

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SANDOZ INC.,  
Petitioner,

v.

PHARMACYCLICS LLC,  
Patent Owner.

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IPR2019-00865  
Patent 9,795,604 B2

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Record of Oral Hearing  
Held: June 19, 2020

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Before SHERIDAN K. SNEDDEN, SUSAN L. C. MITCHELL, and  
DAVID COTTA, *Administrative Patent Judges*.

IPR2019-00865  
Patent 9,795,604 B2

APPEARANCES:

ON BEHALF OF THE PETITIONER:

KIRK BRADLEY, ESQ.  
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ON BEHALF OF THE PATENT OWNER:

WILLIAM B. RAICH, ESQ.  
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The above-entitled matter came on for hearing on Friday, June 19, 2020, commencing at 9:00 a.m. EDT, by video/by telephone.

PROCEEDINGS

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JUDGE COTTA: Good morning. This is the Final Hearing in IPR2019-00865 regarding Claims 1, 4, 6 through 10, 13, 15, 24, 28 through 31, 35, 39, 43 through 46, 50 through 53 and 55. This is patent number 9,795,604. The Petitioner is Sandoz, Inc., the Patent Owner is Pharmacyclics LLC. The hearing is open to the public and a full transcript of the hearing will be made part of the record.

I'm Judge Cotta, with me are Judges Snedden and Mitchell. Counsel for Petitioner, could you please identify yourself for the record?

MR. BRADLEY: Good morning, Your Honors, this is Kirk Bradley of Alston & Bird on behalf of the Petitioner, Sandoz, Inc.

JUDGE COTTA: Okay and counsel for Patent Owner, would you kindly identify yourself for the record?

MR. RAICH: Good morning, Your Honors, this is Bill Raich from Finnegan on behalf of Patent Owner, Pharmacyclics.

JUDGE COTTA: Okay, so as set forth in our Hearing Order of May 15th, each side has one hour to present its case. My colleagues and I will do our best to keep track of time, but we suggest that the parties do the same. Counsel for the Petitioner, would you like to reserve any time for rebuttal?

MR. BRADLEY: Yes, Your Honor, I would like to reserve 15 minutes, please.

JUDGE COTTA: Okay. And counsel for Patent Owner, you're entitled to the last word today, if you wish, would you like to reserve any of your time?

MR. RAICH: I would, Your Honor, I'd like to reserve 10 minutes.

1 JUDGE COTTA: Okay. Before we begin there are a few things that  
2 I'd like to cover. First, on behalf of the Board, we'd like to thank you all for  
3 your flexibility in participating in this all video hearing. Given that this is a  
4 departure from our typical practice, I first emphasize that our primary  
5 concern is your right to be heard. So, if at any point during the proceeding  
6 you encounter technical or other difficulties that you feel undermine your  
7 ability to adequately represent your client, please let us know immediately.

8 Second, when you're not speaking, please mute your microphone to  
9 make for a clearer record. Third, for the benefit of the court reporter, please  
10 identify yourself every time you speak. Fourth, we have access to the entire  
11 record including demonstratives. For the benefit of the record and to enable  
12 us to follow along better please when referring to each demonstrative paper  
13 or exhibit do so by slide or page number and give us a few seconds to find it.

14 Finally, should you come to a good faith belief that the pace of this  
15 proceeding prevents you from adequately explaining your position, please  
16 speak up and we'll consider extending the allotted time.

17 Petitioner, you go first as you bear the burden of showing  
18 unpatentability of the challenged claims. You can begin whenever you're  
19 ready.

20 MR. BRADLEY: Thank you, Your Honors, and good morning again.  
21 Kirk Bradley on behalf of Petitioner. I would like to start in our slide deck  
22 at slide 24, please. Slide 24, the '085 Publication anticipates and renders  
23 obvious all challenged claims. And I want to start here because, really, this  
24 is the core of all four of Petitioner's independent ground of unpatentability  
25 for all of its challenged claims.

1 Moving to Slide 25 we see here Claim 1 of the 604 Patent. The main  
2 thing I want to point out here is that the chemical structure is shown in the  
3 claim, but there's no dispute that that chemical structure represents the drug  
4 compound Ibrutinib. And I do want to note for Your Honors also that there's  
5 a certificate of correction appended to the patents that corrects the stereo  
6 chemistry shown here. But in any event, there's no dispute that the  
7 compound itself is Ibrutinib.

8 Moving to slide 26. On this slide we've taken the exact language of  
9 the claim and substituted the chemical compound for the word Ibrutinib and  
10 then we've broken it down into three parts: the preamble; the one method  
11 step that recited; and, then the thereby clause. And we power coded these so  
12 that we can follow along easier.

13 On Slide 27, it's really the beginning of the focus of the claim where  
14 we have the preamble reciting a method of treating chronic GVHD. The  
15 '085 Publication expressly discloses that limitation, if it's a limitation. I note  
16 that it's a preamble, the Board doesn't have to decide whether this preamble  
17 is limiting or not. It doesn't matter because it's expressly disclosed.

18 Here we see on Slide 27, paragraph 116 through 120 of the '085  
19 Publication where the publication describes and defines the word treating. It  
20 defines it as including inhibiting the disease and for leaving the disease.  
21 And, in fact, that definition of treating is very similar to the definition of  
22 treating used in the '604 Patent. It's found in the '604 Patent at column 26  
23 line 47 to 51. In the '604 patent, it talks about lessening the severity of the  
24 disease, relieving a condition of the disease and that's the same thing we see  
25 here in the '085 Publication. In paragraph 120, we see a specific reference to

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