

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HUMAN GENOME SCIENCES, INC.,)
)
 Plaintiff,)
)
 v.) Civ. No. 08-166-SLR
)
 GENENTECH, INC.,)
)
 Defendant.)

Steven J. Balick, Esquire, John G. Day, Esquire, Tiffany Geyer Lydon, Esquire and lauren E. Maguire, Esquire of Ashby & Geddes, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Richard L. DeLucia, Esquire, John R. Kenny, Esquire and A. Antony Pfeffer, Esquire of Kenyon & Kenyon LLP, New York, New York.

Philip A. Rovner, Esquire of Potter Anderson & Corroon LLP, Wilmington, Delaware. Counsel for Defendant. Of Counsel: Matthew D. Powers, Esquire and Vernon M. Winters, Esquire of Weil, Gotshal & Manges LLP, Redwood Shores, California; Elizabeth Scotland Weiswasser, Esquire, Peter Sandel, Esquire and Rebecca Fett, Esquire of Weil, Gotshal & Manges LLP, New York, New York.

MEMORANDUM OPINION

Dated: December 16, 2008
Wilmington, Delaware


ROBINSON, District Judge

I. INTRODUCTION

Plaintiff Human Genome Sciences, Inc. (“HGS”) filed the present action against Genentech, Inc. (“Genentech”) on March 25, 2008, seeking review of a Decision on Motions entered on November 28, 2007 and Final Judgment entered February 20, 2008 by the Board of Patent Appeals and Interferences (the “Board”) of the United States Patent and Trademark Office (“PTO”) in Interference No. 105,361 (“the ‘361 interference”). (D.I. 1) Genentech filed a motion to dismiss on May 25, 2008. (D.I. 9) For the reasons that follow, the court grants the motion.

II. BACKGROUND

A. Procedural Background

The American patent law system recognizes the first to invent, rather than the first to file. Consequently, there exists a complicated administrative process by which the PTO has jurisdiction in the first instance to determine priority of invention. The process, an “interference,” has been described as “tortuous,” “arcane,” “highly specialized,” and “virtually incomprehensible to the uninitiated.” Patents and the Federal Circuit, Fourth Edition, Robert L. Harmon, § 15.2 at 724-25 (1999).

At the beginning of an interference, the party that is first to file an application describing and enabling the “count” declared in the interference is designated the “Senior Party,” and the second the “Junior Party”; the Junior Party bears the burden of proof during the priority phase. 37 C.F.R. § 41.207(a). “A common two-party interference before the PTO is an administrative proceeding expected to be concluded in 24 months.” *General Instrument Corp. v. Scientific-Atlanta, Inc.*, 995 F.2d 209, 211

(Fed. Cir. 1993). The first phase in an interference is the preliminary motions phase. Because a party may not raise any issue at a final hearing that was not, but could have been, raised by a preliminary motion, “the preliminary motions which a party files or does not file . . . can have far reaching consequences for both the outcome of the interference and subsequent ex parte prosecution.” *Id.* at 212. Consequently, the Federal Circuit has advised that a party’s preliminary motions take into account its “long-range strategy with respect to . . . priority and patentability issues in the interference.” *Id.* (alteration in original). Preliminary motions generally are filed to redefine the scope of a contested case, to change the benefit date accorded for the contested subject matter, or for judgment in the contested case. 37 C.F.R. § 41.121 (a)(1). “To be sufficient, a motion must provide a showing, supported with appropriate evidence, such that, if unrebutted, it would justify the relief sought. The burden of proof is on the movant.” 37 C.F.R. § 41.208(b).

“If the examiner-in-chief’s rulings on the preliminary motions do not terminate the interference,” *General Instrument*, 995 F.2d at 212, the interference moves into the priority phase, wherein the Board receives testimony and evidence and decides the ultimate issue of priority of inventorship. A party dissatisfied with the Board’s final decision may request reconsideration of that decision, or it may seek judicial review. With respect to the latter course of action, a party may proceed directly to the Federal Circuit for review based on the record before the Board, or it may proceed to a district court for a “hybrid appeal/trial de novo proceeding in which the PTO record is admitted on motion of either party, but it may be supplemented by further testimony.” *Id.* at 212; 35 U.S.C. §§ 141-144, 146. “District court review of an interference proceeding under

section 146 is an equitable remedy of long standing.” *General Instrument*, 995 F.2d at 214. As a proceeding sounding in equity, “the district court may, in appropriate circumstances, exercise its discretion and admit testimony on issues even though they were not raised before the Board.” *Id.* Generally, however, for an issue to qualify for evidentiary review in a § 146 proceeding, “more is required than passing reference to the subject during the course of the interference proceeding.” *Id.*

B. Factual Background

HGS is the owner by assignment of the invention disclosed in U.S. Patent No. 6,872,568 (“the ‘568 patent”). The ‘568 patent, entitled “Death domain containing receptor 5 antibodies,” issued March 29, 2005 to inventors Jian Ni (“Ni”) et al.. (D.I. 1 at ¶ 7) The ‘568 patent was filed on May 4, 2000 as a continuation-in-part of U.S. Patent Application No. 09/042,583, filed March 17, 1998, which claims priority to two provisional applications, U.S. Patent Application Nos. 06/040,846 and 60/054,021, filed March 17, 1997 and July 29, 1997, respectively. Defendant is the owner of U.S. Patent Application No. 10/423,448 (“the ‘448 application”), filed April 23, 2003 and entitled “Apo-2 Receptor.” (*Id.* at ¶ 8)

On August 31, 2005, the Board declared the ‘361 interference between the ‘568 patent and the ‘448 application, and designated two counts.¹ In the declaration notice, the Board accorded Genentech the benefit of a May 14, 1998 filing date, corresponding

¹Claims 1-6, 8-19, 21-32, 34-45 and 47-52 of the ‘568 patent, and claims 114-19, 121-32, 134-45, 147-58, and 160-65 of the ‘448 application were designated as corresponding to count 1. (D.I. 1 at ¶¶ 10-11) Claims 7, 20, 33 and 46 of the ‘568 patent, and claims 120, 133, 146 and 149 of the ‘448 application were designated as corresponding to count 2. (*Id.* at ¶¶ 12-13)

to an earlier-filed Genentech patent application.² HGS was not accorded an earlier filing date than May 4, 2000, the filing date of the '568 patent. (D.I. 11, ex. 1 at 2) Genentech was thus designated the Senior Party, and HGS the Junior Party. (*Id.*)

Pursuant to the Board's Standing Order, HGS filed its list of intended motions with the Board on October 20, 2005. HGS requested that the Board authorize it to file motions seeking, *inter alia*: (1) a motion seeking judgment on priority; (2) a motion for unpatentability of all claims of the '448 application as anticipated under 35 U.S.C. § 102(e) by the '568 patent; and (3) a motion seeking sanctions against Genentech due to alleged misconduct in interfering with the ex parte prosecution of HGS's '568 patent.³ (*Id.*, ex. 2 at 1) HGS did not seek to assert motions for unpatentability on any other grounds, such as obviousness pursuant to 35 U.S.C. § 103. (*Id.*)

The Board did not authorize HGS's proposed motion for priority, and deferred priority motions "to the second phase of the interference." (*Id.*, ex. 3 at 3) HGS's motion for sanctions was authorized. (*Id.*) HGS's motion for unpatentability over HGS's involved patent was not authorized. (*Id.*)

Following oral argument, the Board dismissed HGS's motion for sanctions against Genentech. The Board noted that HGS concurrently submitted a complaint to

²U.S. Patent Application No. 07/079,029.

³More specifically, HGS argued that "certain activities by Genentech during the prosecution of Genentech's Application No. 09/020,746 were inappropriate and unauthorized protests against the patentability of the claims of HGS' Application 09/565,009 which issued as HGS' involved patent. The inappropriate activities relate to the filing of certain declarations which, in HGS's view, were 'all out attacks on the enablement, written description and utility disclosures' of certain applications, the filing dates of which HGS claimed benefit, and HGS's '009 application." (D.I. 11, ex. 4 at 2 (citation omitted))

the PTO's Office of Enrollment and Discipline ("OED"), which is "better suited to addressing matters of potential attorney misconduct occurring during ex parte examination." (*Id.*, ex. 4) That is, "[a]ssuming, without deciding, the truth of the allegations made by HGS, the matters alleged appear to be attorney conduct matters which do not impact the patentability of either HGS'[s] involved patent or Genentech's involved application," rendering OED the more appropriate review body. (*Id.*) The OED subsequently determined that "insufficient evidence" existed to support a "conclusion that there is probable cause to believe that [Genentech's counsel] intentionally violated any [PTO rules]." (*Id.*, ex. 10)

The Board subsequently considered HGS's arguments that it should be accorded the benefit of several earlier-filed provisional applications and one non-provisional application,⁴ and issued its Decision on Motions on November 28, 2007. In its decision, the Board noted that HGS, despite having the burden of proof, failed to provide a "clear and direct comparison of the elements of count 1 or count 2 to the disclosures of any of the cited applications," which "is the pivotal issue involved in any motion for benefit[.]" (*Id.*, ex. 5 at 14) The Board noted that "[t]he panel will not make out the movant's case for it by rooting through reams of testimony for the elements of the count." (*Id.*) The Board proceeded to evaluate HGS's arguments concerning the '846 application, including the opinion of HGS's expert, Dr. Reed, which the Board deemed largely "conclusory." (*Id.* at 18) Having considered the evidence presented

⁴U.S. Provisional Application Nos. 60,040,846 (hereinafter, "the '846 application") (filed March 17, 1997), 60/054,021 (filed July 29, 1997), 06/132,498 (filed May 4, 1999), 60/133,238 (filed May 7, 1999), and 60/148,939 (filed August 13, 1999); U.S. Patent Application No. 09/042,583 (filed March 17, 1998).

vis-a-vis the disclosure of the '846 application, including HGS's legal arguments and expert testimony, the Board ultimately concluded that HGS had failed to show prior possession of an enabled embodiment of either count.⁵ (*Id.*, ex. 5 at 23)

The Board thereafter set a schedule for the priority phase including a February 6, 2008 due date for HGS' priority motion. (*Id.*, ex. 6 at 2, 6) On December 13, 2007, Genentech filed with the Board a "Request for Consideration" of its "Decision on Motions and/or Order Setting Priority Times." (*Id.*, ex. 15) Genentech requested reconsideration of both orders "to the extent these papers advance this interference to a priority contest." (*Id.*, ex. 15 at 1) Genentech asserted that the Board "overlooked the fact that [HGS'] priority statement fail[ed] to overcome [Genentech's] accorded benefit date of May 14, 1998." (*Id.*, ex. 15 at 2) Specifically: (1) the notice declaring interference stated that HGS was accorded no priority date ("none"); (2) HGS's priority statement did not allege a date or location of corroborated actual reduction to practice of either count; and (3) although HGS "reserve[d] the right" to rely on any of the aforementioned provisional and non-provisional applications as constructive reduction to practice, the Board found against HGS in this regard and, therefore, HGS cannot rely on these references in the priority phase. (*Id.*, ex. 15 at 3-4) Genentech noted that HGS must prove by a preponderance of the evidence "nearly two years of reasonable and corroborated diligence," which it admitted it could not do in interference no. 105,240 ("the '240 interference"), another interference involving HGS' '568 patent. (*Id.*,

⁵"[S]imple identification of screening tests for agonist and antagonist antibodies is insufficient to make the leap that HGS has made – to possession of an enabled embodiment [of] the invention within the count. . . . At best, identification of a death receptor-like protein suggests further investigation. . . ." (D.I. 11, ex. 5 at 23)

ex. 15 at 5) Genentech requested that judgment should be entered against HGS or, alternatively, that HGS should be placed under an order to show good cause for litigating priority. (*Id.*)

On February 4, 2008, HGS filed a document with the Board entitled “HGS’s Intention Not to File a Priority Motion.” (*Id.*, ex. 7) In its submission, HGS stated that, during a January 4, 2008 conference call, HGS had requested authorization to file a motion for unpatentability of Genentech’s involved claims under 35 U.S.C. §§ 102(e) and/or 103(a). (*Id.*) HGS noted that its request for authorization to bring its motion during the motions phase was denied and that the Board had not yet ruled on its request to bring its motion during the priority phase. (*Id.*) Notwithstanding, HGS confirmed that it had chosen “not to file a priority motion in this interference in light of the Board’s earlier rulings, but in [an] action under 35 U.S.C. § 146 would seek review of those earlier rulings and with any modification thereof will seek judgment of priority.” (*Id.*) HGS “respectfully submit[ted], however, that the Board should not enter judgment of priority now.” (*Id.*)

On February 20, 2008, the Board issued a miscellaneous order in which it denied HGS’s request for authorization to file a motion that Genentech’s claims are unpatentable. (*Id.*, ex. 8 at 2) The Board stated that HGS previously requested to bring its § 102(e) motion, which request was denied, and HGS did not file a request for reconsideration. (*Id.*) The priority phase commenced February 6, 2008 – two days after HGS’s second request. The Board determined that “permitting [HGS’s] motion at this time would substantially lengthen and increase the cost of this proceeding.” (*Id.* at

3) Moreover, although the Board is required to determine priority between two rival claimants of an invention, it is not absolutely required to determine the patentability of a party's claims. (*Id.* at 2 (citing 35 U.S.C. § 135(a)) The Board denied HGS's motion, noting that "HGS has other remedies," such as "a protest under 37 C.F.R. § 1.291." (*Id.* at 3)

Also on February 20, 2008, the Board issued a document entitled "Judgment – Request for Adverse – Bd. R. 127(b)" in which it noted that HGS failed to submit a priority brief, filed a paper stating that it would not file a priority motion and, therefore, constructively entered a concession of priority. (*Id.*, ex. 9⁶) Judgment on priority was entered against HGS. (*Id.*) Because Genentech was awarded priority, claims 1-52 of the '568 patent were cancelled. (*Id.*, citing 35 U.S.C. § 135(a)) Genentech's request for reconsideration was dismissed as moot in view of the entry of judgment. (*Id.* at n.1) There is no indication that HGS sought reconsideration of the Board's decision.

The present action was filed on March 25, 2008 pursuant to 35 U.S.C. § 146. (D.I. 1) In its complaint, HGS states that it seeks judicial review of the Board's decisions adverse to HGS, including its determinations that: (1) HGS was not entitled to the benefit of its proffered earlier filing dates; (2) HGS "was not entitled to move that each claim of Genentech's '448 application is unpatentable in light of the HGS '568 patent under 35 U.S.C. § 102(e) and/or § 103"; (3) HGS was not entitled to a judgment of priority against the '448 application; and (4) HGS was not entitled to sanctions

⁶"The failure of a junior party to file a priority motion is construed as a concession of priority. Accordingly, it is appropriate to enter judgment." (D.I. 11, ex. 9 at 2 (citing 35 C.F.R. § 41.127(b))

against Genentech relating to its alleged improper attorney conduct. (D.I. 1 at ¶ 14) HGS specifically requests judgment of priority. (*Id.* at 7) Genentech filed its motion to dismiss on May 28, 2008.⁷

III. STANDARD OF REVIEW

Genentech brings its motion to dismiss alternatively under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). When subject matter jurisdiction is challenged under Rule 12(b)(1), the party asserting subject matter jurisdiction bears the burden of proving its existence; the district court is to regard the pleadings as mere evidence and may consider evidence outside the pleadings without converting the proceeding to one for summary judgment. *See Gould Electronics, Inc. v. U.S.*, 220 F.3d 169, 176-77 (3d Cir. 2000) (holding that the district court did not err by considering matters outside the pleadings in resolving a subject matter jurisdiction challenge); *see also Petruska v. Gannon Univ.*, 462 F.3d 294, 302 n.3 (3d Cir. 2006) (stating that when considering a factual attack to subject matter jurisdiction, “there is substantial authority that the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case”).

In considering a motion to dismiss under Rule 12(b)(6), the defendant/movant bears the burden of showing that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief. *See Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). The court must accept all factual allegations in the complaint as true and take them in the light most favorable to plaintiff. *See Erickson v. Pardus*, --- U.S. ---, 127 S.

⁷Following stipulations to extend time.

Ct. 2197, 2200 (2007); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002).

Nevertheless, a complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief,’ in order to ‘give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.’” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 1964 (2007) (citation omitted). A complaint does not need detailed factual allegations; however, “a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.’” *Id.* at 1965 (citations omitted). The “[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint’s allegations in the complaint are true (even if doubtful in fact).” *Id.* (citations omitted).

IV. DISCUSSION

A. Applicable Law

1. Appellate framework

The Board may take up motions for decisions at its discretion, and “may take such other action appropriate to secure the just, speedy, and inexpensive determination of the proceeding.” 37 C.F.R. § 41.125(a). A rehearing may be requested on a decision on motions within 14 days of the Board’s decision; a panel may be requested for the review.⁸ 37 C.F.R. § 41.125(c).

District courts may only review a final judgment by the Board, disposing of all issues that were, or by motion could have properly been, raised and decided. 37 C.F.R.

⁸No such rehearing was requested by HGS in this case.

§§ 41.125(b), 41.127(a)(1) & (2). “A party may at any time in the proceeding request judgment against itself. Actions construed to be a request for adverse judgment include . . . [c]oncession of priority or unpatentability of the contested subject matter[.]” 37 C.F.R. § 41.127(b)(3). Section 146 provides in relevant part that “[a]ny party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference, may have remedy by civil action[.]”

2. Jurisdictional and prudential exhaustion

A plaintiff must exhaust all required administrative remedies before bringing a claim for judicial relief. See *Robinson v. Dalton*, 107 F.3d 1018, 1020-21 (3d Cir. 1997) (citing *McKart v. U.S.*, 395 U.S. 185, 193 (1969)). When exhaustion is required by statute, its application is not subject to judicial discretion. *Cerro Metal Products v. Marshall*, 620 F.2d 964, 970-71 (3d Cir. 1980). This “judicial exhaustion” is a prerequisite to a court’s subject matter jurisdiction.⁹ *Wilson*, 475 F.3d at 174 (citing *Nyhuis v. Reno*, 204 F.3d 65, 69 (3d Cir. 2000)).

In contrast, prudential exhaustion is not a prerequisite to the district court’s jurisdiction.¹⁰ “A prudential exhaustion requirement is generally judicially created, aimed at respecting agency autonomy by allowing it to correct its own errors.” *Id.* (citing *Robinson*, 107 F.3d at 1020). Under prudential exhaustion principles, courts have discretion to hear unexhausted claims. This discretion

⁹Therefore invoking Rule 12(b)(1).

¹⁰It follows that prudential exhaustion is resolved under Rule 12(b)(6) covering motions to dismiss for failure to state a claim. See *Carstetter v. Adams County Transit Authority*, No. Civ. A. 06-1993, 2008 WL 2704596, *3 (M.D. Pa. July 8, 2008); accord *Robinson*, 107 F.3d at 1022 (citation omitted).

must be guided by the rationales advanced for the judicially created exhaustion doctrine. The doctrine has been said to serve the following purposes: [i]t (1) promotes administrative efficiency by preventing premature interference with the agency processes, (2) respects executive autonomy by allowing an agency the opportunity to correct its own errors, (3) facilitates judicial review by affording courts the benefit of the agency's experience and expertise, and (4) serves judicial economy by having the agency or other tribunal rather than the district court, compile a factual record. . . . [R]equiring exhaustion also exemplifies deference within the constitutional framework to Congress's decision as to the proper forum for the initial resolution of disputes under its statutes.

Cerro, 620 F.2d at 970-71 (internal citations and quotations omitted).

Because it is generally a judicially-created doctrine, rather than a rigid jurisdictional rule, prudential exhaustion provides exceptions for waiver, estoppel, tolling or futility. See *Metropolitan Life Ins. Co. v. Price*, 501 F.3d 271, 279 (3d Cir. 2007) (citations omitted). The futility exception has been described as "narrow," applying only in "situations in which enforcing the exhaustion requirement would mean that parties would be required to go through obviously useless motions in order to preserve their rights." *Corus*, 502 F.3d at 1379 (citation omitted). "In order to invoke the futility exception to exhaustion, a party must provide a clear and positive showing of futility before the [d]istrict [c]ourt." *Wilson v. MVM, Inc.*, 475 F.3d 166, 175-76 (3d Cir. 2007) (citation and internal quotations omitted).

3. Discussion

The question presented in the case at bar is whether exhausting remedies on the issue of benefit (the motions phase) is equivalent to exhausting remedies on the issue of priority for purposes of defining an appealable "decision" pursuant to § 146. The parties have not pointed to, nor has the court on its own efforts identified, Federal Circuit caselaw on point.

a. Prior analogous litigation

This case parallels in many respects Civ. No. 07-780 (hereinafter, “the ‘240 interference litigation”), filed by HGS pursuant to 35 U.S.C. § 146 for review of an adverse Board decision on motions. A brief review of that case will facilitate the court’s analysis here.

The ‘240 interference litigation also concerned the ‘568 patent. HGS filed suit after it had requested (and obtained) adverse judgment on priority. HGS represented to the Board that it was unlikely to prevail in the priority phase in view of the Board’s ruling that the ‘568 patent would not be accorded the benefit of any of the earlier patent applications in its chain. The Board had reached that conclusion because, despite submitting hundreds of pages of evidence, HGS ultimately failed to connect the disclosure of the ‘568 (continuation-in-part) patent with that of any prior applications.

Defendant in the ‘240 interference litigation, Immunex Corp. (“Immunex”), filed a motion to dismiss the ‘240 interference litigation under Rules 12(b)(1) and 12(b)(6). Immunex argued that HGS’s appeal was moot, insofar as it had voluntarily conceded priority before the Board. (Civ. No. 07-780, D.I. 9 at 8-11, 13-14) Immunex also argued that HGS had failed to state a claim upon which relief could be granted; absent a Board decision on priority, judicial review was premature. (*Id.* at 12-13)

The court ultimately agreed with Immunex. Although no authority was found that specifically limited HGS’s right to appeal under 35 U.S.C. § 146, the court nevertheless determined that HGS had not demonstrated subject matter jurisdiction. (Civ. No. 07-

780, D.I. 27 at 15¹¹) Prior to its appeal, HGS presented to the Board “little more than conclusory arguments.” The court determined that HGS was not entitled to poorly present its benefit case to the Board during the motions phase and subsequently elect to terminate the action prior to the priority phase to obtain supplemental discovery in the context of a § 146 action. Put another way, HGS did not justify “usurp[ing] the Board’s original jurisdiction to determine priority” on that record.¹² (*Id.*)

The case at bar is quite similar. The record indicates that HGS presented a poor benefit case to the Board in the first instance. The Board noted that HGS provided no separate arguments with respect to four of its six identified priority references. (D.I. 11, ex. 5 at 13) With respect to the others, HGS failed to compare the elements of the counts to the disclosures of the references. (*Id.* at 14) HGS presented what was essentially an enablement argument on its two main references, supplemented by the largely “conclusory” declaration of its expert. (*Id.* at 15-18) Ultimately, the Board analyzed HGS’s expert testimony and prior published statements by HGS’s experts, and concluded that the prior publications were not sufficient to describe and enable the inventions of the counts. (*Id.* at 22) HGS voluntarily terminated the ‘361 interference after the decision on motions and took this § 146 appeal.

b. Exhaustion of remedies

The Board is in a unique position to determine priority. Accordingly, Congress

¹¹*Human Genome Sciences, Inc. v. Amgen, Inc.*, 552 F. Supp. 2d 466 (D. Del. 2008).

¹²The court stated that its decision was based on a lack of proof of subject matter jurisdiction (Rule 12(b)(1)).

has mandated that the Board “shall determine questions of priority.” 35 U.S.C. § 135(a). No determination on the merits occurred below. HGS focuses on the fact that **judgment** on priority was ultimately issued against it in this case. (D.I. 15 at 25-26) HGS’s argument ignores the plain import of § 135(a), which requires that the Board “determine **questions of priority**” – not merely issue judgment on the issue. There is truly no priority decision by the Board to review.¹³

Even if judicial exhaustion principles were inapplicable, however, the court would find that prudential exhaustion warrants the dismissal of HGS’s suit. The absence of a developed record¹⁴ frustrates, rather than promotes, judicial economy in this instance. *See Cerro*, 620 F.2d at 970-71; *see also Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 (Fed. Cir. 1994) (“[T]he parties to an interference must make a complete presentation of the issues at the Board level so that the interference is efficient and not wasteful of administrative and judicial resources.”). Little can be gained from reconsidering the first portion of this interference record, based more on the absence of fruitful argument by HGS than actual disagreement on the law or evidence, absent a reviewable discussion of priority by the Board.

HGS has advanced a futility argument in this case. HGS stated that, but has not detailed why, it cannot provide evidence corroborating two years of reasonable

¹³Arguably, the Board’s decision on HGS’s motion for reconsideration in the ‘381 interference, wherein the Board discussed the futility of a priority phase involving invalid claims, may be considered a “decision on priority” for purposes of satisfying § 135(a).

¹⁴The court distinguishes the developed motions phase record from the undeveloped priority phase record.

diligence pre-dating the filing date of the '568 patent. (D.I. 15 at 13¹⁵) Genentech argues that HGS cannot make the required “clear and positive showing” of futility on counsel’s affirmations alone.¹⁶ The court agrees. The futility exception (to administrative exhaustion) is a narrow one, and the exception should not swallow the rule.

The court’s conclusion in this regard is bolstered by the fact that the Board did not articulate, in either the '240 or '361 interferences, that the priority phase would be unproductive. In contrast, the Board in interference no. 105,381, another interference involving HGS, issued an order to show cause why that interference should proceed following a decision on motions that the claims of HGS’s application were unpatentable under 35 U.S.C. § 102(e).¹⁷ HGS attempted to persuade the Board to determine

¹⁵ “[T]o prevail after the Board’s benefit decisions, HGS had to prove not only that it conceived of the invention prior to Genentech’s accorded benefit date (*i.e.*, at a minimum prior to May 14, 1998), but that it also had exercised reasonable diligence from prior to May 14, 1998 (or an even earlier conception date if proven by Genentech) to May 4, 2000, a period of almost 2 years. The requirements for such a showing made it impossible for HGS to meet the necessary standard. Because HGS could not make the required showing on conception and diligence, it could not win the priority contest under the Board’s decision on benefit.”

¹⁶ This argument is not at odds with Genentech’s motion for reconsideration, wherein Genentech stated that, based upon HGS’s representations of record in the '240 interference, HGS could not likely establish priority. Genentech’s recognition of HGS’s prior representation should not alleviate HGS of its burden to establish the applicability of the futility exception.

¹⁷ The Board framed the issue as “whether th[e '381] interference should continue for the sole purpose of allowing a junior party with unpatentable claims to attempt to take away senior party Immunex’s patent.” (Civ. No. 07-526, D.I. 33 at 12 & n.56)

priority,¹⁸ but the Board concluded that “no significant need to address priority” existed, insofar as HGS’s claims were deemed unpatentable. (*Id.* at 15 & n.67¹⁹) HGS filed suit in this court pursuant to § 146, and that suit remains pending. (Civ. No. 07-526-SLR-MPT)

Another example of the Board’s willingness to articulate exhaustion of the administrative process can be found in interference no. 104,646, captioned *Rasmusson v. SmithKline Beecham Corporation*.²⁰ Rasmusson, the junior party, chose not to assert a priority or derivation challenge following adverse decisions in the motions phase. (D.I. 16, ex. F at 5) The Board issued an order to show cause why the interference should proceed; subsequently, an “order vacating [the order to show cause] and entering final judgment” was entered. Therein, the Board specified that its prior decisions on motions should be merged and considered “final” for purposes of appeal. (*Id.* at 6) The Board noted that “termination of the interference at this point is consistent with securing the just, speedy and inexpensive determination of the interference by avoiding needlessly subjecting the parties to redundant and unnecessary expenditures of time, effort and

¹⁸In responding to the Board’s order to show cause why the ‘381 interference should not be terminated, HGS argued to the Board that the Board is “statutorily obligated [to] resolve fairly and fully raised priority questions,” and that this “obligation is grounded in the plain language of [35 U.S.C. § 135(a)] and fully supported by both Federal Circuit and Board decisions.” (D.I. 11, ex. 14 at 1)

¹⁹“While there is a strong public interest in resolving patent validity, resolving the validity of an issued patent is not the purpose of an interference proceeding. The purpose of the interference is to resolve who between rivals of the same patentable invention should obtain the patent. It has been determined in this interference that HGS’ involved claims are unpatentable over prior art. So the determination has been made that HGS is not entitled to a patent.”

²⁰Cited by HGS.

money.” (*Id.*) (citation and internal quotations omitted). An appeal was subsequently considered by the Federal Circuit pursuant to 35 U.S.C. § 141. See *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005).²¹

The Board did not provide a comparable signal in either the ‘240 or ‘361 interferences.²² In both cases, the Board appeared willing to move forward on priority, an issue within its “experience and expertise,” see *Cerro*, 620 F.2d at 970-71, and did not note any potential futility in doing so. Prior to conceding priority for purposes of appeal, HGS did not file motions for reconsideration based on the decisions on motions. Both § 146 appeals were initiated by HGS, not the Board, based upon HGS’s belief that it could not establish priority.

The caselaw indicates that “[t]he mere fact that an adverse decision may have been likely does not excuse [HGS] from a statutory or regulatory requirement that it exhaust administrative remedies.” See *Corus Staal BV v. U.S.*, 502 F.3d 1370, 1379 (Fed. Cir. 2007) (citation omitted). Based upon the foregoing, and in view of the lack of Federal Circuit precedent mandating otherwise, the court declines to review the underdeveloped and incomplete record below as a matter of judicial economy, and declines to adopt a position that would freely allow litigants to circumvent Board

²¹HGS asserts that no difference exists between the appellate right under sections 141 and 146. (D.I. 15 at 21 n.12) The court finds a substantial difference between the situation at bar and that presented in *Rasmusson*, where the Board deemed it necessary to make its decisions on motions “final,” and an appeal was taken to the Federal Circuit without the benefit of additional discovery.

²²The Board had a specific opportunity to so state upon Genentech’s motion for reconsideration in the ‘361 interference, but did not.

decisions on priority.²³

V. CONCLUSION

Genentech's motion to dismiss, therefore, is granted. (D.I. 9) An appropriate order shall issue.

²³In view of its holding, the court need not reach Genentech's arguments regarding whether HGS's § 103 and sanctions claims are appropriately before the court, *i.e.*, whether HGS adequately raised the issues below. The court notes, however, that it would be disinclined to allow either claim. HGS has offered no justification for failing to raise § 103 in the motions phase. HGS's sanctions claims were not directed to any interference issue and the merits of HGS's claim were ultimately considered by the OED, not the Board. On its face, section 146 applies only to review of Board decisions. Although HGS claims that it appeals only the Board's decision to dismiss its sanctions claim, it effectually seeks usurpation of a decision on the merits by the OED.

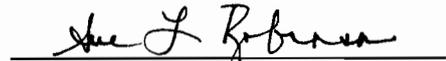
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HUMAN GENOME SCIENCES, INC.,)
)
 Plaintiff,)
)
 v.) Civ. No. 08-166-SLR
)
 GENENTECH, INC.,)
)
 Defendant.)

ORDER

At Wilmington this 16th day of December, 2008, consistent with the memorandum opinion issued this same date;

IT IS ORDERED that defendant's motion to dismiss (D.I. 9) is granted.


United States District Judge