IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS X LLC,
Petitioner,

v.

ANACOR PHARMACEUTICALS, INC.,
Patent Owner.

Case No. IPR2015-01776
Patent No. 7,582,621

PATENT OWNER'S IDENTIFICATION OF NEW ARGUMENTS AND EVIDENCE IN PETITIONER'S REPLY

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

Pursuant to the Board's September 20, 2016 e-mail authorization, Anacor hereby provides a listing of new arguments and evidence in Petitioner's Reply.

I. Low MIC values and molecular weight in Austin alone provide a reasonable expectation of success.

See Ex. 1044 ¶ 94, p. 62, l. 19–p. 63, l. 2 ("Therefore, based on the disclosure of Austin *alone*, which shows very low MIC values associated with a low molecular weight antifungal (tavaborole), a POSITA would have had a reasonable expectation of successfully treating onychomycosis."); Reply, p. 15, ll. 6–8 ("Tavaborole's combination of low MIC values and low molecular weight makes it the first compound to choose from *Austin* for treatment of onychomycosis."); Reply p. 18, ll. 2–4 ("A POSITA only needs to know the molecular weight and MIC values of a compound to have a reasonable expectation of success.") (citing in part Ex. 1044 ¶ 94 (quoted above)); Reply p. 23, l. 4 ("Regardless, *Austin* discloses the activity of tavaborole, not *Freeman*"); *cf.* Petition, Grounds 1–3, at iii; Petition p. 33, ll. 6–16; Petition p. 34, ll. 18–20; Petition p. 47, ll. 3–7; Ex. 1008 ¶ 98, p. 32, ll. 6–17; Ex. 1008 ¶ 100, p. 33, ll. 5–8; Ex. 1008 ¶ 127, p. 43, ll. 6–12; Ex. 1008 ¶ 132, p. 45, ll. 6–8.

II. Activity against *C. albicans* was predictive of activity against dermatophytes, and provides a reasonable expectation of success.

See Reply p. 2, ll. 13–14 ("Antifungal activity against *C. albicans* furnishes a reasonable expectation of success against dermatophytes."); Reply p. 16, ll. 10–

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

12 ("It was known in the art before 2005 that antifungal compounds with fungicidal activity against *C. albicans* (a yeast) almost always had the same or better activity against dermatophytes.") (citing Mertin, Ex. 1065, as the only prior art support in Section V); Ex. 1044 ¶ 89, p. 58, ll. 1–2 ("[I]f effectiveness against yeasts (e.g., *C. albicans*) is known, a POSITA would reasonably expect effectiveness against dermatophytes.") (discussing Mertin); *cf.* Petition p. 40, l. 34–p. 41, l. 12 (citing only Brehove for Claim 6's limitation of treating tinea unguium); Petition p. 37, ll. 8–18; Petition p. 54, ll. 13–26 (citing only Freeman for Claim 6's limitation of treating tinea unguium); Petition p. 49, ll. 7–11; Ex. 1008 ¶ 98, p. 32, ll. 6–17; Ex. 1008 ¶ 130, p. 44, ll. 8–18.

III. Nail penetration was predictable based on molecular weight alone, irrespective of structural similarities between the compounds.

See Reply p. 18, ll. 8–9 ("*Mertin* established that the ability of a compound to penetrate the nail is directly proportional to its molecular weight."); Reply p. 19, ll. 16–18 ("The lower the molecular weight of a compound, the greater the ability of the compound to penetrate the nail."); Reply p. 19, ll. 5–9 ("*Murdan* … concluded 'molecular size has an inverse relationship with penetration into the nail plate … .'"); *cf.* Petition p. 32, l. 18–p. 33, l. 1 (citing the "effective *Brehove* compounds" for "successfully penetrating the nail"); Ex. 1008 ¶ 95, p. 31, ll. 4–9; Petition p. 50, l. 3 (citing Freeman's "compounds for treating and inhibiting onychomycosis"); Ex. 1008 ¶ 134, p. 46, ll. 4–8.

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

IV. Topical administration avoids toxicity.

See Reply p. 10, ll. 12–14 ("Consistent with the prior art, Petitioner's experts concluded that boron toxicity would not be a concern in early 2005 when developing a topical formulation for delivery to the nail."); Reply p. 10, ll. 7–9 ("Dr. Reider failed to address the differences between oral or intravenous administration versus topical administration"); Ex. 1044 ¶ 46, p. 24, ll. 1–3 ("I do not believe that information regarding selective toxicity was necessary for the selection of tavaborole for use in the ***topical*** treatment of onychomycosis"); *cf.* Petition p. 34, ll. 1–4; Ex. 1008 ¶ 103, p. 34, l. 19–p. 35, l. 5; Ex. 1006 ¶ 44, p. 14, ll. 12–13.

V. Structural differences between the compounds of Austin and Freeman would have led a POSA to expect different biological activities.

See Ex. 1043 ¶ 24, p. 14, l. 12–p. 15, l. 4 ("In contrast [to phenylboronic acid from Freeman], the boron within the oxaboroles disclosed by *Austin* is confined within the 5-membered ring. … This decreases the 'promiscuity' of boron because the number of configurations boron can adopt is reduced by its location within the ring … ."); Reply p. 13, ll. 14–16 ("PO's arguments also fail to address that boron's location within the heterocycle of tavaborole reduces the ability of tavaborole to interact indiscriminately.") (citing Ex. 1043 ¶¶ 24–25); *cf.* Petition p. 48, l. 20–p. 49, l. 3; Ex. 1008 ¶ 127, p. 43, ll. 9–12.

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

Date: September 27, 2016

Respectfully submitted,

By

Andrea G. Reister
Registration No. 36,253
COVINGTON & BURLING LLP
One CityCenter, 850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000
Attorney for Patent Owner

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.