

Filed on behalf of: Acrux DDS Pty Ltd. and Acrux Limited

Paper _____

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACRUX DDS PTY LTD. AND ACRUX LIMITED,
Petitioner,

v.

KAKEN PHARMACEUTICAL CO., LTD. and
VALEANT PHARMACEUTICALS INTERNATIONAL, INC.,
Patent Owner.

Case IPR2017-00190
Patent 7,214,506 B2

PETITIONERS UPDATED EXHIBIT LIST

Further to 37 C.F.R. § 42.63(e), Petitioner Acrux DDS Pty Ltd. and Acrux

Limited hereby submits a current listing of Petitioner exhibits.

EXHIBIT	DESCRIPTION
1001	U.S. Pat. No. 7,214,506 to Tatsumi et al. (“506 Patent”)
1002	Japanese Pat. App. No. 11/214369 to Tatsumi et al. and Certified English Translation Thereof (“priority document”)
1003	Press Release: “Valeant Pharmaceuticals Announces FDA Approval of Jublia® for the Treatment of Onychomycosis” (Jun. 9, 2014)
1004	Orange Book Excerpt for Valeant’s Jublia® Product, “Approved Drug Products with Therapeutic Equivalence Evaluations” (accessed July 29, 2016)
1005	Declaration of Kenneth Walters (“Walters Decl.”)
1006	Prosecution History of U.S. Pat. No. 7,214,506 (June 14, 2006)
1007	U.S. Pat. No. 5,620,994 to Naito et al.
1008	U.S. Pat. No. 5,716,969 to Naito et al.
1009	Comparison between the Priority Document (see Ex. 1002) and U.S. Pat. App. No. 10/685,266 (“266 application”)
1010	Publication of PCT/JP00/04617 (filed July 11, 2000).
1011	Japanese Pat. App. Pub. No. 10-226639 (“JP ’639”) and Certified English Translation Thereof
1012	“Synthesis and Antifungal Activities of (2R,3R)-2-Aryl-1-azolyl-3-(substituted amino)-2-butanol Derivatives ad Topical Antifungal Agents.” Ogura, H. et al., <i>Chem. Pharm. Bull</i> , 47(10) 1417-1425 (1999) (“Ogura”)
1013	U.S. Pat. No. 5,391,367 to DeVincentis (“367 Patent”)
1014	“Tioconazole nail solution—an open study of its efficacy in onychomycosis.” Hay, R.J., et al., <i>Clinical and Experimental Dermatology</i> , 10:111-115 (1985) (“Hay”)
1015	Abstracts F78, F79 and F80 from Abstracts of the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), 36 th ICAAC, held on September 15-18, 1996 (1996) (“Kaken Abstracts”)

EXHIBIT	DESCRIPTION
1016	“Bioavailability, skin- and nail penetration of topically applied antimycotics.” Stuttgen, G. and Bauer, E., <i>Mykosen</i> , 25(2): 74-80 (1992) (“Stuttgen and Bauer”)
1017	“Ciclopirox nail lacquer 8%: in vivo penetration into and through nails and in vitro effect on pig skin.” Ceschin-Roques C.G., et al., <i>Skin Pharmacol</i> , 4: 89-94 (1991) (“Ceschin-Roques”)
1018	“Absorption of amorolfine through human nail.” Franz, T.J., <i>Dermatol</i> , 184(Suppl 1): 18-20 (1992) (“Franz”)
1019	“Nail penetration of the antifungal oxiconazole after repeated topical application in healthy volunteers, and the effect of acetylcysteine.” van Hoogdalem, E.J. et al., <i>Eur J Pharm Sci</i> 5: 119-127 (1997) (“van Hoogdalem”)
1020	“The effect of keratolytic agents on the permeability of three imidazole antimycotic drugs through the human nail.” Quintanar-Guerrero, D. et al., <i>Drug Dev Ind Pharm</i> , 24: 685-690 (1998) (“Quintanar-Guerrero”)
1021	“In vitro permeability of the human nail and of a keratin membrane from bovine hooves: Influence of the partition coefficient octanol/water and the water solubility of drugs on their permeability and maximum flux.” Mertin, D. and Lippold, B.C., <i>Journal of Pharmacy and Pharmacology</i> , 49(1): 30-34 (1997) (“Merton and Lippold I”)
1022	“In vitro permeability of the human nail and of a keratin membrane from bovine hooves: Penetration of chloramphenicol from lipophilic vehicles and a nail lacquer.” Mertin, D. and Lippold, B.C., <i>Journal of Pharmacy and Pharmacology</i> , 49(3): 241-245 (1997) (“Mertin and Lippold II”)
1023	“In vitro permeability of the human nail and of a keratin membrane from bovine hooves: Prediction of the penetration rate of antimycotics through the nail plate and their efficacy.” Mertin, D. and Lippold, B.C., <i>Journal of Pharmacy and Pharmacology</i> , 49(9): 866-872 (1997) (“Mertin and Lippold III”)

EXHIBIT	DESCRIPTION
1024	“Enhancing effect of N-acetyl-L-cysteine or 2-mercaptoethanol on the in vitro permeation of 5-fluorouracil or tolnaftate through the human nail plate.” Kobayashi Y. et al., <i>Chem Pharm Bull</i> 46: 1797-1802 (1998) (“Kobayashi”)
1025	Valeant 10(q)
1026	“Management of Onychomycoses.” Niewerth, M. and Korting, H.C., <i>Drugs</i> 58(2):283-296 (1999) (“Niewerth and Korting”)
1027	“Diffusion of water through dead plantar, palmar and torsal human skin and through toe nails.” Burch, G.E. and Winsor, T., <i>Arch Derm Syphilol</i> 53: 39-41 (1946) (“Burch and Winsor”)
1028	“A comparative study of the physicochemical properties of human keratinized tissues.” Baden H.P., et al., <i>Biochim Biophys Acta</i> 322:269–278 (1973) (“Baden”)
1029	“The azole antifungal drugs.,” Hay, R.J., <i>Journal of Antimicrobial Chemotherapy</i> 20: 1-5 (1987) (“Hay 1987”)
1030	“Amorolfine nail lacquer: a novel formulation.” Marty, J.L., <i>Journal of the European Academy of Dermatology and Venereology</i> 4 (Supp. 1)(1995) S17-S21 (1995) (“Marty”)
1031	“Epidemiology and ecology of onychomycosis.” Summerbell, R.C., <i>Dermatology</i> , 194 (Supp. 1): 32-36 (1997) (“Summerbell”)
1032	“Ecology and epidemiology of dermatophyte infections.” Aly, R., <i>J. Am. Acad. Dermatol.</i> , 31:S21–S25 (1994) (“Aly”)
1033	“Onychomycosis: therapeutic update.” Scher, R.K., <i>Journal of the American Academy of Dermatology</i> , 40 (Suppl):S21–6 (1999) (“Scher”)
1034	“New therapies for onychomycosis.” Odom, R. B., <i>Journal of the American Academy of Dermatology</i> , 35:3(2): S26-S30 (1996) (“Odom”)
1035	“Miconazole alcoholic solution in the treatment of mycotic nail infections.” Vanderdonckt, J., et al., <i>Mykosen</i> , 19(7):251-256 (1975) (“Vanderdonckt”)
1036	“Comparison of Two Topical Preparations for the Treatment of Onychomycosis: <i>Melaleuca alternifolia</i> (Tea Tree) Oil and Clotrimazole.” Buck, D.S. et al., <i>The Journal of Family Practice</i> , 38(6): 601-605 (1994) (“Buck”)

EXHIBIT	DESCRIPTION
1037	“Amorolfine- A Review of its Pharmacological Properties and Therapeutic Potential in the Treatment of Onychomycosis and Other Superficial Fungal Infections.” Haria, M. and Bryson, H.M., <i>Drugs</i> , 49(1): 103-120 (1995) (“Haria”)
1038	“Measurement of water vapor loss through human nail in vivo.” Spruit, D., <i>J Invest Dermatol</i> , 56(5): 359-361 (1971) (“Spruit”)
1039	“Bioavailability, skin and nail penetration of topically applied antimycotics.” Stuttgen, G. and Bauer, E., <i>Mycoses</i> 25: 74-80 (1982) (“Stuttgen and Bauer”)
1040	“Physicochemical characterization of the human nail: I. Pressure sealed apparatus for measuring nail plate permeabilities.” Walters, K.A., Flynn, G.L. and Marvel, J.R., <i>J Invest Dermatol</i> , 76: 76-79 (1981) (“Walters 1981”)
1041	“Physicochemical characterization of the human nail: Permeation pattern for water and the homologous alcohols and differences with respect to the stratum corneum.” Walters, K.A., Flynn, G.L. and Marvel, J.R., <i>J Pharm Pharmacol</i> 35: 28-33 (1983) (“Walters 1983”)
1042	“Penetration of the human nail: the effects of vehicle pH on the permeation of miconazole.” Walters, K.A., Flynn, G.L. and Marvel, J.R., <i>J Pharm Pharmacol</i> , 37: 498-499 (1985) (“Walters 1985 I”)
1043	“Physicochemical characterization of the human nail: solvent effects on the permeation of homologous alcohols.” Walters, K.A., Flynn, G.L. and Marvel, J.R., <i>J Pharm Pharmacol</i> , 37: 771-775 (1985) (“Walters 1985 II”)
1044	Jublia® (efinaconazole) topical solution, 10% [package insert]. Shizuoka, Japan: Kaken Pharmaceutical Co. Ltd; 2014
1045	About Acrux http://www.acrux.com.au/about (Accessed 10/27/2016)
1046	Acrux Product Pipeline http://www.acrux.com.au/what-we-do/research-development-pipeline/ (Accessed 10/27/2016)
1047	Reissue Preliminary Statement from Prosecution History of In Re Reissue Application of U.S. Pat. No. 7,214,506 (01/12/2017)

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