

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BAXTER HEALTHCARE CORP., APATECH, INC., and
APATECH LIMITED,
Petitioner,

v.

MILLENIUM BIOLOGIX, LLC,
Patent Owner.

Case IPR2013-00582 (Patent No. RE41,251)
Case IPR2013-00590 (Patent No. 6,585,992)

Before MICHELLE R. OSINSKI, SCOTT E. KAMHOLZ, and
BRIAN P. MURPHY, *Administrative Patent Judges*.

MURPHY, *Administrative Patent Judge*.

ORDER
Conduct of the Proceeding
37 C.F.R. § 42.5

On September 23, 2014, Petitioner filed its Reply to Patent Owner's Response to the Petition, and an Updated Exhibit List. Papers 23 and 24.¹ As part of its Reply papers, Petitioner filed a number of additional exhibits, including the Declaration of Professor Andrew Ruys ("Ruys Declaration"). Ex. 1135. Professor Ruys is the named author of Petitioner's Exhibit 1011 (the "Ruys '93a" article), one of the prior art references on which we based our decision to institute *inter partes* review of US Patent RE41,251 ("the '251 patent"). Paper 8. Petitioner also filed Exhibits 1143-1171, which are exhibits to the Ruys Declaration, and a Reply Declaration of their expert Dr. Antonios Mikos ("Mikos Reply Declaration"). Ex. 1134.

By emails dated October 1 and October 2, 2014, on which counsel for Petitioner was copied, Patent Owner objected to Petitioner's submission of the Ruys Declaration and attendant exhibits (Ex. 1135, 1143-1171), and the portions of the Mikos Reply Declaration (Ex. 1134 ¶¶ 49-61) containing testimony relating to the Ruys Declaration and exhibits. Patent Owner objected to the identified evidence as "improper, belatedly presented evidence as set forth in the Trial Practice Guide at page 48,767, paragraph I." Petitioner maintained "that the evidence is appropriately in

¹ Our citations are to the papers and exhibits filed in IPR2013-00582. These documents appear as Papers 24 and 25 in IPR2013-00590. While there are differences between Petitioners' Reply to Patent Owner's Response to the Petition in IPR2013-00582 (Paper 23) and IPR2013-00590 (Paper 24), such differences generally relate to the differences in the claims of the patent being challenged in each case. Both documents, however, include reference to Professor Ruys' reproduction of experiments. The Updated Exhibit List in IPR2013-00590 (Paper 25) is identical to that submitted in IPR2013-00582 (Paper 24), except for the inclusion of additional Exhibit Nos. 1172-1177.

reply to Patent Owner's arguments and /or evidence." Patent Owner requested guidance on how to proceed with its objection.

On October 6, 2014, the Board (Judges Osinski, Kamholz, and Murphy) convened a telephone conference with counsel for the parties to hear argument on Patent Owner's objection and Petitioner's response. Counsel for Patent Owner explained that the dispute revolves around the substantive issue of whether the Ruys '93a reference inherently discloses a silicon-substituted calcium phosphate material having the "microporous structure" claimed in the '251 patent, as asserted by Petitioner. Paper 1, Pet. 43-45. Patent Owner objected to the Ruys Declaration, which describes experiments conducted by Professor Ruys from approximately July 23, 2014 to sometime in September 2014 (Ex. 1144, 4-7 (Ruys Notebook entries)) that were asserted by Petitioner (Paper 23, Pet. Reply 7)² to replicate the experiments described in Ruys '93a (Ex. 1135 ¶¶ 8-15). Patent Owner further objected to the Ruys Declaration exhibits, which include test data in the form of Scanning Electron Micrographs ("SEMs"), pore size distribution curves, and Nano-CT images (Ex. 1145-1171) bearing on the issue of whether the material recently prepared by Professor Ruys formed a microporous structure. Patent Owner also objected to the portion of the Mikos Reply Declaration (Ex. 1134 ¶¶ 49-61) testimony based on the Ruys Declaration and exhibits.

Patent Owner argued that the Board should not consider the new evidence in support of Petitioner's inherent anticipation argument, because the evidence was belatedly-presented new evidence that contravened the

² See Paper 24, Pet. Reply 8-9 in IPR2013-00590.

Board's rule governing the proper scope of a petitioner's reply. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,767 (Aug. 14, 2012) (citing 37 C.F.R. § 42.23). Patent Owner argued that at the time the Petition was filed, Petitioner had the opportunity to "set the table" by presenting arguments and evidence in support of its Petition, but Petitioner had not presented any experimental evidence to support the asserted inherent disclosure of the material in Ruys '93a having a microporous structure. Patent Owner further argued that it would be unfairly prejudiced if it had to respond to the new evidence submitted by Petitioners, given the very limited time remaining pursuant to the Scheduling Order, as recently modified by the parties at Petitioner's request. Paper 22.³ Patent Owner argued that it was unfair for Patent Owner to have to depose Professor Ruys, possibly conduct tests of its own and prepare a rebuttal declaration, prepare observations on Professor Ruys's deposition and a possible motion to exclude, all by October 10 (Due Date 4), little more than two weeks after Petitioner's Reply had been filed.

Counsel for Petitioner responded that the Ruys Declaration and exhibits were submitted in response to Patent Owner's argument that "without actually making material as described by Ruys and testing it to determine if it has interconnected microporosity, one of skill in the art could not conclude anything about the pore size or connectivity of Ruys based on example 5 of RE'251." PO Resp. 14-15 (Paper 20) (citing Ex. 2026 ¶ 52)⁴.

³ See Paper 23 in IPR2013-00590.

⁴ The Patent Owner Response appears as Paper 21 in IPR2013-00590. While the paper in IPR2013-00590 does not include the same quotation, it does refer to Mikos' failure to "offer . . . independent technical analysis"

Petitioner argued that it also was responding to Dr. Ong's deposition testimony where Petitioner asked Dr. Ong why he had not tried to reproduce the methods disclosed in Ruys '93a. Ex. 1133. 119:13-122:21. Petitioner further argued it was merely attempting to disprove Dr. Ong's "hypothesis," that without actually making and testing the material disclosed in Ruys '93a one of ordinary skill lacked sufficient information to conclude the material has a microporous structure.

We are persuaded by Patent Owner's arguments. Rule 42.23(b) provides that "[a] reply may only respond to arguments raised in the . . . patent owner response." 37 C.F.R. § 42.23(b). Our Trial Practice Guide provides that "a reply that raises a new issue or belatedly presents evidence will not be considered and may be returned. . . . Examples of indications that a new issue has been raised in a reply include new evidence necessary to make out a *prima facie* case for the patentability or unpatentability of an original or proposed substitute claim, and new evidence that could have been presented in a prior filing." 77 Fed. Reg. 48,767 ¶ I. We see no reason why Petitioner could not have presented experimental evidence to support its argument of inherent anticipation by Ruys '93a at the time the Petition was filed, and Petitioner did not argue to the contrary. Nor did Petitioner request authorization to file supplemental information in support of its Petition more than one month after trial was instituted, even though Patent Owner's

(Paper 21, 36) and asserts that differences in size of hydroxyapatite particles and sintering temperature in Ruys and the '992 patent "is of such significance that it would be impossible [to] assess a probability, much less conclude with certainty, that they would result in products having the same properties" (Paper 21, 39) (citing Ex. 2026 ¶ 47).

Response was filed on June 27, 2014 (Paper 20). 37 C.F.R. § 42.123(b).⁵ Petitioner did not argue, for example, that Dr. Mikos was unable to run the experiments from the information presented in Ruys '93a or that Professor Ruys was unavailable prior to Petition filing. When questioned by the Board as to why Petitioner had not presented the Ruys Declaration and exhibits at the time its Petition was filed, counsel responded that Dr. Mikos “felt comfortable” working from the Ruys '93a disclosure and other references on which he relied for his opinion that Ruys '93a inherently discloses a material having a “microporous structure,” as claimed in the '251 patent.

We are cognizant that, although Petitioner’s newly submitted evidence might have been stimulated by Patent Owner’s Response to the Petition (Pet. Reply 7), it was Petitioner who decided to rely on the declaration of its expert without experimental evidence in support of its inherent anticipation argument. Petitioner’s Reply now includes, for the first time, experimental evidence of asserted microporosity in the material disclosed in Ruys '93a. Petitioner’s Reply does more than merely respond to (i.e., rebut), points made in Patent Owner's Response. Specifically,

⁵ *Late submission of supplemental information.* A party seeking to submit supplemental information more than one month after the date the trial is instituted, must request authorization to file a motion to submit the information. The motion to submit supplemental information must show why the supplemental information reasonably could not have been obtained earlier, and that consideration of the supplemental information would be in the interests-of-justice. *See Corning Incorporated v. DSM IP Assets B.V.*, Case IPR2013-00047, Paper 84, 16-17 (PTAB, May 1, 2014) (“To permit consideration of the ‘new’ evidence would, in our judgment, be unfair to DSM--absent a possible rebuttal period which might have been ordered had Corning timely sought leave to file supplemental information.”).

Petitioner's new evidence bears on the question of whether the Ruys '93a material *actually* is microporous, not whether one of ordinary skill in the art would know from the Ruys '93a disclosure that the material was microporous. We believe it is unfair to Patent Owner, and not in the interests of justice at this late stage of the case, to impose additional time and financial burdens on Patent Owner to respond to Petitioner's new evidence.

For the reasons given above, we determine that Petitioner's challenged evidence exceeds the permissible scope of reply. *See* 37 C.F.R. § 42.23(b); 77 Fed. Reg. 48,767 ¶ I.

ORDER

In view of the foregoing, it is

ORDERED that Petitioner's Reply evidence, Exhibit 1134 ¶¶ 49-61, Exhibit 1135, and Exhibits 1143-1171, will not be considered by the Board in rendering final written decisions in the above-captioned cases.

Case IPR2013-00582

Patent RE41,251

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