

UNITED STATES INTERNATIONAL TRADE COMMISSION

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In the Matter of

Investigation No.

CERTAIN PLANT-DERIVED RECOMBINANT 337-TA-1238

HUMAN SERUM ALBUMINS ("rHSA") AND

PRODUCTS CONTAINING SAME

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OPEN SESSIONS

Pages: 1 through 261 (with excerpts)

Place: Washington, D.C.

Date: November 4, 2021

HERITAGE REPORTING CORPORATION

Official Reporters

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1 BY MS. HOEKEL:

2 Q. Mr. Deeter, can you introduce yourself to the
3 court with your name and your title and who you work for?

4 A. I'm Scott Edward Deeter. I'm CEO of Ventria
5 Bioscience.

6 Q. How long have you been with Ventria Bioscience?

7 A. I started in 2001.

8 Q. How long have you been with CEO of Ventria
9 Bioscience?

10 A. Since that time.

11 Q. Can you please tell the Court about your
12 educational background?

13 A. Sure. I received my Bachelor of Science in
14 economics and math at University of Kansas, and then went to
15 University of Chicago for graduate school, and received an
16 MBA at Chicago, and then received a Master's in Economics
17 from London School of Economics.

18 Q. We're going to start by talking a little bit
19 about the history of the company.

20 If I can have the demonstrative slide 1, please.

21 MS. HOEKEL: We're sharing it, Your Honor. It's
22 just taking a minute.

23 Can everyone see the demonstrative slide 1?

24 Q. When was Ventria founded?

25 A. Ventria was formed from a predecessor company

1 that Ventria is claiming in this case are covered by the
2 '951 patent, correct?

3 A. Yes, I am.

4 Q. And what are the brand names of those products?

5 A. The brand names of those products are Cellastim,
6 Exbumin, and Optibumin. Those are the three recombinant
7 protein products. We also have an albumin included in
8 ITSE + A that is Cellastim, and we have three media
9 products, one for vero cells called OptiVERO, one for HEK
10 cells called OptiPEAK HEK-293, and one for T lymphocytes for
11 cancer therapies called OptiPEAK T lymphocyte. Those three
12 medias also contain albumin.

13 Q. Is ExpressTec used in the expression of those
14 products?

15 A. It is used to make the protein components.

16 Q. Of each of those products?

17 A. Of those products, yes.

18 Q. And when did Ventria first start selling a
19 rice-derived albumin?

20 A. We started the selling around 2007, early in
21 2007. I want to say April, May, of 2007 is when we had our
22 first sales.

23 Q. What was the brand name of that product?

24 A. That was Cellastim.

25 Q. Has Cellastim as a product evolved over the

1 years?

2 A. Yes. We made a lot of advancements over the
3 years to improve the quality and the utility of the albumin
4 product line.

5 Q. Let's look at demonstrative slide 4, please.

6 Prior to Ventria's use of rice for derived
7 albumin, what were other sources common for cell culture
8 albumin?

9 A. The most common standard is fetal bovine serum,
10 which comes from a pregnant cow that's slaughtered. The
11 fetus, the blood from the fetus is drained and used as a
12 cell culture product that includes the albumin. Also from
13 the blood of both cattle as well as humans albumin can be
14 extracted. Those are the primary sources of blood-derived
15 albumin and serum.

16 Q. Were there sources for recombinant albumin?

17 A. There was a yeast-derived albumin that was
18 manufactured as well.

19 Q. What are some of the benefits that Ventria has a
20 rice-derived albumin compared to other hosts for albumin?

21 A. Compared to the blood or fetal bovine serum type
22 origin, there's a significant benefit of using rice because
23 it's a plant, number one; number two, it doesn't harbor the
24 viruses and pathogens that may come from the blood supply.
25 So any type of virus that might come from blood, HIV would

1 be one, and the case of COVID actually could be an issue, or
2 in the case of cattle blood, there was -- there's a big
3 concern and still is today about prion contamination that
4 causes mad cow disease in cattle and Creutzfeldt-Jakob
5 disease in humans. And so there was a need to have a
6 scalable and effective source of albumin that did not come
7 from a blood source.

8 And the yeast-derived product was available, as I
9 mentioned, but it's very, very expensive, and it limited the
10 market opportunity for that product, because it was just too
11 expensive.

12 Q. May I ask to put up demonstrative slide 5 for a
13 moment.

14 Are there supply chain and availability benefits
15 to rice over other hosts?

16 A. Rice is attractive in a scalability sense
17 because, as you might think about growing rice, you know, it
18 involves water, it involves land, air, and a rice plant, and
19 the energy source is the sun. And so we can, because of our
20 yield of recombinant albumin in the seed, that was a key
21 advantage, we could make a large amount of albumin per acre
22 of land. And it's a significant advancement for scalable
23 manufacturing of recombinant protein.

24 Q. I'm going to ask Ms. Hitchens to pull up Joint
25 Exhibit 117, JX-117.

1 Mr. Deeter, do you recognize Exhibit JX-117?

2 A. Yes.

3 Q. What is this?

4 A. This looks to be one of our selling sheets or
5 product brochures that was used for the marketing of the
6 product.

7 Q. And can you tell me which -- about what year this
8 document is from? We can look at the second page, if that
9 helps you.

10 A. Okay. It looks like the last quarter of 2006
11 approximately. It says that's when the product would be
12 available.

13 Q. There's a revision date at the bottom of this
14 page. It's really small. Do you see that?

15 A. Let me see. Is that -- July of 2006.

16 Q. Does that comport with your recollection of when
17 Ventria started offering Cellastim?

18 A. Yeah, this would have been when we were beginning
19 the activities to think about the marketing of the product.

20 Q. And when, again, was Cellastim first sold?

21 A. In early 2007.

22 Q. How did the market first receive rice-derived
23 albumin in 2006-2007?

24 A. Initially it was a struggle. We had a lot of --
25 there was a lot of interest conceptually to the idea that we

1 talked about for plant-derived and rice-derived albumin.
2 The challenge was making a high-quality product
3 consistently.

4 Q. Did you have any issues with Cellastim in 2007
5 with respect to the quality of the product?

6 A. Yeah. We had customers who set specifications
7 related to our product, most notably the performance and the
8 endotoxin levels of the product and the quality of the
9 product.

10 Q. What kind of steps did you have to do to gain
11 market acceptance?

12 A. We needed to lower those impurities.

13 Q. And was that something that was easy for Ventria
14 to do, difficult for Ventria to do?

15 A. It was very difficult.

16 Q. How long did that take?

17 A. It took us several years and a lot of trial and
18 error, mostly error. There was a lot of effort made to try
19 different strategies to improve the quality of the product.
20 It was a classic case of the scientific method. We would
21 have a hypothesis. We would test it. Most of the times it
22 didn't work or it didn't achieve our objective. And so it
23 was difficult to reach the goals that the customers had for
24 the product in the early days.

25 Q. Did Ventria encounter any application acceptance

1 issues?

2 A. You mean by the customer?

3 Q. By the customer. Did the customer come to
4 Ventria with any problems with how do we use this?

5 A. Yeah, there was a lot of -- it's actually why we
6 started our cell culture lab was so that we could replicate
7 the problems that the customer was seeing.

8 You know, I was pretty naive when we started,
9 myself and our team of scientists that worked on this. We
10 thought we could just extract and purify the protein and
11 sell it and everything would be great and we would scale up
12 and go.

13 What we learned, though, as the customers tested
14 the product, it didn't work for them as expected. And so
15 what we had to do was develop our own cell culture lab, and
16 we hired cell culture scientists, virologists, people that
17 had expertise in this area so they could teach us how the
18 protein was used, how it compared to fetal bovine serum, how
19 it compared to human serum albumin, and how it compared to
20 bovine serum albumin.

21 And so that cell culture lab was really a key to
22 us understanding the performance of the product. And then
23 we also had to understand how to improve processing,
24 different processing methods, that would work to get, not
25 only the performance, but also the endotoxin targets that

1 the media industry and the injectable drug industry required
2 so that you're not injecting either the cell or the human
3 with a high level of endotoxin, which could be toxic.

4 Q. Did you employ additional people when you added
5 the cell culture teams?

6 A. Yes. We had -- Ning was our VP of R&D, and he
7 really was the lead scientist, and working for him was Steve
8 Pettit and Mary Ann Santos, Dana Lee. We hired several
9 people to develop the cell culture lab so that we could
10 replicate what the customers see.

11 Q. Were these primarily scientists?

12 A. Yeah, all scientists.

13 Q. We haven't introduced the patent yet, but some of
14 the names that you gave me, were those inventors on the '951
15 patent?

16 A. Yes.

17 Q. And did that include Ning Huang?

18 A. Yes, Ning was our VP of R&D.

19 Q. Is Mr. Huang retired?

20 A. He retired from the company, yes.

21 Q. Let's talk about the market for rice-derived has.
22 Currently how big is the U.S. market for rice-derived has --
23 rHSA?

24 A. It's impossible to state exactly, but I believe
25 it's around \$50 million.