

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS
USA, INC., and AKORN INC.

Petitioners,

v.

ALLERGAN, INC.,

Patent Owner.

Case IPR2016-01127 (8,685,930 B2)

Case IPR2016-01128 (8,629,111 B2)

Case IPR2016-01129 (8,642,556 B2)

Case IPR2016-01130 (8,633,162 B2)

Case IPR2016-01131 (8,648,048 B2)

Case IPR2016-01132 (9,248,191 B2)

Before SHERIDAN K. SNEDDEN, TINA E. HULSE, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

ORDER

Granting-in-part Petitioner's Motion for Additional Discovery

37 .F.R §§ 42.51(b)(2), 42.52(a)

IPR2016-01127 (8,685,930 B2); IPR2016-01128 (8,629,111 B2);
IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);
IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

INTRODUCTION

Pursuant to our authorization, Petitioner filed a motion for additional discovery. Paper 22¹ (“Motion” or “Mot.”). Patent Owner filed an opposition. Papers 27 (“opposition” or “Opp.”). In its Motion, Petitioner requests an order requiring Patent Owner to produce (i) the phase 2 clinical trial (192371-001) data, (ii) the phase 3 clinical trial data (192371-002 and -003), and (iii) the pharmacokinetic (“PK”) data underlying Schiffman Exhibits B–F (Ex. 1004, 213–223), Attar Exhibits B–D (Ex. 1004, 237–242), and Sall Figures 1–4 (Ex. 1007).

Additional discovery may be ordered if the party moving for the discovery shows “that such additional discovery is in the interests of justice.” 37 C.F.R. § 42.51(b)(2). The Board has identified five factors (“the *Garmin* factors”) important in determining whether additional discovery is in the interests of justice. *Garmin Int’l, Inc. v. Cuozzo Speed Techs. LLC*, Case IPR2012-00001, slip op. at 6–7 (PTAB Mar. 5, 2013) (Paper 26) (informative). These factors are: (1) more than a possibility and mere allegation that something useful will be discovered; (2) requests that do not seek other party’s litigation positions and the underlying basis for those positions; (3) ability to generate equivalent information by other means; (4) easily understandable instructions; and (5) requests that are not overly burdensome to answer. *Id.* We address each of Petitioner’s requests in view of the *Garmin* factors below.

¹ Identical papers were filed in each of the identified cases. Hereinafter, reference will be made to papers filed in IPR2016-01127.

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A. *PK data underlying Schiffman Exhibits B–F and Attar Exhibits B–D*

Based on the specific facts of this case, we are persuaded that it is in the interest of justice to allow the requested discovery with regard to the PK data underlying Schiffman Exhibits B–F and Attar Exhibits B–D in order for Petitioner to develop fully its rebuttal to Patent Owner’s evidence of unexpected results. Here, the first *Garmin* factor is most relevant. Patent Owner relies upon the figures in the Schiffman and Attar declarations to support its response to Petitioner’s obviousness grounds. As noted by Petitioner, however, the figures “failed to provide the necessary parameters for scientific interpretation, including raw data values and error rates.” Mot. 2 (citing Paper 3, 47–57). Thus, we agree with Petitioner that the underlying data is necessary to evaluate figures fully, will aid Petitioner’s rebuttal to Patent Owner’s arguments and evidence, and will afford Petitioner a fair cross-examination of Patent Owner’s witnesses. 37 C.F.R.

§§ 42.51(b)(2)(i)-(ii). Accordingly, we find that there is more than a possibility that something useful will be discovered by granting Petitioner’s discovery request for this information. We further note that our rule § 42.65 favors the disclosure of the underlying facts or data on which an expert’s testimony is based. 37 CFR § 42.65.

Regarding the remaining *Garmin* factors, we acknowledge Patent Owner’s arguments, but find that the request does not seek to uncover an opponent’s litigation position (*Garmin* Factor 2), does not seek information that could be obtained through other means (*Garmin* Factor 3), is easily understood (*Garmin* Factor 4), and is limited in scope and does not place an undue burden on Patent Owner (*Garmin* Factor 5).

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Accordingly, we grant Petitioner's motion and order Patent Owner to produce the PK data underlying Schiffman Exhibits B–F and Attar Exhibits B–D.

B. PK data underlying Sall Figures 1–4

We deny Petitioner's request as to the PK data underlying Sall Figures 1–4. As noted by Patent Owner, Sall is a peer-reviewed publication that summarizes the efficacy data of Patent Owner's phase 2 and phase 3 clinical trial studies. Opp. 1. Unlike the figures presented in the Schiffman and Attar declarations, Sall Figures 1–4 are shown with mean value and standard error rates. Ex. 1007, 635–636. Thus, Sall Figures 1–4 do not suffer from the same deficiencies identified by Petitioner in the exhibits of the Schiffman and Attar declarations. We otherwise agree with Patent Owner that Sall Figures 1–4 discloses the “necessary information to answer the question of whether the efficacy results are significant.” Opp. 1.

Petitioner fails to identify any other deficiency in the manner in which Sall Figures 1–4 are presented. Accordingly, in view of the above, we are not persuaded that something useful will be discovered by granting Petitioner's discovery request with regard to Sall Figures 1–4.

C. Phase 2 Clinical Trial Data and Phase 3 Clinical Trial Data

We deny Petitioner's request as to phase 2 and phase 3 clinical trial data. Petitioner seems to suggest that the requested phase 2 and phase 3 clinical trial data was used to produce Schiffman Exhibits B–F, Attar Exhibits B–D, and Sall Figures 1–4. Mot. 4. To the extent that this request overlaps Petitioner's requests with regard to Schiffman Exhibits B–F, Attar Exhibits B–D, and Sall Figures 1–4, we addressed those requests above. To

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the extent that Petitioner's request does not overlap with its other requests, Petitioner's request is overly broad and is not narrowly tailored to any specific issue in these proceedings. Accordingly, Petitioner's request is unlikely to uncover something useful and is overly burdensome, thus failing *Garmin* Factors 1 and 5.

ORDER

Accordingly, it is:

ORDERED that Patent Owner shall produce the pharmacokinetic ("PK") data underlying Schiffman Exhibits B–F and Attar Exhibits B–D; and

FURTHER ORDERED that Petitioner's motion is *denied* as to all other requests for additional discovery.

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