

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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INTAS PHARMACEUTICALS LTD.,

Petitioner

v.

ATOSSA THERAPEUTICS, INC.,

Patent Owner

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Case PGR2023-00043

Patent No. 11,572,334

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**PETITIONER’S OBSERVATIONS ON THE CROSS-EXAMINATION OF  
STEPHEN G. DAVIES, D. PHIL.**

Pursuant to the Board's email (Ex. 3001), Petitioner provides the following observations on the cross-examination of Dr. Stephen G. Davies (Ex. 1033).

Citation	Responsive To	Statement of Relevance
22:23-24:20; 25:14-27:24; 28:17-30:6 30:21-32:7; 32:19-25; 40:16-41:6	Paper 21 at 11-12 (Patent Owner arguing Dr. Bihovsky modified Liu's synthetic pathway)	Dr. Davies admits that the alleged modifications Dr. Bihovsky made to Liu's synthesis were not beyond the ordinary skill of a POSA and were either (1) due to the differences in scale; (2) an attempt to avoid introducing water which Liu suggests is necessary; or (3) routine.
42:5-43:8	Paper 21 at 11-12 (Patent Owner arguing Dr. Bihovsky's synthesis modifications suggest a POSA could not follow Liu's purification teachings)	Dr. Davies acknowledges that Dr. Bihovsky obtained crude endoxifen similar in E to Z ratio as Liu reports following the synthesis, and before purification.
63:13-64:19	Paper 21 at 11-12 (Patent Owner arguing Dr. Bihovsky modified Liu's purification teachings and this cuts away from suggesting enablement)	Dr. Davies acknowledges that many of the modified experiments that allegedly do not follow Liu's crystallization procedures were not the subject of Dr. Bihovsky's declaration
54:7-14; 56:24-57:10; 61:4-62:12; 70:2-72:22	Paper 21 at 11-12 (Patent Owner arguing Dr. Bihovsky modified Liu's purification teachings and this cuts away from suggesting enablement)	Dr. Davies acknowledges that Dr. Bihovsky performed two purification schemes addressed by Liu (sequential recrystallization and isomerization), and Dr. Davies addressed only the sequential recrystallization pathway (Liu Examples 5 and 7), and not the isomerization pathway (Liu Examples 6 and 7)—both of which independently achieved 90% pure (Z)-endoxifen.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

Dated: September 30, 2024

By: /Alejandro Menchaca/  
Alejandro Menchaca  
Reg. No. 34,389  
*Lead Counsel for Petitioner*  
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## CERTIFICATE OF SERVICE

Under 37 C.F.R. §§ 42.6(e)(4) and 42.105, the undersigned certifies on this date, a true and correct copy of these Observations and Exhibit 1033 were sent to counsel for Patent Owner at the following email addresses:

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Dated: September 30, 2024

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