United States Patent [19]

Vorys

[11] **4,292,315**

[45] **Sep. 29, 1981**

[54] **FOLLICULAR PHASE ESTROGEN OR PROGESTIN WITH PHYSIOLOGIC ESTROGEN/PROGESTIN LUTEAL PHASE REPLACEMENT DRUG DELIVERY SYSTEM**

[76] Inventor: **Nichols Vorys**, 336 S. Columbia Ave., Columbus, Ohio 43209

[21] Appl. No.: **69,275**

[22] Filed: **Aug. 24, 1979**

Related U.S. Application Data

[62] Division of Ser. No. 865,851, Dec. 30, 1977, abandoned.

[51] **Int. Cl.**[3] **A01N 45/00**; A61K 31/56

[52] **U.S. Cl.** **424/240**; 424/238; 206/533

[58] **Field of Search** 424/238, 240

[56] **References Cited**

U.S. PATENT DOCUMENTS

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Primary Examiner—Elbert L. Roberts
Attorney, Agent, or Firm—Kenyon & Kenyon

[57] **ABSTRACT**

A method, formulation, and steroid drug delivery system for the administration of sex steroids for menstrual cycle regulation is disclosed. The invention is useful in clinical applications for pregnancy spacing and treatment of menstrual dysfunction. Progestin and estrogen are administered in a treatment cycle mimicking sex steroid hormones in the normal menstrual cycle. The steroid treatment cycle is divided into arbitrary and discrete follicular and luteal phase segments beginning with the onset of menstruation. In the early segment of the follicular phase no exogenous steroid is administered. Depending on the clinical and/or physiologic situation of a patient, unopposed progestin or estrogen is then administered. In the preferred embodiment an early luteal phase follows with low dose administration of combination estrogen/progestin; mid luteal estrogen and progestin is administered in a dose adequate to suppress pituitary FSH and LH and to maintain the endometrium; and terminally, a reduced dosage of combination estrogen/progestin is administered. The clinical success of the method and formulation depends not only upon the biologic potency of the progestin molecule administered but also depends upon the dose and temporal relationship of administration of exogenous estrogen, progestin, and combination estrogen/progestin. As a consequence, any FDA approved synthetic estrogen or progestin, in pharmacologically appropriate dosage is suitable for formulation in accordance with the present invention. Menstrual cycle regulation and effective contraception is achieved by hypothalamic-pituitary dysrhythmia rather than sustained FSH, LH, endogenous estrogen suppression. A reduced exposure to the adverse endocrine and metabolic effects of high dose estrogen and progestin administered concurrently is accomplished. Upon discontinuation of the administration of the present invention, prompt FSH and subsequent LH recovery ensue, providing for an appropriate return of ovulation and appropriate menstruation in the prior to drug normal ovulating patient. The method and formulation further allow the physician to take physiologic corrective measures in menstrual dysfunction patients who may or may not seek contraception and present as hypoestrogen, euestrogen, or hyperestrogen ovulation dysfunction or anovulatory.

20 Claims, 9 Drawing Figures

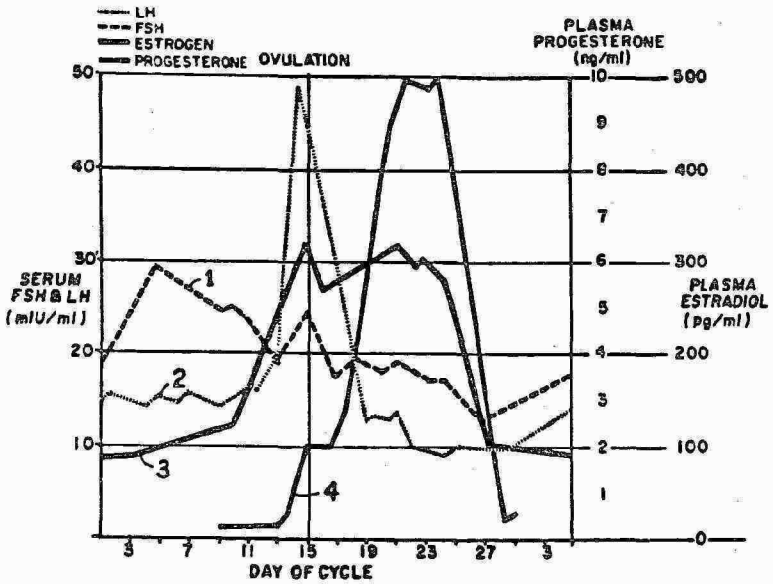


FIG. 1

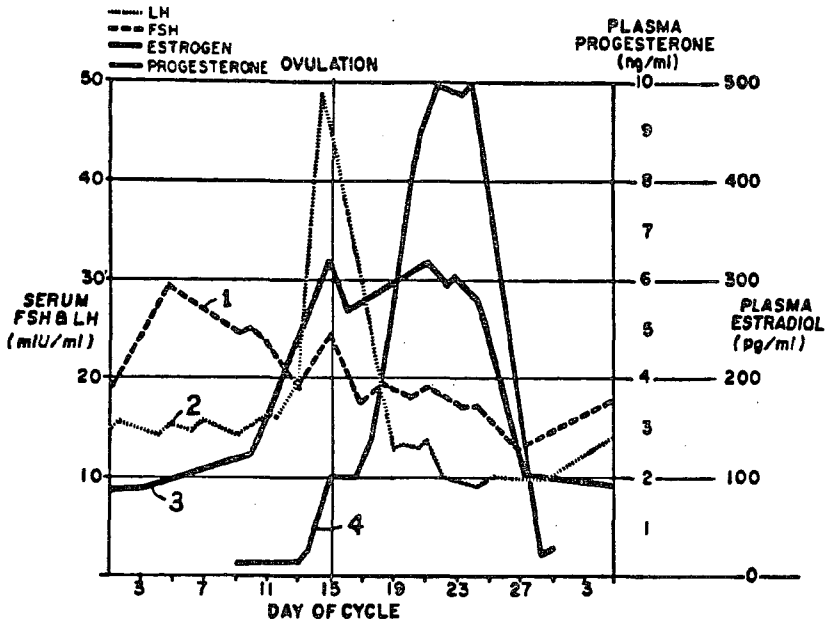


FIG. 2

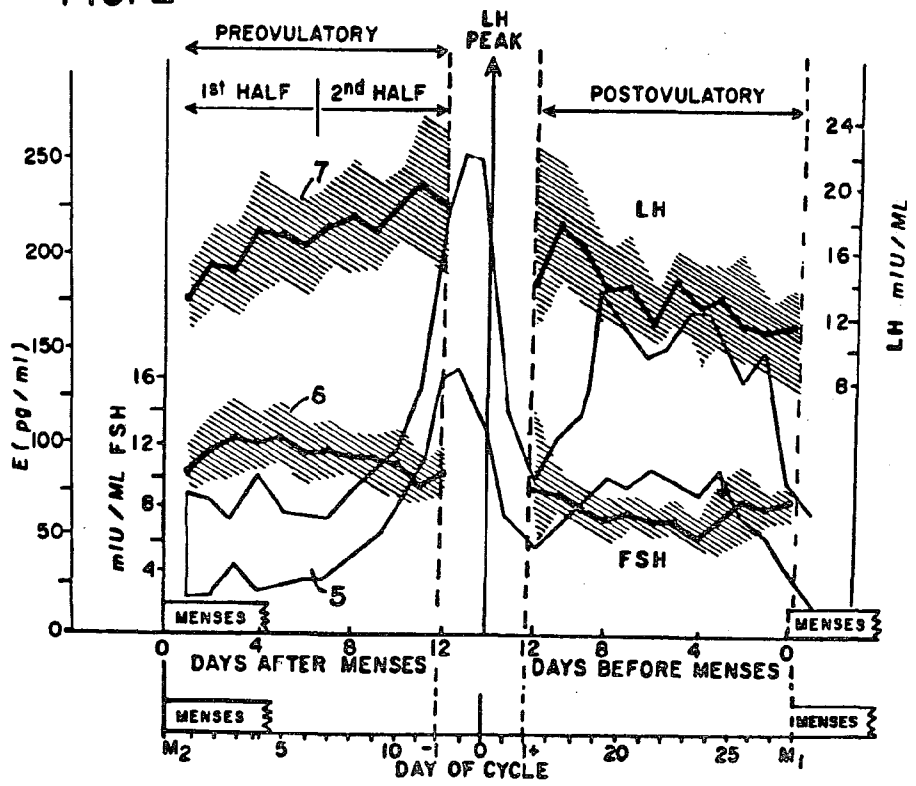


FIG. 3

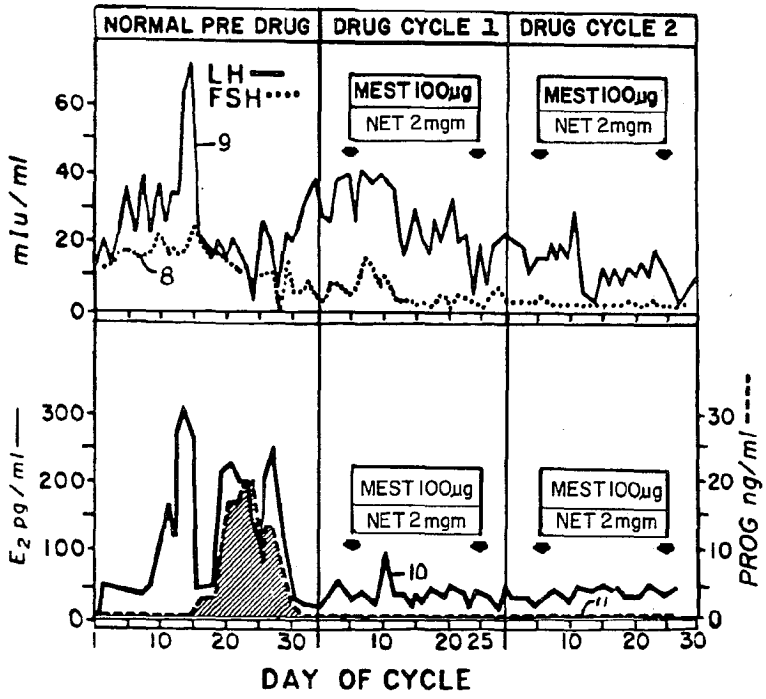
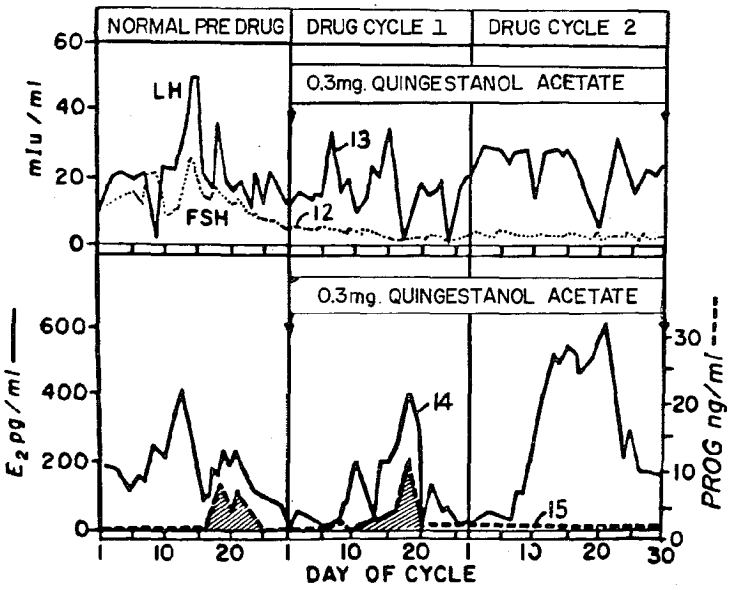


FIG. 4



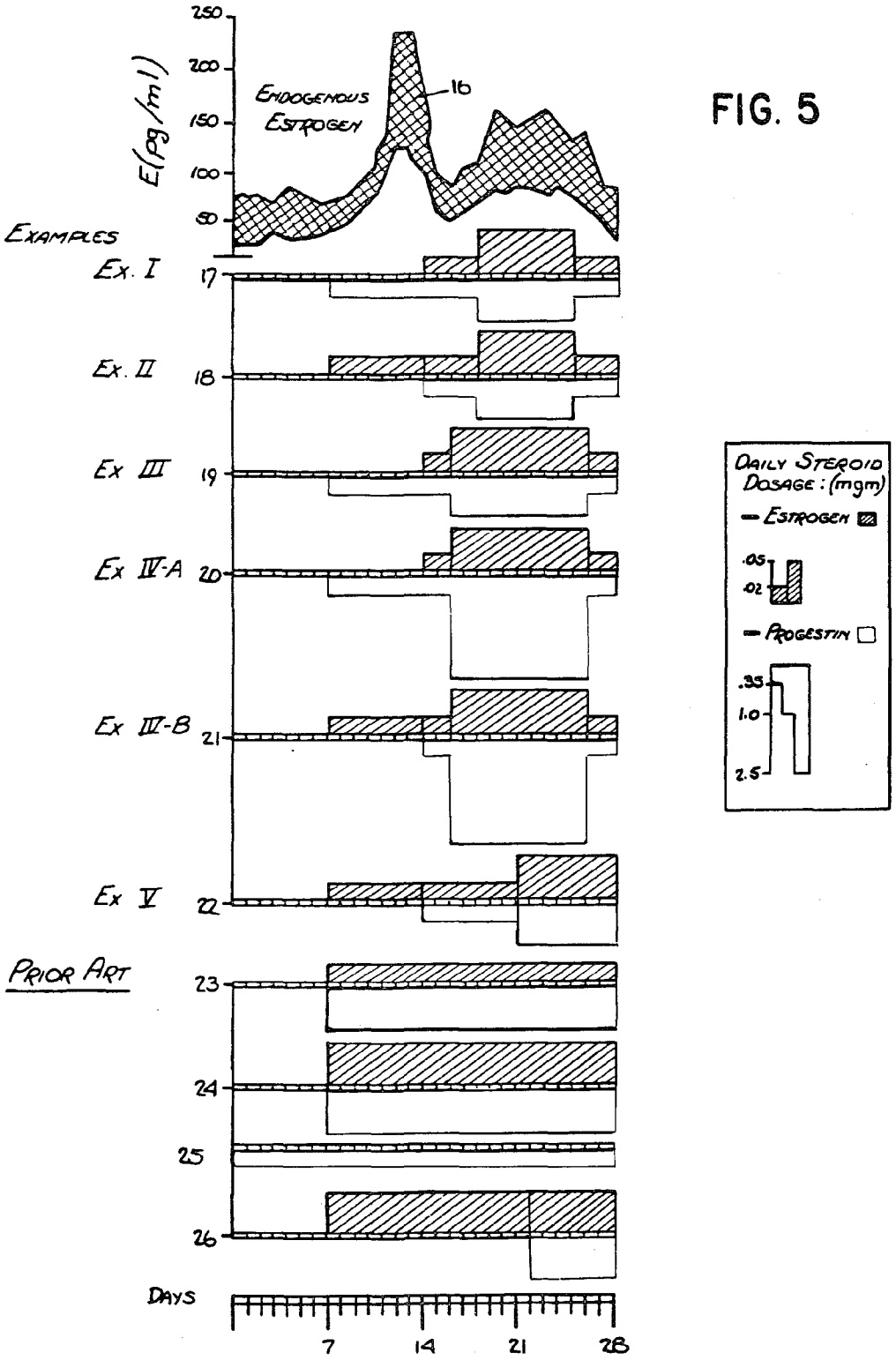
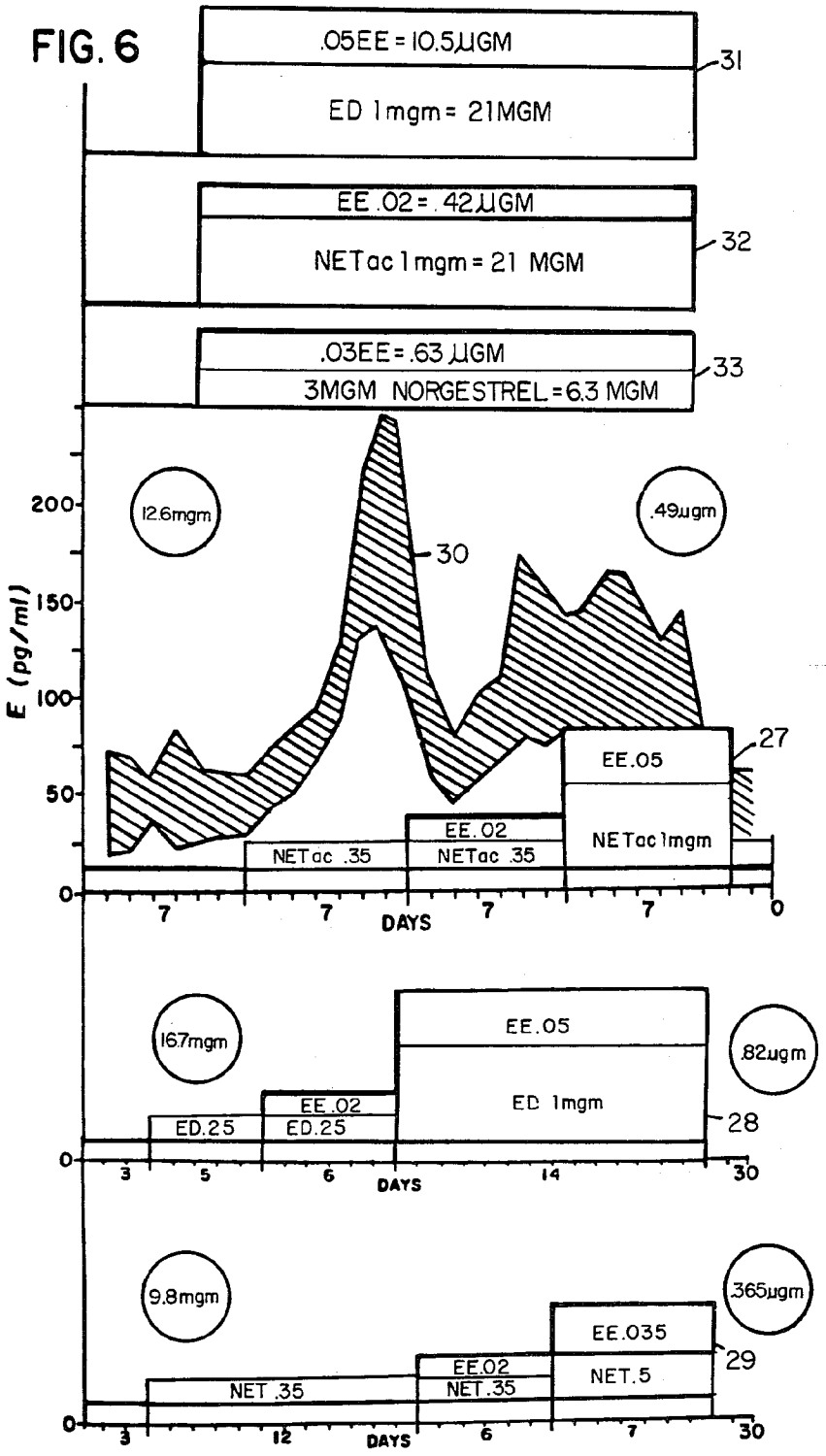


FIG. 5

FIG. 6



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