MEMORANDUM OPINION AND ORDER [FN1]

*1 This interference involves an application of Fritsch et al. and an application of Lin. Lin has filed a petition asking that his application be issued as a patent and that the interference continue as an application/patent interference instead of an application/application interference. For reasons hereinafter given, the petition is denied.

Background [FN2]

On May 9, 1989, an Examiner-in-Chief declared an interference between Fritsch's application, Serial No. 693,258, which has been accorded an effective filing date of January 3, 1985, and Lin's Patent No. 4,703,008, based on Serial No. 675,298 which has been accorded an effective date of December 13, 1983.

The Fritsch application is owned by Genetics Institute, Inc., a Delaware corporation. Genetics has given a license to Chugai Pharmaceutical Co. of Japan. Chugai markets products in the United States via a 'joint venture' with The Upjohn Co.

The Lin patent is owned by Amgen, Inc., a Delaware corporation.

The subject matter ('count') of the interference relates to a 'starting material,' viz., a purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.

Since Fritsch's effective filing date was more than three months later than Lin's effective filing date, Fritsch was required to provide a showing under 37 CFR § 1.608(b) [Rule 608(b)]. The Rule 608(b) showing was accepted by the Examiner-in-Chief and Interference No. 102,096 was declared between Fritsch's application and Lin's patent.

Fritsch's application and an application of Lin, Serial No. 113,179, disclose a 'process' which uses the 'starting material' of Interference No. 102,096 to prepare recombinant erythropoietin (rEPO). The effective filing date of the Lin application is December 13, 1983. The effective date of the Fritsch application is January 3, 1985. Notwithstanding a 13-month difference in effective filing dates, the Primary Examiner
forwarded the Fritsch and Lin applications to the Board for interference proceedings. The Group Director gave his approval for institution of interference proceedings by signing the Form PTO-850 used to transmit applications to the Board. See Manual of Patent Examining Procedure, § 2303 (page 2300-9, col. 1) and § 2309.02 (page 2300-24, col. 1) [5th ed., 9th rev., Sept., 1988]. Upon receipt of the Form PTO-850, the Examiner-in-Chief had some questions and informally sought assistance from the Primary Examiner. After that assistance was provided, Interference No. 102,097 was declared on May 9, 1989.

The Examiner-in-Chief has required preliminary motions and preliminary statements to be filed in both interferences on or before August 9, 1989.

Another significant matter is a Fritsch representation in his opposition to the petition. Fritsch suggests (opposition, p. 5, ¶ I and p. 8, n.3) that he may file a preliminary motion in Interference No. 102,097 seeking the benefit of the filing date of application, Serial No. 546,650, filed October 28, 1983 (now U.S. Patent No. 4,757,006). 37 CFR § 1.633(f). If the motion is timely filed and is granted, Fritsch would become senior party in Interference No. 102,097.

*2 In addition, Fritsch suggests that he may file a preliminary motion in Interference No. 102,097, seeking to deny Lin the benefit of his December 13, 1983, filing date (opposition, p. 6, ¶ II and 8, n.3). 37 CFR § 1.633(g). If this motion is timely filed and granted, Fritsch's burden of establishing priority may be easier—he can prevail by establishing a date of invention which is later than the date he would have no establish if Lin is entitled to an effective filing date of December 13, 1983.

Fritsch also represents (opposition, p. 6, ¶ IV) that he will file a preliminary motion for judgment based on alleged unpatentability under 35 U.S.C. § 102(b) and (e) of the Lin claims corresponding to the count. 37 CFR § 1.633(a). If the motion is granted, Lin's claims corresponding to the count would be unpatentable.

Positions of the parties

I.

In the petition, Lin outlines his claim for relief with 'Points' (A) through (D), as follows:

(A) The Lin application was accorded a 'special' status within the Patent and Trademark Office (PTO). On February 16, 1988, the Assistant Commissioner for Patents entered an order in Lin's application, Serial No. 07/113,179 stating 'should this case become involved in an interference, consideration of . . . [the] interference will be expedited by all Patent and Trademark Office officials concerned, contingent . . . upon diligent prosecution by the applicant [Lin].' The case was made 'special' pursuant to the Manual of Patent Examining Procedure, § 708.02(II) [5th ed., 9th rev., Sept. 1988], based on Lin's claim of actual infringement.
(B) Prosecution of the application was improperly 'suspended' pending institution of interference proceedings.

(C) A request, characterized by Lin as being an ex parte request, was 'improperly handled' by the Examiner-in-Chief as an inter partes matter; Lin reasons, therefore, that the declaration of the interference was 'improper' and 'premature.'

(D) Lin's assignee, Amgen, will suffer 'irreparable harm' if the Lin application is not issued as a patent forthwith.

II.

Fritsch's opposition maintains that the Commissioner lacks jurisdiction to grant the relief requested in Lin's petition. Even if the Commissioner has jurisdiction to grant relief, Fritsch argues that the Examiner-in-Chief properly declared the interference based on Fritsch's request for an interference under 37 CFR § 1.604 [Rule 604] on September 6, 1988. Fritsch further argues that Lin has failed to provide any 'substantive' justification in support of his petition.

Fritsch alleges that his assignee and its licensees will suffer 'irreparable harm' if a patent is issued to Lin's assignee Amgen. According to Fritsch, issuance of a patent could 'potentially' deny Amgen 'the right to market erythropoietin upon which . . . [Amgen] hold[s] a patent, U.S. [Patent No.] 4,677,195.' Fritsch represents that Amgen has been 'adjudicated to infringe U.S. [Patent No.] 4,677,195 by its manufacture of erythropoietin.' Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94, 9 USPQ 2d 1833 (D. Mass. 1989) (as noted earlier, Chugai is a licensee of Genetics Institute--the owner of the Fritsch applications involved in the two interferences).

Opinion

1. The Commissioner has jurisdiction over the subject matter of the petition and has discretion to grant relief

*3 The normal practice of PTO is not to issue patents based on applications involved in an ongoing interference. The interference rules authorize petitions to the Commissioner in interference cases for the purpose of seeking a waiver of a rule of practice. 37 CFR § 1.644(a)(3) [Rule 644]. Inasmuch as Rule 644 is not inconsistent with law, it has the force and effect of law. In re Rubinfield, 270 F.2d 391, 123 USPQ 210 (CCPA 1959), cert. denied, 362 U.S. 903 (1960). Rule 644 gives the Commissioner jurisdiction to reach the merits of Lin's petition.

Fritsch maintains that 35 U.S.C. §§ 41, 101, 102, 103, 112, and 135 preclude granting the relief sought. No cogent rationale is articulated in support of this position.

On the present record, i.e., the record as of the date this decision is being entered, Lin's claims corresponding to the count have been
held patentable under 35 U.S.C. §§ 101, 102, 103, and 112 by the Primary Examiner subject to the interference. Whether preliminary motions filed on a date subsequent to this decision will make any difference is not a matter relevant to the Commissioner's jurisdiction to grant relief. Likewise, as a matter of law, nothing in §§ 41 and 135(a) precludes issuance of a patent to a senior party in an interference.

2. There is no basis on this record for issuing a patent to Lin at this time

Consistent with long-standing PTO practice of not issuing patents based on applications involved in a pending interference, Lin's request that his application be issued as a patent is denied. There is no basis for waiving PTO practice in this case. Myers v. Feigelman, 455 F.2d 596, 601, 172 USPQ 580, 584 (CCPA 1972) (waiver of rules absent compelling circumstances would defeat the purposes of the rules and substantially confuse interference practice).

The record shows that the interference was properly declared and that it should continue to be handled in the normal manner in accordance with established PTO procedure. Nothing raised in Lin's petition, particularly 'Points' (A) through (D), demonstrates that relief should be granted.

Point A

The record demonstrates that Lin's application was accorded a 'special' status by the Assistant Commissioner for Patents. Included in the 'special' status ordered by the Assistant Commissioner was expeditious handling of any interference by PTO personnel. The Assistant Commissioner's order contemplated an interference. It did not suggest that if an interference is declared, Lin's application should nevertheless be issued as a patent. Rather, it held that any interference would be handled with special dispatch within PTO.

Point B

Lin argues that prosecution of his application was improperly 'suspended' pending institution of interference proceedings. There are two independent reasons why this argument must be rejected.

1. Lin's petition is a belated petition seeking to vacate the examiner's ex parte suspension order. Accordingly, it is not timely, having been filed more than 60-days after the Primary Examiner entered the order. 37 CFR § 1.181(f). The suspension order was entered on December 9, 1988, and states:

   All claims are allowable. However, due to a potential interference, ex parte prosecution is SUSPENDED FOR A PERIOD OF UP TO SIX MONTHS FROM THE DATE OF THIS LETTER.

   Upon expiration of the period of suspension, applicant should
make an inquiry as to the status of the application.

On December 20, 1988, the Primary Examiner prepared a Form PTO-850 to have an interference declared. The board received the Form PTO-850 on January 10, 1989. On February 27, 1989, the Examiner-in-Chief requested clarification from the Primary Examiner. The Primary Examiner responded on April 12, 1989. On May 2, 1989, Lin filed what he calls an ex parte request asking that the 'suspension' order be lifted. [FN3] The interference was declared on May 9, 1989--five months after entry of the examiner's six-month suspension order.

If Lin had an objection to the examiner's suspension order, he should have petitioned immediately, but in no event later than two months from December 9, 1988. Lin knew that the examiner was considering an interference. Lin knew that the suspension order was for a six-month period. On January 19, 1989, Lin's assignee was served with an order entered by an Administrative Law Judge (ALJ) of the International Trade Commission (ITC). The order discussed whether Amgen's '008 patent claimed a process--meaning, of course, that sometime prior to January 19th Amgen was aware (based on having briefed the issue before the ALJ) that it might need a patent explicitly claiming a process. On January 31st, the U.S. District Court for the District of Massachusetts entered an order holding that Amgen's '008 patent does not contain a process claim. Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94, 110, 9 USPQ 2d 1833, 1846 (D. Mass. 1989). Thus, notwithstanding a known possibility that a 'process' patent might be necessary to protect whatever rights Amgen believes it has in the invention, no petition was filed in PTO seeking to have the examiner lift his stay. In view of the delay, and the fact an interference has been declared and has reached the preliminary motion/preliminary statement stage, the Lin petition is manifestly untimely.

2. Apart from, and independent of, the belated nature of the petition, Lin's Point B is not correct on the merits. It is true that Lin's effective filing date is more than 13 months earlier than Fritsch's effective filing date. Normally, if there is more than a three-month difference in effective filing dates, the 'senior' party's application is issued, and the 'junior' party is required to copy claims and make a Rule 608(b) showing. In the case of Amgen's '008 patent directed to the 'starting material,' a patent issued and Fritsch copied claims. Fritsch filed a Rule 608(b) showing to establish that he is prima facie entitled to a judgment vis-a-vis Lin.

*5 The 'evidence' in the PTO at the time the Primary Examiner was considering an interference on the 'process' included Fritsch's Rule 608(b) showing. A Rule 608(b) showing is not considered on the 'merits' by a Primary Examiner. 37 CFR § 1.617(a). Nevertheless, the Primary Examiner does inspect a Rule 608(b) showing to 'determine that at least one date prior to the effective filing date of the patent is alleged . . ..' Manual of Patent Examining Procedure, § 2308.02, p. 2300-19, col. 2 [5th ed., 9th rev., Sept., 1988]. In this case, the Primary Examiner inspected the Rule 608(b) showing, found an appropriate date alleged, and forwarded the patent and Fritsch's application to the board for an interference on the 'starting material.' It was entirely logical for the Primary Examiner to also institute an interference on the process of using the starting material.

Lin does not have access at this time to the Rule 608(b) showing. 37
Lin will not have access until any preliminary motions are filed and decided. However, the Rule 608(b) showing has been inspected in camera, and it demonstrates that there is a plausible basis for concluding that Fritsch had made the 'process' invention prior to Lin's effective filing date. It follows that the Primary Examiner properly sought and obtained approval of the Group Director to institute an interference on the 'process' notwithstanding the 13-month difference in effective filing dates. The Primary Examiner's decision, approved by the Group Director, is particularly compelling in view of (a) the complicated technology involved and (b) the conservation of board resources given the related nature of the inventions involved in the two interferences—it is much better for the board to handle the two interferences simultaneously.

Lin cannot prevail on the basis of his argument that his application was improperly suspended pending institution of interference proceedings.

Point C

Lin argues that PTO has improperly treated a May 2, 1989, request seeking to withdraw the Primary Examiner's 'suspension' order of December 9, 1989. Lin says that the request was filed on May 2, 1989, because it was not until April 10, 1989, that the ITC 'finally ruled' that it lacked jurisdiction. In the Matter of Certain Recombinant Erythropoietin, 10 USPQ 2d 1906 (ITC 1989). The Examiner-in-Chief declared Interference No. 102,097 on May 9, 1989. In declaring the interference, the Examiner-in-Chief said:

It is noted that a 'Request for Withdrawal of Suspension' was filed in involved application Serial No. 113,179 on May 2, 1989, almost five months after the primary examiner suspended ex parte prosecution in the application. The instant interference is hereby being declared, and no action on the aforementioned request appears to be necessary, since the group director has given his approval to the institution of an interference between applications having effective filing dates more than six months apart . . .

*6 Lin argues that the Examiner-in-Chief lacked jurisdiction on May 9, 1989, to determine that 'no action on the . . . request appears to be necessary.' Lin says this is so because an Examiner-in-Chief acquires jurisdiction over an interference when it is declared. 37 CFR § 1.614. Instead, argues Lin, the Group Director should have entered a decision on the 'request' prior to declaration of the interference.

1. The Examiner-in-Chief observed that the May 2, 1989, request was filed almost five months after the Primary Examiner entered a suspension order on December 9, 1988. In effect, the Examiner-in-Chief held that the request was belated. He was right! There is no doubt on this record that had this matter been referred to the Group Director, he too would have held the May 2, 1989, request to be too late. Lin argues that the request was 'timely' because ITC 'finally ruled' on April 10th that it lacked jurisdiction. But, Lin's assignee Amgen knew in January of 1989 that it might lose at ITC and that its patent had been determined by a district court not to contain process claims. Lin's attempt in May to do what he should have done in January-February
at the latest--simply does not justify his belated request to withdraw the Primary Examiner's 'suspension' order of December 9, 1988.

2. The Examiner-in-Chief also held that in view of the Group Director's approval of Form PTO-850, there was no need to 're'-transmit the files to the Group Director for consideration of the request. The decision of the Examiner-in-Chief is affirmed. [FN5] The following facts demonstrate the correctness of the Examiner-in-Chief's decision on the merits:

(1) the Rule 608(b) showing, which Lin is not yet entitled to see, establishing to the satisfaction of the Examiner-in-Chief that a prima facie case for judgment had been made out on the 'starting material' and manifestly making out an equal case on the 'process';

(2) the imminent declaration of two interferences on complicated subject matter which efficient administration of justice dictates should be handled simultaneously;

(3) the Fritsch Rule 604 [FN6] request for an interference on the 'process;' and

(4) the Examiner-in-Chief's readiness to declare the two interferences.

Point (C) provides no basis for granting relief in this case.

Point D

The last point raised by Lin is that Amgen 'will suffer further irreparable harm' if the Lin application is not issued as a patent. Some 'harm' might occur to Amgen if a patent is not issued. Nevertheless, Lin is not entitled to a patent at this time.

According to Lin, the 'harm' arises because Chugai cannot be barred from importing rEPO into the United States. Amgen cannot obtain relief under 19 U.S.C. § 1337, because it does not have a 'process' patent. Lin argues that Amgen cannot rely on its 'starting material' patent, because Chugai already has the starting material in Japan and use in Japan of the 'starting material' in the 'process' of Interference No. 102,097 is not 'infringement' in the United States. Lin reasons that if a patent was issued, Amgen could file a civil action under 35 U.S.C. § 281. In the civil action, Amgen could then seek (a) either an injunction or (b) a right to collect damages for infringement which takes place while the interference is pending--provided, of course, that Lin 'wins' the interference. Lin also suggests that Amgen could proceed under 19 U.S.C. § 1337 seeking to bar importation of rEPO by Chugai.

*7 While Lin's argument has some plausibility, it fails at this time on this record. [FN7] The present PTO record does not establish that Lin is the first inventor. Fritsch's Rule 608(b) showing suggests that Fritsch might win the interference. Moreover, as noted above, Fritsch plans to file certain preliminary motions. Those motions are all logical motions to be filed in these interferences. If granted, Fritsch
could become senior party and/or Lin's claims corresponding to the counts could be held unpatentable. Obviously, Fritsch's claims likewise could be held unpatentable, in which case judgment would be entered against both parties. What this all says is that assessing Lin's likelihood of success on the merits in the interferences is not reasonably possible at this point.

Lin's representations make it entirely clear that Amgen might file a civil action or seek relief under 19 U.S.C. § 1337. In either case, Chugai could defend on the ground that Amgen's patent is not valid under 35 U.S.C. § 102(g). Priority of invention would be contested simultaneously before (1) PTO, (2) ITC, [FN8] and (3) a U.S. district court. Having three priority contests conducted simultaneously is simply not efficient administration of justice. Inasmuch as Congress has determined [35 U.S.C. § 135(a)] that the Commissioner in the first instance should resolve interferences, a very good case exists for having Interference No. 102,097 proceed expeditiously in PTO-- not some other forum.

In balancing all factors apparent on the record in PTO, and given PTO's long-standing practice of not issuing patents based on applications pending in ongoing interferences, the better view is to maintain the status quo.

3. Further proceedings in these interferences

Inasmuch as it appears that Chugai can continue to import rEPO into the United States without any need to compensate Amgen, and Lin could win the interferences, there is an argument that Fritsch has a 'built-in' reason for 'delaying' resolution of these interferences. The counter argument is, of course, that if Fritsch delays and loses, it could effectively be put out of the rEPO business in the United States if a district court, in its discretion, determines that Fritsch's overall conduct justifies an injunction in any civil action brought on any patent which may issue to Lin. However, PTO does not resolve infringement issues and does not determine whether entities should be barred from importing material or enjoined from making, using, or selling material which infringes patents. What PTO can do, however, is expedite these interferences so that the respective rights of Fritsch and Lin, as well as their respective assignee and licensees, may be settled with reasonable dispatch. Expedited handling of the interferences is consistent with the decision of the Assistant Commissioner.

*8 Accordingly, this interference and Interference No. 102,096 are to be carried out with special dispatch. The Examiner-in-Chief should set a reasonably 'tight' schedule designed to resolve these interferences as expeditiously as possible. Counsel will be expected to arrange their respective calendars to meet any schedule set by the Examiner-in-Chief. Additionally, the Examiner-in-Chief is authorized to treat these interferences as the highest priority on his docket. In short, neither side can expect to succeed with delay.
For the reasons given herein, Lin's petition asking that its application, Serial No. 113,179, involved in Interference No. 102,097 be issued as a patent notwithstanding pendency of the interference is denied.

FN1. A copy of this opinion is being placed in the file of related Interference No. 102,096.

FN2. This background outlines some of the significant events. Attached hereto and made an Appendix to this opinion is a list of events in chronological order.

FN3. In the petition, Lin states that the request was filed on May 1, 1989. See e.g., Petition, p. 9. PTO records show that the request was filed on May 2, 1989. Lin's contentions regarding the May 2nd request are answered under Point (C), infra.

FN4. Preliminary motions are due on August 9, 1989. At the direction of the Commissioner, the Examiner-in-Chief orally advised counsel for both parties during the week of July 24-28th that PTO expects any preliminary motions to be timely filed and that neither party should expect any extension of time to file motions.

FN5. To the extent that the Examiner-in-Chief's decision should have been made by the Group Director and not the Examiner-in-Chief, an issue not here decided, the decision is ratified and thus becomes a decision of the Commissioner. There can be no question that the Commissioner could have decided Lin's May 2, 1989, request.

FN6. At the time Fritsch filed the Rule 604 request, Lin was not entitled to access to the request. 35 U.S.C. § 122.

FN7. If Lin 'wins' the interference, Amgen will have a patent with a 17-year life. 35 U.S.C. § 154. Hence, the interference in no way shortens the patent term.

## APPENDIX

### Past Events

1. **02-16-88**  
   Assistant Commissioner for Patents issues order that proceedings in any interference 'will be expedited by all Patent and Trademark officials concerned' (Paper No. 5 in S/N 07/113,179)

2. **06-01-88**  
   Fritsch files Rule 608(b) affidavit to provoke interference between his application and Lin's U.S. Patent 4,703,008

3. **09-06-88**  
   Fritsch requests interference between his application and the Lin application in what would eventually become Interference No. 102,097

4. **12-09-88**  
   Primary Examiner enters 'suspension' order in Lin Serial No. 07/113,179 due to potential interference

5. **12-20-88**  
   Form PTO-850 signed by Primary Examiner
   
   Form PTO-850 signed by Group Director

6. **01-10-89**  
   Examiner's request for interferences received by Board

7. **01-19-89**  
   Administrative Law Judge (ALJ) at International Trade Commission (ITC) enters order in a § 337 proceeding holding that ITC has jurisdiction, but Amgen is not entitled to relief because the '008 patent is not a 'process' patent

8. **01-31-89**  
   
   (1) An Amgen product infringes Genetics Institute's Patent No. 4,677,195 and
   
   (2) Amgen's '008 patent does not contain process claims

   D.Mass. refused to stay its hand pending outcome of ITC proceeding

9. **02-27-89**  
   Examiner-in-Chief sends cases to Primary Examiner requesting clarification of certain matters prior to declaring interferences

10. **04-10-89**  
    ITC dismisses § 337 proceeding on ground of lack of jurisdiction--holds that '008 patent does not claim a process--In the Matter of Certain Recombinant Erythropoietin, 10 USPQ 2d 1906 (ITC 1989)

11. **04-12-89**  
    Primary Examiner provides answers to questions by the Examiner-in-Chief

12. **05-02-89**  
    Lin files a request asking that stay be lifted and that
S/N 07/113,179 be passed to issue (in the petition, Lin says the request was filed on 05-01-89)

13. 05-09-89 Interference 102,096 declared
   Junior Party
   Fritsch, Serial No. 693,258, effective date 01-03-85;
   Genetics Institute, Inc. (Delaware Corp.) [a license has apparently been given to Chugai Pharmaceutical Co. of Japan--it in turn markets products in the U.S. via a 'joint venture' with The Upjohn Co.]
   Lead Atty: George A. Skoler
   Senior Party:
   Lin, Patent No. 4,703,008 (Serial No. 675,298) effective date 12-13-83; Amgen, Inc. (Delaware Corp.)
   Lead Atty: Paul N. Kokulis
   Count
   A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.

14. 05-09-89 Interference 102,097 declared
   Junior Party:
   Fritsch, Serial No. 693,258, filed 01-03-85; Genetics Institute, Inc. (Delaware Corp.) [a license has apparently been given to Chugai Pharmaceutical Co. of Japan--it in turn markets products in the U.S. via a 'joint venture' with The Upjohn Co.]
   Lead Atty: George A. Skoler
   Senior Party:
   Lin, Serial No. 113,179, effective date 12-13-83 Amgen, Inc.
   (Delaware Corp.)
   Lead Atty: Paul N. Kokulis
   Count
   A process for the preparation of an in vivo biologically active glycosylated polypeptide comprising [steps set out].

15. 06-01-89 Amgen receives FDA approval of its NDA for rEPO

16. 06-21-89 Lin motion (37 CFR § 1.635) to stay interference and to issue S/N 113,179 as patent; Lin incorporates petition to Commissioner by reference (Paper No. 8 of Interference No. 102,097)
   Lin files petition to Commissioner asking that S/N 133,179 be issued as a patent (Paper No. 9 of Interference No. 102,097) and continue Interference No. 102,097 between an
issued patent to Lin and Fritsch's application

17. 07-06-89  Fritsch serves opposition to Petition
18. 07-21-89  Lin serves reply to opposition to Petition

Future events

19. 08-09-89  Preliminary Statements and Preliminary Motions due

August 4, 1989

DONALD J. QUIGG

Commissioner of Patents and Trademarks

ORDER CORRECTING OPINION [FN1]

*9 On page 5, in the third and fourth lines from the bottom, in the MEMORANDUM OPINION AND ORDER entered August 2, 1989, the word "Amgen" should be "Genetics Institute". Thus, the last full sentence on page 5 should read:


FN1. A copy of this opinion is being placed in the file of related Interference No. 102,096.

14 U.S.P.Q.2d 1795

END OF DOCUMENT