

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)	
AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	
)	CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD,)	
ROCHE DIAGNOSTICS GMBH,)	
and HOFFMANN-LA ROCHE INC.,)	
)	
Defendants.)	
_____)	

**ROCHE’S OPPOSITION TO AMGEN’S BRIEF ON THE
APPLICATION OF STARE DECISIS TO THE CLAIM
CONSTRUCTION TO BE HELD BY THIS COURT**

Introduction

The United States Supreme Court in *Markman v. Westview Instruments* (hereinafter “*Markman IP*”)¹ did indeed seek to strive for uniformity in claim interpretation as a goal; however, the Court also characterized the process that this Court must undertake in claim construction -- “construing a term of art after receipt of evidence” -- as a “mongrel practice,” (*id.* at 378) and noted that the issue may “ ‘fall[] somewhere between a pristine legal standard and a simple historical fact,’ ” (*id.* at 388). That the process of claim construction has been reserved for the Court, and not a jury, comes from the recognition that when an issue “falls somewhere between a pristine legal standard and a simple historical fact, the *fact/law distinction* at times has turned on a determination that, as a matter of sound administration of justice, one judicial actor is better positioned than another to decide the issue in question.” *Id.* What the Supreme Court

¹ 517 U.S. 370 (1996).

recognized was that in such cases where legal issues predominate, but are supported by intricate factual underpinnings, such as during a review of the intrinsic and extrinsic evidence during claim construction, as between a jury and a Judge, it is the Judge who is better equipped and trained to make that determination, equating the process somewhat to contract interpretation. *Id.* at 388-89. This language of the Supreme Court in *Markman II* suggests also that there is no absolute application of the *stare decisis* principle in claim construction, deferring instead to the sound judgment of the trial court in the particular circumstances of each case.

From that position, Courts have wrestled, and continue to wrestle, with the concept of whether once claim construction has taken place in one case for a certain term, is that definition fixed by *stare decisis* for all future litigants of those same patent claims, or do fundamental due process protections surrounding principles of claim preclusion (collateral estoppel) come into play. What the Court should take away from these cases, even those cited by Amgen, is that the Supreme Court looked to the trial court to apply its judgment and discretion in each case. Particularly troubling for courts is the recognition that during claim construction in one litigation, a party may select to present, or not to present, certain intrinsic evidence to the Court which would have a dramatic impact on how that term is interpreted. A party then to a later lawsuit, with different and additional claim terms at issue, might choose to offer intrinsic evidence not presented by the earlier litigant which puts the interpretation of the earlier claims into a wholly different light for the Court. *See, e.g., International Communication Material, Inc. v. Ricoh Co., Ltd.*, 108 F.3d 316, 318 (Fed. Cir. 1997) (Court recognized that the material presented to the district judge “pertaining to claim interpretation was incomplete.”). The Courts acknowledge that claim construction is for the Court to perform as a matter of law.²

² *See, Cybor Corp. v. FAS Tech., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998).

Against this backdrop, Roche contends that it should not be bound under principles of *stare decisis* to the prior claim construction. In the words of the District Court in *Texas Instruments, Inc. v. Linear Technologies Corp.*, 182 F.Supp. 2d 580, 589-90 (E.D. Tex. 2002):

“in those cases where, as here, defendants have had no chance to litigate their claims, the application of *stare decisis* in the form of an adoption of claims construed without Defendants' participation could cause an *injustice of precisely the sort that due process seeks to avoid.*” (emphasis added).

Argument

I. Fundamental Fairness Counsels Against the Application of Stare Decisis

Amgen claims that prior claim construction rulings both of this Court and of the Federal Circuit in the *HMR/TKT* litigation bind Roche even though Roche was not a party to the proceedings that generated those rulings, under the doctrine of *stare decisis*.³ As Roche describes herein, there is an established body of case law that supports the proposition that *stare decisis* should not govern claim construction when the same, and different, claim terms are later litigated by new and different parties. Several Courts have chosen to apply a more “fair” approach to prevent injustice in circumstances where a later litigant should not be blindly bound to a prior claim construction ruling. *Stare decisis* should yield to collateral estoppel in circumstances like those presented here.

The application of *stare decisis* to a prior claim construction ruling starts with the concept that claim construction is done by the trial judge as a matter of law. The concern was that a future trial judge visiting a patent for the first time, should apply some uniformity in interpretation of the claims of that patent from a prior litigation. Here, however, Roche and Amgen are before the very trial court that decided previously the meanings of certain terms of

³ Amgen Inc.'s Response to the Court's Questions Regarding Precedential Effect of Prior Claim Constructions and Defendants' Reply Brief Regarding Claim Construction, dated April 11, 2007 (hereafter “Amgen Br.”) Court Docket No. 370.

the patents-in-suit, and therefore has a better familiarity with the issues here than a judge coming to these patents for the first time. Moreover, rather than contending that the process of claim construction in this instance for these patents is purely legal, Amgen itself concedes and has argued to the United States Supreme Court that claim construction rests on factual determinations:

“the Federal Circuit is wrong. Claim construction rests on factual determinations, appellate deference to which is *required* by Federal Rule of Civil Procedure 52(a) and this Court’s precedents.”⁴

Amgen also concedes, as it must, that under a collateral estoppel analysis, Roche is not bound to those prior claim construction rulings, which explains its attempts to argue for rigid adherence under *stare decisis*. (Amgen Br. at 1).

It is well-established that claim construction is grounded in intrinsic evidence (an in some instances extrinsic evidence) and depends significantly on which evidence a party puts before the Court. At any given time during claim construction what evidence a party relies on is driven by that party’s individual agenda and strategies. For example, the Court might envision a situation in one case where the parties agree not to present the Court with any part of the file history, or chose not to cite from relevant portions of the specification. *Kwitek v. Pilot Corp*, 2007 WL 1091023, *3 (E.D.Tex. 2007) (“[T]he claim construction hearing is supposed to be an opportunity for each side to provide to the court the information necessary to define the disputed terms of the claims. A party which declines that opportunity should not be allowed to later leap from behind its log swinging a sandbag labeled, ‘the judge didn’t read the mind of our expert who was not there.’”). Those litigation choices may lead to one result in claim construction, where a different party on a different record might present compelling and important intrinsic evidence that may put the claim term in a wholly different context. It is fundamentally unfair for

⁴ Cert Pet. at 17; *see also* Cert. Pet. at 3 ((Amgen Br. at 2) (emphasis in original)).

Amgen to seek to bind Roche, who had no voice nor presence in that earlier action, with what prior defendants chose to argue in prior lawsuits regarding so core an issue as claim construction. Here, with the same Judge analyzing the same patents, any concern for uniformity and lack of appropriate knowledge are allayed.

As the Court is well aware, claim construction starts with the words of the claims and then expands to include such other intrinsic evidence as the specification and file history (itself a record of statements, dialogue and representations during the evolutionary life of the patent claims) and then even to extrinsic evidence such as expert testimony and treatises if the Court deems them helpful. Throughout this process, the Supreme Court and Federal Circuit have determined that the trial court is the better “judicial actor” to decide the question in issue with this factual evidence. Yet in practice, trial courts have struggled with balancing the need for interpretative uniformity with the protection of a new litigants due process rights. In *Texas Instruments, Inc.*, 182 F.Supp. 2d at 590 (emphasis added), the Court applied the proper standard and held that “where, as here, defendants have had no chance to litigate their claims, the application of *stare decisis* in the form of an adoption of claims construed without Defendants’ participation could cause an injustice of precisely the sort that due process seeks to avoid.” Following the Supreme Court’s intent and language, and given this Court’s familiarity with the prior rulings and the patents-in-suit, the need to protect Roche’s due process right to justice far outweighs any general concern for interpretative consistency.

Moreover, there are still outstanding terms from the Court’s prior rulings, again at issue in this upcoming Markman hearing that the Federal Circuit has remanded to this Court for determination, or which have never been interpreted. As Roche has argued to the Court, with regard to Claim 1 of the '422 patent, the Federal Circuit has said that the parties and the Court on

remand should be "mindful" of the legal doctrine that old compositions are not new just because they come from a different source or process. Roche contends that, with regard to the claim term "purified from mammalian cells grown in culture," this is a source limitation and that it does not impart any structure.

A. Other Courts have Followed *Markman*'s Instruction and Rejected *Stare Decisis*

For its part, Amgen has cited no case holding that a district court *must give stare decisis* effect to its prior claim construction determinations against a party that was not part of the proceedings in which those determinations were made. Indeed, Amgen concedes that Roche can challenge this Court's previous rulings by acknowledging that Roche is not precluded under collateral estoppel principles from challenging the prior rulings of the Federal Circuit on claims construction before that court. (Amgen Br. at 1). Thus, the precedential force of the prior claim construction rulings of this Court, must be evaluated under issue preclusion doctrine, and fundamental fairness. Amgen's contention that this Court's prior claim construction determinations in other cases are binding on Roche is wrong. *Stare decisis* does not apply to bind a district court to the claim construction determinations of a district court in a different case over the same patent. See *Visto Corp. v. Sproqit Technologies, Inc.*, 445 F. Supp. 2d 1104, 1107 (N.D. Cal. 2006) (stating that as to a claim construction ruling on the patent at issue by another district court, "[s]tare decisis, of course, does not literally apply."); *Lamps Plus, Inc. v. Dolan*, 2003 WL 22435702, *2 (N.D. Tex. 2003) (holding that "*stare decisis* does not dictate" the adoption of claim construction of a different district court on the patent at issue).

Even if the same district court is construing the same patent in a second case, it is not bound to adopt the earlier rulings on claim construction. See *KX Indus. v. PUR Water Purification Products, Inc.*, 108 F. Supp. 2d 380, 387(D. Del. 2000). In *KX Indus.*, a case on

which Amgen relies (Amgen Br. at 3, n. 8), the court stated that it could adopt its own earlier claim construction ruling (in a case involving a different defendant) only “to the extent the parties do not raise new arguments.” *Id.* In fact, the court in *KX Indus.* entertained new arguments on claim construction and then held that one of its prior claim construction rulings “was wrong,” demonstrating that *stare decisis* does not bind the new party. *Id.* at 389.

This Court’s prior claim construction rulings, however, are binding on Amgen as Amgen was a party to the earlier litigation.

B. The Application of the Prior Rulings are Within This Court’s Discretion

Amgen argues that under the Supreme Court decision in *Markman II*, any court ruling on the construction of terms on a patent has the force of *stare decisis* as to any subsequent litigation. As explained above, *Markman II* does not stand for such a broad proposition. The Supreme Court in *Markman II* acknowledged a general guideline, but left it to the sound discretion of the trial courts to determine what “reasonable” standard should apply as the best “judicial actor” for this task. 517 U.S. at 388. The portion of the *Markman* case on which Amgen so heavily relies was pure *dicta* in which the Court was explaining the rationale for why claims construction is better resolved by the judge rather than a jury. Significantly, the Court did not rule that *stare decisis* must apply to an appellate court’s determination of claims construction issues on a patent. Indeed, the Court’s language includes the disclaimer that such certainty by application of *stare decisis* principles is “not guarantee[d]”, making clear that the Court was offering a view that relegated the application of whether *stare decisis* should as a matter of course apply, to the sound discretion of the trial court. *Id.* at 391.

More significantly, Amgen seeks to impose on Roche the Federal Circuit claim construction rulings that Amgen itself vehemently disagrees with and is in the process of

appealing to the Supreme Court for reversal. Amgen has recently filed a petition for a writ of certiorari to the Supreme Court of the Federal Circuit's claim construction rulings in the *HMR/TKT* case -- a petition that it inexplicably fails to mention in its brief. In its petition, Amgen asserts that the Federal Circuit wrongly decided claim construction issues and seeks reversal of that decision by the Supreme Court. Specifically, Amgen claims that the Federal Circuit erred by applying a *de novo* standard of review of this Court's claim construction rulings which Amgen contends "are fundamentally assessments of fact, not law" and thus are entitled to a deferential standard of review. (Cert Pet. at 17); *see also* (Cert. Pet. at 3) ("the Federal Circuit is wrong. Claim construction rests on factual determinations, appellate deference to which is *required* by Federal Rule of Civil Procedure 52(a) and this Court's precedents") (emphasis in original).

Amgen cannot be right both before this Court and the Supreme Court. If this Court accepts Amgen's position and determines that Roche is bound by the claim construction rulings in the *HMR/TKT* case under *stare decisis*, and then later the Supreme Court accepts Amgen's argument that claim construction is a question of fact, not of law, this Court will have to revisit the whole issue of claim construction -- likely after trial of the merits.

Indeed, courts since *Markman II* was decided have applied a collateral estoppel test -- not *stare decisis* -- to the issue of the precedential effect of a prior ruling on claim construction that was adopted or affirmed by the Federal Circuit. In *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 243 F. Supp. 2d 31 (S.D.N.Y. 2003), the court was confronted with the situation here -- claims in the patent at issue had been construed in a different case involving the same plaintiff by a district court and then affirmed on appeal by the Federal Circuit. The court analyzed the precedential force of the prior claims construction against the plaintiff under the collateral

estoppel doctrine. *Id.* at 35; *see also, Rockwell Int'l Corp. v. SDL, Inc.*, 2000 U.S. Dist. LEXIS 21910, *46 (N.D. Cal. 2000). The cases that Amgen cites suggesting that *stare decisis* may bind subsequent litigants in fact support Roche's argument that this Court should use its own judgment on how to apply its prior rulings with flexibility and fairness.⁵

Conclusion

Accordingly, Roche respectfully submits the precedential force of the Federal Circuit's construction of the claims in the patents-at-suit should be analyzed under issue preclusion (collateral estoppel) principles, which, as Amgen admits, do not operate to bind Roche.

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April 16, 2007

Respectfully submitted,

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⁵ *See Wang Laboratories, Inc. v. Oki Electric Industry Co., Ltd.*, 15 F. Supp. 2d 166 (D. Mass. 1998); *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*, 185 F. Supp. 2d 588 (D. Md. 2002); *Hynix Semiconductor Inc. v. Rambus Inc.*, 2004 U.S. Dist LEXIS 23230 (N.D. Cal. 2004). Indeed, in the cases Amgen relies upon the courts made their own determination of whether the claims construction of the Federal Circuit were reasonable, rather than slavishly applying them to a subsequent litigant. For example, in *Hynix* the court performed its own analysis to determine whether the claims construction reasoning of the Federal Circuit in the prior cases was "persuasive." *Hynix*, 2004 U.S. Dist LEXIS 23230 at *23. Similarly, in *Tate*, the court determined whether, under the facts of the subsequent case involving a different defendant, the Federal Circuit constructions were "reasonable and consistent with the basic principles of claim construction." 185 F. Supp. 2d at 595.

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