UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
PATENT NO. 10,131,682

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SYNAFFIX B.V.,
Petitioner,
vs.
HANGZHOU DAC BIOTECH CO., LTD.,
Patent Owner.
- - - - - - - - - - - - - - - - - -x

DEPOSITION OF RAVI CHARI, a witness called by counsel for the Patent Owner Hangzhou DAC Biotech Co., Ltd., Massachusetts, before Jane M. Werner, Registered Merit Reporter and Notary Public in and for the Commonwealth of Massachusetts, at the Offices of Foley & Lardner, 111 Huntington Avenue, Boston, Massachusetts, on Thursday, November 14, 2024, commencing at 9:32 a.m.

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I N D E X

WITNESS:	DIRECT	CROSS
RAVI CHARI		
(By Mr. Calvosa)	4	

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(Previously Marked Exhibits)

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P R O C E E D I N G S

RAVI CHARI

a witness called for examination by counsel for the Patent Owner Hangzhou DAC Biotech Co., Ltd., having been satisfactorily identified by the production of his driver's license and being first duly sworn by the Notary Public, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. CALVOSA:

Q. Good morning. Is it "Dr. Chari"?

A. Good morning. You can call me "Dr. Chari." You can call me "Ravi." Whatever you want to call me is fine.

Q. I'll call you "Dr. Chari."

My name is Frank Calvosa. I'm an attorney with a law firm called "Quinn Emanuel." This is Jihong Lou. And we represent the patent owner in a case filed by Synafix at the Patent Trial and Appeal Board.

Do you recall putting in a declaration?

A. Yes, I do.

Q. And I'm going to hand you a copy of that. That way you have it, in case you need it.

A. That's great. Thank you.
Q. It's been previously marked as Exhibit 1003 in the IPR.
A. Thank you.
Q. And feel free to take a look, but what I'd like you to do is to confirm that this is the declaration that you submitted.
A. It looks familiar, yes. It looks like it. Yes, okay, thank you.
Q. And I ask today to please keep your voice up and try to speak slowly for the court reporter so we can make a nice clean record. And let's not talk over each other, to the best we can.
A. That's great.
Q. Any reason you can't testify truthfully today?
A. No.
Q. Any reason you can't testify accurately to the best of your ability today?
A. No.
Q. Have you ever had your deposition taken before?
A. Yes.
Q. How many times?

A. Just once.
Q. When was that?
A. That was a couple of years ago. Two years ago, about.
Q. Can you please turn to Page 108 of your declaration.
A. Okay.
Q. And is that your signature there?
A. That's correct, yes.
Q. You signed this on February 9, 2023?
A. That's correct.
Q. Have you reviewed this declaration recently?
A. Yes, I have.
Q. Do you stand by the opinions set forth in this declaration?
A. Yes.
Q. Do you have any corrections to the declaration?
A. No.
Q. Does the declaration set out all of your opinions that you have formed to date in this matter?
A. Yes. In writing, yes.

Q. I'm sorry?
A. Yes.
Q. Can you please turn to Page 9 of your declaration.
A. Okay.
Q. Do you see in Paragraph 16 there, it says, "I understand that the assessment of the patentability of the claims of the '682 patent must be undertaken from the perspective of the POSA as of the earliest priority date of the '682 patent, which I have been informed is November 24, 2012"?
A. Yes.
Q. Did you provide your opinions from the perspective of a POSA in this case?
A. Yes.
Q. And if you turn to Page 13 of your declaration and Paragraph 23, that's where you set forth your opinion on who the POSA at the time of the what you call the alleged invention of the '682 patent would be, right?
A. That's correct.
Q. Any corrections to that definition of the POSA?
A. No. I think it's accurate.

Q. When I ask you questions today from the perspective of a POSA or I include the word "POSA" in my question, this is the definition that I am using. Do you understand that?

A. That is correct.

Q. Have you ever heard the term "functional group" before?

A. Yes.

Q. What would a POSA understand a functional group to be?

MR. HOUSTON: Objection, form.

A. It can be something -- it can be a methoxy. It could be an amino. It could be a variety of very broad definitions.

Q. And again, just try to slow down a little bit for the court reporter.

A. Okay, sorry.

MR. HOUSTON: Can we go off the record for one second.

(Discussion off the record)

BY MR. CALVOSA:

Q. Let me ask it again. What would a POSA understand a functional group to be?

MR. HOUSTON: Objection, form.

A. Well, a functional group could be anything that's not a substitute, basically. It could be a methoxy. It could be a hydroxy. It could be a fluoro. It could be anything that is different from a CH.

Q. And why do you say that a functional group could be anything that's different from a CH?

A. It impacts the activity of the compound. It may have some -- it could act as a link, for example. It could also have some effect on the electronic effects. It's not like a simple aromatic group. It has some impact.

Q. And when you say "CH," what do you mean by "CH"?

A. Methylene. For example, the phenyl group is all CHs, right? There is no substitute in there. It has to have a substitute in it. It can't be just CH, CH2 or whatever.

Q. So maybe I'm not understanding. You're telling me ethylene can be a functional group?

A. Ethylene is different from part of the ring. It can be a functional group, yes. It's not part of the aromatic ring. It sticks out. It's reactive, for example, or has an impact, yes.

Q. Have you ever heard of -- would a POSA in 2012 have been familiar with ethylene as a functional group?

A. I would think so, yes.

Q. Let me know if you agree with this statement: A POSA would understand that a functional group is a specific identifiable group of atoms within a molecule that directly contributes to its characteristic chemical properties and reactivity.

A. Yes. That's pretty accurate.

Q. Do you know what an amide is?

A. Yes, I do.

Q. Would a POSA have understood what an amide was in 2012?

A. Absolutely, yes.

Q. And what would a POSA have understood an amide to be?

A. CONH. CONH is part of an amide group. Carbonyl and an amino have been linked to be an amide, CONH.

Q. Would you be able to draw an amide group for me today?

A. Absolutely, yes.

Q. I'm going to hand you a piece of paper and a pen. And if you could please draw an amide group.

A. (Witness complies) It could be anything. It could be R. It could be methyl. It could be anything. The basic thing is CONH.

Q. And can you just write "amide" on there.

A. Okay. (Witness complies)

Q. And I'm going to mark this as Exhibit 2035. And I'll hand it right back to you.

A. Okay.

(Document marked as Chari Exhibit 2035 for identification)

Q. Would a POSA understand that amide is a functional group?

A. No.

Q. And why do you say that?

A. Because it doesn't have much impact for reactive, for example. It doesn't react to anything. It may or may not have functional activity. It's hard to know. It depends on where it is in the molecule. It all depends on the context, basically. It depends on the context. It may or it may not, depending on the context.

Q. And do you know what an amine is?

A. Yes.
Q. Would a POSA in 2012 have known what an amine is?
A. Absolutely, yes.
Q. What is an amine?
A. NH2.
Q. And I'm going to hand you a piece of paper. And can you please draw an amine for me.
A. (Witness complies) Primary amine. I put "primary." I'll draw it again for you.
Q. Let me give you a new piece of paper, and let me ask you a couple of questions. An amine is not necessarily NH2; is that fair?
A. I was thinking an amine can be primary, secondary or tertiary, but all have an N in it. It has to have an N.
Q. And an N is a nitrogen, right?
A. Exactly.
Q. And an amine is an N connected to two Rs, right?
A. An R can be three Rs, but you can't just have two Rs. Amine is trivalent. It has three substitutes. It can't have two.
Q. Let me ask my question again.

An amine is a nitrogen connected to three Rs, right?

A. Yes.

Q. And the Rs can be hydrogens?

A. If it's all hydrogen, it will be ammonia. It wouldn't be amine anymore. You can only have two hydrogens.

Q. Can you on this piece of paper draw the structure of an amine and label it "amine."

A. (Witness reviews document)

MR. CALVOSA: And I'm going to mark this as Exhibit 2036.

(Document marked as Chari Exhibit 2036 for identification)

Q. And just so it's clear -- and your counsel can take a look as well -- you have an N with 3Rs, and you note that all three Rs cannot be H, right?

A. At the same time, yeah.

Q. An amine is different than an amide, right?

A. Absolutely, yes.

Q. And a POSA would have known that in 2012?

A. Yes.

Q. An amine and an amide have different chemical properties, right?

A. Yes.
Q. And a POSA would have known that in 2012?
A. Yes.
Q. An amine and an amide can enable different types of reactions, right?
A. Yes.
Q. And a POSA would have known that in 2012?
A. Yes.
Q. I'd like to turn to Page 14 of your declaration. And I'm looking on Page -- sorry, Paragraph 24 on Page 14.
A. Okay.
Q. And halfway through that paragraph you say, "The challenged claims are directed to a bifunctional hydrophilic linker of formula (1)," and then you continue.
A. Okay.
Q. And feel free to read whatever you like. But my question for you is, What is a "bifunctional hydrophilic linker"?
A. Two reactive groups on a molecule are bifunctional, is what a POSA would say. Two reactive groups.
Q. And in the compound that's formula (1) in

the claims of the '682 patent, the two reactive groups are Y and Z; is that right?

A. I have to see the definition of Y and Z. Are they defined in here? (Witness reviews document) Yup. Yeah, Y and Z, that's right; that's correct.

Q. In your opinion, in the claims of the -- or in claim 1 of the '682 patent, would a POSA understand that Y and Z serve the same function?

A. Yes, they can serve the same function. Depending on the reactive group on Y and Z, part of the invention is one side is a cell-binding agent with different functional groups, reactive groups. The other side of the drug has different reactive groups. So depending on what reactive group is available, you can interchange Y and Z. Maybe you can't.

Q. In a bifunctional hydrophilic linker like the one of formula (1), which is on Page 14 of your declaration, the Z reactive functionality can link with a drug, right?

A. Yes.

Q. And what would a POSA understand linkage to mean in that context?

A. Just to connect the link together. It means it's connected. You can say it's a covalent bond.

Q. I'd like you to turn to Page 51 of your declaration.

A. Okay.

Q. And I'd like you to take a look at Paragraph 87. Again, feel free to review anything you'd like within there. But my question is going to focus on the second sentence of Paragraph 87. So just let me know when you're ready.

A. Yeah, I'm ready.

Q. You say that, "...claim 1 simply requires that Z is a functional group that enables reaction of the compound of formula (1) with a cytotoxic drug via a disulfide, thioether, thioester," and then it continues to list a bunch of other bonds that I won't make the nice court reporter type.

A. Okay.

Q. Is it your understanding that the Z functional group that's claimed in claim 1 of the '682 patent must enable a reaction?

A. Yes.

Q. Are you, sitting here today, positive that

that's what the claim language actually says?

A. Yes. It will enable a reaction. That's what it says, right? I don't have the claim language here, but -- do you have the patent that's filed?

Q. Sure. I'm happy to give you a copy of the re-examined claims. Or if you'd like, there is an appendix that you attached to your declaration at the end that lists the claims. So whichever is easiest for you.

A. I think let's see the re-examined -- not my appendix, but the original --

Q. You would like to see the document?

A. Yes, exactly.

Q. Sure.

A. Is it published? Is it the claim? Did they publish the claim?

Q. Yes. And this has been previously marked as Exhibit 1002 in the IPR.

A. Z is the functional group that enables linkage. That's what it says here. So I agree with the definition of Z. It enables linkage.

Q. So Z does not have to enable a reaction, right?

A. You cannot link without a reaction. You have to have a reaction to link.

Q. I understand that. But the claim language here says, "Z represents a functional group that enables linkage."

A. Exactly.

Q. It does not say, "Z represents a functional group that enables reaction," right?

A. That's correct.

Q. If you go to Y, a couple of lines up.

A. Yeah.

Q. Unlike Z, Y represents a functional group that enables a reaction, right?

A. Yeah.

Q. And I want to go back to Z. When there is a thioether bond, which is one of the ways that the linkage could be enabled according to Z -- do you agree with that?

A. Yes.

Q. And a POSA would agree with that, reading the claims?

A. Yes.

Q. What is a thioether bond?

A. A thioether bond is an SR; S with an R. R

is not an H or S or a heteroatom. Heteroatom means O, M, whatever. It cannot be H, S or any of the heteroatoms.

Q. A thioether could be a sulphur linked to a carbon, correct?

A. Right.

Q. And are you familiar with the term "vinyl"?

A. Yes.

Q. What do you understand "vinyl" to be?

A. It should be a CH double bond CH2. CH double bond CH2.

Q. And a POSA in 2012 would have known what a vinyl is, right?

A. Yes.

Q. And a POSA in 2012 would have understood that vinyl is a functional group, right?

A. Yes.

Q. Would a POSA have understood that a vinyl enables linkage via a thioether bond?

A. No. Vinyl won't react unless there is some reactivating thing. It doesn't react by itself. You would have something else other than vinyl. I don't think it would react, no. It won't react by itself.

Q. Why wouldn't vinyl react by itself?

A. It's not reactive. You need to have something next to it to make it react, like sulphur or carbonate or something like that. It doesn't react by itself. It needs to be activated so it can react. A POSA would understand vinyl does not react by itself.

Q. And why would a POSA understand that vinyl is unreactive by itself?

A. A POSA would know what makes a reaction happen. The carbon does not charge enough for it to -- the way reactions work is you need to have an attack on the carbon. The carbon is not positively charged enough for the reaction to occur. It needs something to activate the carbon to make sure it can react.

Q. So a vinyl alone would not be able to enable the reaction?

A. Not unless you do some kind of real reaction; not a normal reaction. Like, you do it in water.

Q. And the '682 patent is talking about normal reactions?

A. Exactly. I mean, not normal. I mean, you

can have some heated reaction disorder; something that is not normally used in the context of this patent.

Q. Would a POSA in 2012 have known what a vinyl sulfone was?

A. Yes, I think so, yes.

Q. Why do you say you think so?

A. I think they should know. People should know what sulfone is. Yeah, I think they should know.

Q. Is a vinyl sulfone functional group different than a vinyl functional group?

A. Yes. It's much more reactive.

Q. And a POSA would have known that those were different functional groups in 2012, right?

A. Yes.

Q. In the vinyl sulfone, what is the atom that's enabling the reaction?

MR. HOUSTON: Objection, form.

A. All you need is -- you need some group that will activate the vinyl sulfone. You need one that helps draw electrons from the vinyl to make it react. Sulfone would be the reason why it would react.

Q. So sulfone would be what would be enabling the reaction?

A. Exactly.

Q. And when I say, "enabling the reaction," what do you understand that to mean?

A. It means it can react. Say you have nucleophile or whatever, it would react. It can react from nucleophile. Nucleophile, N-U-C-L-E-O-P-H-I-L-E.

Q. I'd like you to please go to Pages 30 through 31 of your declaration. I'm going to be looking at Paragraph 48, okay?

A. (Witness reviews document) Okay, I read that.

Q. You mention -- or you include a quote that's talking about "aqueous environments." Do you know what an "aqueous environment" means?

A. Yes, "aqueous" stands for water.

Q. And would a POSA have known in 2012 what an aqueous environment is?

A. Yes.

Q. Why is an aqueous environment relative to what we're talking about for the '682 patent?

MR. HOUSTON: Objection; form, foundation.

A. It depends on the cell-binding agent. Many of them are soluble in water. Cell-binding agents are soluble in water. That's why it might be important. I think the data in the patent talks about the antibody is only soluble in water.

Q. The antibody is only soluble in water, right?

A. Exactly. Most proteins are only soluble in water. That's why an aqueous environment becomes important.

Q. And if a POSA was looking at whether something was a cell-binding agent, they would be looking at an aqueous environment?

A. Not necessarily. There are some which are -- the problem is you can only inject a patient with something that is not soluble in water. According to the patent, many of the cell-binding molecules listed are not soluble in water. It depends on the context. What's a cell-binding agent.

Q. In the context of -- let me ask a different question.

In 2012, were you determining whether any protein or other molecule was a cell-binding agent?

MR. HOUSTON: Objection, form.

A. I do not know. There are many cell-bindings that are known to be not proteins in 2012.

Q. Let me ask another question. And I just want to make sure you understand what I'm asking.

A. Okay.

Q. In 2012, were you determining whether any molecule, whatever the type is, was a cell-binding agent?

MR. HOUSTON: Objection, form.

A. I don't understand the question. Can you please repeat? What are you implying?

Q. My question is, how do you know -- or how does a POSA in 2012 know whether something is or is not a cell-binding agent?

A. For it to bind to a cell, according to the patent -- I think binds to a cell is a cell-binding agent. It's very broadly defined, according to the patent you showed in front of me. It broadly defines something that binds to a cell.

Q. And what are the conditions for binding to a cell?

MR. HOUSTON: Objection, form.

A. It could be in vitro cell culture, for starters.

Q. And what conditions are used in in vitro cell cultures?

A. Again, it could be an aqueous solution. It could be cells growing. Cells have to grow in a buffer. They have to grow in some media. So that's probably typical to use cells to grow in media, in particular aqueous in a lab with a cell-binding agent to see if it binds.

Q. Would a POSA have done -- we're talking in vitro now -- a cell culture experiment in orange juice?

A. No. It has to be in media for cells to grow. Cells cannot grow in orange juice. It has to be specific media for each cell. Each cell type has specific media that is defined by the manufacturer. So you have to have a specific aqueous media for cells to be happy and grow.

Q. Would you want more -- or would a POSA want the cells to be dried?

A. No. It has to be in solution, so they can -- it has to be in suspension.

Q. Why wouldn't dried cells be of value?

A. Dried cells are probably not growing, even. They're probably dead. I don't know what you mean by a "dried cell."

Q. What about treatment with methanol?

A. A small amount, they can survive. A small percent will survive, but not too much. The cells will die. They don't like methanol. I'm sure they don't like methanol. Small amounts, like low percent, may be okay.

Q. And what percent would be the cutoff?

A. Well, depending on the media, for example, you might precipitate all the proteins out of the media. It's hard to know the percent, depending on the media. It's not just the cell. It's also the media. A media component has to be soluble for cells to grow. If you put methanol in, you might precipitate out the media. So I don't know the percent, depending on the media.

Q. But methanol wouldn't have been a good choice for that testing?

A. Pardon me?

Q. A POSA would have understood that methanol would not have been a good choice for that testing?

MR. HOUSTON: Objection as to form.

A. A small amount can always be okay. Like, percent, 2 percent; but not, like, 20 percent. Small amounts.

Q. What about paraformaldehyde?

MR. HOUSTON: Objection, form.

A. I don't know -- I have no opinion on that. I don't know anything about paraformaldehyde -- again, it might be a small amount. I just don't know.

Q. You just don't know?

A. I don't know.

Q. Would a POSA in 2012 have known what haloethyl is?

A. Yes.

Q. What would they have understood haloethyl to be?

A. It could be halogen, it could be fluorine, chlorine, bromine, iodine linked to an ethyl group.

Q. And what is an ethyl group?

A. CH2, CH3, ethyl group.

Q. Would a POSA have understood that haloethyl is a functional group?

A. Again, depending on the halo. With halos, some of them will react; some cannot react. Iodine

would react. CL may react. Iodine may react. It depends on the halogen. Or F may not. Anyway, go ahead.

Q. Are you offering any opinions in this case -- I didn't see any -- but please correct me if I'm wrong -- that haloethyl alone would be able to enable a reaction with a cell-binding agent?

MR. HOUSTON: Objection, form.

A. Again, depending on the halo. Define "halo." Even then, we need to figure it out, because it all depends on many cell-binding agents, the concentration, the solvent. Many -- all the contexts. Typically, it doesn't react.

Q. Would a POSA in 2012 have known what a haloethyl sulfone is?

A. Yes, I think so.

Q. Would a POSA have understood that a haloethyl sulfone is a different functional group than a haloethyl?

MR. HOUSTON: Objection, form.

A. I think so, yes.

Q. As part of your opinions in this case, did you review a reference written by Julia Morales-Sanfrutos?

A. Yes, I did. There's a publication in JOC, yes.

Q. I am going to hand you a copy of that reference. And that has been previously marked as 1005 in the IPR.

A. Thank you.

Q. And I'd like you to turn to -- and again, feel free to look at whatever you need to, but my question is going to be on Page 6.

A. Okay.

Q. And I want to focus on the compound that's HRP-4.

A. Okay.

Q. In Scheme 4.

A. Okay.

Q. And I'm looking at the bottom right of that compound. There's three lines of that are together at the end of the compound. Do you see that?

A. Can you point it out, please?

Q. Sure. Right there.

A. Okay. Where does it say three lines? I only see one arrow.

Q. I'm looking at the bond, the triple bond.

A. Oh, triple bond, okay, I see. I get it

now. Okay, thank you.

Q. I apologize for my layman's explanation there.

A. Okay, that's fine.

Q. Do you see the triple bond, HRP-4?

A. Yes, I do see it, yes.

Q. And is there a name for that triple bond?

A. Alkyne, A-L-K-Y-N-E.

Q. In Morales-Sanfrutos, what does that reference disclose that triple bond is reacting with?

A. It reacts with biotin, it looks like.

Q. Is there a disclosure in Morales-Sanfrutos of that triple bond alkyne reacting with anything else besides biotin?

A. Well, they have to have a functional group to react. Let me read this. (Witness reviews document)

It reacts with biotin -- it has a reactive group that reacts with a triple bond. That's why it reacts with biotin.

Q. And what is that reactive group with biotin?

A. Azido group, A-Z-I-D-O.

Q. Besides the alkyne reacting with the Azido group in biotin, does Morales-Sanfrutos disclose that alkyne group reacting with anything else?

A. Let me see what it says here. (Witness reviews document) It looks like it can react with anything within the Azido group; biotin -- it looks like a triple bond alkyne can react to anything in the Azido group. The compound is in Scheme 2, three different compounds. They can all react.

Q. Which compounds are you referring to?

A. Azido clickable derivatives. This is Scheme 2.

Q. You're referring to compound 6, 7 and 8?

A. That is correct.

Q. On Page 3 of Exhibit 1005, right?

A. That's correct, yes.

Q. And nowhere in Morales-Sanfrutos does it disclose that any of compound 6, 7 or 8 are cell-binding agents, right?

A. No.

Q. And nowhere in Morales-Sanfrutos does it disclose that biotin is a cell-binding agent, right?

A. No. I don't see it anywhere.

Q. And you reviewed Morales-Sanfrutos as part

of putting your declaration together?

A. That's correct.

MR. CALVOSA: We've been going a little less than an hour now. Is now a good time for a break?

THE WITNESS: I'm okay if you want to go for longer.

MR. CALVOSA: Go for longer? Sure.

BY MR. CALVOSA:

Q. I want to go back to Scheme 2.

A. Okay.

Q. And a term that you brought up; the azide, A-Z-I-D-E, clickable tag derivatives.

A. Yes.

Q. What does that term "clickable" mean?

A. Well, click chemistry was disclosed in 2001 by Professor --

THE COURT REPORTER: I'm sorry?

A. It was disclosed in 2001. It reacts with the alkyne; a very simple reaction. Nobody else talked about it until 2001. So people -- a POSA would know what it is. It's reacting azide with a alkyne.

Q. And how does Morales-Sanfrutos disclose

that this click chemistry happens?

A. They do the reaction; dissect the product and make sure it reacted. They do the chemistry, do the reaction. It's unique to click reaction to show that the reaction has occurred.

Q. And what would a POSA in 2012 understand "reaction" to mean?

MR. HOUSTON: Objection, form.

A. A reaction is something -- you put two things together to get something else. It's reacted. They don't react separately by each other.

Q. Is reaction the process to get that connection together?

A. Yes, that's correct.

Q. And a POSA would have understood that in 2012?

A. Yes.

Q. The way Morales-Sanfrutos discloses the reaction of that click chemistry happens is through the use of a copper catalyst, right?

A. Yes.

Q. Morales-Sanfrutos also discloses that the copper catalyst is not a good thing, right?

A. Yes. I mean -- yes. Good things, thet

don't remove it. So why remove it.

Q. A copper catalyst is toxic for a living organism?

A. But there's a new method that doesn't use copper catalyst, also known before 2012.

Q. So before 2012, a POSA would have known they moved away from copper catalysts?

A. Exactly, that is correct.

Q. Do you remember the Harris reference that you discussed in your declaration?

A. Yes.

Q. Let me give you a copy of that.

A. That would be great.

Q. And this was previously marked as Exhibit 1007 in the IPR.

A. Okay. (Witness reviews document)

Q. Correct me if I'm wrong, but there's no specific compound in Harris that you include in your declaration that matches the compounds claimed in the '682 patent, right?

MR. HOUSTON: Objection, form.

A. Let me study this. (Witness reviews document) It says here it has the basic structure. It encompasses --

Q. Where are you?
A. I'm on Declaration 103, Page 59.
Q. 59, okay, go ahead.
A. It has the basic structure. It encompasses PEGs, derivatives, comprising 2 sulfone moieties. That track, with the variables, defines the compound of formula (1) claimed in the '682 patent.
Q. That wasn't quite my question. So let me ask you it again.
A. Yeah.
Q. There is no specific compound in Harris that you include in your declaration which matches any compound claimed in the '682 patent?
MR. HOUSTON: Objection, form.
A. (Witness reviews document) The problem with Harris is there's no specific components in the claim. But in general, it's obvious in claim 1 that it will match with the claim 1 of the '682 patent. Everything in here; water soluble, polyethylene glycol, polyethylene oxide.
THE COURT REPORTER: I'm sorry, can you repeat that?
A. Let me read from here -- ethylene oxide, and having at least one active sulfone moiety.

From here, you can match exactly what the '682 patent has; one active sulfone moiety, polyethylene glycol, polyethylene oxide.

Q. It's your opinion that the claims of the '682 patent require one active sulfone moiety?

A. Yes, I think so, yes. Let me look at the patent.

Q. Let me ask you a different question.

Do you recall reviewing the Singh reference as part of your declaration?

A. Yes.

Q. What is the Singh reference?

A. The Singh reference is saying you can put a polyethylene glycol to make things more soluble, more hydrophilic.

Q. And poly -- I guess the inventors -- or the purported inventors on Singh found that polyethylene glycol led to increased solubility?

A. Hydrophilicity, yes.

Q. I apologize, hydrophilicity.

A. Yes.

Q. This was previously marked as Exhibit 1008 in the IPR.

The Singh reference was published in May of

2010?

A. Yeah, okay. If you say so.

Q. Do you not know?

A. I have to look at it to make sure. Okay, May 2010; okay, that's right.

Q. Before your participation in this IPR, had you ever seen the Singh reference before?

A. I am a co-inventor in the Singh reference. I've seen it before, yes.

Q. You were one of the co-inventors. That's you, Ravi Chari, right?

A. Yes.

Q. 2010 is pretty close to 2012, right?

MR. HOUSTON: Objection to form.

A. But this was filed in 2009, provisional -- 2006 -- so filed in 2008 basically originally, provisionally. So it's quite far.

Q. What's that?

A. It's quite far. 2008 and 2012 are not close really. In 2008 it was filed provisional, April 2008, and published in 2010.

Q. You understand you can make changes to a patent as it goes through the prosecution, right?

A. Yes.

Q. This is not an issued patent, the Singh patent, right?

A. Yeah, I don't think so. This is only the application, yes.

Q. And do you understand that when it says in parentheses (63) on Page 1 of Exhibit 1008 -- it says, Continuation-in-part was filed in April 2009. Do you know what that means?

A. I know, yes.

Q. What does that mean?

A. That means you can make some changes before it publishes.

Q. So things were being added over time?

A. Yeah.

Q. You agree with me that the work you did and that's discussed in here published in 2010 does not include the Q and T elements of the '682 patent's claims, right?

A. Q and T; are those the sulfones?

Q. Yes.

A. It doesn't include sulfones, that's right.

Q. It does not?

A. It does not.

Q. And that was your work?

A. Yes, that's correct.
Q. Going back to Harris.
A. Okay.
Q. Did you do any exercise to see with all of the different possible linkers that could be formed, what the complete universe of linkers disclosed in there is?
A. For us, disclosing the 2010 patent was good enough. We didn't look any more. There's millions of possibilities. We didn't look at them all. We just looked at what was sufficient for what we wanted to do at that time, 2010. Polyethylene glycol was sufficient for what we wanted to achieve.
Q. So with your publication in 2010, you thought it was sufficient to use polyethylene glycol alone to achieve the hydrophilicity?
A. Right. For what we needed, yes.
Q. Did you have any regret about that?
A. No.
Q. You didn't regret it in 2011?
A. No.
Q. You didn't regret it in 2012?
A. No. It was sufficient for what we wanted to do, so there were no regrets. In order to get

high drug to antibody ratio, that could be achieved with the PEG.

Q. In your view, there was no reason to add anything else?

A. Not at that time, right.

Q. Going back to Harris, I want to focus on the Harris reference specifically.

A. Okay.

Q. Did you do any exercise to see, with all of the different possible combinations of elements disclosed for linkers, how many different linker combinations you could come up with in Harris?

MR. HOUSTON: Objection, form.

A. Repeat the question, please?

Q. Sure. Would all of the different groups that could be added on to the linkers or spacers that could be used, using the disclosures of Harris, did you do any calculations to see the total number?

A. No.

Q. Do you know what the total number of possible combinations in Harris is?

A. No.

Q. Do you know if it's in the thousands?

A. I would have to read the patent more

carefully to know.

Q. Let me ask you, you didn't do that exercise before today?

A. No. All I know is it exists. It may get better. But is it needed?

Q. What do you mean by that?

A. I mean, according to the patent of Dac, there is no say to have improvement, that you need a sulfone beyond a PEG. There's no data in the patent.

Q. And it's your opinion before 2012, a POSA wouldn't think that you need a sulfone in addition to a patent?

MR. HOUSTON: Objection, form.

A. Repeat the question again, please?

Q. It's your opinion that before 2012, a POSA wouldn't think you would need a sulfone in addition to a PEG?

MR. HOUSTON: Objection; form, beyond the scope.

A. I don't know. I don't know what a POSA would think. But they might try. I just don't know.

Q. But you didn't think you needed one?

A. We didn't need it for our purposes. In our context, we didn't need anything more than a PEG.

Q. You're not offering an opinion -- I didn't see one in your declaration -- that a POSA looking at either Singh or Harris, would -- pay attention to the language -- would it once envisage the claim compounds of the '682 pound, right?

MR. HOUSTON: Objection, form.

A. I don't understand the question. It's obvious -- I'm looking at Singh and Harris -- that you make the '682 patent from Singh and Harris. That's all it is. There is no invention there. Just the obvious; combining two different elements makes it hydrophilic.

Q. My question was, Do you offer an opinion anywhere in your declaration -- point me to it -- where you say a POSA would have once envisaged -- E-N-V-I-S-A-G-E -- the claim compounds of the '682 patent from either Singh or Harris?

MR. HOUSTON: Objection, form.

A. Singh or Harris, you said?

Q. Correct.

A. Harris discloses -- I should be quiet as I'm reading it. (Witness reviews document).

My opinion here is Harris actually discloses a hydrophilic linker for the reasons below. "Harris' basic structure -- Page 59, Line 3.

Q. Sorry, you're just reading from your declaration, right?

A. Exactly, yes.

Q. I'm asking, Does it say anywhere in your declaration that a POSA would have once envisaged the claim compounds of the '682 patent based on either Singh or Harris?

MR. HOUSTON: Objection, form.

A. Harris' basic structure encompasses the compound of Claim 1. That's what it says. That's what I maintain.

Q. But you don't know how many compounds or possible linkers Harris discloses?

A. How many compounds...

Q. Again, back to the calculation question. You didn't do that calculation for Harris?

A. I think the first claim is very broad. Hydrophilic would be -- it doesn't say how many compounds.

Q. The first claim of Harris alone is very broad, right?

A. Hydrophilic and sulfone.
Q. Sir, my question is, the first claim of Harris alone is very broad, right?
A. Yeah. It's enough to say, Look, it's obvious to me -- not obvious. Like, clearly what's the word? Clearly one or two -- what's the word? Not "prior art." What's the other word? Let me see if it's in here. (Witness reviews document) It's some technical word that you guys use for one or two.
Q. I want to focus on the disclosures; not the legal terms.
A. Disclosure in claim 1 to me is absolutely -- what's the word? I can't find it.
Q. Would you agree with me that the disclosures of Harris outside of claim 1 are also very broad?
MR. HOUSTON: Objection, form.
A. Well, you know, I don't know. I mean, the patent design wasn't broad enough. I don't know. There's probably enough support in here for the claim, but I haven't studied this report carefully.
Q. Did you read the entire Harris reference in preparing your declaration?

A. Yes, I read the whole thing. I'm trying to find in my declaration, there is a word -- (Witness reviews document)

Q. Dr. Chari, the Singh reference, which is your reference, did you do any calculation to see, with all the different possibilities, how many linkers are disclosed?

A. I don't know what you mean by "calculation." We have not been able to -- we obtained the PEG size. The size of the PEG can be -- anything more than 24 is not defined. You want to make sure they're reproducible what you can buy. It's discrete. It means it's a defined size.

Q. I'm just asking a simple question.

Did you do any calculations to determine --

A. No, no calculations. We just did practically what you can do. No calculation, no.

Q. And you didn't do that as part of your exercise in preparing your declaration?

A. I don't know what you mean by "calculation."

Q. Did you calculate -- did you figure out the number of possible different permutations of molecules or linkers disclosed in the Singh

reference?

A. No.

MR. CALVOSA: Why don't we take a break now.

(Recess taken from 10:47 to 11:02)

BY MR. CALVOSA:

Q. All right, Dr. Chari, welcome back.

If you would take your declaration back out, Exhibit 1003, and turn to Page 51. And I'm focusing on Paragraph 86.

A. 87?

Q. 86.

A. Okay.

Q. At the top of the Page 51, in Paragraph 86 of your declaration, you're discussing the Y element of claim 1, right?

A. Yeah.

Q. Okay. And near the bottom, you say, "The '682 patent discloses exemplary compounds of formula (1) that contain a vinyl functional group located adjacent to a sulfone moiety which is capable of reacting with a thiol (-SH) functional group." Do you see that?

A. Yeah.

Q. And then you cite to four compounds from the '682 patent, right?
A. Okay, yes.
Q. Compound 75, compound 99, compound 119 and compound 138?
A. Yeah.
Q. And it's your opinion there that that is the '682 patent showing vinyl as a Y of formula (1); is that right?
A. Let me please study the '682 patent.
Q. You can. I'm asking you, is that your opinion that you're offering?
A. I have to see what I actually said. Let me see.
Q. Dr. Chari, before you look at the patent, my question for you is, is the opinion that you're offering in Paragraph 86 that compound 75, 99, 119 and 138 are showing vinyl as the Y element?
A. Well, I can't say until I look at this patent. Is it possible to see the 101 --
Q. It is. My question -- and maybe you just don't know.
Do you know if in Paragraph 86, you're offering an opinion?

A. I need to see what Compound 75, 99, 119 and 138 are structurally.

Q. So you can't answer my question without looking at the patent; is that fair?

A. Yeah. Yes, that's fair.

Q. Okay, no problem. Here is the '682 patent, which has been previously marked as Exhibit 1001.

And if you turn to Sheet 5 of 23, compound 75 is on the left-hand side; about three rows down.

A. (Witness reviews document) Yes, that's correct.

Q. I just asked you to look at the compound. So let me ask you a question.

In your opinion, compound 75 is showing the vinyl as Y?

A. (Witness reviews document) Vinyl sulfone, I would say. Vinyl sulfone is Y.

Q. The vinyl sulfone, in your opinion, together is Y?

A. Exactly.

Q. And how about for compound 99 on the next page, Sheet 6 of 23?

A. The same. The vinyl sulfone is Y.

Q. And how about compound 119 on Sheet 7 of

23?

A. It looks like the vinyl sulfone is Y.

Q. And one more page. Turn to Sheet 8 of 23, compound 138. What's Y there?

A. Also vinyl sulfone.

Q. Why do you say that for each of compounds 75, 99, 119 and 138?

A. It says it enables a reaction. To me, you need a vinyl sulfone to enable the reaction. That's why I say that.

Q. The vinyl alone would not be sufficient?

A. No; not to -- no.

Q. If you go to Page 102 of your declaration, Exhibit 1003, Paragraph 81, I have a question for you on that.

A. 181?

Q. 181, thank you.

A. Okay.

Q. Just let me know when you're ready.

A. I'm ready.

Q. Okay, I apologize.

In the second sentence there you say, "A POSA would have been motivated to use the well-known val-cit-PAB linker of Bhakta," B-H-A-K-T-A, "to

replace, e.g., the disulfide linkage of Singh in order to obtain the selective and efficient release of the Drug, at target cancer cells."

Do you see that?

A. Yup.

Q. Why are you discussing target cancer cells in your declaration?

A. The Singh patent raises target cancer cells. That's why I did. It raises the same target cancer cells, the same patent.

Q. And how are target cancer cells relevant to what's in the '682 patent?

MR. HOUSTON: Objection; form, beyond the scope.

A. (Witness reviews document) The only piece of data in the Singh patent -- in the '682 patent that is biological is on target cancer cells. It's Figure number -- Figure 21.

Q. And the targeting of cancer cells, is that done through the cell-binding agent?

A. Yes, that is correct. At least it is in this patent, in the '682.

Q. In the '682 patent?

A. Yes.

Q. And in the '682 patent, the cell-binding agent is a molecule that sort of binds to or reacts with the moiety of the cell population sought to be therapeutically or otherwise biologically modified?

MR. HOUSTON: Objection, form.

A. The example -- the only example that shows is an antibody.

Q. Okay.

A. That's Figure 21.

Q. And what I just said about a cell-binding agent is consistent with the example in the patent?

MR. HOUSTON: Objection, form.

A. Defined by what?

Q. Maybe if we look at that, that would be easier. Maybe I didn't say it correctly. But I'm looking at Column 14, Lines 39 through 44.

A. This is the '682 patent?

Q. The '682 patent.

A. Page what?

Q. There's no page numbers on the patent. It's column numbers. So if you go to Column 14, you go past all the pictures.

A. Oh, yeah, okay. (Witness reviews document)

Q. And my question for you is, Column 14,

Lines 39 through 44 provide a definition that the '682 patent used for a cell-binding agent?

MR. HOUSTON: Objection, form.

A. A cell-binding molecule, yeah.

Q. I want to go back to the Morales-Sanfrutos reference.

A. Okay.

Q. And I want to go back to Scheme 4 on Page 6.

A. Let me find it.

Q. Sure. And that's Exhibit 1005, Page 6, Scheme 4.

A. All right, okay. What's the question?

Q. I'm looking at compound 11.

A. Okay.

Q. In compound 11, what is the part of that molecule that would correspond to the Y that enables reaction with the horseradish peroxidase?

A. The vinyl sulfone in compound 11.

Q. And why do you say that?

A. Because it's the only reactive group left of the whole molecule that I can see. So it would have to react. It's the only reactive group.

Q. Not the vinyl alone?

A. No. I think vinyl alone will not react.

MR. CALVOSA: Pending any questions from your counsel, I have nothing else.

MR. HOUSTON: We'll take a break.

MR. CALVOSA: We can go off the record.

(Recess taken from 11:19 to 11:54)

MR. HOUSTON: No redirect from Petitioner.

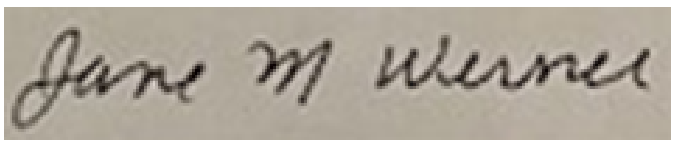
(Whereupon, the deposition was concluded at 11:54 a.m.)

COMMONWEALTH OF MASSACHUSETTS)
SUFFOLK, SS.)

I, Jane M. Werner, RMR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 14th day of November, 2024, at 9:32 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of his knowledge touching and concerning the matters in controversy in this cause; that he was thereupon examined upon his oath, and his examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness.

I further certify that I am neither attorney or counsel for, nor related to or employed by, any attorney or counsel employed by the parties hereto or financially interested in the action.

In witness whereof, I have hereunto set my hand and affixed my notarial seal this 18th day of November, 2024.



Notary Public
Commission expires 1/27/2028

Michael P. Houston, Esq.

mhouston@foley.com

November 22, 2024

RE: SYNAFFIX B.V. vs. HANGZHOU DAC BIOTECH CO., LTD.

11/14/2024, Ravi Chari (#7023710)

The above-referenced transcript is available for review.

Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at cs-ny@veritext.com.

Return completed errata within 30 days from receipt of testimony.

If the witness fails to do so within the time allotted, the transcript may be used as if signed.

Yours,

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SYNAFFIX B.V. vs. HANGZHOU DAC BIOTECH CO., LTD.

11/14/2024 - Ravi Chari (#7023710)

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Ravi Chari Date

SYNAFFIX B.V. vs. HANGZHOU DAC BIOTECH CO., LTD.
11/14/2024 - Ravi Chari (#7023710)

ACKNOWLEDGEMENT OF DEPONENT

I, Ravi Chari, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

_____ _____

Ravi Chari Date

*If notary is required

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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