

PATENT COOPERATION TREATY

PCT

REC'D 11 MAR 2004

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1238.02.1	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US02/29150	International filing date (day/month/year) 13 September 2002 (13.09.2002)	Priority date (day/month/year) 17 September 2001 (17.09.2001)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 9/14, 9/16, 9/20, 9/48, 31/47 and US Cl.: 424/451, 452, 464, 465, 484, 486, 489, 490; 514/311, 313, 314		
Applicant PARKS, L.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:
 - I Basis of the report
 - II Priority
 - III Non-establishment of report with regard to novelty, inventive step and industrial applicability
 - IV Lack of unity of invention
 - V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI Certain documents cited
 - VII Certain defects in the international application
 - VIII Certain observations on the international application

Date of submission of the demand 02 April 2003 (02.04.2003)	Date of completion of this report 18 April 2003 (18.04.2003)
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Susan Tran Telephone No. (703) 308-1235

I. Basis of the report

1. With regard to the **elements** of the international application:*
- the international application as originally filed.
- the description:
pages 1-12 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- the claims:
pages 13-15, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- the drawings:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:
- the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- contained in the international application in printed form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4. The amendments have resulted in the cancellation of:
- the description, pages NONE
- the claims, Nos. NONE
- the drawings, sheets/fig NONE
5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**
- * Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).
- ** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>1-10</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-10</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-10</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claim lack 1-5 do not lack an inventive step over Sanz et al. US 5,612,354 A.

Sanz teaches the use of quinoline derivatives for the treatment of poststatic cancer. Sanz does not teach the effect of 13-cis-retinoic acid for the treatment of cancer.

Claims 1-5 lack an inventive step under PCT Article 33(3) as being obvious over Sporn et al. US 5,821,254A.

Sporn teaches a pharmaceutical composition comprising 9-cis-retinoic acid or derivatives thereof for the treatment of cancer, including, prostate cancer (column 4, lines 21-53). The composition is suitable for oral administration further comprises excipients, and carriers (columns 7-8).

Sporn does not teach the use of 13-cis-retinoic acid as claimed. However, the generic teaching by Sporn at column 7, line 45 suggests retinoic acid or derivatives, permits the skilled artisan to, by routine experimentation select 13-cis-retinoic acid for the treatment of cancer, including, prostate cancer.

Claims 6-10 do not lack an inventive step over Steiner et al. US 6,413,535.

Steiner teaches a method for chemoprevention of prostate cancer comprises administering an effective dose of an antiestrogen to the patient. Steiner does not teach the use of 13-cis-retinoic acid for the same treatment.

Claims 1-10 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----