Amgen Inc. v. F. Hoffmann-LaRoche LTD et al Case 1:05-cv-12237-WGY Document 501-64 Filed 06/14/2007 Page 1 of 5

EXHIBIT P-2

Moore Decl to Motion for SJ re ODP - Public

Manual of PATENT EXAMINING PROCEDURE

Original Eighth Edition, August 2001 Latest Revision August 2006



U.S. DEPARTMENT OF COMMERCE United States Patent and Trademark Office The U.S. Patent and Trademark Office does not handle the sale of the Manual, distribution of notices and revisions, or change of address of those on the subscription list. Correspondence relating to existing subscriptions should be sent to the Superintendent of Documents at the following address:

 Superintendent of Documents
 Telephone: 202-512-2267

 Mail List Section
 Washington, DC 20402

 Inquiries relating to purchasing the Manual should be directed to:
 Telephone: 202-512-1800

 Superintendent of Documents
 Telephone: 202-512-1800

 United States Government Printing Office
 Washington, DC 20402

Orders for reproduced copies of individual replacement pages or of previous revisions of the Manual should be sent to the following address:

Mail Stop Document Services Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 Telephone: 1-800-972-6382 or 571-272-3150

Previous editions and revisions of the Manual are available on microfilm in the Patent Search Room. The Manual is available on CD-ROM and on diskette from:

> U.S. Patent and Trademark Office Office of Electronic Information Products MDW 4C18, P.O. Box 1450 Alexandria, VA 22313-1450

Telephone: 571-272-5600

Employees of the U.S. Patent and Trademark Office should direct their requests for the Manual, replacement pages, notices, and revisions to the Office of Patent Training. Telephone: 571-272-7222

Pursuant to the Patent and Trademark Office Efficiency Act (PTOEA) (Pub. L. 106-113, 113 Stat. 1501A-572), the head of the United States Patent and Trademark Office (USPTO) is the "Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office." The Director is assisted by the "Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office." The patent operations of the USPTO are now headed by the "Commissioner for Patents." The trademark operations of the USPTO are now headed by the "Commissioner for Trademarks." Under section 4741(b) of the PTOEA, any reference to the Commissioner of Patents and Trademarks, the Assistant Commissioner for Trademarks is deemed to refer to the Director, the Commissioner for Patents, or the Commissioner for Trademarks is deemed to refer to the Director, the Commissioner for Patents, or the Commissioner for Trademarks of the Patent and Trademark Office as the United States Patent and Trademark Office" published in the *Federal Register* at 65 FR 17858 (Apr. 5, 2000), and in the *Official Gazette of the United States Patent and Trademark Office* at 1234 O.G. 41 (May 9, 2000).

Additions to the text of the Manual are indicated by arrows (><) inserted in the text. Deletions are indicated by a single asterisk (*) where a single word was deleted and by two asterisks (**) where more than one word was deleted. The use of three or five asterisks in the body of the laws, rules, treaties, and administrative instructions indicates a portion of the law, rule, treaty, or administrative instruction which was not reproduced.

First Edition, November 1949 Second Edition, November 1953 Third Edition, November 1961 Fourth Edition, June 1979 Fifth Edition, August 1983 Sixth Edition, July 1998 Eighth Edition, July 1998 Eighth Edition, August 2001 Revision 1, February 2003 Revision 2, May 2004 Revision 3, August 2005 Revision 4, October 2005 Revision 5, August 2006

TYPES, CROSS-NOTING, AND STATUS OF APPLICATION

201.06

201.05 Reissue Application [R-3]

A reissue application is an application for a patent to take the place of an unexpired patent that is defective **>as a result of an error in the patent which was made without deceptive intention.< A detailed treatment of **>reissue applications can< be found in Chapter 1400.

201.06 Divisional Application [R-2]

A later application for an independent or distinct invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or "division." >A divisional application is often filed as a result of a restriction requirement made by the examiner.< The divisional application must claim the benefit of the prior nonprovisional application under 35 U.S.C. 121 or 365(c). *>See MPEP § 201.11 for the conditions for receiving the benefit of the filing date of the prior application. The divisional application should set forth at least the portion of the earlier disclosure that is germane to the invention as claimed in the divisional application.

Divisional applications of utility or plant applications must be filed under 37 CFR 1.53(b). Divisional applications of design applications< may be filed pursuant to 37 CFR 1.53(b) or 1.53(d). 37 CFR 1.60 and 1.62 have been deleted as of December 1, 1997.

**>Effective July 14, 2003, continued prosecution application (CPA) practice set forth in 37 CFR 1.53(d) has been eliminated as to utility and plant applications.< An application claiming the benefits of a provisional application under 35 U.S.C. 119(e) should not be called a "division" of the provisional application since the application will have its patent term calculated from its filing date, whereas an application filed under 35 U.S.C. 120, 121, or 365(c) will have its patent term calculated from the date on which the earliest application was filed, provided a specific reference is made to the earlier filed application(s). 35 U.S.C. 154(a)(2) and (a)(3).

In the interest of expediting the processing of newly filed divisional applications filed as a result of a restriction requirement, applicants are requested to include the appropriate U.S. Patent and Trademark Office classification of the divisional application and the status and *>assigned art unit< of the parent application on the papers submitted. The appropriate classification for the divisional application may be found in the Office communication of the parent application wherein the >restriction< requirement was made. It is suggested that this classification designation be placed in the upper right hand corner of the letter of transmittal accompanying these divisional applications or in an application data sheet as set forth in 37 CFR 1.76(b)(3).

Use form paragraph 2.01 to remind applicant of possible divisional status.

¶ 2.01 Definition of Division

This application appears to be a division of Application No. [1], filed [2]. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or "division." The divisional application should set forth the portion of the earlier disclosure that is germane to the invention as claimed in the divisional application.

Examiner Note:

1. In bracket 1, insert the Application No.(series code and serial no.) of the parent application.

2. In bracket 2, insert the filing date of the parent application.

3. An application claiming the benefits of a provisional application under 35 U.S.C. 119(e) should not be called a "division" of the provisional application since the application will have its patent term calculated from its filing date, whereas an application filed under 35 U.S.C. 120, 121, or 365(c) will have its term calculated from the date on which the earliest application was filed, provided a specific reference is made to the earlier filed application(s), 35 U.S.C. 154(a)(2) and (a)(3).

<

A design application may be considered to be a division of a utility application (but not of a provisional application), and is entitled to the filing date thereof if the drawings of the earlier filed utility application show the same article as that in the design application sufficiently to comply with 35 U.S.C. 112, first paragraph. However, such a divisional design application may only be filed under the procedure set forth in 37 CFR 1.53(b) not under 37 CFR 1.53(d). ** See MPEP § 1504.20.

While a divisional application may depart from the phraseology used in the parent application there may be no departure therefrom in substance or variation in the disclosure that would amount to "new matter" if introduced by amendment into the parent application. Compare MPEP § 201.08 and § 201.11.

201.06(a)

For notation to be put *>in< the file *>history< by the examiner in the case of a divisional application, see MPEP § 202.02.

201.06(a) Former 37 CFR 1.60 Divisional-Continuation Procedure [R-2]

* 37 CFR 1.60 was deleted effective December 1, 1997. See 1203 O.G. 63, October 21, 1997. A continuation or divisional application filed under 37 CFR 1.60 on or after December 1, 1997, will automatically be treated as an application filed under 37 CFR 1.53(b). All continuation and divisional applications filed under 37 CFR 1.60 prior to December 1, 1997 will continue to be processed and examined under the procedures set forth in former 37 CFR 1.60. **>For more information pertaining to practice and procedure under former 37 CFR 1.60, see MPEP § 201.06(a) in the MPEP 8th Edition, Rev. 1 (February 2003)(available on the USPTO web site at www.uspto.gov/web/offices/ pac/mpep/mpep.htm).<

201.06(b) Former 37 CFR 1.62 File Wrapper Continuing Procedure [R-2]

*37 CFR 1.62 was deleted effective December 1, 1997. See 1203 O.G. 63, October 21, 1997. A >request for a< continuation or divisional application filed under former 37 CFR 1.62 on or after December 1, 1997, >, in an application that was filed on or after June 8, 1995,< will be treated as ** a request for continued examination (RCE) under 37 CFR *>1.114<, see MPEP 706.07(h), paragraph IV. **>A request< filed on or after December 1, 1997, under former 37 CFR 1.62 *>for< a continuation-in-part (CIP) application, **>, or for a continuation or divisional of an application having a filing date before June 8, 1995,< will be treated as an improper application.

**

All continuation, divisional and CIP applications filed under former 37 CFR 1.62 prior to December 1, 1997, will continue to be processed and examined under the procedures set forth in former 37 CFR 1.62. **>For more information pertaining to practice and procedure under former 37 CFR 1.62, see MPEP § 201.06(b) in the MPEP 8th Edition, Rev. 1 (February 2003)(available on the USPTO web site at www.uspto.gov/web/offices/ pac/mpep/mpep.htm).<

201.06(c) 37 CFR 1.53(b) and 37 CFR 1.63(d) Divisional-Continuation Procedure [R-5]

37 CFR 1.53. Application number, filing date, and completion of application.

(b) Application filing requirements - Nonprovisional application. The filing date of an application for patent filed under this section, except for a provisional application under paragraph (c) of this section or a continued prosecution application under paragraph (d) of this section, is the date on which a specification as prescribed by 35 U.S.C. 112 containing a description pursuant to \S 1.71 and at least one claim pursuant to \S 1.75, and any drawing required by \S 1.81(a) are filed in the Patent and Trademark Office. No new matter may be introduced into an application after its filing date. A continuing application, which may be a continuation, divisional, or continuation-in-part application, may be filed under the conditions specified in 35 U.S.C. 120, 121 or 365(c) and \S 1.78(a).

(1) A continuation or divisional application that names as inventors the same or fewer than all of the inventors named in the prior application may be filed under this paragraph or paragraph (d) of this section.

(2) A continuation-in-part application (which may disclose and claim subject matter not disclosed in the prior application) or a continuation or divisional application naming an inventor not named in the prior application must be filed under this paragraph.

37 CFR 1.63. Oath or Declaration.

(d)(1)A newly executed oath or declaration is not required under § 1.51(b)(2) and § 1.53(f) in a continuation or divisional application, provided that:

(i) The prior nonprovisional application contained an oath or declaration as prescribed by paragraphs (a) through (c) of this section;

(ii) The continuation or divisional application was filed by all or by fewer than all of the inventors named in the prior application;

(iii) The specification and drawings filed in the continuation or divisional application contain no matter that would have been new matter in the prior application; and

(iv) A copy of the executed oath or declaration filed in the prior application, showing the signature or an indication thereon