IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

VANDA PHARMACEUTICALS INC.,	)	Civil Action
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
ROXANE LABORATORIES, INC.,	)	
	)	
Defendant.	)	No. 14-757-GMS

- - -

Wilmington, Delaware
Monday, February 29, 2016
9:00 a.m.
Trial Day 1

- - -

BEFORE: HONORABLE GREGORY M. SLEET, U.S.D.C.J.

APPEARANCES:

KAREN JACOBS, ESQ., and
ETHAN H. TOWNSEND, ESQ.
Morris Nichols Arsht & Tunnell LLP
-and-
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Counsel for Defendant

- - -

molecule, which actually failed. They gave the license to Titan Pharmaceuticals, a San Francisco-based company, which in turn sought to find a partner to develop iloperidone product. That partner was Novartis, who sublicensed the product from Titan.

Q. And did Novartis own the rights to iloperidone in the period that's shown here from '97 to 2004?

A. That is correct.

Q. And was that during the period of time -- it was during that period of time that you worked at Novartis?

A. I overlapped the period of time at Novartis from '98 to 2003.

Q. All right. And during that period of time were you personally involved in some of the work on developing iloperidone?

A. Yes, I was.

Q. Please describe for us what Novartis was doing during that period of time.

A. Novartis undertook an extensive clinical development program for the purpose of eventually obtaining the U.S. FDA approval in commercializing the product for the treatment of schizophrenia, so in that course, it is likely that they expended great resources of hundreds of millions of dollars, and numerous studies, both pre-clinical and clinical.

Q. And what happened next in terms of the ownership of

2:38:34 1 **Fanapt?**
2:38:35 2 A. **Novartis decided around 2003 to stop the program and**
2:38:45 3 **seek to identify a party that would outline the**
2:38:51 4 **productivity. I had founded Vanda in 2003, and we obtained**
2:38:55 5 **the license to iloperidone in 2004.**
2:38:58 6 Q. **And describe briefly, there's no need to get into**
2:39:05 7 **anything confidential, the terms of that transaction by**
2:39:10 8 **which Vanda acquired the rights to Fanapt or iloperidone**
2:39:15 9 **from Novartis in 2004.**
2:39:17 10 A. **Yes. It was a small, up-front payment of about a**
2:39:23 11 **half-a-million dollars, and Vanda would be responsible for**
2:39:27 12 **all further development and commercialization, and Novartis**
2:39:32 13 **would receive on the back end a royalty are payment of about**
2:39:37 14 **ten percent and some milestones.**
2:39:39 15 Q. **And so then what happened in 2004 once Vanda had**
2:39:46 16 **obtained the rights to iloperidone?**
2:39:48 17 A. **Well, using all the information available, and**
2:39:54 18 **concluding the pharmacokinetics that were started, in**
2:39:59 19 **discussions with the FDA, we began the next phase of the**
2:40:05 20 **clinical development program with a large Phase 3 efficacy**
2:40:09 21 **study which resulted in an NDA filing, and finally, NDA**
2:40:17 22 **approval in May of 2009.**
2:40:18 23 Q. **And after FDA approval, was there a further**
2:40:25 24 **transaction in terms of the ownership of the product?**
2:40:27 25 A. **That is correct.**

2:40:30 1 Q. **How did that come about?**
2:40:32 2 A. **At the time of approval, Vanda did not have any**
2:40:35 3 **commercial capacity, and we sought to identify a commercial**
2:40:40 4 **partner for the product to commercialize in the U.S.**
2:40:43 5 **Novartis at that time showed interest in**
2:40:47 6 **reacquiring the rights, and at this time, the publicly**
2:40:52 7 **announced deal was with a 200 million up-front payment, and**
2:40:59 8 **so royalties and milestones based on net revenue.**
2:41:04 9 Q. **And why the difference in those up front payments of**
2:41:11 10 **500,000 in 2004 and 200 million five years later?**
2:41:17 11 A. **Well, at the beginning there was a compound that**
2:41:22 12 **was going nowhere, and in 2009 it was an FDA-approved**
2:41:27 13 **compound.**
2:41:28 14 Q. **Why is it that in 2004 it was going nowhere?**
2:41:31 15 A. **Novartis had decided to abandon the program in part,**
2:41:38 16 **maybe in large part due to their identification of the QT**
2:41:44 17 **prolonging effects of the molecule that they felt they may**
2:41:47 18 **not be able to overcome for regulatory approval.**
2:41:50 19 Q. **And did Novartis follow in the transaction in 2009**
2:41:57 20 **actually commercialize the molecule?**
2:41:59 21 A. **Yes, they did. They commercialized Fanapt in the U.S.**
2:42:03 22 **in the beginning of 2010.**
2:42:04 23 Q. **And has it been on the market ever since?**
2:42:06 24 A. **That is correct.**
2:42:07 25 Q. **And please explain for us this last transaction that**

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