PATENT
Attorney Docket No. 11285.0056-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
John R. Evans et al.	)	Group Art Unit: 1628
	)	
Application No.: 12/285,887	)	Examiner: HUI, San Ming R.
	)	
Filed: October 15, 2008	)	Confirmation No.: 1199
	)	
For: FORMULATION	)	**VIA EFS-WEB**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)

A. Documents Listed in the Attached SB/08 Form

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicants brings to the attention of the Examiner the documents on the attached listing. This Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of $180.00 as specified by Section 1.17(p).

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

B. Teva's Paragraph IV Letter Dated November 25, 2009

The undersigned wishes to make of record the following information. Teva Parenteral Medicines, Inc., ("Teva") filed Abbreviated New Drug Application ("ANDA") No. 200479 with the FDA seeking approval of a generic 50 mg/mL Fulvestrant injection. In connection with ANDA No. 200479, Teva sent a letter to AstraZeneca Pharmaceuticals LP dated November 25, 2009, ("Teva's Letter") concerning U.S. Patent Nos. 6,774,122 and 7,456,160 ("the '122 and '160 patents").

The instant application claims the benefit of priority from each of the '122 and '160 patents. Teva's Letter alleges that the '122 and '160 patents are obvious in light of, *inter alia*, Howell *et al.* (cited in the Information Disclosure Statement filed on June 4, 2009) and McLeskey *et al.* (cited in this Information Disclosure Statement).

All documents cited in Teva's Letter are listed in the table below. To the extent Teva's Letter provided a pinpoint citation for any of the documents, the citation is also provided below. Otherwise, the phrase "generally" appears when Teva's Letter referred to the disclosure in the given document without a citation.

References cited in Teva's Paragraph IV Letter Dated November 25, 2009, Concerning AstraZeneca's U.S. Patent Nos. 6,774,122 and 7,456,160	
Reference	**Citation**
U.S. Patent No. 5,183,814 to Dukes et al., and its "European cognate," European Patent Application No. EP 0 346 014	Generally; Col. 3, l. 66 - Col. 4, l. 4; Col. 6, ll. 20-26; Col. 9, ll. 15-25; Example 3, col. 11, ll. 1-11

References cited in Teva's Paragraph IV Letter Dated November 25, 2009, Concerning AstraZeneca's U.S. Patent Nos. 6,774,122 and 7,456,160	
Reference	**Citation**
U.S. Patent No.4,659,516 to Bowler et al. (and European Patent Application No. EP 0 138 504, which was termed an "equivalent" of U.S. Patent No.4,659,516 in Teva's Letter)	Generally
European Patent Application No. EP 0 346 014, which was termed the "European cognate" of U.S. Patent No. 5,183,814 in Teva's Letter	Generally
Howell *et al.*, "Pharmacokinetics, Pharmacological, and Anti-tumour Effects of the Specific Anti-oestrogen ICI 182780 in Women with Advanced Breast Cancer," *Brit J. Cancer* 74:300-308 (1996).	Generally; 300; 301; 302; 303; 305 Figure 2;
McLeskey *et al.*, "Tamoxifen-Resistant Fibroblast Growth Factor-Transfected MCF-7 Cells are Cross-Resistant *In Vivo* to the Antiestrogen ICI 182,780 and Two Aromatase Inhibitors," *Clin. Cancer Res.* 4:697-711 (1998).	Generally; 698
Wakeling *et al.*, "A Potent Specific Pure Antiestrogen with Clinical. Potential," Cancer Res., 51:3867-73 (1991).	Generally; 3869
U.S. Patent No. 4,212,863	Col. 1, ll. 30-32
P.K. Gupta and GA. Brazeau (eds), *Injectable Drug Development:Techniques to Reduce Pain and Irritation*. Chapters 11 & 17 Interpharm Press, Denver, Colorado (1999).	405 418

AstraZeneca Pharmaceuticals LP and other AstraZeneca related corporate entities brought suit against Teva and other Teva related corporate entities charging

them with infringement of the '122 and '160 patents. The suit was filed on January 7, 2010 in the U.S. District Court for the District of Delaware and was assigned Civil Action No. 10-18-JAP.

Subsequently, Teva withdrew ANDA No. 200479 and is no longer seeking approval of a generic 50 mg/mL Fulvestrant injection from the FDA. Civil Action No. 10-18-JAP was dismissed without prejudice on June 15, 2011.

Unless already of record, all documents cited in the preceding table are being submitted to the Office in the attached SB/08 form.

C. Documents from the prosecution of European Patent Applications member of the same family as the instant application

Applicants submitted documents from the opposition against European Patent Application No. 01900186.6 with the Information Disclosure Statement filed June 4, 2009. Applicants now supplement that submission with documents submitted after the June 4, 2009, Information Disclosure Statement. Applicants are also enclosing the search reports from European Patent Application Nos. 10180667.7 and 10180661.0. European Patent Application Nos. 01900186.6, 10180667.7, and 10180661.0 are European members of the same patent family as the instant application.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the documents listed in the attached SB/08 form or in the table above are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claims in the application and Applicant determines that the cited documents do not constitute "prior

art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement not included herein, please charge the fee to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 20, 2011

By: _____

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