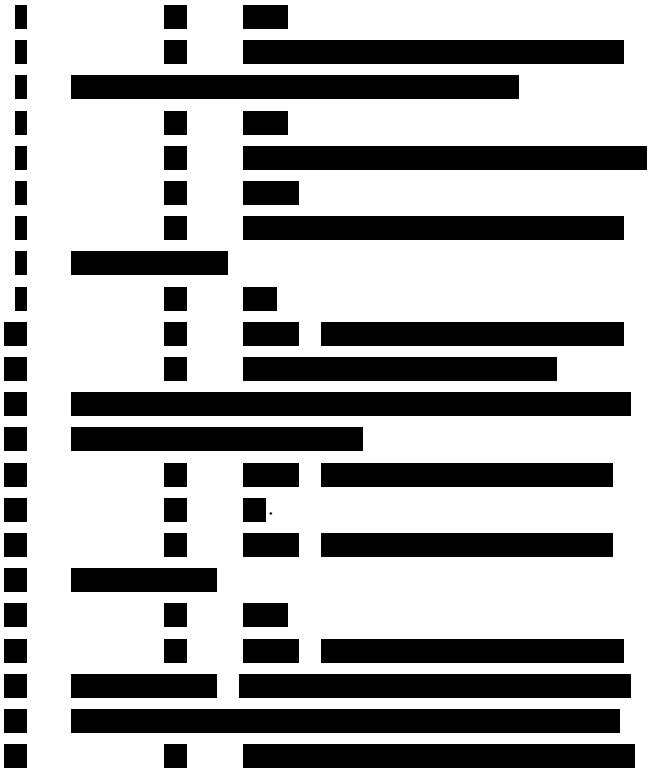

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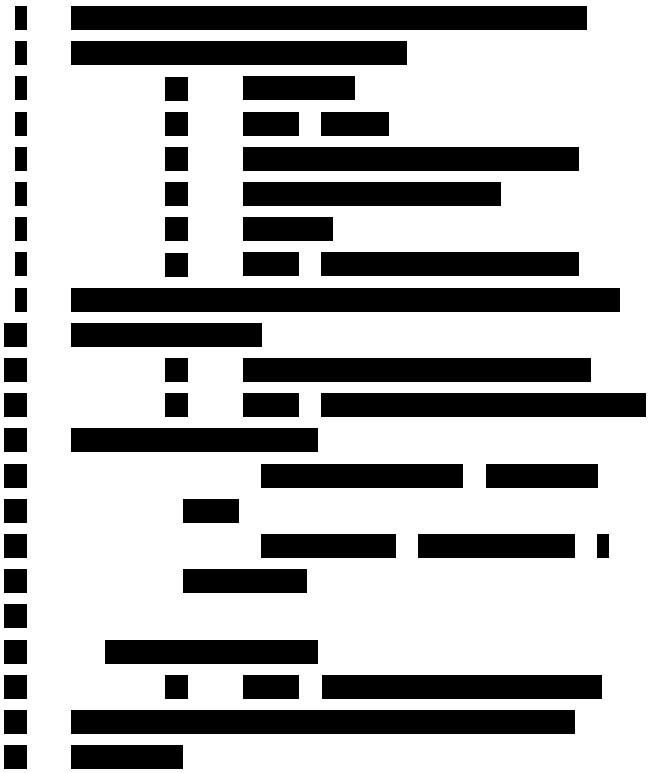

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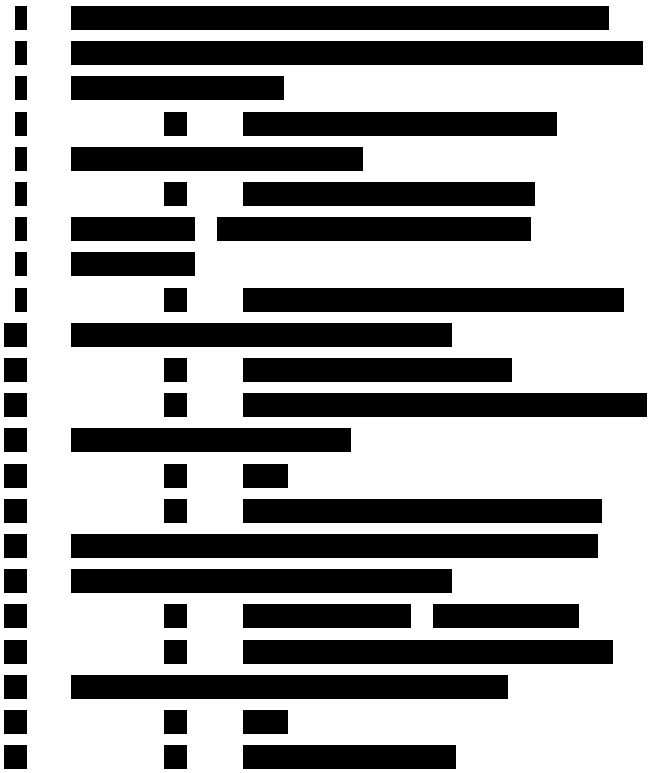

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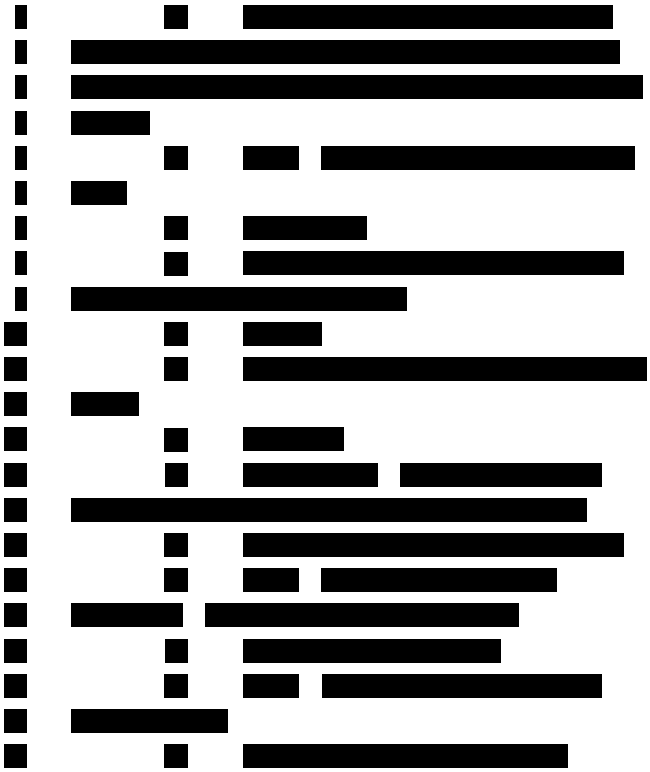

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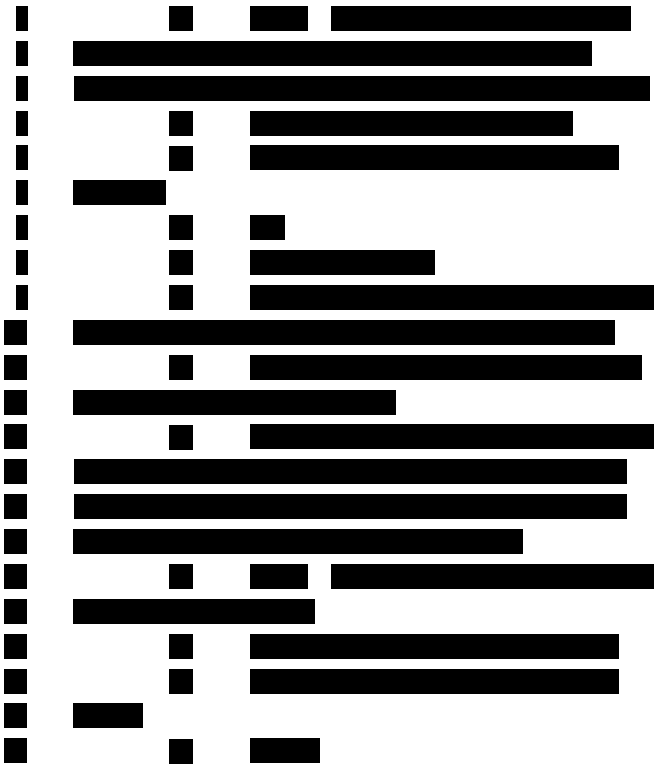

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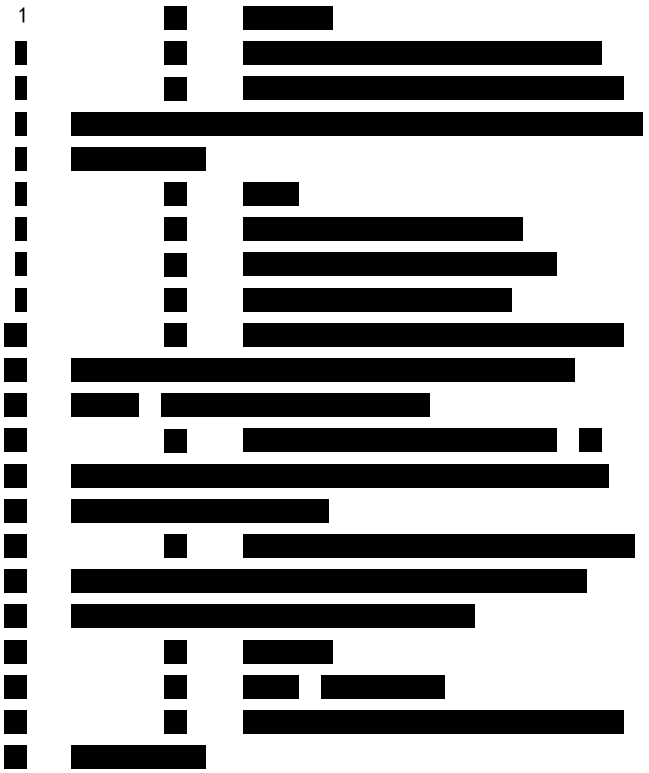

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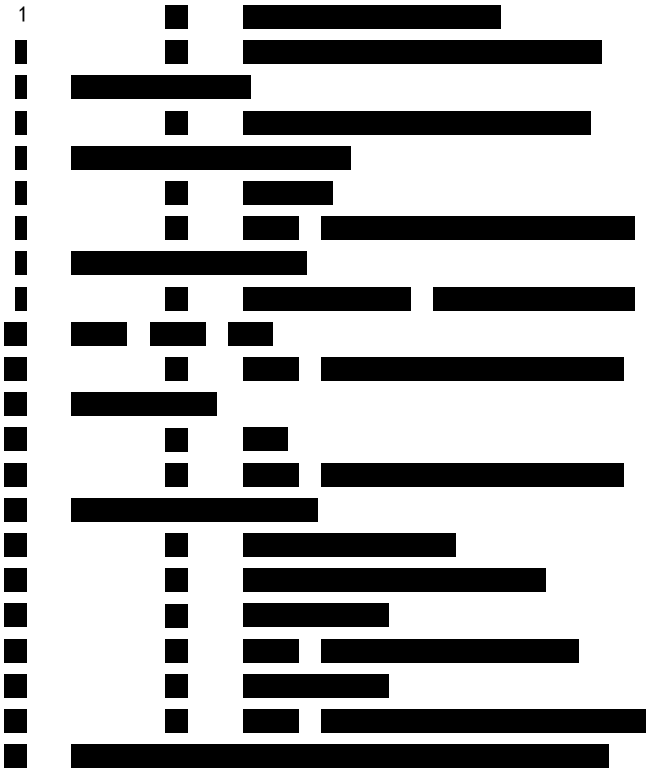

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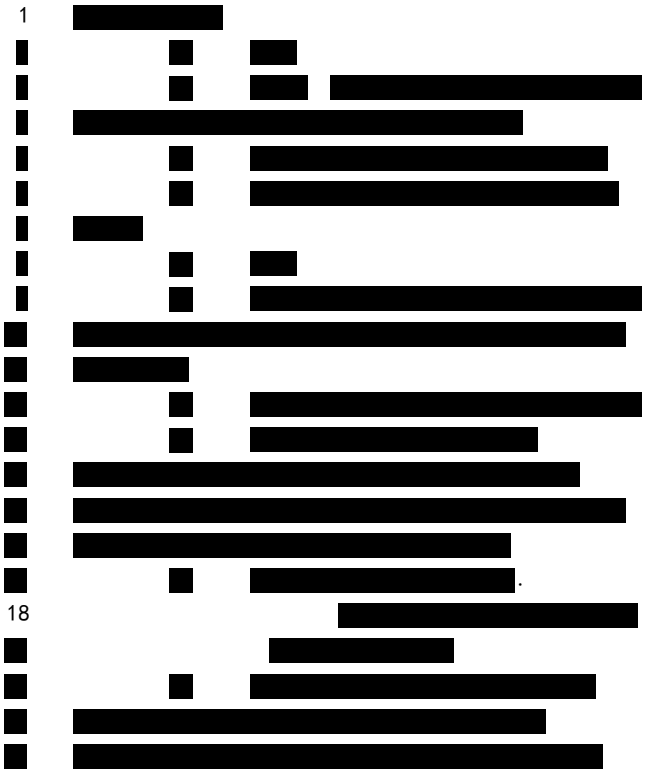

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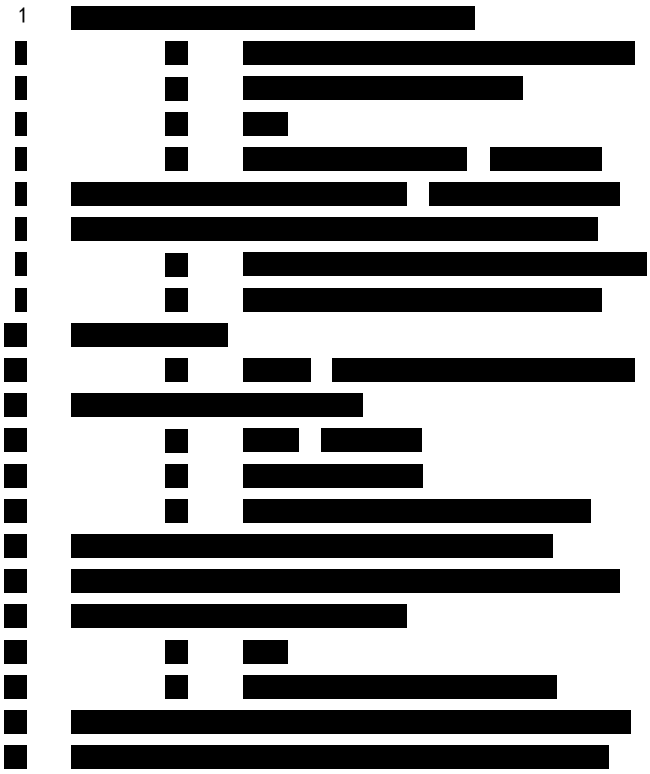

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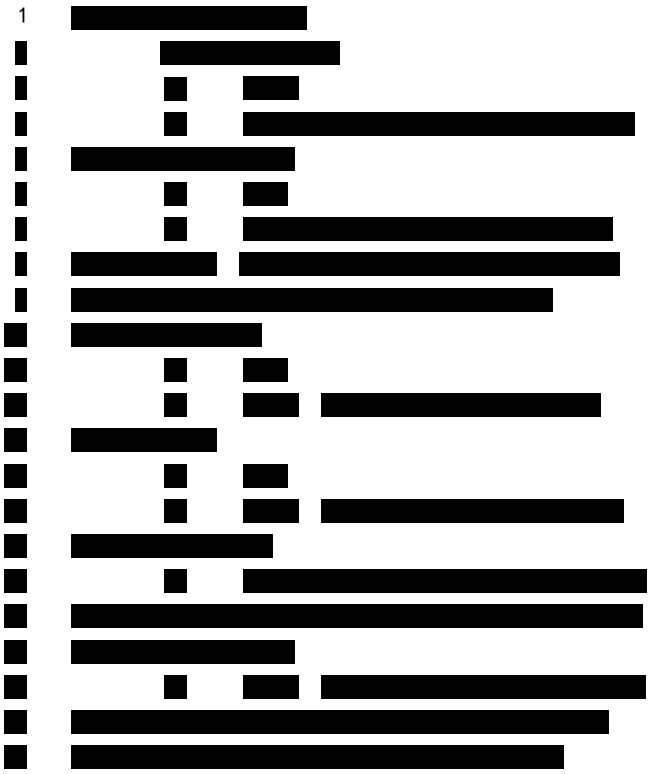

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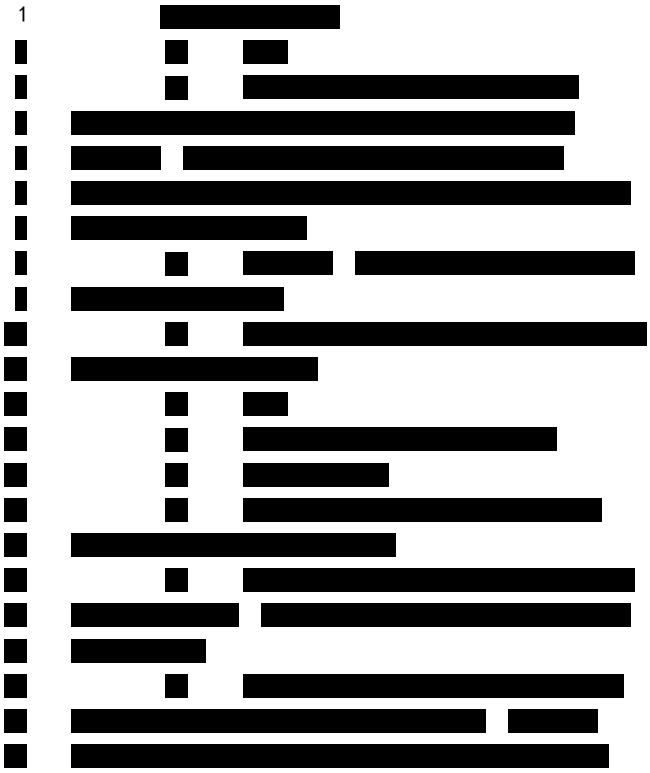

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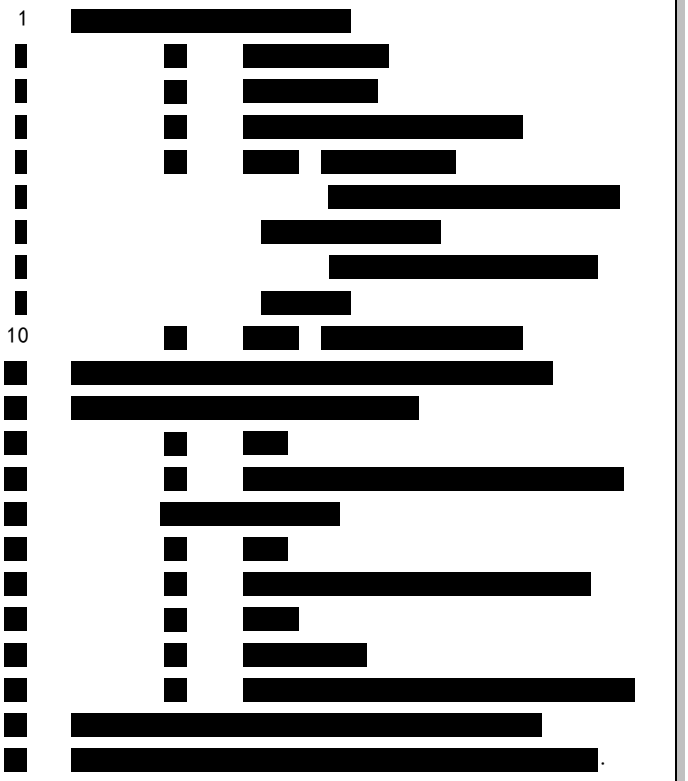

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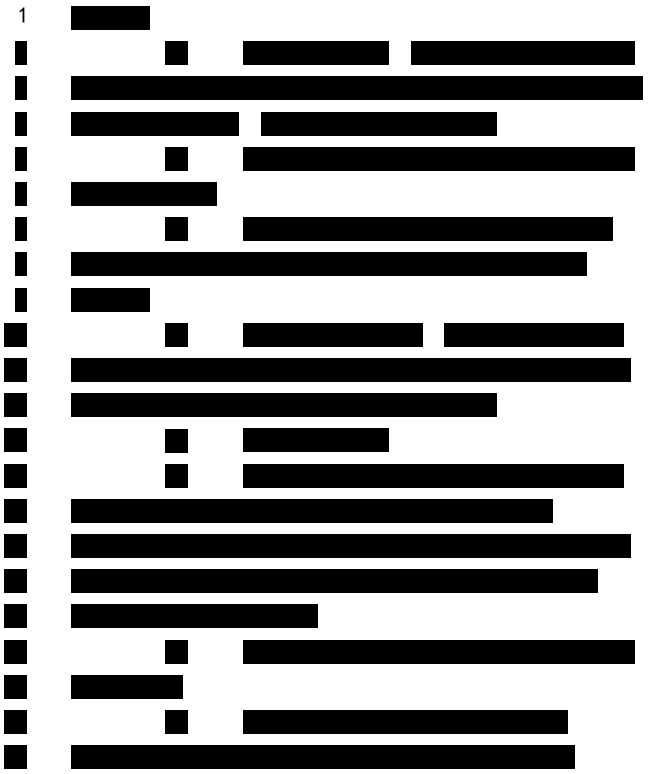

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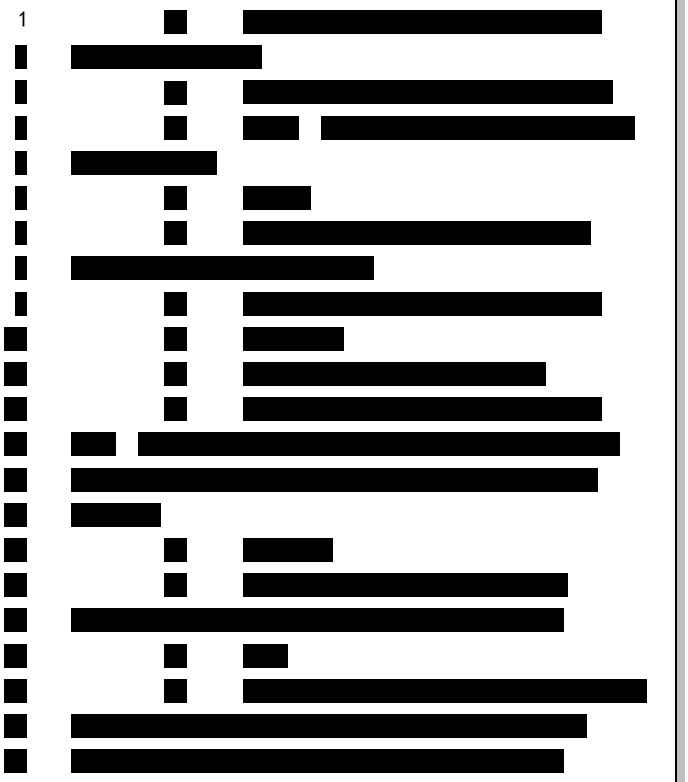

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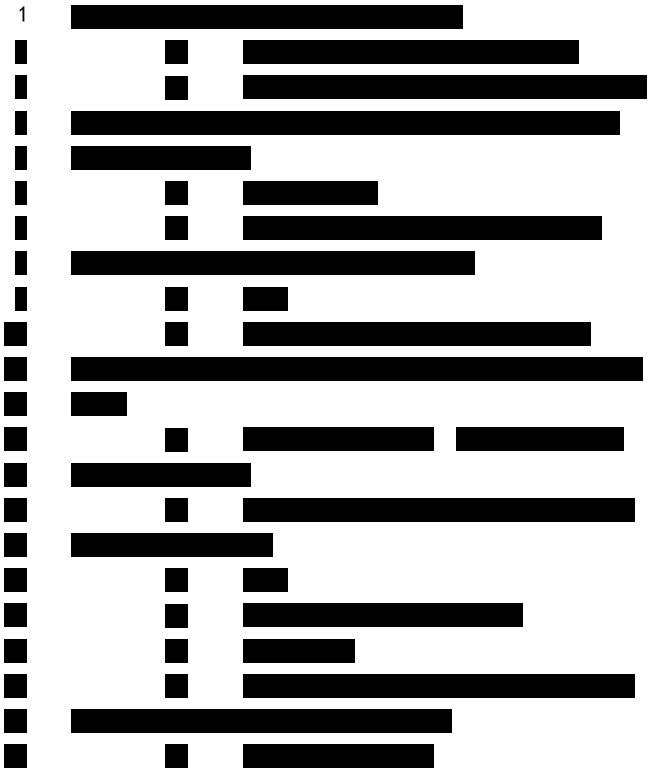

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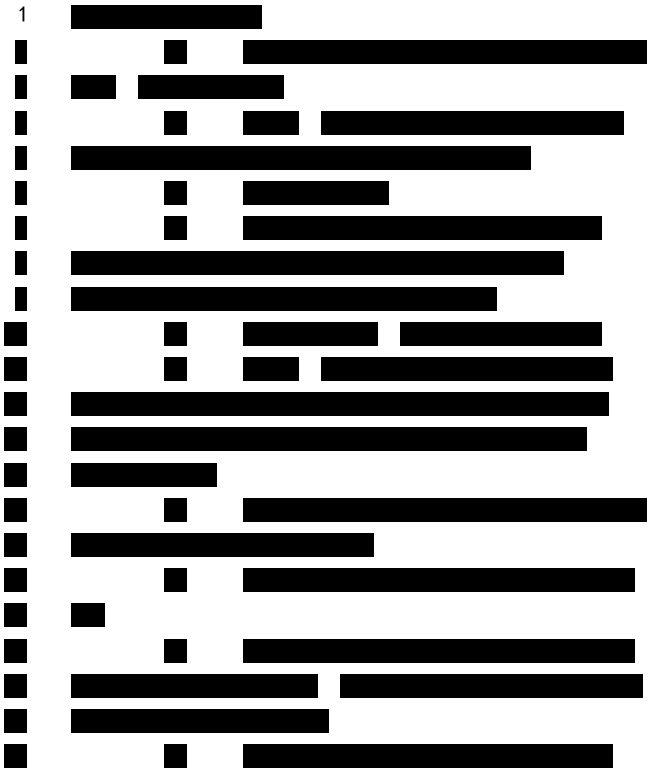

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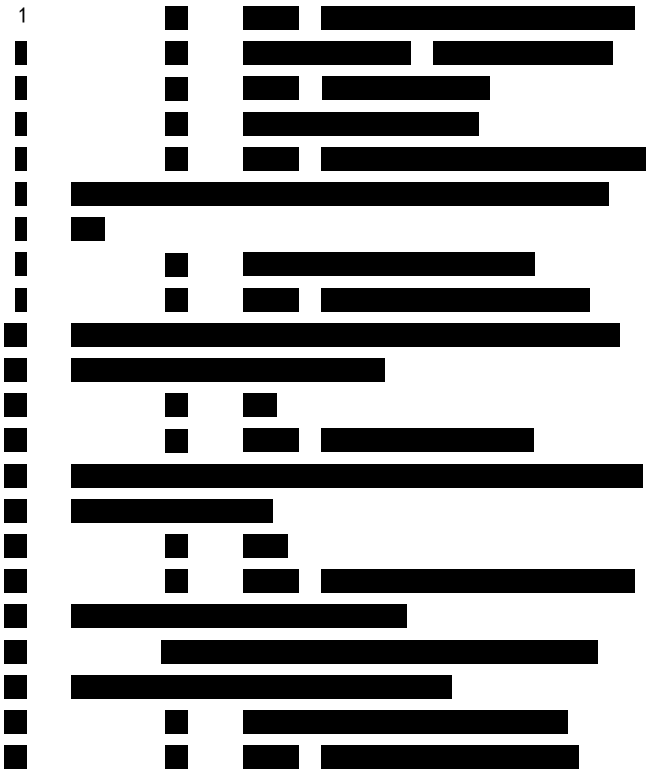

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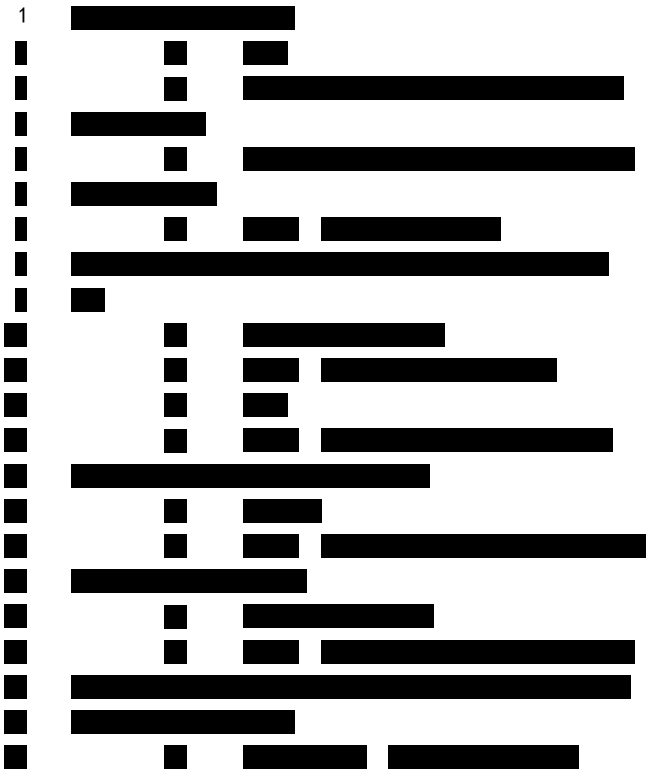

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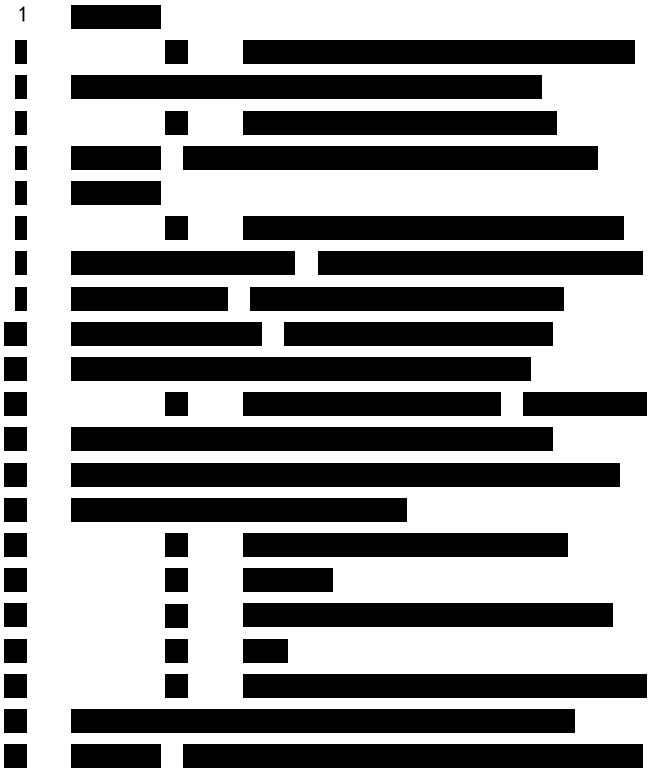

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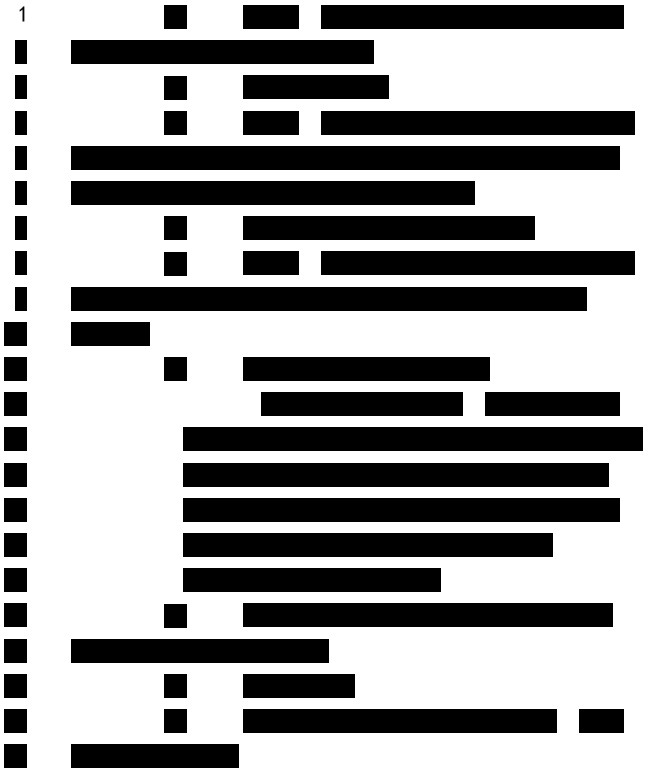

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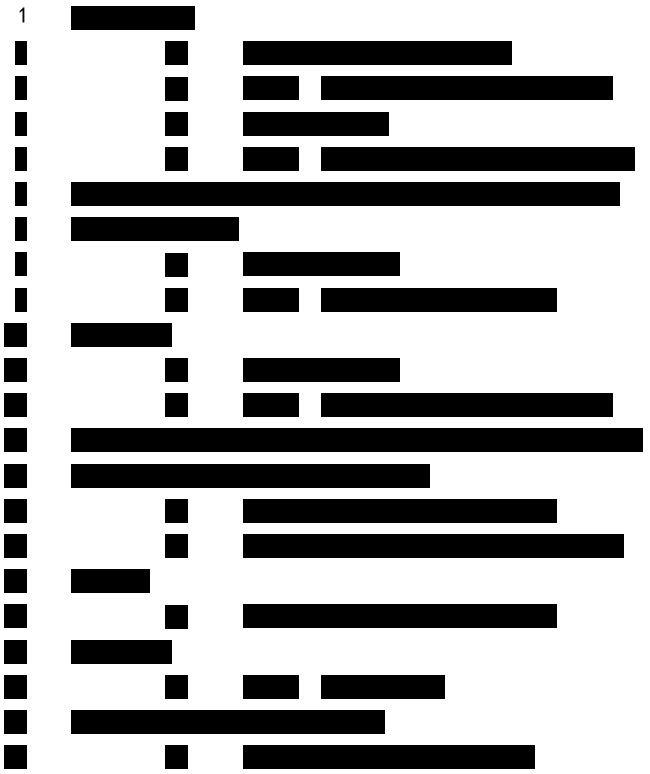

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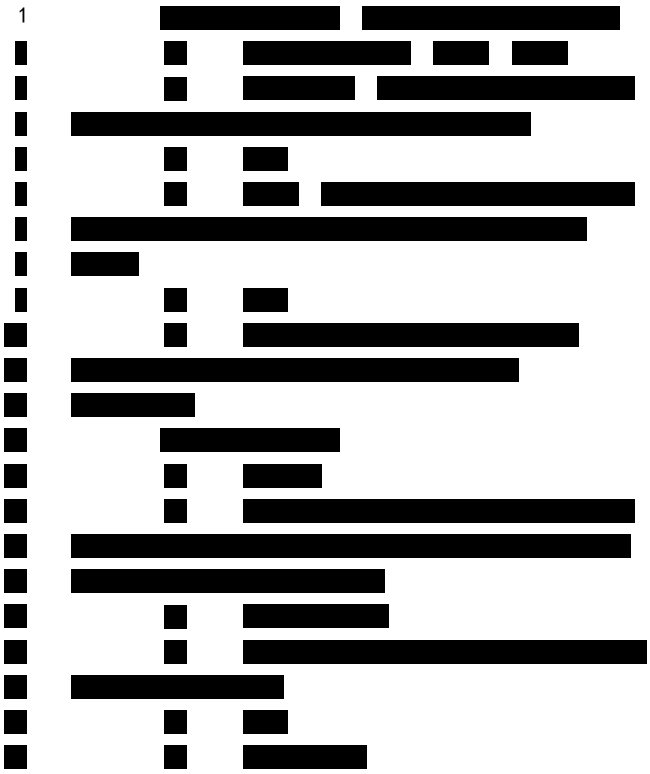

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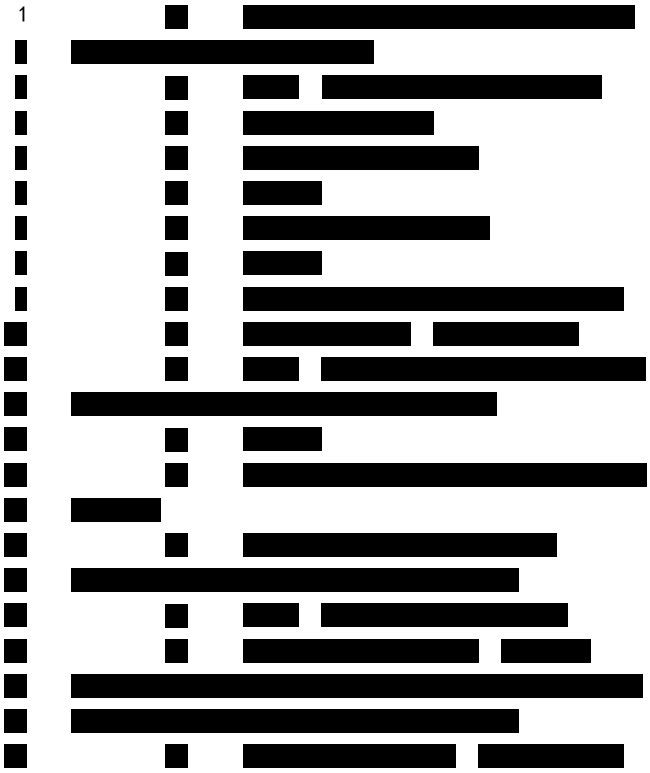

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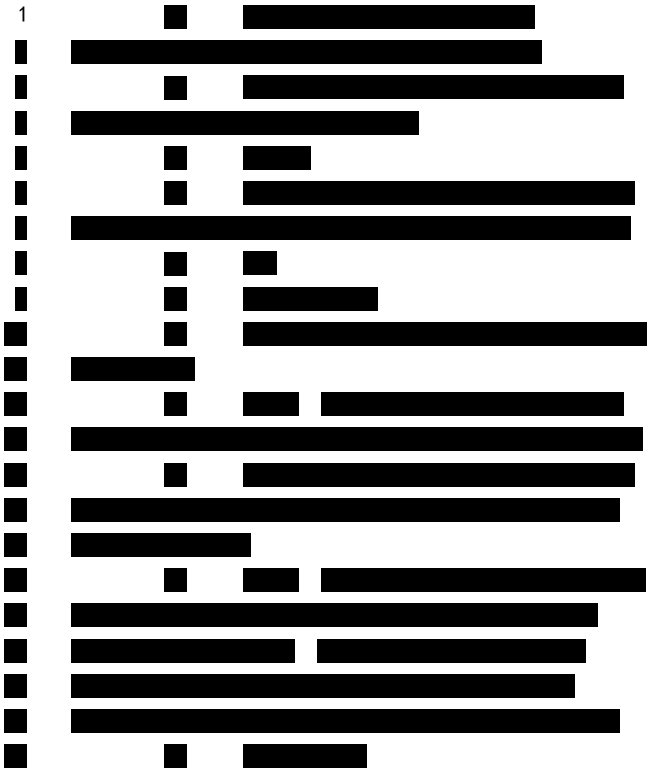

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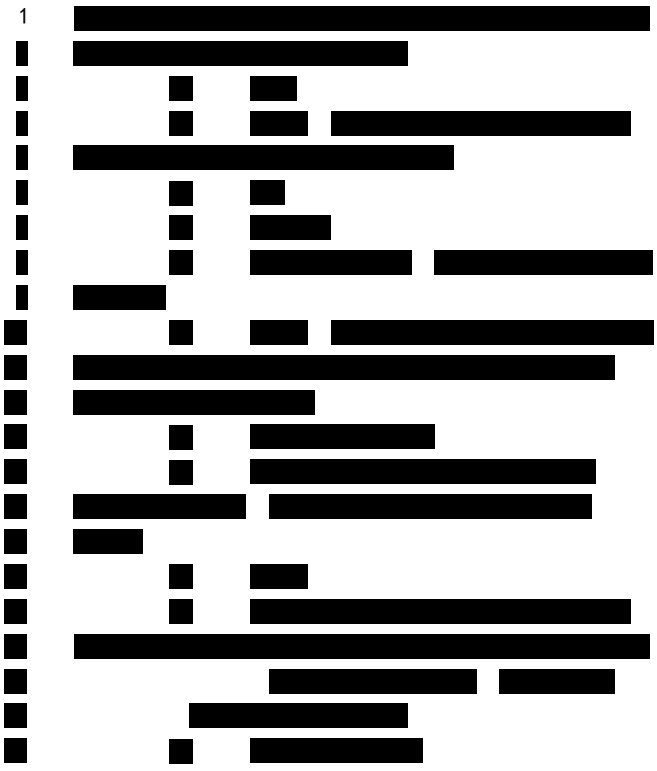

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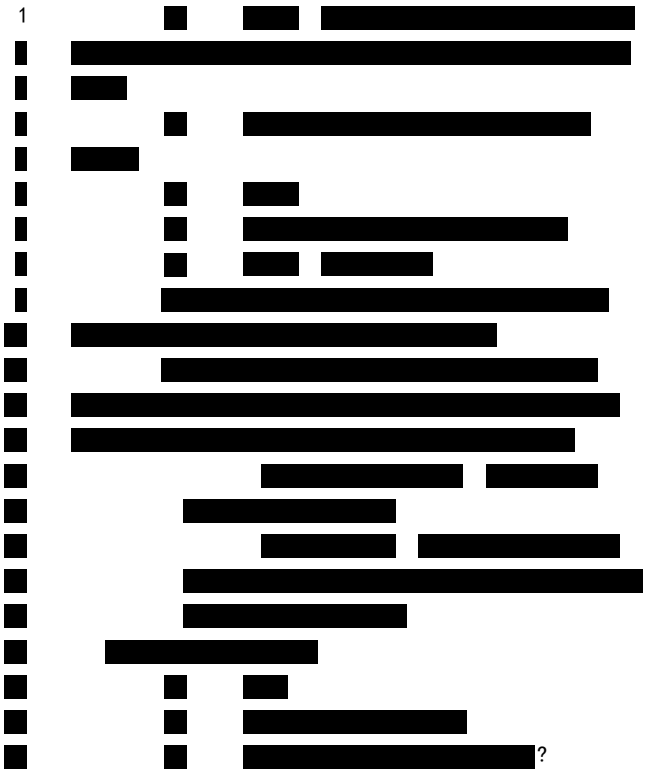

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[redacted]

Q. Biofrontera has demonstrated the XL at trade shows in the United States; correct?
A. Yes.
Q. And do you know how many trade shows?
A. Guesstimate.
Q. What's your guesstimate?
A. Six.
Q. Okay. What's the purpose for Biofrontera demonstrating the XL at trade shows? Why does it do it?
A. It gives an opportunity for

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prospects and potential customers to see the lamp in person.
Q. Okay. There is no clinical benefit or clinical research benefit to doing the trade shows demonstrations? Another question.
The intended audience for trade-in is not for clinical research; correct?
A. Correct.
Q. Are those demonstrations done with real Ameluz or placebo at the trade shows?
A. Certainly not real Ameluz.
Q. Okay. Beyond the placebo of Ameluz, are the demonstrations of the XL at the trade shows performed in accordance with the user manual?
A. There's a demonstration, yes.
Q. I want to circle back to something we discussed earlier just to make sure we're on the same page. With regard to training by your sales team on the XL device --
A. Uh-huh.
Q. -- so your sales team trains healthcare professionals on how to use the XL;

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right?
A. Correct.
Q. And the Biofrontera sales team has trained healthcare professionals in the United States on how to use the RhodoLED XL for PDT with Ameluz; right?
A. Yes.
Q. And that training is provided in accordance with the RhodoLED XL user manual; right?
A. Yes.
Q. And you agree that Biofrontera has trained RhodoLED XL users in the United States on how to use the RhodoLED XL; correct?
A. Correct.
Q. You agree that at least one person in the United States outside of the context of the clinical trials has used the RhodoLED XL in combination with Ameluz to treat actinic keratosis; correct?
A. You said one?
Q. At least one.
A. At least one, correct.

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ATTORNEY HABBAZ: We can take a break now.
(Recess taken from 2:31 p.m. to 2:49 p.m.)
BY ATTORNEY HABBAZ:
[redacted]

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[redacted]

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BY ATTORNEY HABBAZ:

Q. We're back on the record. Have you discussed the substance of your testimony during the break?

A. I did not.

Q. Have there been any answers that you've given under oath that you'd like to reconsider or correct at this time?

A. No.

[redacted]

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[redacted]

Q. What's an in-service?

A. In-service is typically were you're in an office and you're providing instruction, education on products or service.

Q. Is this a healthcare professional group that has already purchased the RhodoLED XL?

A. No.

Q. Is this for a potential customer?

A. There could be a variety of -- there could be a variety of different types of in-servicing.

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[redacted]

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[redacted]

Q. What are the Biofrontera personnel doing when they're demonstrating the positioning of lights?
A. They are following the user manual on how to position the lights appropriately.
Q. And they are instructing the healthcare professional how to do that positioning in accordance with the manual?
A. Yes.
Q. When they do this demonstration of the positioning, is the patient there, or is this

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before the patient gets there? Do you know?
A. My interpretation could be both. It could be before or during.
Q. So there are instances where a Biofrontera personnel is in the treatment space or room with the patient and the healthcare professional; true?
A. True.
Q. And the Biofrontera sales personnel could be the individual actually doing the positioning of the lamp near the patient. Is that correct?
A. Correct.
Q. And the Biofrontera sales personnel is not actually going to touch the patient, correct, by putting on the Ameluz?
A. My recollection is they're instructing the staff on how to do that.
Q. They're not touching the patients themselves; correct?
A. Correct.
Q. Then would you expect that the

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healthcare professional may adjust the position of the lamp following the administration of the Ameluz?
A. Repeat your question.
Q. Would you expect the healthcare professional to adjust the position of the lamp in the in-service treatment day after providing the Ameluz to the patient?
A. I'm still not following. So they apply the medicine, and then they --
Q. Would the healthcare professional have repositioned the lamp to be near the patient?
A. Yes.
Q. Okay. And sometimes that could be done by a Biofrontera sales personnel?
A. Yes.
Q. Okay. You can set that aside.
(Exhibit 16 was marked for identification.)

[redacted]

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[redacted]

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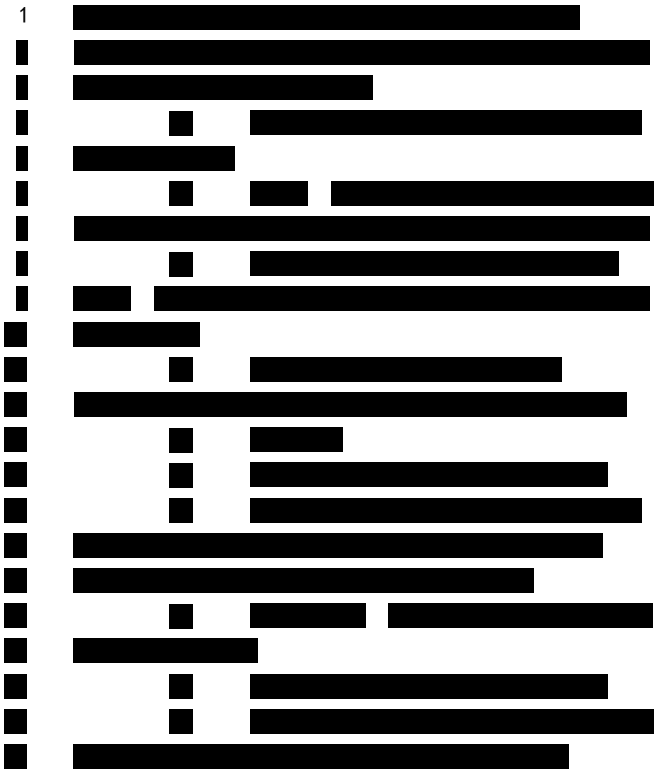

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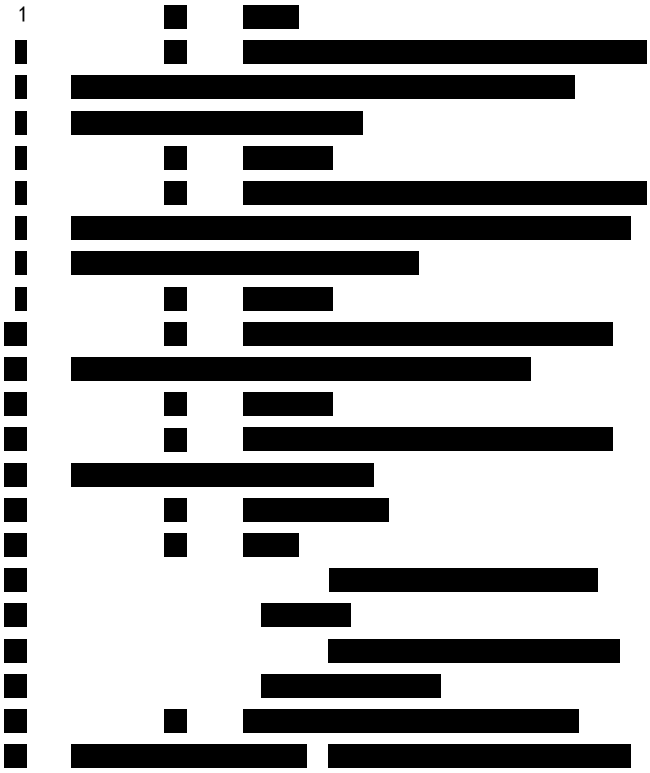

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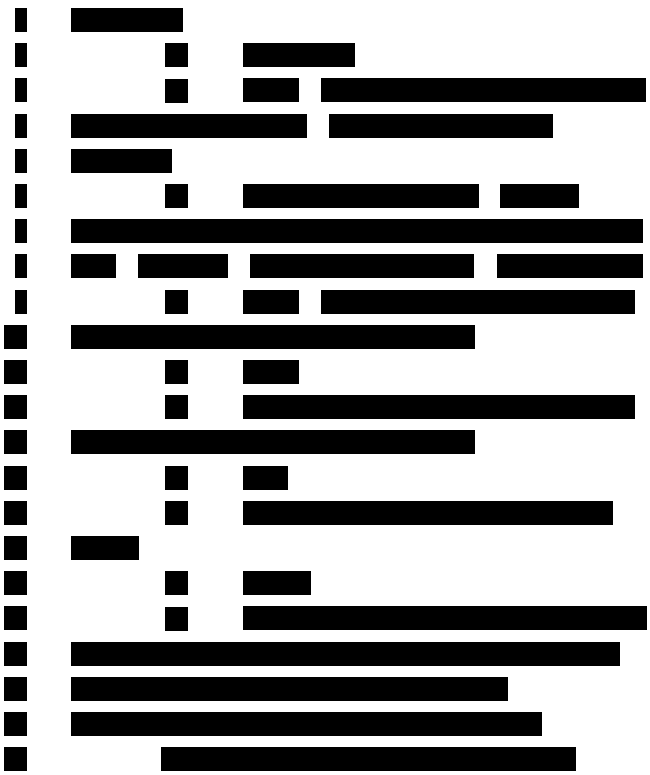

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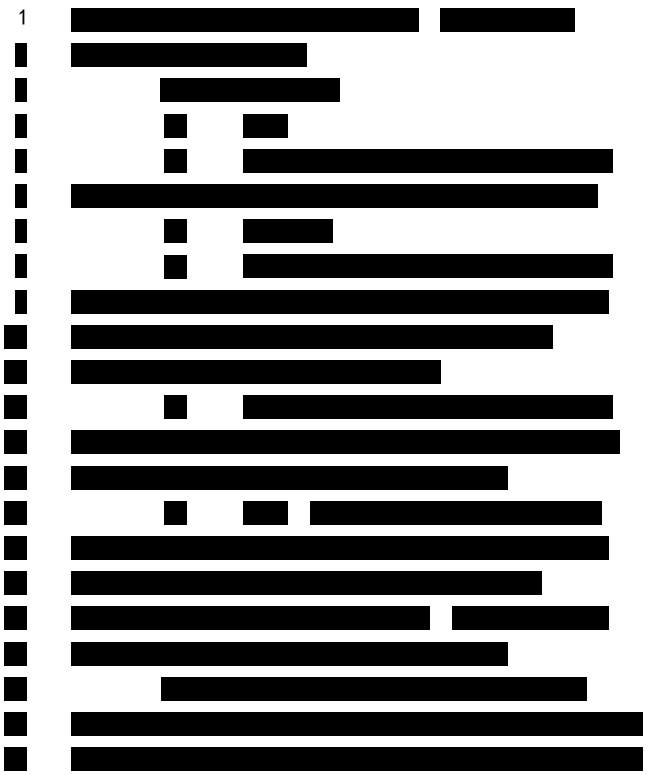

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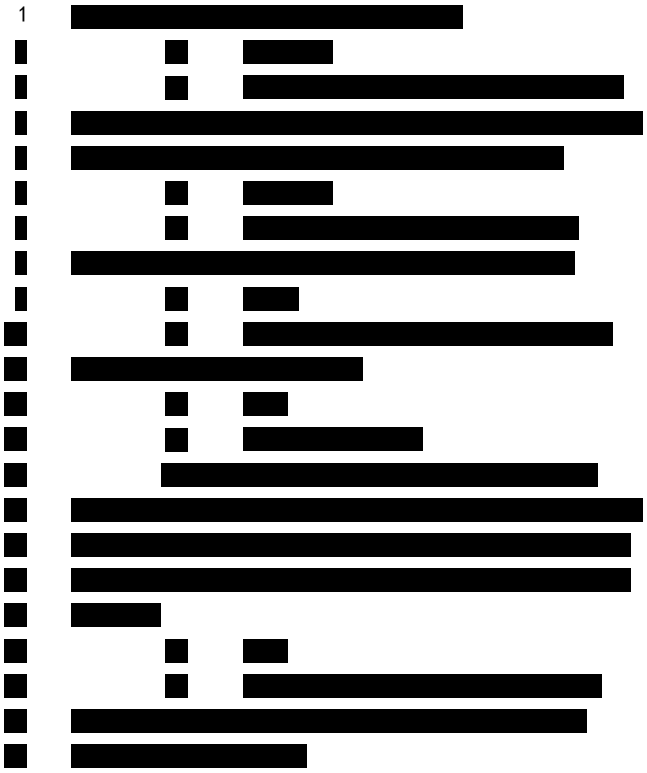

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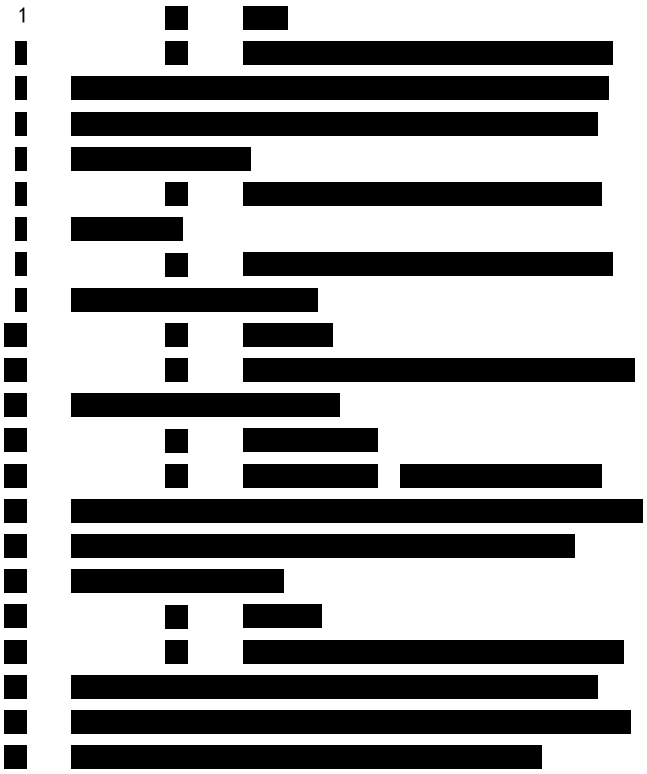

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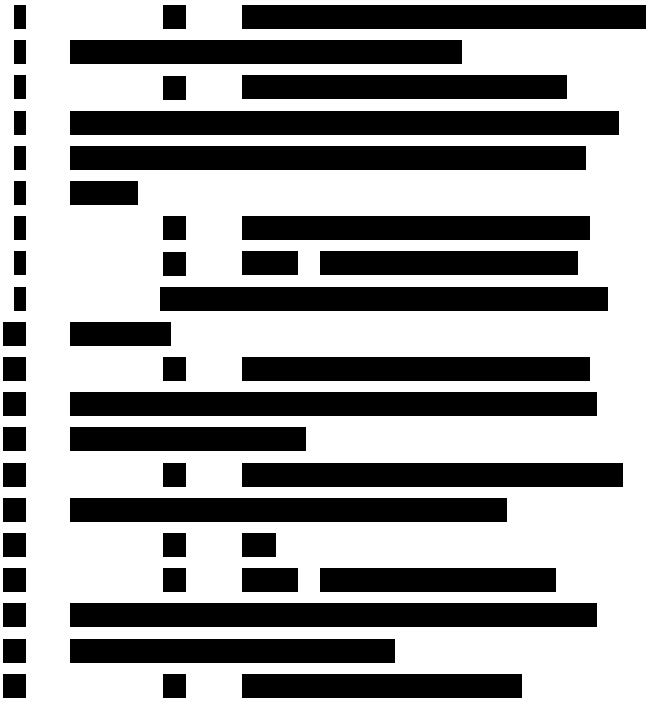

Q. When did you learn about Sun Pharma's new device?

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A. October or November of '22. Yeah, October or November of 2022.

Q. And that was before the launch of the Biofrontera RhodoLED XL device; correct?

A. The launch, yes.

Q. When did you first hear -- sorry. Who did you first hear about it from?

A. A Sun representative told me.

Q. A sales representative?

A. Yes.

Q. Do you know why?

A. Yes.

Q. Why?

A. I was walking to my booth. We had the XL there, and two representatives were taking pictures of our XL.

Q. Two Sun Pharma representatives?

A. Were taking pictures of our XL. I approached them and said, "Hey, you're taking a picture of my lamp. Why is that?"

"Oh, we're coming out with one ourselves. We wanted to see how it compares to yours."

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And that was the fall clinic in Las Vegas October, November of 2022, so that's how I found out.

Q. Did they tell you anything about the device at that time?

A. The representative said she had someone in California that was using it.

Q. Anything about the features of the device or the design?

A. It was going to be a lamp like ours.

Q. Okay. With a five-panel device?

A. I don't recall them saying five-panel.

Q. Since that time in October-November of 2022, have you heard more information about the new lamp from Sun?

A. Yes.

Q. From who?

A. There's a study that was initiated where they're using that new lamp.

Q. Clinical trial?

A. Correct.

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Q. Or clinical study?

A. Correct.

Q. Okay. Have there been discussions in Biofrontera about comparisons between the new Sun device and the XL device from Biofrontera?

A. Comparisons? Not that I'm aware of.

Q. Okay. Have there been efforts within Biofrontera to obtain the new Sun device?

ATTORNEY PETERSON: Objection. Scope.

THE WITNESS: The new device? I'm not aware.

BY ATTORNEY HABBAZ:

Q. Okay. Have you heard from your sales representatives or the customers directly about interest in the new device from Sun?

A. I have not.

Q. Okay. And you're here as a corporate representative. One of the topics is competitive intelligence on Sun and its new BLU-U lamp. Is there anything else that Biofrontera knows about competitive news on Sun Pharma beyond

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the discussion we had about the November 2022 conference?

A. No.

Q. Okay. Does Biofrontera have any facts to support Biofrontera's contention that a domestic industry does not exist?

A. You're going to have to rephrase that question.

Q. One of the topics that you're designated on is topic 56, which is the facts and allegations supporting -- tending to support, contradicting, or tending to contradict your contention -- that's Biofrontera's contention -- that a domestic industry for the purpose of the ITC investigation does not exist?

A. My interpretation of the question is is there an industry for a light in the U.S?

Q. Correct.

A. Which light?

Q. So specifically does -- are you aware of Biofrontera's contention that Sun Pharma does not have a product in the United States that

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practices a patent?

ATTORNEY PETERSON: Objection. To the extent it calls for a legal conclusion.

You can answer if you know.

THE WITNESS: Yeah, I don't know.

BY ATTORNEY HABBAZ:

Q. Okay. Do you have any facts at all as Biofrontera's representative to support or contradict your contention that a domestic industry does not exist?

A. No, I don't know.

Q. Those are two different answers.

A. I should say I don't know because I still don't understand the question.

Q. If you want, we can bring up the topic that we had all the way in the beginning. Would that be helpful?

So the topics I read to you is on the piece of paper that's on Exhibit 1, and we can put that in front of you, you can tell me whether you're prepared on that topic and whether you have any

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facts.

ATTORNEY PETERSON: I was going to say asked and answered.

ATTORNEY HABBAZ: I asked do you have any facts, and there's a no and an I don't know. So if the representation is that he as a representative has no facts, then that's the answer. But I think that clarification needs to be on the record.

THE WITNESS: This page?

BY ATTORNEY HABBAZ:

Q. Yes. Can you turn to topic 56.

A. (Witness complies with request.)

Q. Do you see topic 56?

A. I do. Your contention that a domestic industry does not exist.

Q. Sir, this is topic 56. That's one of the topics that you were designated by Biofrontera as a corporate representative, correct?

A. Correct.

Q. Okay. And sitting here today, you can't provide me with any facts that support or

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tend to support, contradict, or tend to contradict Biofrontera's contention that a domestic industry does not exist; true?

A. I don't know how to answer this one.

Q. Are there any facts that you can provide me with regard Biofrontera's contention as to whether a domestic industry exists? The answer can be no, I don't have any facts to provide.

A. No, I don't have any facts to provide.

ATTORNEY HABBAZ: Okay. I think with that, I'll pass the witness.

EXAMINATION BY

ATTORNEY PETERSON:

(Discussion held off the record.)

[redacted]

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[redacted]

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[redacted]

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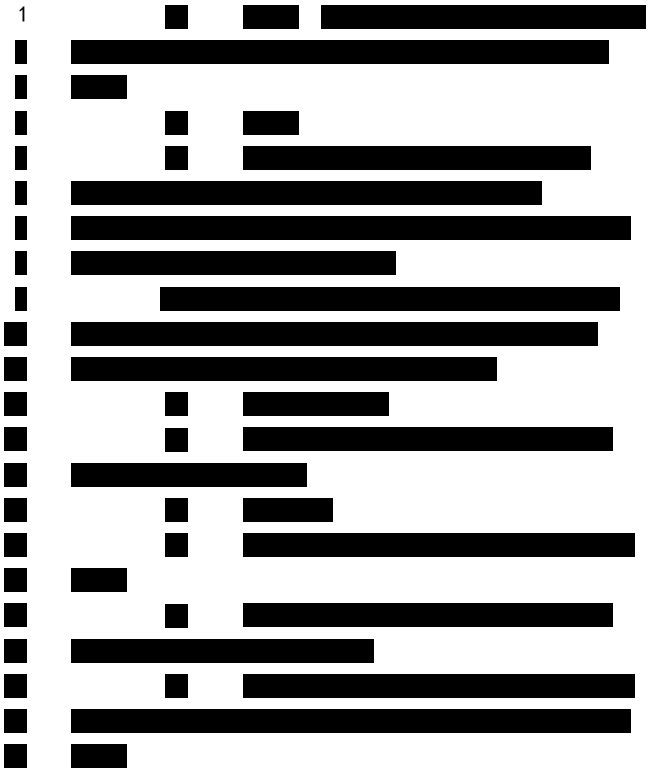

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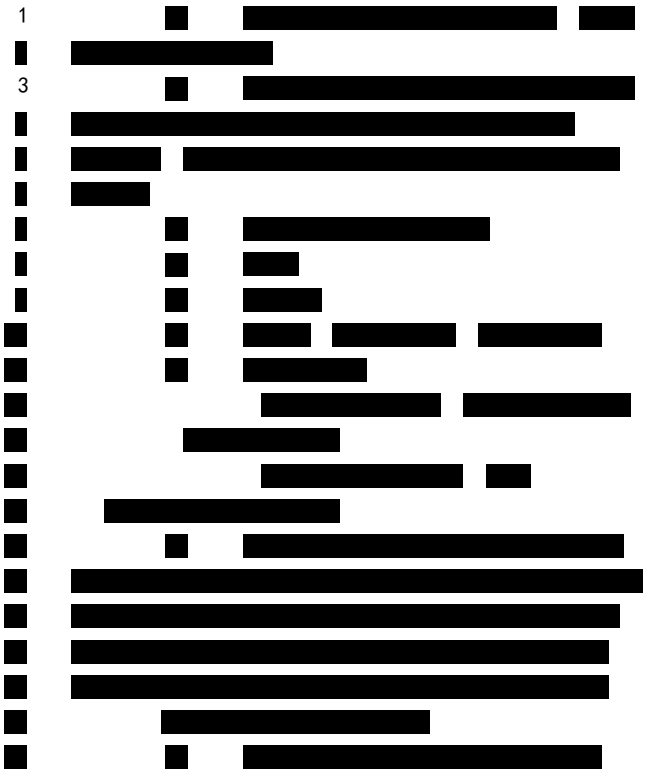

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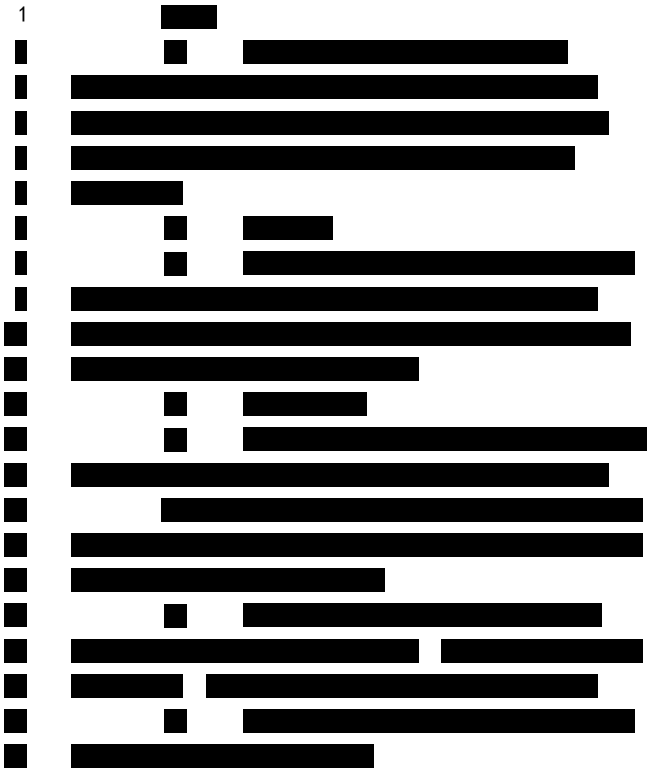

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ATTORNEY PETERSON: I have no further questions.

THE COURT REPORTER: Would you like to state your transcript order on the record now.

ATTORNEY PETERSON: I'd like a rough and the regular delivery. I would also like to mark the transcript as confidential business information. And we would like to review and sign.

(Proceedings adjourned at 3:31 p.m.)

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CERTIFICATE

DISTRICT OF COLUMBIA: SS

I, Barbara Moore, a Registered Court Reporter of the District of Columbia, do hereby certify that these proceedings took place before me at the time and place herein set out, and the proceedings were recorded stenographically by me and this transcript is a true record of the proceedings.

I further certify that I am not of counsel to any of the parties, nor an employee of counsel nor related to any of the parties, nor in any way interested in the outcome of this action.

BARBARA MOORE, CRR, RMR

My Commission Expires:
September 30, 2028