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	) **Mail Stop RCE**
	) **VIA EFS-WEB**

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

Sir:

RESPONSE TO OFFICE ACTION, SUBMISSION UNDER 37 C.F.R. § 1.114, AND PETITION FOR EXTENSION OF TIME

In reply to the Final Office Action mailed September 16, 2011 ("Office Action"), Applicants respectfully request reconsideration of the claimed invention in view of the following amendments and remarks. This paper fulfills the requirements of a submission under 37 C.F.R. § 1.114, and is filed together with a Request for Continued Examination (RCE).

Applicants hereby petition for a one-month extension of time to respond to the Office Action, extending the period for response to January 16, 2012. The requisite extension-of-time fee is being paid concurrently with this filing.

Amendments to the Claims are reflected in the listing of claims, which starts on page 2 of this paper. **Remarks** follow the amendment sections of this paper and start on page 7.

REMARKS

I. Status of the claims and amendments

Upon entry of the instant amendments, claims 24, 26, 27, 29, 30, 32, 34-36, 38, 39, 41, 42, 44, 46, 47, and 54-57 will be pending in this application. Claims 25, 28, 31, 33, 37, 40, 43, 45, and 48-53 are cancelled in this Response without prejudice or disclaimer. New claims 54-57 are added in this Response and find support, for example, in the specification at ¶ [0053].[1]

Applicants amended claim 24 to recite a formulation comprising "about 50 mgml-1 of fulvestrant; about 10% w/v of ethanol; about 10% w/v of benzyl alcohol; and about 15% w/v of benzyl benzoate." Support for this amendment can be found, for example, in the specification at ¶¶ [0072]-[0075]. Applicants also amended claim 24 to recite that the method achieves a therapeutically significant blood plasma fulvestrant concentration "for at least four weeks." Support for this amendment can be found, for example, in the specification at ¶ [0052]. Applicants amended claim 36 in a similar manner to claim 24, with support in the same portions of the specification as the amendments to claim 24 mentioned above. Applicants amended claims 32, 34, 44, and 46 to change their dependency because the claim from which each depended has been cancelled in this Response. None of the claim amendments introduce new matter.

Claims 24, 26, 27, 29, 30, 32, 34, 35, 54 and 55 are directed to methods for treating a hormonal dependent benign or malignant disease of the breast or

[1] Unless otherwise specified, all citations to the instant specification refer to the pagination in the published application, US 2010/0152149.

reproductive tract comprising administering intramuscularly to a human in need of such treatment a formulation *comprising* various components. Claims 36, 38, 39, 41, 42, 44, 46, 47, 56, and 57 are identical to claims 24, 26, 27, 29, 30, 32, 34, 35, 54 and 55 except that the phrase "formulation *consisting essentially of*" replaces the phrase "formulation *comprising*" the various components.

II. Statement of Substance of Interview under 37 C.F.R. § 1.133(b)

Applicants would like to thank Examiner San Ming Hui for granting a personal interview to Applicants on August 4, 2011. Applicants present this Statement of Substance of Interview in connection with that interview conducted between Examiner San Ming Hui, the undersigned, Dr. Paul R. Gellert (AstraZeneca Pharmaceuticals), and Mr. Allen F. Giles (AstraZeneca Pharmaceuticals).

During the interview, the undersigned and the Examiner discussed the then pending claims 24-53 and the disclosures of the following references: a) Howell et al., "Pharmacokinetics, Pharmacological, and Anti-tumour Effects of the Specific Anti-Estrogen ICI 182780 in Women with Advanced Breast Cancer," *Brit J. Cancer* 74:300-308 (1996), b) European Patent Application No. EP 0 346 014, and 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).

At the interview, the undersigned also mentioned the status of the lawsuit between AstraZeneca Pharmaceuticals and Teva Parenteral Medicines concerning a generic product containing 50 mg/ml of fulvestrant, which was also mentioned in the Information Disclosure Statement filed on June 20 , 2011.

No agreement was reached and the Examiner indicated he would consider the information presented at the interview in the preparation of the next Office Action.

III. Double Patenting Rejection

The Office rejected claims 24-53 under the nonstatutory obviousness-type double patenting doctrine as being unpatentable over: (a) claims 1-9 of U.S. Patent No. 6,774,122 ("the '122 patent") and (b) claims 1-12 of U.S. Patent No. 7,456,160 ("the '160 patent").

With the sole purpose of expediting prosecution, Applicants submit a Terminal Disclaimer concurrently with this Response, which shows common ownership of the instant application and the '122 and '160 patents and should obviate this rejection. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The filing of the Terminal Disclaimer is not an admission of the alleged obviousness of the instant claims in light of the claims in the '122 and '160 patents. *See, e.g.*, M.P.E.P. § 804.02.II; *Quad Environmental Technologies, Corp. v. Union Sanitary District*, 946 F.2d 870, 874 (Fed. Cir. 1991).

IV. Errors in the specification

Applicants would like to remind the Office of certain errors appearing in the instant specification. Applicants mentioned those errors in the Declaration Under 35 U.S.C §1.132 of Dr. Paul Gellert filed on August 2008 ("the Gellert Declaration"), in the parent application (Application No. 10/872,784). Applicants listed the Gellert Declaration in an Information Disclosure Statement being filed concurrently with this Response.

V. Rejections under 35 U.S.C. 103(a)

The Office rejected claims 24-53 under 35 U.S.C. 103(a) as being unpatentable over McLeskey et al., *Clinical Cancel Research* 4:697-711 (1998) ("*McLeskey*"); in view of European Patent Specification No. EP 0 346 014, which names Michael Dukes as inventor ("*Dukes*"); Osborne et al., *Journal of National Cancer Institute*, 87(20):746-750 (1995) ("*Osborne*"); and the abstract of Wakeling et al., "ICI 182,780, *J. Steroid Biochemistry and Molecular Biology*, 43(1-3):173-177 (1992) ("*Wakeling*"). Office Action at 5.

According to the Office, *McLeskey* teaches "a stud[y] employing subcutaneous injection of fulvestrant to nude mice" and a "fulvestrant formulation contain[ing] 50mg/ml in a vehicle of 10% ethanol, 15% benzyl benzoate, 10% benzyl alcohol brought to volume with castor oil." *Id.* The Office acknowledges that *McLeskey* does not expressly teach "the use of fulvestrant in treating hormonal dependent diseases of breast", "the dosing regimen to be once a month, intramuscular administration", "the volume administered", or "the herein claimed serum concentration of fulvestrant." *Id.*

In the Office's view, *Dukes* teaches that "antiestrogen agent[s], including fulvestrant, via intramuscular route of administration may be used in a dosage of 50mg to 5g in vehicle comprising castor oil and benzyl alcohol." *Id.* at 5-6.

The Office cites *Osborne* as teaching that fulvestrant is "useful in treating human breast cancer" (*id.* at 6) and *Wakeling* as teaching that "the administration of fulvestrant (ICI 182780) demonstrat[es] the antiestrogenic effect for over a 1 month period." *Id.*

According to the Office "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to employ fulvestrant in [*McLeskey*], in the

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