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Shire LLC v. Sandoz Inc.: Issue Preclusion and *Markman* Decisions

Earlier this year, the Federal Circuit agreed to hear an appeal of an interlocutory order from a case in the District of Colorado captioned *Shire LLC v. Sandoz, Inc.*¹ to decide the issue of whether a patentee – who settles an earlier patent infringement case after a *Markman* claim construction ruling has issued – is precluded under the doctrine of collateral estoppel from relitigating the claim construction issues in connection with the same patent in a later case.² This article describes the current split among district courts on the issue of whether a *Markman* ruling is preclusive.

In general, the doctrine of collateral estoppel³ is that a prior judgment bars a party to an earlier lawsuit (and those in privity with them) from relitigating issues necessary to and actually litigated in the earlier lawsuit.⁴ However, the due process guarantees of the Fifth and Fourteenth Amendments protect a person not involved with the earlier lawsuit from being bound by a judgment to which they were not a party, even if all of the other preclusion requirements are met.⁵

In the context of *Markman* rulings, the doctrine of collateral estoppel is generally invoked by a new defendant litigating against a patentee who has had a say in a previous litigation of its patent. In such cases, some courts have found the application of collateral estoppel to be appropriate. However, when it is the patentee who seeks

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It Only Took a Hundred Years: The Federal Circuit Finally Settles the Doctrine of Infringement of Product-By-Process Claims

For over a century, patent applicants have been able to claim their inventions using product-by-process claims, wherein “the product is defined at least in part in terms of the method or process by which it is made.”¹ Traditionally, product-by-process claims have been particularly important for the chemical and biochemical fields, because they allowed inventors to patent complex reaction products when it was impossible to conclusively identify or characterize the products. In the early 1990s, however, the Federal Circuit issued conflicting opinions² regarding the infringement of product-by-process claims. Recently, the Federal Circuit addressed those opinions when it issued its *en banc* panel decision in *Abbott Labs. v. Sandoz, Inc.*,³ and held that infringement of a product-by-process claim requires practicing all of the claimed process steps.⁴ This bright-line rule

has obvious ramifications on claim scope, and will likely impact the use of product-by-process claims in the future.

A Brief History of Product-By-Process Claims

Product-by-process claims have been used since at least 1891, when the U.S. Patent Office issued its decision in *Ex parte Painter*,⁵ noting that it was sometimes impossible to describe an invention without referring to the process of production, and that one’s right to patent it should not be “determined by the limitations of the English language.”⁶ Product-by-process claims are now allowed under all circumstances, provided the claims fully comport with 35 U.S.C. §112.⁷

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to have a *Markman* order from an earlier litigation applied against a defendant who did not participate in the previous case, some courts have resisted the application of collateral estoppel.

The Federal Circuit has identified the following four elements as necessary to invoke collateral estoppel:

- 1) the issue must be identical to the one in the prior litigation;
- 2) the issue must have been actually litigated in the prior litigation;
- 3) the determination of the issue in the prior litigation must have been a critical and necessary part of the judgment in that action;⁶ and
- 4) the party against whom the earlier decision is asserted must have had a full and fair opportunity to litigate the issue in the earlier proceeding.⁷

Even if all of these elements are met, a court may in some circumstances decline to apply collateral estoppel where it would be unfair to the defendant.⁸ Examples include situations where (1) the defendant had little incentive to defend vigorously in the first suit because he was sued for small or nominal damages; (2) the first judgment is inconsistent with one or more previous judgments in the defendant's favor; or (3) the second action affords the defendant procedural opportunities (e.g., discovery procedures) that were unavailable in the first action, and that could cause a different result.⁹

As such, collateral estoppel is only appropriate when there has been a final judgment in an earlier case. However, the Federal Circuit has yet to decide whether *Markman* rulings are sufficiently definite to be considered final for the purposes of collateral estoppel. There are ramifications either way. To illustrate, if the Federal Circuit deems *Markman*

rulings final for purposes of collateral estoppel, does that afford a right to immediately appeal?¹⁰ If so, this will increase the burden on appellate-level resources.

However, it could be argued that denying interlocutory appeal of *Markman* rulings may have a chilling effect on settlements. For example, consider a case in which a narrow claim construction makes infringement clear in one case, but is too limiting for enforcing the patent against future infringers.¹¹ Without a right to appeal, there may be a reduced

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While collateral estoppel is being considered by the courts, lawmakers are also tackling the issue in The Patent Reform Act of 2009.

incentive for the patent holder to settle the case. Moreover, the Federal Circuit has recognized that “[d]istrict courts may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves.”¹² If a *Markman* order is final, does that tie the hands of district courts when evidence is received that would otherwise cause the court to amend the claim construction?

The issue of whether a *Markman* ruling has a preclusive effect is a complex one, impacted by both factual issues (e.g., procedural posture of the underlying case) and policy considerations (e.g., the application of collateral estoppel – i.e., single, uniform claim construction – would promote certainty for litigants and reduce the burden on judicial

resources). Certain circumstances exist where the application of collateral estoppel would seem appropriate and fair, e.g., a second litigation involving the same litigants as an earlier case, where the second litigation involved the same patents as the first, the litigants had the opportunity to appeal the claim construction in the first litigation, and the second litigation involved no new claim construction arguments. However, such circumstances rarely occur, so district courts, and now the Federal Circuit, have had to decide the issue of when to apply collateral estoppel in cases where only some of these facts are present. District courts have exercised broad discretion in determining when to apply collateral estoppel¹³ with the end result being a split among the circuits on the issues of whether *Markman* rulings are final for the purposes of collateral estoppel. The Federal Circuit has an opportunity to weigh in on the issue in *Shire*.

And it should be noted that, while this is being considered by the courts, lawmakers are also tackling the issue. The Patent Reform Act of 2009 includes a provision (at S. 515 sec. 8(b)) that would permit interlocutory appeals of claim construction orders, at the discretion of the district court.

Shire at a Glance

In *Shire*, the patents at issue at the district court level had been the subject of three prior litigations. In two of these earlier cases (considered by the same court), the claims were construed in a *Markman* order, but the parties later agreed to settle.¹⁴ In the present *Shire* litigation, now on appeal to the Federal Circuit, the defendant maintained that the patent holder should be precluded from arguing claim construction because of the earlier *Markman* order.¹⁵

In deciding the collateral estoppel issue, continued on p. 3

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the district court looked to the Restatement of Judgments,¹⁶ the Federal Rules of Civil Procedure,¹⁷ and Federal Circuit decisions.¹⁸ Ultimately, the district court held that it was impossible to apply collateral estoppel, even if it was otherwise appropriate, because although the two previous *Markman* orders from different district courts addressed the patents in the case, (1) the previous decisions took opposite positions regarding the issues affecting the claim construction, and (2) one of the courts failed to provide any reasoning underlying the findings in its *Markman* order.¹⁹ The district court later granted certification for interlocutory appeal, citing the divide among circuits as to whether *Markman* orders are final.²⁰

The Circuit Split

Circuits Treating *Markman* Rulings as Preclusive

Several district courts have held that a *Markman* order is a final judgment for collateral estoppel purposes. The hallmark case for this position is *TM Patents, LP v. International Business Machines Corp.*²¹ Courts in agreement with *TM Patents* reason that collateral estoppel helps preserve judicial precedent and removes the ability of wealthy litigants to buy away unfavorable preclusive effects through settlement.²² Whereas, courts that have declined to follow *TM Patents* label claim construction rulings as tentative, and note that there is no opportunity for Federal Circuit review of claim constructions that are not attached to final judgments.²³

First Circuit

In *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, the plaintiff had been in a previous litigation where the same court conducted a *Markman* hearing construing the terms of the patents at issue.²⁴ The court determined that, in the absence of any new arguments in the current case, fairness required adherence

to the prior claim construction.²⁵ The court held that it would only consider modifying its previous decision if an argument was presented that would alter the prior claim construction, because to do otherwise would create ambiguity and uncertainty.²⁶

Second Circuit

The court in *TM Patents* addressed the issue of preclusion under the following factual scenario: a prior case that involved the same patents, but a different defendant, and which settled following a *Markman* hearing in the same district court.²⁷ The court in *TM Patents* held that the judge's prior claim construction was sufficiently final to permit collateral estoppel even though the matter was never reduced to a final judgment.²⁸ The court believed that a verdict would not have altered the *Markman* order, and thus nothing remained to be decided on the issue of claim construction.²⁹ The court noted that the purpose of a *Markman* hearing is to construe patent claims so that a jury can be instructed on the meaning of the patent, and that the jury is not free to override the court's construction.³⁰ Moreover, the court opined that a party who cuts off his right to review by settling cannot complain that the question was never reviewed on appeal.³¹ Since the *Markman* order in the earlier case was not vacated as part of the settlement, the court held that it remained preclusive.³² In the court's view, the ruling was preclusive due to the special finality of a *Markman* order in a patent case, not because it was made before a jury returned a verdict.³³

Sixth Circuit

In *Louisville Bedding Co. v. Perfect Fit Indus., Inc.*, the court held that the patentee was collaterally estopped from raising the issue of the scope of the patent because it was determined in a prior case.³⁴ In that prior action, in the same court, the claims from the patents at issue were construed, and the

parties settled after unfavorable judgments for the plaintiff on claim interpretation and infringement.³⁵ The court reasoned that the settlement, if anything, underscored the preclusive effect of the *Markman* orders because it cemented them and made them non-appealable.³⁶ As in *TM Patents*, since the *Markman* orders were not vacated as part of the settlement, they remained preclusive.³⁷

Seventh Circuit

In *Abbott Laboratories v. Dey, L.P.*, the court held that collateral estoppel barred plaintiffs from relitigating claim construction issues decided in a prior action against a different alleged infringer, even though that claim construction was currently on appeal.³⁸ The court stated that exhaustion of appellate remedies is not a normal requirement of collateral estoppel, and that a final judgment by a district court has a preclusive effect even though judgment is pending on appeal.³⁹ Since the claim construction was the reason for the plaintiffs' loss on the issue of infringement in the prior suit, and the court did not believe that the prior ruling was "plainly wrong," the court reasoned that the application of collateral estoppel was not unfair.⁴⁰

Circuits Declining to Treat *Markman* Rulings as Preclusive

In contrast, many district courts have declined to consider a *Markman* order as a final judgment for purposes of collateral estoppel. In particular, as discussed below, the Third and Fourth Circuits in *Graco Children's Products, Inc. v. Regalo International, LLC*⁴¹ and *Kollmorgen Corp. v. Yaskawa Electric Corp.*,⁴² respectively, have declined to follow the ruling in *TM Patents*.

Third Circuit

In *Graco*, the plaintiff had earlier prevailed on a claim of patent infringement following

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a jury trial, but lost on an issue of claim construction that could not be independently appealed.⁴³ Significantly, the previous court's interpretation of the claim term was not essential to the final judgment in the case.⁴⁴ The district court, in the second case, while recognizing the significance of a uniform and consistent treatment of a patent, noted that *Markman* did not guarantee that collateral estoppel would apply in every case.⁴⁵ The court further noted that granting a preclusive effect to claim construction could discourage settlement and increase appeals to correct what the party perceived as an unduly narrow claim construction.⁴⁶ Thus, the court did not apply collateral estoppel.

Fourth Circuit

In *Kollmorgen*, the district court determined that *TM Patents* incorrectly interpreted the effect of a *Markman* construction.⁴⁷ As in *TM Patents*, the parties to an earlier case settled after the court issued a *Markman* order, and there was no jury verdict on the ultimate issue of infringement.⁴⁸ The *Kollmorgen* court held that collateral estoppel applies only when the previous court's *Markman* order was essential to a final judgment on the question of the patent's infringement.⁴⁹ The court opined that other courts need not blindly apply collateral estoppel to a prior *Markman* order, since the Federal Circuit's review of a lower court's ruling is crucial to providing the public with a uniform and proper patent claim construction.⁵⁰ In this case, the court declined to apply collateral estoppel, since the *Markman* order was not essential to a final determination of patent infringement in light of the settlement of the case before a decision was reached on the issue of infringement.⁵¹

Fifth Circuit

The court in *Texas Instruments, Inc. v. Linear Techs. Corp.* held that the construction of claims in a prior suit did not preclude an

unrelated defendant from obtaining a new claim construction.⁵² The court concluded that there had been no cases that invoked collateral estoppel by a plaintiff against independent *defendants*; instead, cases had addressed the application of collateral estoppel against the same *plaintiffs* in subsequent suits involving the same claims.⁵³ Also, the court reasoned that previous claim constructions should be followed only to the extent that the parties do not raise new arguments.⁵⁴ Since defendants may raise new arguments, the court found no authority to

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The Federal Circuit has not yet addressed the issue of whether a *Markman* hearing is a final judgment for the application of issue preclusion.

utilize the prior claim construction.⁵⁵ Thus, the district court held that the claim construction in the prior suit did not collaterally estop an unrelated defendant from obtaining a new claim construction.⁵⁶

In *Cisco Sys., Inc. v. Telcordia Techs.*, the court considered preclusion in the context of a joint motion to vacate the *Markman* order in light of a settlement, and noted that *Markman* orders are not final and indeed may be altered by the court prior to, or during, trial.⁵⁷ The court concluded that the strong public interest in settlement and the conservation of judicial resources outweighed the benefit of the limited collateral estoppel effect, and thus granted the motion.⁵⁸

Ninth Circuit

The court in *Rambus Inc. v. Hynix Semiconductor Inc.* held that, because Hynix could

not exercise its right to appeal a prior claim construction, it was not precluded from relitigating the scope of the claims.⁵⁹ The court did not find the previous claim construction order to be "sufficiently firm," because there had not been a final judgment in the earlier proceedings, which prevented Hynix from obtaining appellate review.⁶⁰ The court distinguished this case from *TM Patents* in that the claim construction in that case could not be appealed because of settlement, not because the law prevented appellate review.⁶¹ The *Rambus* court reasoned that collateral estoppel applies only when review is precluded as a matter of law, such as from settlement, and it does not apply in cases where review is available but cannot yet be sought.⁶²

The Future

The Federal Circuit has not yet addressed the issue of whether a *Markman* hearing is a final judgment for the application of issue preclusion.⁶³ Although appellate jurisdiction in the substantive area of patent law, including claim construction, resides with the Federal Circuit, the Federal Circuit applies regional circuit law to the procedural aspects of collateral estoppel.⁶⁴ And, regional trial courts have broad discretion to determine when collateral estoppel applies.⁶⁵ As shown by the discussion above, district courts have addressed the issue by taking careful consideration of the specific factual scenario at issue. Given the wide ranging postures in which the question of whether a *Markman* ruling should be preclusive can arise, it is unlikely that the issue will be the subject of any bright-line test or rule. However, the Federal Circuit in *Shire* will undoubtedly provide guidance to future district courts wrestling with the issue, since the finality of a *Markman* order is an issue so unique to patent law that it would seem amenable to exclusive adjudication by the Federal Circuit.

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Endnotes

1. *Shire LLC v. Sandoz, Inc.*, No. 07-cv-00197, 2008 WL 4402251 (D. Colo. Sept. 24, 2008); see also *Shire LLC v. Sandoz, Inc.*, No. 07-cv-00197, 2008 WL 5120728 (D. Colo. Dec. 5, 2008) (order certifying controlling question of law for immediate appeal under 28 U.S.C. § 1292(b)).
2. *Shire LLC v. Sandoz, Inc.*, Misc. No. 893, 2009 WL 330235, at *1 (Fed. Cir. Feb. 6, 2009).
3. Collateral estoppel is also commonly referred to as issue preclusion. *In re Trans Tex. Holdings Corp.*, 498 F.3d 1290, 1296-97 (Fed. Cir. 2007) (citing RESTATEMENT (SECOND) OF JUDGMENTS § 27 (1982)).
4. *Watts v. XL Sys., L.P.*, No. 1:06-CV-653, 2008 WL 5731945, at *3 (W.D. Tex. July 2, 2008) (citing 18 WRIGHT, MILLER, & COOPER, FEDERAL PRACTICE AND PROCEDURE § 4403 (2d ed. 2002)).
5. *Id.* at *4 (citing 18A WRIGHT, MILLER, & COOPER, FEDERAL PRACTICE AND PROCEDURE § 4448, at 327 (2d ed. 2002)).
6. In many courts, this factor is stated as whether the “resolution of the issue was essential to a final judgment in the first action.” See *Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 494 F. Supp. 2d 54, 59 (D. Mass. 2007); *Graco Children’s Prods., Inc. v. Regalo Int’l, LLC*, 77 F. Supp. 2d 660, 662 (E.D. Pa. 1999); *Kollmorgen Corp. v. Yaskawa Elec. Corp.*, 147 F. Supp. 2d 464, 466 (W.D. Va. 2001).
7. *RF Del. Inc. v. Pac. Keystone Techs. Inc.*, 326 F.3d 1255, 1261 (Fed. Cir. 2003).
8. *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 331 (1979); *Chi. Truck Drivers v. Century Motor Freight*, 125 F.3d 526, 531 (7th Cir. 1997); see also *Abbott Labs. v. Dey L.P.*, 110 F. Supp. 2d 667, 670 (N.D. Ill. 2000) (considering the preclusive effect to be given to the claim construction decision of a prior court involving the same patents and the same patent holders, but not to the same opposing party, and noting considerations of unfairness to a defendant).
9. *Parklane Hosiery*, 439 U.S. at 330-31.
10. The Federal Circuit has consistently refused to entertain the review of claim construction on interlocutory appeal. However, more than 40% of all *Markman* orders are either revised or overturned by the Federal Circuit; to some observers, this indicates that the Federal Circuit should grant litigants the opportunity to seek interlocutory review. See Timothy Le Duc, *The Application of Collateral Estoppel to Markman Rulings: The Search for Logical and Effective Preclusion of Patent Claim Construction*, 3 MINN. INTELL. PROP. REV. 297, 318 (2002); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1476 (Fed. Cir. 1998) (Rader, J., dissenting).
11. *Cybor*, 138 F.3d at 1475-77 (Rader, J., dissenting).
12. *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002).
13. *Watts*, 2008 WL 5731945, at *3 (referring to *Parklane Hosiery*, 439 U.S. at 331).
14. *Shire*, 2008 WL 4402251 at *5 (noting that the court issued an order construing the terms in the patents at issue on Feb. 9, 2005, and that, on Jan. 19, 2006, the plaintiff announced the settlement of the suit).
15. *Id.* at *6.
16. RESTATEMENT OF JUDGMENTS (SECOND) § 13 (1982) (suggesting that unless a judgment is declared tentative, the preclusive effect of the judgment should be determined by weighing the following factors: 1) whether the parties were fully heard, 2) whether the court supported its decision with a “reasoned opinion,” and 3) whether the decision was subject to appeal).
17. FED. R. CIV. P. 54(b) (stating that any order that is not made final and does not adjudicate all of the claims is subject to revision at any time before the entry of judgment, so all orders of partial summary judgment are arguably tentative and should not be given preclusive effect).
18. *Shire*, 2008 WL 4402251, at *6 (discussing *Guttman*, 302 F.3d at 1351, which acknowledged that district courts may engage in a rolling claim construction, suggesting that not every claim construction is a final judgment for the purpose of collateral estoppel).
19. *Id.* at *7.
20. *Shire*, 2008 WL 5120728 (Order certifying controlling question of law for immediate appeal under 28 U.S.C. § 1292(b)).
21. 72 F. Supp. 2d 370 (S.D.N.Y. 1999).
22. See *Manders v. McGhan Med. Corp.*, No. 02-1341, 2006 U.S. Dist. LEXIS 57467, at *6 (W.D. Pa. Aug. 15, 2006).
23. *Id.*
24. 494 F. Supp. 2d 54, 60 (D. Mass. 2007) (citing to *TM Patents* in opinion).
25. *Id.*
26. *Id.*
27. 72 F. Supp. 2d at 375.
28. *Id.* at 375-79.
29. *Id.* at 377.
30. *Id.* at 378-79.
31. *Id.* at 378.
32. *Id.*
33. *Id.* See also *Edberg v. CPI-The Alternative Supplier, Inc.*, 156 F. Supp. 2d 190, 194-96 (D. Conn. 2001) (following *TM Patents*).

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34. 186 F. Supp. 2d 752, 757 (W.D. Ky. 2001) (following *TM Patents*).
35. *Id.* at 756 (In the prior litigation, Judge Simpson issued a memorandum opinion that set out his construction of the claims and his determination that the patent was not infringed based on the construction).
36. *Id.*
37. *Id.* See also *Fitzgibbon v. Martin County Coal Corp.*, No. 05-36, 2007 WL 1231509, at *4-7 (E.D. Ky. Apr. 25, 2007) (distinguishing *TM Patents* only because the district court did not decide whether collateral estoppel applied to a claim construction from a prior case in a different district because the action in which the *Markman* order was issued was still pending).
38. 110 F. Supp. 2d 667, 669-74 (N.D. Ill. 2000) (citing *TM Patents* and distinguishing *Graco Children's Products, Inc. v. Regalo International, LLC*; even though the court applied collateral estoppel, it still conducted its own claim construction to determine if the prior construction was plainly wrong).
39. *Id.* at 671.
40. *Id.* at 671-72. See also *Kim v. The Earthgrains Co.*, No. 01-C-3895, 2005 WL 66071 (N.D. Ill. 2005) (citing *TM Patents*, but stopping short of applying collateral estoppel to the construction of the claims in order to determine the accuracy of the prior construction).
41. 77 F. Supp. 2d 660, 661-62 (E.D. Pa. 1999).
42. 147 F. Supp. 2d 464, 467 (W.D. Va. 2001).
43. *Graco*, 77 F. Supp. 2d at 661-62.
44. *Id.* at 664.
45. *Id.* at 663.
46. *Id.* at 664.
47. *Kollmorgen*, 147 F. Supp. 2d at 467.
48. *Id.* at 465.
49. *Id.* at 469.
50. *Id.* at 470.
51. *Id.* at 469-70.
52. 182 F. Supp. 2d 580, 585-90 (E.D. Tex. 2002) (citing *TM Patents*, *Kollmorgen*, and *Graco*).
53. *Id.* at 586.
54. *Id.* at 588-89. The court's use of the term "parties" appears to leave room for a plaintiff to challenge a previous *Markman* order if the plaintiff has a viable new argument to present.
55. *Id.* at 589-90.
56. *Id.*
57. 590 F. Supp. 2d 828, 830 (E.D. Tex. 2008) (citing *TM Patents*, *Kollmorgen*, and *Graco*).
58. *Id.* at 831.
59. 569 F. Supp. 2d 946, 968 (N.D. Cal. 2008) (citing *TM Patents*).
60. *Id.*
61. *Id.*
62. *Id.*; see also *Smith & Nephew, Inc. v. Arthrex, Inc.*, No. CV 04-29, 2007 WL 1114229, at *4 (D. Or. Apr. 12, 2007) (holding that Smith & Nephew were bound by the prior claim construction because they had successfully obtained appellate review and the Federal Circuit had confirmed the construction; citing to *TM Patents* and distinguishing *Graco* and *Kollmorgen*).
63. See *Watts v. XL Sys, L.P.*, No. 1:06-CV-653, 2008 WL 5731945, at *3 (W.D. Tex. July 2, 2008).
64. *Id.* at *3 (citing *RF Del., Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1261 (Fed. Cir. 2003)); see also *Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1345 (Fed. Cir. 2002) (noting that whether collateral estoppel is available is a mixed question of law and fact, in which the legal issues predominate, and is subject to *de novo* review).
65. *Watts*, 2008 WL 5731945, at *3.

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It Only Took a Hundred Years: The Federal Circuit Finally Settles the Doctrine of Infringement of Product-By-Process Claims

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In 1983, the Federal Circuit decided *In re Thorpe*,⁸ in which an inventor sought to patent a known color developer for copying systems as the product of his novel, inventive process.⁹ While Thorpe's process was clearly patentable (and claims to the process issued in a patent), his product-by-process claims were rejected because the product was already known in the art and was simply being prepared by a different method.¹⁰ The court's reasoning made it clear that product-by-process claims directed towards a known product are anticipated by the same compound in the prior art, even if the method of making the known product is novel. Thus, under *Thorpe*, the process steps are not limitations and cannot impart novelty; consequently, the claim is only directed toward the product. If the product is known, then the claim is not patentable.

Scripps Clinic and Atlantic Thermoplastics: The Split in Precedent

The court's reasoning from *In re Thorpe* was the basis of the Federal Circuit's decision in *Scripps Clinic & Research Found. v. Genentech, Inc.* In *Scripps*, the Federal Circuit examined Scripps' claim that Genentech infringed product-by-process claims directed towards a blood-clotting protein that could not be defined structurally,¹¹ even though Genentech utilized a different process for producing the protein.¹² The court held that the claims were to a product, not a process, and cited *Thorpe* to emphasize that, in determining patentability, the product is not limited by the process steps.¹³ The court then reasoned that because claims are construed the same way for infringement as for validity, the process terms should not be considered, and the only relevant question was whether the defendant's product was equivalent to the plaintiff's claimed product.¹⁴ Genentech was found liable for infringement.

A year after *Scripps* was decided, the Federal Circuit appeared to reverse its stance on the issue in the case of *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, in which Atlantic owned a patent claiming a method of producing shoe insoles, where one of the claims described the product obtained from the claimed method.¹⁵ Atlantic sued a competitor for producing an identical product through a different method, claiming that the holding from *Scripps* required a finding of infringement.¹⁶ The Federal Circuit panel, however, held that "process terms in product-by-process claims serve as limitations in



In *Abbott*, the Federal Circuit adopted the rule from *Atlantic*, that all of the process steps of a product-by-process claim must be performed to find infringement.

determining infringement,"¹⁷ meaning that all of the process steps must be performed (literally or under the doctrine of equivalents) to find infringement.

While this holding was completely at odds with the result of *Scripps*, the *Atlantic* panel briefly noted that "a decision that fails to consider Supreme Court precedent does not control if...the prior panel would have reached a different conclusion if it had considered controlling precedent."¹⁸ The panel then cited to several Supreme Court cases, primarily relying on the quote that "nothing can be held to infringe that patent which is not made by the process," from *Cochrane v. Badische Anilin & Soda Fabrik* ("BASF"),¹⁹ to support its conclusion that the process claims were properly construed as limita-

tions for infringement.²⁰ The panel further noted that treating product-by-process claims as pure product claims would ignore the "mainstay patent doctrine" that infringement requires the presence of every claim element.²¹

Despite the conflicting holdings of *Scripps* and *Atlantic*, the Federal Circuit did not rehear the case *en banc*.²² The dissenters (as to whether to hear the case *en banc*) agreed with the holding of *Atlantic* itself, but argued that the *Scripps* and *Atlantic* cases were factually dissimilar because Atlantic admitted during prosecution that its claim was to a process, and consequently there was no reason to determine how *all* product-by-process claims should be construed.²³ Because the parties most affected by this decision were companies in complex industries such as pharmaceutical chemistry, rather than the producers of relatively simple shoe components, the dissenters felt the *Atlantic* decision was not the proper time to issue such a sweeping mandate.²⁴ Judge Newman also pointed out that the cases cited by the *Atlantic* panel to establish precedent were factually distinguishable from *Scripps* because they all involved old products or process claims, not new but indefinable products.²⁵

Abbott v. Sandoz: Infringement Requires Process Limitations

The Federal Circuit finally resolved this split in precedent with its *en banc* ruling in *Abbott Labs. v. Sandoz, Inc.*, formally adopting the rule from *Atlantic*.²⁶ Abbott owned a patent claiming a crystalline form of cefdinir, an antimicrobial agent. The first claim of the patent recited X-ray diffraction angles particular to a specific form of the crystal ("Crystal A"), while the remaining claims described crystalline structures that were "obtainable" from four different processes.²⁷ The

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methods recited by Abbott in these claims could produce a different, more hydrated form of the crystalline structure (“Crystal B”). The appellees filed Abbreviated New Drug Applications (ANDAs) to produce the Crystal B form of cefdinir. Abbott appealed after its claims of infringement (against the appellees who had received FDA approval) were dismissed and motions for preliminary injunctions denied.

The majority affirmed both decisions, holding that process terms are always considered claim limitations for infringement.²⁸ The majority justified the holding by stating that the “rule finds extensive support in Supreme Court opinions that have addressed the proper reading of product-by-process claims.”²⁹ Virtually all of the Supreme Court cases cited by the majority come from the nineteenth century, with the analysis hinging on the *BASF* case. In *BASF*, the Supreme Court examined a patent for an artificial form of alizarin, a compound used as a textile dye for many years.³⁰ The patent in question claimed a process of producing artificial alizarin as well as the product of that process.³¹ The *Abbott* majority briefly noted that alizarin was present in the prior art, but then immediately switched the focus of the opinion to “the scope and validity problems that arise when product-by-process claims are ignored.”³² In *BASF*, the Supreme Court noted that, while the defendant’s product appeared to be similar to the product of the patented process and because the product was not defined without reference to the process of production, the only way to establish infringement was to show that the process itself was followed.³³

Judge Newman filed a lengthy dissent vigorously attacking this analysis, stating that *BASF* was a case where the product was known in the prior art and this was why performing the claimed process was

required to find infringement.³⁴ Judge Newman methodically addressed the rest of the cases cited by the majority, contending that all of them dealt with different factual situations or did not support the reasoning of the majority, concluding that the holdings of distinguishable cases were being used to disqualify protection of what had been truly invented: new and novel products.³⁵ Judge Newman stated that, in complex technology fields, when it was *genuinely necessary* to claim a new product using the process, the product should be entitled to the full scope of product protection.³⁶ Judge Newman also reasserted her contention that claims are

snippets.

After *Abbott*, inventors should not rely solely on product-by-process claims to protect their property right to a product.

to be construed the same for validity and infringement, so process claims should not be a limitation of a product.³⁷

Judge Lourie also dissented and raised several salient arguments, first recognizing that the Supreme Court cases cited by the majority often “applied overly broad language to fact situations involving old products or used vague language that makes it difficult to determine whether the products were old or new.”³⁸ Therefore, he argued that, when a product is new and claimed by the process of its preparation, the cited Supreme Court precedent does not foreclose the possibility of the product being infringed even when made by another process.³⁹ Judge Lourie then noted that complex chemical and biological products today should be treated

differently than mechanical products of more than a century ago.⁴⁰ Finally, alluding to the recent *KSR*⁴¹ and *eBay*⁴² decisions overturning Federal Circuit rulings, he noted the Supreme Court’s negative view of universal, bright-line rules, stating that “bright lines have their uses, but judging should take account of differing circumstances.”⁴³

Ramifications for Drafting Claims

In the wake of the *Abbott* holding, it is clear that inventors should not rely solely on product-by-process claims to protect their property right to a product, regardless of how complex or genuinely difficult it is to define the invention. With the wide gamut of analytical techniques available today, inventors should make significant efforts to find any sort of distinctive or identifiable characteristics of a new product and use those to set forth distinct product claims. The *Abbott* majority, however, stressed that product-by-process claims were still a legitimate way to claim an invention, and that previous cases have noted product-by-process claims’ worth as a hedge against the invalidation of overly broad product claims.⁴⁴ Therefore, to ensure the broadest possible scope of protection, patent applicants should consider filing product claims and claims to the method of production, as well as product-by-process claims.

Endnotes

1. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 158 (1989).
2. *Scrrips Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991); *Atl. Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992).
3. 566 F.3d 1282 (Fed. Cir. 2009).
4. *Id.* at 1293.
5. 1891 C.D. 200, 57 O.G. 999 (Comm’r. Pat. 1891); see also, *In re Bridgeford*,

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- 357 F.2d 679, 682 (C.C.P.A. 1966).
6. *Ex parte Painter*, 1891 C.D. at 200-01.
7. MPEP § 706.03(e) (2008).
8. 777 F.2d 695 (Fed. Cir. 1985).
9. *Id.* at 698.
10. *Id.*
11. *Scripps*, 927 F.2d at 1581.
12. *Id.* at 1563.
13. *Id.* at 1583.
14. *Id.*
15. *Atlantic*, 970 F.2d at 836.
16. *Id.* at 838.
17. *Id.* at 846-47.
18. *Id.* at 839.
19. 111 U.S. 293, 310 (1884) .
20. *Atlantic*, 970 F.2d at 846-47.
21. *Id.* at 846.
22. *Atl. Thermoplastics Co., Inc. v. Faytex Corp.*, 974 F.2d 1279 (Fed. Cir. 1992).
23. *Id.* at 1280.
24. *Id.* at 1280-81.
25. *Id.* at 1293.
26. *Abbott*, 566 F.3d at 1291.
27. *Id.*
28. *Id.* at 1293.
29. *Id.* at 1291.
30. *Id.* at 1292.
31. *BASF*, 111 U.S. at 310.
32. *Abbott*, 566 F.3d at 1292.
33. *BASF*, 111 U.S. at 310.
34. *Abbott*, 566 F.3d at 1311.
35. *Id.* at 1311-17 (Newman, P., dissenting).
36. *Id.* at 1319.
37. *Id.* at 1317-18.
38. *Id.* at 1320 (Lourie, J., dissenting).
39. *Id.*
40. *Id.*
41. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).
42. *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006).
43. *Abbott*, 566 F.3d at 1320.
44. *See, e.g., In re Hughes*, 496 F.2d 1216, 1219 (C.C.P.A. 1974).

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Copyright Basics: What Every Business Owner Should Know

Many business owners¹ have internally developed or hired outside contractors to create manuals, software programs, websites, and other business-related materials for use as products, marketing materials, or training materials. Given the substantial costs and time invested in developing these materials, a business owner's ability to control and prevent others from copying or using the work without permission is critical. While businesses typically focus on patents and trademarks as the main source of intellectual property protection, businesses should not overlook copyrights. Indeed, copyrights are a distinct form of intellectual property that provides additional breadth and flexibility to a business's intellectual property portfolio.

Because copyrights are a distinct form of intellectual property, copyright law's rules and requirements differ from those of patent law and trademark law. This article provides an overview of what copyright law protects, who owns the copyright, and whether registration is needed.²

Copyright Law Protects "Original Works of Authorship"

A copyright protects "original works of authorship" including "literary works...musical works...dramatic works...[and] pictorial, graphic, and sculptural works," and is available for both published and unpublished works.³ It also provides authors of original works with a bundle of exclusive rights, which includes the right to authorize reproduction of a work, public display or performance of a work, creation of a derivative work, and distribution of copies of a work.⁴ Authors may be, as examples, writers, artists, musicians, computer programmers, website designers, and graphic artists.

Copyrightable works fall into a number of statutory categories which include literary works, e.g., employee training manuals,

computer software, and databases; pictorial, graphic, and sculptural works, e.g., websites and photographs; and audiovisual works, e.g., training videos.⁵ These categories are non-exhaustive, and some works may fit into more than one category.

In order to be copyrightable, a work must be (i) fixed in a tangible medium of expression and (ii) original.⁶ The work can be "fixed" in a variety of ways including recording the work on tape, CD, or video, or by transcribing the work onto paper. The work does not need to be published, but only saved in a tangible form.⁷ For example, an unrecorded improvised speech probably is not copyrightable because it is not "fixed," but a visual recording of the performance is copyrightable. Originality, for copyright purposes, simply requires that the work be independently created by the author, and that the work possesses some minimal level of creativity; there is no requirement that the work be novel, artistic, lawful, or even meritorious.⁸ For instance, a court held that engravings of eighteenth- and nineteenth-century paintings were original and copyrightable.⁹

Copyright does not protect ideas, procedures, processes, systems, methods, concepts, principles, or discoveries; copyright only protects physical representations such as written or recorded descriptions and illustrations.¹⁰ Such ideas, procedures, processes, systems, methods, concepts, principles, and discoveries might be protectable under patent law.¹¹

Also, according to the Copyright Office, copyright does not protect "words and short phrases such as names, titles, and slogans."¹² However, some words or titles may be protected under trademark law.¹³

The "Author" Owns the Copyright

The ownership of a copyright in a work

normally vests in the author (also known as the creator) who created the work.¹⁴ In most cases, the author is an individual or group of individuals that created the work. Only the author, or those deriving their rights through the author, can rightfully claim copyright. A copyright is considered personal property, and any portion of the bundle of rights can be freely transferred by the author.¹⁵

Ownership of a physical copy of a copyrighted work, e.g., a book, software, or a photograph, allows the owner of the copy to lend, resell, or otherwise dispose of that item.¹⁶ However, mere ownership or possession of a copy of a work is not the same as owning the copyright in the work. That is, the transfer of ownership of any material object, e.g., a CD, that embodies a protected work, e.g., software, does not, in and of itself, convey any rights in the copyright such as the right to make or distribute copies. Even if the author's name is included in a copied work, unauthorized copying of a copyrighted work could be an infringement.¹⁷

An Employer May Be the Author of "Works Made for Hire"

In some cases, the actual author or creator is not considered the author of the work. Instead, a business owner may be considered the author. In such cases, the work is a "work made for hire." Copyright law defines a "work made for hire" as (i) a work prepared by an employee within the ordinary scope of his or her employment or (ii) a work specially ordered or commissioned for use under at least one of nine statutory categories,¹⁸ where the parties expressly agree in a written-and-signed agreement that the work is one made for hire.¹⁹

Thus, in the first instance, if the creator of the work is an employee and not an independent contractor, it is clear that a work **continued on p. 11**

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created within the scope of an employee's job is a work made for hire, and the employer is considered the author and owner of the copyright. Typical examples of works made for hire by employees within the scope of their employment include a software program created by an employee programmer or an employee training manual created by a human-resources employee.

If, however, a business hires outside contractors, e.g., graphic artists, website designers, or computer programmers, to create copyrightable work on behalf of the business, the work created by the outside contractor will only be considered a work made for hire if (i) the work is specially ordered or commissioned and encompasses at least one of the nine categories of works listed in 17 U.S.C. § 101; and (ii) there is a written agreement between the parties that the work is a work made for hire.²⁰

The determination of whether or not a work is a work made for hire has a major impact on the business owner's ability to use the work. If the work is not a work made for hire, the business is not the copyright owner, and the business owner's ability to use the work may be limited to the terms of the agreement with the outside contractor. Alternatively, the conduct of the outside contractor and the business owner could create an implied license in the work, but this usually only provides limited rights to the business.²¹ For example, the use of a computer program to maintain business records,²² a computer program for orbital simulations,²³ source code for Internet-based video conferencing,²⁴ and even a Microsoft Excel spreadsheet for scheduling energy trades²⁵ have been litigated because there was no express "work made for hire" written agreement. Therefore, if a business owner must use an outside contractor to create works for his or her business, the business owner should

execute an agreement with the contractor before the work is started, and the agreement should include "work made for hire" language. In particular, close attention should be paid to works created by multiple outside contractors, as any one of these contractors could potentially limit the use of the work by the business owner.²⁶ For instance, a training video may include scripts, digital images, or sound effects, each independently created by different outside contractors who may have rights in the video if "work made for hire" language is not included in each separate agreement.



Determine what materials may be protected with a copyright registration as part of building an overall intellectual property portfolio.

Even if the work is not made for hire, the outside contractor, as the copyright owner, can assign the copyright to the business. Usually, a not-insignificant fee is involved.²⁷ In such cases, the outside contractor retains the right to terminate the assignment, either through agreement or through statute.²⁸ Of course, this will impact the business's right to use the copyrighted subject matter. For this reason, if at all possible, it is better for businesses to treat the development of outsourced materials as works made for hire.

Copyright Registration is Not Necessary but Highly Recommended

Copyright automatically exists when an original work of authorship is fixed in a tangible form of expression, such as the first time it is written or recorded. While publication, registration, or other action in the U.S. Copyright

Office is not required to secure a copyright, registration provides several important advantages to a business. First, with minimum effort and expense, federal copyright registration provides a public record that may deter others from copying the work without permission. Second, registration before or within five years after first publication also creates a presumption, which is useful in litigation, that the copyright is valid and that the asserted facts (e.g., ownership, creation date, and publication date) are accurate.²⁹ Finally, and most importantly, registration of the work at the Copyright Office is required before a copyright owner can bring a copyright infringement lawsuit.³⁰

Registration may also entitle the copyright owner to special remedies, including statutory damages and attorney's fees.³¹ Furthermore, registration entitles the copyright owner to record its registration with the U.S. Customs services, enabling Customs to stop the importation of infringing copies of the copyrighted work into the United States.³²

Conclusion

With these copyright basics in mind, business owners should consider taking stock of materials that have been created for or on behalf of the business, and should consult with an attorney to determine what materials may be protected with a copyright registration, as part of building the business's overall intellectual property portfolio.

Importantly, business owners should pay particular attention to employees and outside contractors who create works on behalf of the business, in order to ensure that the business owns the copyright in the created work. Before a work is started, business owners and the outside contractors should execute agreements that include "work made for hire" language.

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Endnotes

1. “Business owner” is used throughout the article to mean either the owner or a fiduciary of any business entity including a sole proprietorship, a partnership, and a corporation.
 2. Copyright notice is beyond the scope of this article. Copyright notice is discussed in the earlier *snippets* article Sandra B. Weiss, *The ABC’s of ® and ©: Taking Note of Notice*, SNIPPETS, Spring 2009, at 11.
 3. 17 U.S.C. § 102(a) (2006).
 4. 17 U.S.C. § 106 (2006).
 5. *Id.* § 102(a).
 6. *Id.*
 7. *Id.* § 104; see also *id.* § 101 (defining “publication”).
 8. *Feist Publ’ns v. Rural Tel. Serv. Co.*, 499 U.S. 340, 369 (1991); see also *Bleistein v. Donaldson Lithographing Co.*, 188 U.S. 239 (1903) (articulating what is now referred to as the non-discrimination principle). Case law rather than the Copyright Act provides the definition for originality. See 17 U.S.C. § 101 (providing no definition for “originality”).
 9. *Alfred Bell & Co. v. Catalda Fine Arts, Inc.*, 191 F.2d 99 (2d Cir. 1951).
 10. 17 U.S.C. § 102(b) (2006); see also *Baker v. Selden*, 101 U.S. 99 (1879) (articulating what is now referred to as the idea/expression dichotomy).
 11. 35 U.S.C. §§ 101-103 (2006). Patent law is beyond the scope of this article.
 12. 37 C.F.R. § 202.1(a) (2008).
 13. 15 U.S.C. § 1052 (2006). Trademark law is beyond the scope of this article.
 14. 17 U.S.C. § 201(a) (2006).
 15. See *id.* § 201(d).
 16. *Id.* §§ 109(a), 202; see also *Bobbs-Merrill Co. v. Straus*, 210 U.S. 339 (1908) (articulating what is now referred to as the first sale doctrine).
 17. 17 U.S.C. § 501 (2006) (copyright infringement); *id.* § 106(1) (reproduction right).
 18. The nine statutory categories are “part of a motion picture or other audiovisual work, as a translation, as a supplementary work, as a compilation, as an instructional text, as a test, as answer material for a test, or as an atlas.” *Id.* § 101.
 19. *Id.*
 20. *Id.* § 101(2).
 21. See, e.g., *Effects Assocs., Inc. v. Cohen*, 908 F.2d 555 (9th Cir. 1990) (holding that the conduct of the parties created an implied license for special effects to be incorporated into a motion picture).
 22. *Aymes v. Bonelli*, 980 F.2d 857 (2d Cir. 1992). On remand, the district court dismissed the author’s complaint because the court held that there was no infringement because only one copy of the program was used on one computer. 1994 U.S. Dist. LEXIS 3416 (S.D.N.Y. Mar. 22, 1994), *aff’d*, 47 F.3d 23 (2d Cir. 1995).
 23. *Avtec Sys. Inc. v. Peiffer*, 21 F.3d 568 (4th Cir. 1994).
 24. *Nos. Licensing, LLC v. bVisual USA, Inc.*, No. CV-09-65-EFS, 2009 WL 2058056, (E.D. Wash. July 15, 2009).
 25. *Carson v. Dynegy Inc.*, 344 F.3d 446 (5th Cir. 2003).
 26. Each joint author owns an undivided, equal interest in the copyrighted work. See, e.g., *Thomson v. Larson*, 147 F.3d 195, 199 (2d Cir. 1998). Each joint author may give licenses in the copyrighted work subject only to an obligation to account for profits to the other joint authors. *Id.*
 27. 17 U.S.C. § 101 (2006) (defining “transfer of copyright ownership” which expressly excludes nonexclusive license); *id.* § 204 (writing requirement for “transfer of copyright ownership”).
- Accordingly, an oral nonexclusive license in a copyright may be enforceable.
28. *Id.* § 304(c)–(d) (terminating transfers in copyrights existing before January 1, 1978); § 203 (terminating transfers in copyrights existing on or after January 1, 1978).
 29. *Id.* § 410(c).
 30. *Id.* § 411.
 31. *Id.* § 412.
 32. 19 U.S.C. § 1337 (2006). U.S. Customs will stop importation “only if an industry in the United States, relating to the articles protected by the . . . copyright . . . exists or is in the process of being established.” *Id.*

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