Labor Law Preemption: The Ninth Circuit Grants Malpractice Immunity to Union Attorneys—Peterson v. Kennedy, 771 F.2d 1244 (9th Cir. 1985)

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LABOR LAW PREEMPTION: THE NINTH CIRCUIT GRANTS MALPRACTICE IMMUNITY TO UNION ATTORNEYS—Peterson v. Kennedy, 771 F.2d 1244 (9th Cir. 1985)

In Peterson v. Kennedy, a union’s in-house attorney allegedly advised a union member to file the wrong type of grievance, thus allowing the statutory filing period to expire and denying the member an opportunity to have his dispute arbitrated. The Ninth Circuit held that under federal law, a union attorney could not be sued for legal malpractice arising out of representation of a member in a collective bargaining dispute. This holding represents a broad extension of the immunity originally granted to individual union members by section 301 of the Labor Management Relations Act (LMRA).

This Note traces the development of federal preemption in labor law, examining Peterson as an illustration of the tendency of courts to broadly interpret federal statutory labor policy. In particular, this Note questions whether preemption in a legal malpractice action is appropriate, since professional negligence is not expressly or impliedly addressed under federal statute, and is not an essential part of the national labor policy expressed in legislative history. This Note concludes that federal law should not have preempted the state cause of action in Peterson. Finally, this Note suggests that recognition of state legal malpractice actions would be an ideal signpost announcing the outer limits of federal preemption under Section 301.

I. BACKGROUND

A. Immunity

In 1947, Congress enacted the Taft-Hartley Act (Labor Management Relations Act, or LMRA) in part to control certain “bad practices” developed by unions in the era of labor protectionism. The LMRA also for the first time granted federal jurisdiction over damage actions arising from

1. 771 F.2d 1244 (9th Cir. 1985), cert. denied, 106 S. Ct. 1642 (1986).

1503
collective bargaining disputes. While authorizing federal jurisdiction, section 301 of the LMRA also contains a clause exempting members and agents of unions from personal liability for judgments against the union. Congress enacted this immunity clause in reaction to incidents like the infamous "Danbury Hatters" case, in which individual union members were subjected to personal judgments totalling over a quarter million dollars for their part in an illegal secondary boycott.

The Supreme Court first squarely addressed section 301 immunity in *Atkinson v. Sinclair Refining Co.* In *Atkinson*, the employer sought damages in separate counts from both the union and individual officers involved in a union-authorized strike. Citing the legislative history of section 301, the Court held that when a union is liable for violation of a no-strike clause, national labor policy protects officers and members from liability for damages. *Atkinson* set the stage for an expansive reading of congressional intent to extend immunity to individuals within the labor union.

*Atkinson* left open the question of whether unauthorized strikers receive similar immunity under section 301. In *Complete Auto Transit, Inc. v. Reis*, the Court answered in the affirmative, again relying on legislative history. The Court found that Congress intended to shield individual employees from damages arising from their breach of a collective-bargaining agreement, whether or not the union participated in or authorized the illegality.

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5. "Suits for violation of contracts between an employer and a labor organization representing employees in an industry affecting commerce as defined in this chapter, or between any such labor organizations, may be brought in any district court of the United States having jurisdiction of the parties, without respect to the amount in controversy or without regard to the citizenship of the parties." 29 U.S.C. § 185(a) (1982).


6. 29 U.S.C. § 185(b) (1982). "Any money judgment against a labor organization in a district court of the United States shall be enforceable only against the organization as an entity and against its assets, and shall not be enforceable against any individual member or his assets."


10. See *infra* notes 58-60 and accompanying text for a discussion of legislative history.


14. Id. at 407.
agreement, the “penumbra” of section 301 law indicates that Congress also meant to exclude unauthorized strikers from personal liability for breach of a no-strike provision in the contract.

B. Preemption

Under the preemption doctrine, when a state law conflicts with an act of Congress, the federal statute will prevail over the state law. Two distinct lines of preemption have developed in labor law. First, “primary jurisdiction” preemption involves the choice of forum for resolving labor disputes, affirming the primary jurisdiction of the National Labor Relations Board (NLRB) over that of state and federal courts when statutorily-defined conduct is involved. Second, “substantive rights” preemption deals with choice of law when a state cause of action is asserted. Under this line of preemption, decisional law surrounding a federal statute will control regulation of an activity which impinges upon the federal labor scheme, thereby preempting any inconsistent state law. While courts occasionally commingle these two lines of cases, the distinction should be kept in mind to eliminate confusion.

16. Id. at 415. The petitioner in Complete Auto pointed to a statement in Hines v. Anchor Motor Freight, Inc., 424 U.S. 554, 562 (1976), that § 301 “contemplates suits by and against individual employees.” (emphasis omitted). Complete Auto, 451 U.S. at 415, n.17. The Court found petitioner’s reliance on that statement to be “misplaced” in a damages action involving wildcat strikers. Id.
19. The NLRB was established by the Wagner Act, supra note 4, to prosecute and adjudicate unfair labor practice claims. “(Congress has confided) primary interpretation and application of its rules to a specific and specially organized tribunal. . . .” Garner v. Teamsters Union, 346 U.S. 485, 490 (1953).
The leading case on primary jurisdiction preemption is *San Diego Building Trades Council v. Garmon*. In that case, the Court held that adjudication of activity arguably protected by section 7, or arguably prohibited by section 8 of the NLRA, would be deferred to the exclusive jurisdiction of the NLRB, to prevent local interference with national labor policy. State law would continue to control, however, where the activity in question was a mere "peripheral" concern of the NLRA, or where such activity touched "deeply-felt state interests." *Garmon* remains the test for primary jurisdiction preemption.

The second, "substantive rights" type of preemption occurs when an activity not addressed by the NLRA becomes the source of a labor dispute, the outcome of which might conflict with the federal labor scheme. In such cases the courts will consider federal labor policies and examine the case law surrounding the NLRA. If recognition of a state cause of action would conflict with the NLRA, the state claim must defer to federal law, under the supremacy clause of the United States Constitution. The state interest/peripheral concern exception of *Garmon* applies in substantive rights preemption.

This second line of preemption was developed in *Local 20, International...*
Brotherhood of Teamsters v. Morton. Morton held that if an activity was not arguably addressed by the NLRA, and thus under exclusive NLRB jurisdiction, a court must still apply federal law if application of state law would frustrate the congressional goal of maintaining a balance of power between union and management. Under Morton, the key question was whether legislative history indicates that Congress has "focused" on the particular activity, even though it may have chosen not to regulate. If so, preemption would result. If not, a claim is not preempted unless application of state law would significantly frustrate the federal scheme.

Some years later, in Lodge 76, International Association of Machinists v. Wisconsin Employment Relations Commission, the Court expanded the Morton test, drawing a negative inference from congressional inaction in a particular area. The Court declared that certain "economic weapons" possessed by the unions, neither prohibited nor protected by sections 7 or 8, were intended to be left unregulated, controlled only by the economic forces of labor-management relations.

The Wisconsin Employment opinion focused on a balancing of economic power between the employer and the union. The case established a presumption that, where application of state law would give an advantage to either party, Congress would have intended federal law to preempt, had the particular question been considered. The Court has backed away from this position to some extent, holding in a plurality opinion that this

32. 377 U.S. 252 (1964). In Morton, the employer sought damages under Ohio law after the union persuaded a customer to stop doing business with Morton during a labor dispute.

It has long been established that § 301 provides substantive law along with its grant of federal jurisdiction. This substantive law is federal law, which courts must fashion from national labor policy. Textile Workers Union v. Lincoln Mills, 353 U.S. 448 (1957).


34. The Court has at times abandoned its claim to pure interpretation of legislative history, instead acknowledging its own active role in defining labor policy. See, e.g., Linn v. United Plant Guard Workers, 383 U.S. 53, 63-65 (1966); 2 DEVELOPING LABOR LAW, supra note 18, at 1508.


37. Id. at 140 n.4 (quoting Lesnick, supra note 27, at 478). See also Comment, New York Telephone v. New York State Dep't of Labor: Limiting the Doctrine of Implied Labor Law Pre-emption, 46 BROOKLYN L. REV. 297, 305 (1980).

38. Wisconsin Employment, 427 U.S. at 149 (Brennan, J., concurring) (citing Hanna Mining Co. v. Marine Eng'rs, 382 U.S. 181, 196 (1965): These weapons involved concerted activity in the form of slowdowns, "quickie" strikes, and dissuasion of the employer's clientele.

39. In practice, usually the advantage goes to the employer when state law is applied.

40. Wisconsin Employment, 427 U.S. at 149-50; Comment, supra note 37. But see Belknap, Inc. v. Hale, 463 U.S. 491 (1983) and Golden State Transit Corp. v. City of Los Angeles, 686 F.2d 758 (9th Cir. 1982), cert. denied, 459 U.S. 1105 (1983), for examples of cases where denial of economic self-help is outweighed by a compelling interest on the part of state and local government.

1507
presumption may be avoided if the state law in question is one of general applicability, and not specifically aimed at labor relations.\footnote{41}{New York Telephone Co. v. New York State Dep’t of Labor, 440 U.S. 519 (1979). The Court declined to preempt a New York unemployment insurance statute which provided compensation to striking employees. The opinion, written by Justice Stevens, was joined by Justices White and Rehnquist. The plurality’s recognition of state laws of general applicability was an adoption of Justice Powell’s concurring opinion in Wisconsin Employment, 427 U.S. at 156, and of Professor Cox’s test for preemption. New York Telephone, 440 U.S. 553. Essentially, this test calls for a presumption that state laws of general applicability will not ordinarily upset the federal labor scheme, a presumption rebuttable by affirmative evidence to the contrary. But where a state law is specifically aimed at an aspect of labor relations, it will be presumed to at least potentially interfere with the federal scheme, unless legislative history shows a congressional intent to allow state regulation in that area. Cox, Labor Law Preemption Revisited, 85 HARV. L. REV. 1337 (1972).}

II. \textit{PETE RSON v. KENNEDY}

James Peterson was a linebacker for the Tampa Bay Buccaneers of the National Football League. In 1976, he signed three separate one-year contracts with the team for the 1976, 1977, and 1978 football seasons. Each contract contained a clause providing for payment of full salary in case an injury prevented Peterson from playing during that particular season.\footnote{42}{Peterson v. Kennedy, 771 F.2d 1244, 1248 (9th Cir. 1985), cert. denied, 106 S. Ct. 1642 (1986).}

Peterson injured a knee in the 1976 season. During spring training in 1977, he was released from the team, ostensibly because he lacked the talent to compete.\footnote{43}{Id. at 1249.} Peterson contended that his ineffectiveness on the field was due to the 1976 injury. When the club declined to honor the injury clause in his contract, Peterson contacted the National Football League Players Association (NFLPA), which is the professional football players’ union and exclusive representative in contractual disputes.\footnote{44}{Id.}

In his testimony before the district court, Peterson claimed he was referred to Kennedy, a law school graduate recently employed by the NFLPA, who advised him to commence an injury grievance.\footnote{45}{Berthelsen, the union’s supervising counsel, eventually determined that Peterson should have filed a non-injury grievance, but by that time the statute of limitations had run and arbitration was consequently denied.}

Berthelsen, the union’s supervising counsel, eventually determined that Peterson should have filed a non-injury grievance,\footnote{46}{An “injury grievance” was appropriate in enforcing the club’s obligation to pay a player’s salary after an on-the-field injury. A “non-injury grievance” was appropriate in resolving all other disputes surrounding a player’s contract.} but by that time the statute of limitations had run and arbitration was consequently denied.\footnote{47}{Id. at 1250.}
Peterson brought suit in the district court against the NFLPA for unfair representation, and against Berthelsen for professional negligence. Berthelsen received a directed verdict in his favor; the trial court ruled that the malpractice claim was "subsumed in" the claim against the NFLPA. After the jury returned a verdict against the NFLPA for breach of its duty of fair representation, the court ordered a judgment notwithstanding the verdict, finding as a matter of law that the union had not acted arbitrarily or capriciously in handling Peterson's grievance.

On appeal, the Ninth Circuit held that a union attorney cannot be held personally liable, under the Atkinson doctrine of individual immunity. Implicit in the decision is the presumption that federal common law preempts state legal malpractice claims arising out of the collective bargaining context. Thus, when a grievant is represented in arbitration by a lawyer employed or retained by the union, the Atkinson rule will be applied to prohibit a malpractice action.

III. ANALYSIS

The Peterson decision was erroneous because the immunity clause of section 301 was not intended to cover the attorney-client relationship, and preemption is thus unwarranted in the absence of substantial impact by state law upon federal labor policies.

The Peterson opinion purported to rely on the Atkinson rule, a rule based on section 301(b). However, the court's rationale in fact relied on policy considerations, not statutory interpretation, in concluding that federal law was to be applied under substantive rights preemption. The court contended that these policy considerations dictated against recognition of the state malpractice claim. An examination of the doctrine of federal preemption in labor law reveals that the Ninth Circuit's rationale in Peterson was ill-considered, and that the court's decision to extend personal immunity to union attorneys is counterproductive to national labor objectives.

Federal statutory law applies where Congress expressly preempts regulation of particular conduct, or where such an intent is implied in legislative history. Federal law may also apply in the absence of either express or

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48. Id. at 1251.
49. Id. For a review of the elements constituting breach of a union's duty of representation, see infra note 64.
51. Peterson, 771 F.2d at 1259.
52. See id. at 1256–57.
implied congressional intent if application of state law would frustrate the federal labor scheme more than it serves a legitimate state interest. The Peterson court's decision is analyzed below with reference to the elements of this test.

A. Legislative Intent

The language of section 301 does not mention professional malpractice. There is in fact no mention of a union's duty to fairly represent its members in labor disputes, although the courts have found such a duty to be correlative to the unions' authority to represent their members. In absence of express language, legislative history must be examined to determine whether Congress intended to preempt malpractice actions against union attorneys.

An examination of the rather sparse legislative history of section 301 reveals one predominant reason for granting individual immunity to union members. This was the notorious Danbury Hatters case, which had concluded with rank and file members selling their homes to pay damages awarded a boycotted employer. The plight of these individuals was still fresh in the minds of several members of Congress during debate on section 301. Forcing union members to sell their homes to pay damages for conduct directed by union officials was repugnant to these framers of the nation's labor policy, and they saw the opportunity to eliminate any chance for a revisitation of this scene at the same time as they granted federal jurisdiction over damages actions.

55. See Vaca v. Sipes, 386 U.S. 171, 177 (1967); Humphrey v. Moore, 375 U.S. 335, 342 (1964); Ford Motor Co. v. Huffman, 345 U.S. 330, 337 (1953). State and federal courts retain "concurrent" jurisdiction with the NLRB in such cases, even when federal law is applied.
58. See, e.g., 93 CONG. REC. 6283 (1947): "[The Taft-Hartley bill], while making labor organizations responsible under their contracts and for the acts of their agents, limits judgments to the assets of the organization itself (because of Danbury Hatters concerns)" (remarks of Rep. Case, sponsor of similar House bill vetoed by President Truman).
59. In response to concerns expressed in floor debate, Senator Taft agreed to substitute "labor organizations" instead of "persons." Thus, "the action will be open only against labor organizations promoting this type of [illegal] strike." 93 CONG. REC. 4840 (1947).
The grant of individual immunity was a double benefit to labor unions. First, it deprived management of a major tool of intimidation to wield against potential strikers. Second, it allowed members to follow official directives without fear of personal repercussions. Thus, section 301(b) was intended to advance in one stroke two major goals of federal labor policy: balancing the economic strengths of labor and management, and fostering an attitude of trust essential to union solidarity.60

B. Federal Interests

In the absence of indications that Congress intended to preempt regulation of a particular activity, courts will balance federal and state interests in determining which law to apply.61 The Peterson opinion offers two major federal labor policies in support of its extension of immunity to union attorneys: (1) balancing the relative economic strengths of union and employer; and (2) maintaining nationwide uniformity in labor law. As discussed below, legal malpractice actions would not significantly impact upon either of these federal policies.

1. Balance of Power

Legal malpractice claims against union attorneys involve no threat to the individual from the employer. The employer is a disinterested non-party62

60. Section 301(b) was not a central provision of the Taft-Hartley Act. Far from a "deeply-felt" reaction, Peterson v. Kennedy, 771 F.2d 1244, 1257 (9th Cir. 1985) (quoting Atkinson v. Sinclair Refining Co., 370 U.S. 238, 247-48 (1962) and citing Complete Auto Transit, Inc. v. Reis, 451 U.S. 401, 405 (1981)), the immunity clause appears to have been somewhat of an afterthought. See Note, An Employer's Recourse to Wildcat Strikes Includes Fashioning His Own Remedy: Section 301 Does Not Sanction an Individual Damage Suit, 57 Notre Dame L. Rev. 598, 601 n.33, 606 (1980). Section 301(b) is actually contrary to the the general theme of Taft-Hartley, which was enacted in large part to make unions more responsible for previously unregulated conduct. See supra note 3 and accompanying text. In light of this, caution should be exercised in broadly interpreting congressional intent in § 301(b).


62. Controversies between the individual and the union present little danger of interference with the federal scheme. Cox, supra note 56, at 284. See, for example, Farmer v. Local 25, United Bhd. of Carpenters, 430 U.S. 290 (1977), in which a union member claimed to have been subjected to a campaign of abuse and harassment by his union. The Supreme Court upheld state court recognition of a damages action for intentional infliction of emotional distress, finding that the potential for interference with federal labor policy in such a case was insufficient to overcome state interests. Id. at 304; see also Aragon v. Federated Dep't Stores, 750 F.2d 1447, 1455-56 (9th Cir. 1985).

Similarly, recognition of a state cause of action for legal malpractice would not significantly affect the federal interest in balancing the powers of labor and management. One might argue that unions will not
Further, imposition of a higher standard of care upon union attorneys would not tend to benefit management by discouraging attorneys from working for unions, since the standard of care would then merely be the same as demanded in private practice.

Nor does the Peterson immunity eliminate any disincentive a union might have to represent a member in arbitration. A union currently has no obligation to pursue a member's grievance.63 If union attorneys could be sued for malpractice in the grievance process, the union could still decline to pursue a grievance for policy reasons. Once the union chooses to pursue a grievance, however, its attorney should be obliged to proceed with reasonable care.64 A higher standard of care would provide protection to the union member, and thus better serve the original purpose of section 301.65

Certainly unions would prefer to be able to provide expert representation without the corresponding liability. However, if the concern is one of balancing, it seems that the union attorney should not be protected from malpractice liability, when management counsel is not similarly immune.

2. Uniformity of Regulation

The Peterson opinion suggested a second major federal concern, that of uniformity in the governing of labor-management relations.66 The court

hire lawyer representatives in the face of increased liability, and will thus experience a loss of competency at the negotiation and arbitration tables, or that unions will suffer economically from increased legal liability insurance rates.

Neither argument is viable. In an era where the arbitration process has become a profoundly legal exercise, unions cannot afford not to retain legal representation. See Raffaele, Lawyers in Labor Arbitration, 37 Arb. J., Sept. 1982, at 14–23. The additional insurance premiums would likely be covered by increased dues, and then passed on to the employer in the next wage contract.

64. There is some disparity among the circuits in interpreting Vaca's test of when a union breaches its duty of representation. See Tenorio v. NLRB, 680 F.2d 598 (9th Cir. 1982) (failure to get grievant's version of the story is "arbitrary or perfunctory"); Ruzicka v. General Motors Corp., 649 F.2d 1207, 1209, 1212 (6th Cir. 1981) ("gross negligence" amounting to "reckless disregard" of grievant's rights); Baker v. Newspaper & Graphic Communications Union, Local 6, 628 F.2d 156, 167 (D.C. Cir. 1980) (absence of good faith and honesty of purpose); Medlin v. Boeing Vertol Co., 620 F.2d 957 (3d Cir. 1980) (bad-faith motive is necessary); Baldini v. Local Union No. 1095, UAW, 581 F.2d 145 (7th Cir. 1978) (hostility or discrimination not necessary); Jones v. Trans World Airlines, 495 F.2d 790, 798 (2d Cir. 1974) (bad faith or hostile discrimination not necessary to constitute breach); see also Seay v. McDonnell Douglas Corp., 371 F. Supp. 754 (C.D. Cal. 1973) (fraud, deceit, dishonesty, or intentional discrimination which is severe and unrelated to legitimate union activity are elements of unfair representation).

Suffice to say, proving a breach of the duty of fair representation is usually a difficult task.

65. See supra notes 57–60 and accompanying text.
first expressed a rather vague fear that holding union counsel to a negligence standard, while holding other officials to an arbitrary, discriminatory, or bad faith standard, would give rise to an undesirable anomaly, so that certain union employees would be held to a higher standard of care than the union itself.\textsuperscript{67} The court also foresaw an undesirable discrepancy between the applicable statutes of limitations for federal unfair representation suits and for state malpractice suits.\textsuperscript{68}

The latter of these concerns is insignificant. Disparity in statutes of limitation does not seem to entail the kind of serious disruption that Congress intended to avoid in enacting federal regulation.\textsuperscript{69} Further, such disparity does not in itself justify complete elimination of a long recognized state remedy.

The former concern, that of maintaining a uniform standard of care, ignores the essential difference between the duty of every attorney to competently represent his or her clients, and a union's duty to fairly represent its members. The union's duty arises solely out of its contractual obligations as a bargaining agent. Aside from his or her role in labor-management relations, a role created by the collective bargaining agreement and regulated by the NLRA, the non-lawyer representative has no duty of care. On the other hand, every attorney must perform in accordance with a professional standard of diligence and competence.\textsuperscript{70} This standard, unlike that of the non-lawyer representative, exists independent of the collective bargaining agreement. The remedy for breach of an attorney's duty is in tort, while the remedy for the non-lawyer's breach is based on contract principles.\textsuperscript{71}

Further, subjecting a union attorney to a high duty of care will not have the same practical effect as holding a union official to the same standard. An elected union officer is responsible for formulating policy, and his or her responsibility is to the union as a whole. A union attorney, however, is a non-member employee hired to perform, at least in arbitration, the limited function of representing particular members who have initiated grievances. Thus, union officers need the free range of judgment inherent in an arbitrary and capricious standard, while union attorneys should be subject

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  \item \textsuperscript{67} Peterson, 771 F.2d at 1259.
  \item \textsuperscript{68} Id. at 1259–60. There is a six-month statute on unfair representation claims; malpractice limitations, typically lengthier, vary from state to state.
  \item \textsuperscript{69} Cf. Local 174, Teamsters v. Lucas Flour Co., 369 U.S. 95, 103–04 (1962).
  \item \textsuperscript{70} See, e.g., MODEL CODE OF PROFESSIONAL RESPONSIBILITY DR 6-101 (1980).
  \item \textsuperscript{71} See Aragon v. Federated Dep't Stores, 750 F.2d 1447, 1456–57 (9th Cir. 1985) (quoting Garibaldi v. Lucky Food Stores, 726 F.2d 1367, 1375 (9th Cir. 1984), cert. denied, 105 S. Ct. 2319 (1985)).
\end{itemize}
to a negligence standard in their performance of a more focused and less discretionary or political function.\textsuperscript{72}

Moreover, it is precisely because of the attorney’s legal expertise that he is hired for a position commonly held in the past by non-lawyer employees. More and more unions are using lawyers as representatives, and the arbitration process is rapidly becoming a “legal” environment.\textsuperscript{73} When an attorney’s legal skills are thus utilized, he or she should be held to a higher standard of competence than a non-lawyer employee.

The decision in \textit{Peterson} follows largely from the court’s determination that the union attorney, though pursuing a member’s grievance, in fact represents the union itself in the arbitration process.\textsuperscript{74} As Judge Wiggins’ concurring opinion suggests, under the majority’s approach, the problem of determining who is the client must be resolved on a case by case basis.\textsuperscript{75} Indeed, finding that the attorney in \textit{Peterson} represented the union was a somewhat arbitrary choice.\textsuperscript{76} The law of agency, upon which the attorney-client relationship is based, provides that the relationship is not determined by who selects and pays for the services of the attorney.\textsuperscript{77} Instead, the relationship arises where one consents to the capacity of the attorney to act on his behalf.\textsuperscript{78} Thus, in pursuing a member’s grievance, a union attorney is

\textsuperscript{72} To illustrate: A decision not to arbitrate, made by union officials, is a judgment based upon the interests of the entire union. This discretion is inherently different from negligent representation by the attorney-employee once the decision to proceed has been made.


\textsuperscript{74} \textit{Peterson}, 771 F.2d at 1258. While agreeing that in-house union attorneys should be protected under the \textit{Atkinson} rule, the concurring judge saw no reason for the majority’s extension of immunity to outside retained counsel, since in that case the consequences of malpractice would fall on outside counsel instead of the union. \textit{Id.} at 1264.

\textsuperscript{75} \textit{Peterson}, 771 F.2d at 1263 n.1. This approach in itself will thus be counterproductive to the policy of nationwide uniformity in labor regulation. \textit{See supra} note 29.

\textsuperscript{76} The court asserted that the attorney’s “principal client is the union; it is the union that has retained him, is paying for his services, and is frequently the party to the arbitration proceedings.” \textit{Id.} at 1258. However, the court also noted that a portion of each member’s dues goes to providing effective representation in all phases of the collective bargaining process. \textit{Id.} And it is the individual grievant who has the most to gain or lose in an arbitration proceeding; often the union declines to pursue a member’s grievance at all.

The court also stated that its holding conformed to modern “practical realities” in labor-management relations, because it is the union itself which the member gives credit and holds responsible in resolution of disputes. \textit{Id.} at 1258-59. However, the court also concedes that the “union member surely is justified in expecting the attorney to perform in a competent and professional manner.” \textit{Id.} at 1258.


\textsuperscript{78} Committee on Professional Ethics \& Grievances v. \textit{Johnson}, 447 F.2d 169 (3d Cir. 1971); \textit{Anderson v. Pryor}, 537 F. Supp. 890 (W.D. Mo. 1982). Perhaps the most closely analogous situation arises where an insurance company employs or retains counsel to represent insured individuals. In that case, the lawyer enters into an attorney-client relationship with both the company and the insured, though the lawyer’s primary obligation is said to be to the insured individual. \textit{See American Mutual Liability Ins. Co. v. Superior Court}, 113 Cal. Rptr. 561, 38 Cal. App. 3d 579 (1974); \textit{Lysick v. Walcom}, 65 Cal. Rptr. 406, 258 Cal. App. 2d 136 (1968).
representing the member, though the union's interests may also be served. Generally, an attorney who is employed by an association to represent the members of that association enters into an attorney-client relationship with each member on behalf of whom he appears.\textsuperscript{79} The result in \textit{Peterson} reflects a conscious policy decision to carve an exception to that general rule in the collective bargaining context. Courts should refrain from creating such abrogations absent compelling reasons;\textsuperscript{80} as indicated above, the impact of legal malpractice claims upon the federal scheme is minimal and does not compel preemption of state law.

\textbf{C. State Interests}

The balancing of federal concerns against a state's interest in applying its own laws is the essence of every preemption determination.\textsuperscript{81} If the state interest is compelling, it will preclude preemption if the federal concern is only "peripheral" to the NLRA\textsuperscript{82} scheme. The "state's interest" exception to the preemption doctrine\textsuperscript{83} has been exercised in labor cases involving violence or threat of physical injury,\textsuperscript{84} malicious libel,\textsuperscript{85} wrongful termination contrary to public policy,\textsuperscript{86} intentional infliction of emotional distress caused by outrageous conduct,\textsuperscript{87} and state laws of general applicability.\textsuperscript{88}

As noted earlier, a legal malpractice claim has little substantial impact upon federal labor policy.\textsuperscript{89} On the other hand, the state clearly has a substantial interest in protecting its citizens from professional negligence in the practice of law.\textsuperscript{90} The state has an interest in the public's image of the local bar. Further, the state has an interest in maintaining traditional attorney-client concepts and the uniform application of its professional negligence law, a law of general applicability.\textsuperscript{91} Thus, legal malpractice

\textsuperscript{80} See generally 15A C.J.S. Common Law § 12 (1967).
\textsuperscript{81} Garibaldi v. Lucky Food Stores, 726 F.2d 1367, 1373 (9th Cir. 1984).
\textsuperscript{83} See supra note 27 and accompanying text.
\textsuperscript{84} Int'I Union, United Auto., Aircraft & Agricultural Implement Workers of Am. v. Russell, 356 U.S. 634 (1958).
\textsuperscript{85} Linn v. Local 114, United Plant Guard Workers, 383 U.S. 53 (1966).
\textsuperscript{86} Garibaldi v. Lucky Food Stores, 726 F.2d 1367 (9th Cir. 1984), cert. denied, 105 S. Ct. 2319 (1985)
\textsuperscript{87} Farmer v. Local 25, United Bhd. of Carpenters, 430 U.S. 290 (1977).
\textsuperscript{89} See supra notes 61–80 and accompanying text.
\textsuperscript{90} See Aragon v. Federated Dept't Stores, Inc., 750 F.2d 1447, 1457 (9th Cir. 1985) ("the state's interest in protecting the public from legal malpractice . . . transcends labor law.").
\textsuperscript{91} See supra note 41 and accompanying text.
may appropriately be added to the list of state claims exempted from preemption under the state's interest exception, since the state's interest in protecting the public from legal malpractice transcends labor law and outweighs any peripheral competing federal concerns.92

D. Precedent

On two previous occasions the Ninth Circuit had before it the same issue decided in Peterson. In both cases the court reversed lower court decisions holding that state malpractice claims against union counsel were preempted by federal law. The first case involved a member's malpractice suit against a union-retained law firm.93 The member had been referred to the law firm by his local union for assistance in developing an unfair labor practice charge against the employer.94 In reversing the district court's dismissal of the state claim, the Court of Appeals determined that triable issues of fact existed as to whether an attorney-client relationship existed between the law firm and the union member.95

Barely eight months before deciding Peterson, the Ninth Circuit considered the second case, Aragon v. Federated Department Stores.96 In that case, a union member sued the union local's counsel for unsatisfactory representation in a grievance proceeding. The district court held that a malpractice claim against a union attorney was preempted by the NRLA.97 The Ninth Circuit reversed, finding such a claim to be relatively inconsequential to the collective bargaining process and to the economic balance between labor and management, and finding legal malpractice to be predominantly a state concern.98

The Aragon court also noted that malpractice involves a tort remedy, based on an attorney's standard of care to his client,99 rather than a

92. See Aragon, 750 F.2d at 1457.
93. Weitzel v. Oil Chemical & Atomic Workers Int'l Union, Local I-5, 667 F.2d 785 (9th Cir. 1982).
94. Id. at 786.
95. Id. at 787. If so, according to the Peterson court, the law firm certainly would have been acting primarily on behalf of the individual grievant, and not as the union's agent.
96. 750 F.2d 1447 (9th Cir. 1985).
97. Aragon, 750 F.2d at 1449.
98. Legal malpractice "poses no significant threat to the collective bargaining process, ... does not alter the economic relationship between employer and employee ... [but] furthers the state's interest in protecting the public from legal malpractice, an interest that transcends labor law." Id. at 1456–57.
99. Id. at 1457.
contractual remedy provided for under the collective bargaining agreement. In Aragon, the plaintiff's malpractice claim was thus not preempted, and was remanded to state court for consideration of the merits. Though Aragon appears to be controlling precedent, the Ninth Circuit found little difficulty in reconciling its opinion in Peterson. According to the court, outside counsel might be retained by and working on behalf of the union, or it might be retained by and working on behalf of the member. In the former situation preemption is warranted; in the latter it apparently is not.

The Peterson court's conclusory distinction did not take into account the principles upon which the Aragon decision was based. The court in Aragon specifically decided not to preempt a legal malpractice claim, based upon its conclusion that the action was a purely internal union affair, affecting relations between employer and employee only tangentially, if at all. Further, Aragon specifically noted that legal malpractice actions do not alter the respective economic position of the employer and the union, and that the state has a legitimate interest in preventing professional negligence among its attorneys.

Aragon established strong precedent within the circuit for recognition of legal malpractice claims in labor law. Aragon also correctly analyzed the competing concerns in considering preemption of legal malpractice, an analysis the Peterson court neglected to undertake. Peterson is indicative of the courts' broad reading of the policies of section 301, a reading which has extended far beyond any interpretation contemplated by the Congress of 1947. The strong policy arguments disfavoring preemption in malpractice

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100. Id.; see supra notes 70–71 and accompanying text.
101. Aragon, 750 F.2d at 1458.
102. Peterson, 771 F.2d at 1261.
103. Unlike the union-retained attorney in Aragon, the attorney in Peterson was a union employee, and therefore, according to the court, was acting on behalf of the union, not the member. Id. Interestingly, neither the Weitzel nor the Aragon opinions discussed the status of the attorney-client relationship in arbitration, a point which is crucial to the Peterson court's approach. See Peterson, 750 F.2d at 1265 (Wiggins, J., concurring); supra notes 74–80 and accompanying text.
104. Aragon, 750 F.2d at 1455–56 (quoting Local 100, United Ass'n of Journeymen v. Borden, 373 U.S. 690, 696–97 (1963)).
105. Aragon, 750 F.2d at 1455; see supra note 98 and accompanying text.
106. Aragon, 750 F.2d at 1455. Contrary to implications made in Peterson, it appears that the Aragon court did look closely at the issue of legal malpractice preemption, analyzing it in light of the United States Supreme Court's declarations on labor law preemption, as well as precedent within the Ninth Circuit. Id. at 1455–58. Thus it is significant that the Aragon opinion refers throughout to the "local's counsel," without emphasizing the fact that the particular law firm there involved was regularly retained to handle the union's grievances. In remanding to the state court, the Ninth Circuit made no request that the trial court determine the particular nature of the attorney-client relationship involved. In fact, the firm was representing Aragon in her grievance procedure against the employer, much like the defendants in Peterson.
actions against union counsel make this issue an appropriate guidepost
delimiting the outer limits of federal labor law's incursion into state affairs.
Therefore, whether employed or retained by the union, or retained solely by
the individual member, lawyers should not be granted a lower standard of
responsibility merely because they advocate in the collective bargaining
arena.

IV. CONCLUSION

In Peterson the Ninth Circuit extended the individual immunity granted
to individual strikers in section 301 of the Taft-Hartley Act to include
attorneys, employed or retained by a union, who represent grievants in
arbitration. In doing so, the court ignored fundamental principles of agency
law, misrepresented the impact of a legal malpractice action upon the
federal labor scheme, and disregarded precedent within the circuit ac-
knowledging a state's paramount interest in regulating malpractice among
its attorneys.

The Ninth Circuit has clearly made a policy statement. However, pre-
empting state legal malpractice law may well prove to be counterproductive
to the very policies espoused in the court's expansive interpretation of
legislative intent in labor law.

Tim Adams

I. INTRODUCTION

The standard for biological deposits necessary for compliance with the enablement provisions of the Patent Act of 1952 (codified at Title 35 U.S.C.) has been altered by the Federal Circuit Court of Appeals in In re Lundak. Before Lundak, patent applications dependent on the use of biological materials called for the deposit of a biological sample in an independent depository, out of the inventor's control, on or before the filing date. The Lundak decision now permits an inventor to retain control of the deposit during prosecution of the patent application, so long as the public is guaranteed access to the invention upon issuance of a patent grant.

At first impression this modification of the deposit procedure appears to be relatively innocuous. However, the decision inserts uncertainty and potential for abuse into the protocol for biological deposits. The attractiveness of post-filing deposits is outweighed in most cases by the risk of losing foreign patent protection through failure to deposit on or before filing. In addition, the practical need to provide adequate corroborating evidence of the chain of custody of the deposit from private hands to an independent depository acts as a further disincentive to depositing after the filing date. Thus, pre-filing deposit of the biological material remains the safest route to sufficient disclosure of the patentable subject matter required for attainment of both foreign and domestic protection of proprietary rights.


2. UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 608.01(p) (5th ed. 1983) [hereinafter MPEP] requires a deposit "[w]hen the invention depends on the use of a microorganism which is not . . . known and readily available." See infra note 17. In practice, the deposit requirement has been extended to cover biological materials other than microorganisms. See infra note 3. This Note focuses on biological inventions that require a deposit, while recognizing that some biotechnological products and processes (i.e., those that utilize biological materials that are known or currently available to the public) do not require deposit. See infra note 7.

3. Biological materials requiring deposit include: strains of microorganisms newly isolated from the environment; plasmids, expression vectors, viruses, microorganisms, and more complex living cells containing recombinant DNA; mutated microorganisms or cells; and hybridomas and monoclonal antibodies. Lundak's patent application involved an immortal mouse cell line and hybridomas. See infra note 35.

4. See infra Part IV.A.1.b.
II. THE DEPOSIT REQUIREMENT AND BIOLOGICAL PATENTS

A. Rationale and Purposes of a Deposit Requirement

A patent grants an inventor "the right to exclude others from making, using, and selling the invention throughout the United States." In exchange, the public receives an "enabling" disclosure of the invention that allows a person who is technically familiar with the field of the invention to "make and use the same" without undue experimentation. For some classes of biological patent applications, patent law requires deposit of a sample of the biological material, in addition to submission of a written application. The deposit requirement ensures a quid pro quo of public access to a biological material necessary for enablement in return for the patent monopoly. The rationale for the deposit requirement is that patents covering biological materials cannot be described by words alone. Scientific knowledge has not yet progressed to the point where living cells can be recreated from a written description (the specification), absent necessary starting materials. Therefore, a deposit is required to complement and render enabling a written disclosure of a patentable microorganism or cell line.

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. The public should not be required to reisolate or recreate the particular biological material that is the subject matter of the patent application; therefore, with many biotechnological inventions a deposit is required. However, if all necessary starting materials are known and readily available, a deposit may not be required. See MPEP § 608.01(p). In addition, a deposit demonstrates that the invention was completed at the time of filing.
The deposit requirement is thought to be supported in law by 35 U.S.C. § 114, para. 2 (1982), which addresses models and specimens: "When the invention relates to a composition of matter, the Commissioner may require the applicant to furnish specimens or ingredients for the purpose of inspection or experiment." The Patent Office does not maintain depositories of its own, but rather prescribes standards to be met by recognized, independent depositories, such as the American Type Culture Collection or the Northern Regional Research Laboratory. The American Type Culture Collection will be used as the prototype independent depository throughout this Note; however, other independent depositories are recognized as sufficient to fulfill the enablement requirement of 35 U.S.C. § 112, para. 1 (1982).
8. Lundak, 773 F.2d at 1220, 227 U.S.P.Q. (BNA) at 93.
A deposit verifies that the invention has been reduced to practice, and eliminates any need for the public to do significant experimentation to obtain a starting material or the patentable invention itself. Upon deposit, a sample of the invention, or of a biological element required to make and use the invention, is then available to the Patent and Trademark Office (PTO) for inspection, if necessary.

Under the enablement requirement of 35 U.S.C. § 112, para. 1, the deposit of a biological specimen in conjunction with a written specification fulfills two purposes: (1) it provides the public and the PTO with access to the deposit, and (2) it creates prima facie evidence that the date of invention is the filing date of the application. The procedure by which these purposes are fulfilled has evolved over time.

B. Public Access to a Deposit

Originally, the deposit procedure required unrestricted public access to all deposited material as of the filing date. In re Argoudelis redefined public accessibility in 1970. In Argoudelis, the inventors had deposited on or before the filing date of the application, but had restricted public access to the deposit during pendency of the application.

The Court of Customs and Patent Appeals held that the statutory requirements of section 112 were met by deposit in an independent depository that restricted public access until after issuance of the patent. The court

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10. Actual reduction to practice demonstrates that an invention is operable, i.e., has been reduced to practice. See infra notes 29-30 and accompanying text. Constructive reduction to practice means that there is essentially no question, at filing, that the invention is capable of being reduced to practice; it further demonstrates that no technical problems remain to be solved, and no undue experimentation will be required, before one skilled in the art is able to make and use the invention. See In re Argoudelis, 434 F.2d 1390, 1395, 168 U.S.P.Q. (BNA) 99, 104 (C.C.P.A. 1970) (Baldwin, J., concurring); infra notes 23-30 and accompanying text; cf. note 33.

11. Inspection may be necessary, for example, if a question arises during prosecution regarding enablement on the filing date. Access to the deposit during pendency is determined by the Commissioner of the PTO in accordance with 35 U.S.C. § 122 (1982) or 37 C.F.R. § 1.14(e) (1985). However, in practice the PTO rarely, if ever, requests a sample of a deposit for inspection.

12. See supra note 6.

13. See Argoudelis, 434 F.2d at 1394-95, 168 U.S.P.Q. (BNA) at 103-04 (Baldwin, J., concurring).


17. The court noted four factors relating to permanent availability of the deposited microorganism: (1) the deposit was made in a public depository; (2) the depository was operated by a department of the U.S. Government; (3) the depository had a contractual obligation to place the deposit in a permanent
reasoned that for examination purposes, the PTO could gain access to the deposit, if necessary, through the inventor during pendency. Approval of restricted access during pendency is only reasonable; written descriptions of all patents are kept secret during pendency. By restricting access to a deposit before issuance, an inventor avoids giving competitors access to a deposit during prosecution of the application. The depositor thus retains a significant head start on deriving any patentable improvements on the biological material. Further, restricted access prevents public disclosure until the depositor is assured of patent protection for the invention. After Argoudelis, an application requiring a deposit would not receive a section 112 rejection for lack of public access upon issuance unless the examiner believed that the written disclosure plus deposit would not be enabling when the patent issues. The Argoudelis decision was subsequently incorporated into Patent Office guidelines for microbiological inventions.

The depositing procedure accepted in Argoudelis was broadened in 1975 by Feldman v. Aunstrup, which held that Aunstrup’s restricted access deposit of a specimen in a foreign depository met the requirements of section 112. Since the restrictions on access in Feldman had been lifted at collection, and to supply samples to persons entitled to receive them; and (4) there was no suggestion that the deposit would change or become unusable. Id. at 1394, 168 U.S.P.Q. (BNA) at 103.

18. 35 U.S.C. § 122 (1982) states that “[a]pplications for patents shall be kept in confidence... and no information concerning the same given without authority of the applicant or owner unless necessary to carry out the provisions of any Act of Congress or in such special circumstances as may be determined by the Commissioner.” See also 3 D. Chisum, Patents § 11.02[4] (rev. 1986).

19. See supra notes 5–9 and accompanying text.

20. MPEP § 608.01(p) contains guidelines, issued by the PTO, that set forth minimum standards for a sufficient, enabling deposit:

(1) [T]he applicant, no later than the effective U.S. filing date of the application, has made a deposit of a culture of the microorganism in a depository affording permanence of the deposit and ready accessibility to the public if a patent is granted, under conditions which assure (a) that access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122, and (b) that all restrictions on the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent;

(2) such deposit is referred to in the body of the specification as filed and is identified by deposit number, name and address of the depository, and the taxonomic description to the extent available is included in the specification; and

(3) the applicant or his assigns has provided assurance of permanent availability of the culture to the public through a depository meeting the requirements of (1). Such assurance may be in the form of an averment under oath or by declaration by the applicant to this effect.


22. The four factors enumerated in Argoudelis were interpreted to be sufficient, but not mandatory, for an enabling deposit. See Feldman, 517 F.2d at 1355, 186 U.S.P.Q. (BNA) at 112. In particular, the Feldman court held that use of a private depository not operated by the United States Government, and not operated within the United States was enabling. See id. at 1356, 186 U.S.P.Q. (BNA) at 113; see also supra note 17.

1522
the time of decision, public access upon issuance was assured. As in
Argoudelis, the PTO could obtain access during pendency through the
inventor, and deposit at the time of filing was held to constitute reduction to
practice. Thus, after Feldman, use of either foreign or domestic indepen-
dent depositories adequately fulfilled the enablement requirement of sec-
tion 112.

C. The Doctrine of Constructive Reduction to Practice

The second aspect of the enablement requirement of 35 U.S.C. § 112,
para. 1 establishes the filing date of a patent application as the prima facie
date of invention. The doctrine of constructive reduction to practice
applies to inventions that have not been successfully made or carried out on
or before the filing date, but that could be reduced to practice on the filing
date.

If two or more inventors develop similar inventions very close in time,
the inventor that first reduces the invention to practice is entitled to
priority. In determining priority of invention, three elements are consid-
ered: (1) date of conception (mental discovery of the means and ends of the
invention); (2) date of reduction to practice; and (3) reasonable diligence by
the inventor, from the date of conception to the date of reduction to
practice, in perfecting the invention and pursuing a patent. The date of
reduction to practice becomes significant if an inventor needs to prove
priority of invention.

Demonstration of reduction to practice of an invention verifies that a
product or process has been, or could be, made or performed successfully

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invention was “fully capable of being reduced to practice . . . [and] the second function of § 112, first
paragraph—that of establishing the application filing date as the prima facie date of invention—was
satisfied by Aunstrup’s specification.” Id. at 1355, 168 U.S.P.Q. (BNA) at 113.

24. See supra notes 13, 23 and accompanying text.

25. See infra notes 26–32 and accompanying text.

26. See 3 D. CHISUM, PATENTS § 10.01 (rev. 1986). Two exceptions to this general rule should be
noted: (1) an inventor who is the first to conceive the invention, but the last to reduce it to practice, may
get priority upon a demonstration of reasonable diligence in reducing the invention to practice that
began before the first reduction to practice; and (2) the first to reduce to practice cannot get priority if the
invention is abandoned, suppressed, or concealed. Id.

27. See 35 U.S.C. § 102(g) (codifying prior decisional law). See generally 3 D. CHISUM, PATENTS

28. Priority rules focus on conception, actual reduction to practice, and constructive reduction to
practice, in that order. In contrast, proof of priority emphasizes the same elements in reverse order
(constructive reduction to practice, actual reduction to practice, conception). See 3 D. CHISUM, PATENTS
§ 10.03[1][c] (rev. 1986). For example, an inventor might have to prove an earlier date of actual
reduction to practice or an earlier date of conception to establish priority over another inventor. See also
infra notes 29–32 and accompanying text.
The doctrine of constructive reduction to practice is based on two premises: (1) actual reduction to practice is unnecessary to issuance of a valid patent (i.e., while the invention is still just an idea, it is perfectly capable of working and so is no less an invention); and (2) as a matter of law, the date of filing should be taken as the date of reduction to practice.

If the disclosure of the patent application meets the requirements of 35 U.S.C. § 112, para. 1, for every type of patent the filing date constitutes a constructive reduction to practice. The inventor is entitled to use the filing date as the date of reduction to practice for priority and patentability purposes, even though the invention may not be actually reduced to practice, because the application as filed allows another to practice the invention. In contrast, an applicant demonstrates actual reduction to practice of the invention when a described process is performed or a product is synthesized; the invention is thus proven operable.

In the context of patent applications covering biological compositions of matter, deposits are tangible evidence of an invention (a product) actually reduced to practice. By requiring a deposit upon application, the filing date represents the latest date of actual reduction to practice of the biological material, as well as the date of constructive reduction to practice imposed by patent law.

In summary, before Lundak and for applications requiring a deposit, disclosures were considered enabling under 35 U.S.C. § 112, para. 1 if: (1) the PTO or authorized third parties could gain access to the deposit during pendency of the patent application (restricted public access permitted); (2) the public was assured of access to the deposit upon issuance of the patent; and (3) the deposit was placed in an independent depository, out of the inventor’s hands, on or before the filing date, to fulfill the reduction to practice requirement. Lundak represents a clear departure from the requirement for transfer to an independent depository by the filing date in order to satisfy the enablement requirement of 35 U.S.C. § 112, para. 1.

29. Under 35 U.S.C. § 101 (1982), patentable inventions include “any new and useful process, machine, manufacture, or composition of matter.” However, this Note deals exclusively with products and processes, the types of inventions most commonly arising in biotechnology patent applications.

30. See 3 D. Chisum, Patents § 10.05[2] (rev. 1986). The second premise avoids the difficulty of demonstrating an earlier reduction to practice in most cases. However, where junior and senior applicants are claiming priority, either applicant may establish an earlier date of invention by demonstrating earliest reduction to practice through proper supporting evidence.


32. See id. § 10.06.

33. The possibility that a deposited sample may not be actually reduced to practice cannot be ruled out, since actual reduction to practice requires not only making the invention, but also testing it for its desired results.

34. See supra note 11.
III. THE LUNDAK DECISION

A. Facts

Lundak sought patent protection for a cell line useful for the production of monoclonal antibodies. This claim was unquestionably of a type requiring a deposit. Through inadvertence, Lundak's application was filed approximately one week before the cell line was deposited with the American Type Culture Collection (ATCC), a recognized PTO depository. Prior to and after filing, Lundak maintained his cell line in his own laboratory at the University of California, and in the laboratories of colleagues at that university and elsewhere. Lundak subsequently deposited the cell line with ATCC approximately one week after filing. The examiner rejected Lundak's claims under section 112 for non-enablement, due to the late deposit. In response, Lundak embarked on a series of legal challenges, culminating in a Court of Appeals for the Federal Circuit (Federal Circuit) opinion that modified the deposit requirements under 35 U.S.C. § 112, para. 1.

B. Board Decision

Following the Patent Office examiner's final rejection of the claims, Lundak petitioned the Commissioner of Patents, requesting a post-dating of his application to the date of deposit. The Commissioner denied the petition, in the belief that the application was complete for purposes of assigning a filing date.

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35. Lundak's claims encompassed (1) an immortal human B-cell line and (2) a hybridoma produced from the fusion of an immune lymphocyte and such immortal B-cell. The immortal cell line was obtained through a process of mutagenesis and selection. For a general description of hybridoma techniques and monoclonal antibodies, see Milstein, Monoclonal Antibodies, 243 Sci. Am. 66 (1980).

36. The entire series of Lundak opinions refer only to deposit of the immortal cell line of the first claim, but do not refer to the hybridoma of the second claim, which results from "the fusion of an immunized lymphocyte and a cell line according to Claim 1," Lundak, 773 F.2d at 1218, 227 U.S.P.Q. (BNA) at 91. Immunized lymphocytes are well-known, and since the cell line of claim 1 required deposit, all necessary starting materials for constructing a hybridoma according to the second claim were known and readily available. See supra note 2. Thus, no additional deposit was needed for enablement of claim 2.

37. See supra note 7.

38. Lundak, 773 F.2d at 1219, 227 U.S.P.Q. (BNA) at 92.

39. The Federal Circuit was created by a 1982 Act of Congress, so that all patent cases would be adjudicated by one court of appeals. Congress intended to provide uniformity and stability to appellate patent decisions. The Federal Circuit came into existence on October 1, 1982, and is bound by the precedent of the Court of Customs and Patent Appeals.

40. After denial of his petition by the Commissioner, Lundak brought a mandamus action in the Federal Circuit regarding the Commissioner's refusal to post-date his application. The mandamus action was consolidated into the instant appeal of the examiner's section 112 rejection for non-
Lundak then appealed the examiner's 35 U.S.C. § 112, para. 1 final rejection to the PTO Board of Appeals,\(^4\) arguing that deposit after filing, but before issuance, met the requirements for enablement. The Board of Appeals en banc held the deposit inadequate for enablement at filing.\(^4\) 

Argoudelis and Feldman were distinguished by the Board, because both involved deposits made before or on the filing date.\(^4\)

Although Lundak's cell line was in both his own and his colleagues' hands on the filing date, the Board held that this manner of "deposit" did not guarantee the reliability of maintenance, permanence, or accessibility, as would be provided by a "recognized" depository.\(^4\) The Board further stated that the later deposit was prohibited by the "new matter" provision of 35 U.S.C. § 132,\(^4\) which precludes addition of new matter to the specification after filing of the application.\(^4\) However, six of the eighteen Board members would have allowed Lundak to supplement the record to prove chain of custody from his laboratory to ATCC deposit.\(^4\)

enablement, since both actions arose from a common factual situation. See Lundak, 773 F.2d at 1220, 227 U.S.P.Q. (BNA) at 93.


\(^{42}\) The en banc panel is indicative of the perceived importance of the case within the PTO. Twelve members believed that Lundak had filed an inadequate disclosure; that is, that someone skilled in the art could not make and use the invention. In addition, Lundak did not provide evidence that the cell line was generally known or available through any reasonable source. Ex parte Lundak, slip op. at 9. Two members found evidentiary deficiencies in Lundak's chain of custody from his laboratory to the ATCC, but would have permitted Lundak to prove chain of custody by either (1) filing a continuation application and supplementing the record, or (2) petitioning the Commissioner to reopen the prosecution and then supplementing. A continuation is a second application for the same invention, and may be used to establish a right to further examination by the primary examiner. See 35 U.S.C. § 120 (1982); 37 C.F.R. §§ 1.60, 1.78 (1985); see also Ex parte Lundak, slip op. at 16–17 (McKelvey, concurring). Four members considered their concurrence to constitute a new ground of rejection; under 37 C.F.R. § 1.196(b) (1985), Lundak could have introduced proper declarations or affidavits to prove sufficient maintenance and chain of custody to overcome the § 112 rejection. See Ex parte Lundak, slip op. at 24 (Rzucidlo, concurring).

\(^{43}\) See Ex parte Lundak, slip op. at 7–8.

\(^{44}\) See id. at 6 n.*, 7.

\(^{45}\) According to 35 U.S.C. § 132 (1982), "[n]o amendment shall introduce new matter into the disclosure of the invention."

\(^{46}\) The present practice of many inventors is to deposit at the time of filing, fulfilling the pre-Lundak guidelines for deposit. An application requiring a deposit often contains reference to a timely ATCC deposit (for example, "ATCC Accession No. ————"), and the specific accession number assigned by the ATCC after receipt of the deposit is added later by amendment. The Board believed that Lundak's 20-year contractual arrangement with ATCC left open the real possibility that the deposit could become non-enabling before termination of the patent monopoly. At the time of reconsideration by the Board, Lundak had extended the ATCC contract. However, to overcome non-enablement Lundak needed to show more than being in position to provide an enabling disclosure (i.e., deposit) at some time in the future.

\(^{47}\) See supra note 42.
C. Federal Circuit Opinion

Lundak appealed to the Federal Circuit, which reversed the section 112 rejection of Lundak’s application for non-enablement due to deposit after filing.\(^4\) The court found no controlling distinction between PTO access to Argoudelis’ restricted domestic deposit, Aunstrup’s restricted foreign deposit in Feldman, and Lundak’s private deposit at the University of California.\(^4\) The Lundak decision thus eliminated the prior mandatory transfer of a physical specimen of the invention to an independent depository on or before the filing date.\(^5\) Although the Lundak court did not explicitly have to address the question of timing of transfer to an independent depository, because it had been mooted,\(^5\) the opinion suggested that such transfer must be made some time prior to issuance of the patent.\(^5\)

In response to the PTO’s argument that a post-filing deposit should be barred as new matter, the court analogized Lundak’s deposit one week after filing to material incorporated-by-reference in In re Hawkins.\(^5\) In Hawkins, the inventor had inserted textual material from cross-referenced, co-pending British patent applications into his United States application after the initial filing date. The Hawkins court held that this did not constitute addition of new matter.\(^5\) The Lundak court relied directly on Hawkins, and distinguished White Consolidated Industries, Inc. v. Vega Servo-Control, Inc.,\(^5\) wherein an applicant did not disclose an essential trade secret\(^5\) either during pendency or after issuance.\(^5\)

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48. See supra note 40.
49. See Lundak, 773 F.2d at 1222, 227 U.S.P.Q. (BNA) at 94.
50. In Lundak’s case, public access after issuance was no longer in doubt, because he had deposited with the ATCC during pendency and before PTO prosecution.
51. See supra note 50.
52. At present, prosecution of a biotechnology patent application may take as long as two to three years, suggesting that the applicant would have this extended period of time in which to deposit.
54. Hawkins, 486 F.2d at 575, 179 U.S.P.Q. (BNA) at 162.
56. A trade secret may require elaborate precautions to keep an invention from becoming public knowledge. Once the secret is revealed to an unauthorized person, the invention may become accessible to the public, with no return for the inventor or owner of the trade secret. In contrast to patent protection, which is based on a policy of public disclosure of an invention, for trade secret protection an inventor must maintain absolute control of the secret, keeping it from those not entitled to receive the information. Further, enforcement of trade secrets is expensive and difficult. See generally WASH. REV. CODE ch. 19.108 (1985) (Uniform Trade Secrets Act); RESTATEMENT (FIRST) OF TORTS § 757 (1939).
57. In White Consolidated, the application containing the trade secret was non-enabling as filed. Since no attempt was made to insert the trade secret information, the question of new matter was not addressed. In contrast to Hawkins’ previously filed foreign patent applications, Lundak made reference in his specification to an intended ATCC deposit. On its facts, Lundak appears to be distinguishable from
The Federal Circuit concluded that it was immaterial whether Lundak’s cell line was in his hands, the hands of colleagues, or in the hands of an independent depository as of filing. The court believed that an accession number and deposit date would not enlarge or limit the disclosure of the invention. Further, this was not the type of new matter that 35 U.S.C. § 132 was designed to guard against. The court believed that the disclosure as filed satisfied the requirement for reduction to practice as of filing, since the PTO had conceded that the cell line was in Lundak’s possession at the time of filing.

The court then addressed the PTO’s argument that the deposit procedure approved in Lundak would facilitate filing of sham applications. In a brief dismissal of that possibility, the Federal Circuit stated that any post-Lundak procedural change should not alter the risk or frequency of sham applications. The court asserted that the examiner has always relied on the inventor’s documentation, thereby implying that the pre-Lundak protocol was just as uncontrolled and subject to abuse as a procedure permitting deposit after the filing date.

In what may have been an apparent effort to avoid working a perceived injustice against Lundak, the Federal Circuit reversed the PTO Board of Appeals. The court thus eliminated the former bright line rule requiring a

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Hawkins, because unlike Hawkins’ British applications on file with an independent agency, Lundak’s cell line was not already “on file” in an independent depository. Thus, deposit in university laboratories at filing more closely resembles the trade secret of White Consolidated. The court nevertheless concluded that Lundak’s reference to intended ATCC deposit was sufficient to avoid a new matter prohibition.

58. A unique accession number is assigned to a deposit upon receipt by an independent depository. The accession number identifies the deposit for the depository and for individuals who wish to order samples of the deposit once it becomes publicly available.

59. Lundak, 773 F.2d at 1223, 227 U.S.P.Q. (BNA) at 96.


61. See Lundak, 773 F.2d at 1223–24, 227 U.S.P.Q. (BNA) at 96.

62. Id. at 1224, 227 U.S.P.Q. (BNA) at 96.

63. In retrospect, several alternatives were available to Lundak or the Federal Circuit which might have provided relief for Lundak’s predicament. Prompt filing of a continuation-in-part (CIP) application would have allowed Lundak to add a reference to the late deposit in the specification. Ordinarily, a CIP filed anytime during pendency may use material in the parent application to overcome a reference, or to support priority in an interference action. However, Lundak would have received no benefit from the filing date of the parent application, because the parent was non-enabling as filed. Since Lundak did not promptly file a CIP, thereby securing a filing date that was only days or weeks after the original erroneous filing, the apparent harsh result that would have resulted from denying Lundak’s appeal could have been attributed to his own failure to mitigate potential damages by CIP submission.

The court might also have attempted to narrow the Lundak decision by permitting a deposit one week after the filing date, when supported by sufficient corroboration of a chain of custody, but only in cases where an applicant demonstrates reasonable diligence in transferring a sample to an independent
Biological Deposits and Patents

deposit that is out of the inventor's hands and in an independent depository as of the filing date to satisfy the enablement requirement of section 112.

IV. ANALYSIS

A. Consequences Stemming from Elimination of the Pre-Lundak Bright Line Deposit Rule

After the Lundak decision, applications encompassing biotechnological inventions no longer need to be accompanied by deposit on or before the filing date. Elimination of this requirement fosters uncertainty in the patent application process, because corroborating evidence offered as proof of reduction to practice as of the filing date must now be evaluated on a case by case basis. In addition, the decision increases the potential for filing of sham applications, and is incompatible with foreign patent requirements.

1. Uncertainty in the Application Procedure

a. Surrender of Objectivity with Approval of Post-Filing Deposit

The Lundak decision has injected uncertainty into the deposit procedure, where before there was certainty.64 The Federal Circuit has receded from the pre-Lundak “bright line,” objective determination of constructive/actual reduction to practice for biotechnological inventions. Instead, the PTO has been launched onto a “slippery slope” determination of whether the filing date in each case of late deposit in fact represents the date of

depository. Although a determination of reasonable diligence would not be as finite as the “bright line” in existence before Lundak, at least the necessary transfer would be made sometime early in the pendency period, rather than allowing transfer immediately prior to issuance of a biological patent.

The Federal Circuit might have elected to post-date Lundak's application to the date of deposit, as Lundak originally requested. However, the Federal Circuit may have been reluctant to directly post-date when a mechanism for indirectly post-dating applications, filing of a CIP, was already in place. Further, post-dating could place an administrative burden on the PTO. By withholding assignment of a filing date until both the written application and the deposit have been submitted, the court could have given an inventor significant impetus to deposit as quickly as possible after the written materials had been submitted, in order to obtain the earliest possible filing date. (A later filing date might preclude avoidance of a prior art reference or be fatal to a favorable interference decision.) In contrast, the course chosen by the Federal Circuit encourages postponement of ATCC deposit for as long as possible.

64. Although the expanded Board of Appeals differed as to which of the dual purposes of 35 U.S.C. § 112, para. 1 (1982) (public access on issuance or constructive reduction to practice as of filing) was not met by Lundak's late deposit, the Federal Circuit considered the question of public access to be mooted by Lundak's ATCC deposit one week after filing. The court's opinion therefore focused on the aspect of constructive reduction to practice. See supra notes 26–32 and accompanying text.
invention. While the Lundak decision does offer certain benefits to inventors, any benefits derived from case by case adjudication are outweighed by the sacrifice of certainty.

Before Lundak, the biotechnological applicant had to make an objective showing of reduction to practice (possession of the biological material) by means of a written disclosure with deposit on or before the filing date, in cases where a deposit was required. By permitting post-filing deposits, any showing of reduction to practice by a late depositor must now be subjectively reviewed on an individual basis by the PTO. The late depositor will need to present adequate corroborating evidence that, as of the filing date, the biological material was in the inventor's hands, and that the same biological material has been deposited with an independent depository, in order to obtain the benefit of the filing date. If the PTO determines that deposit of a biological material is necessary for enablement, and that the invention was not reduced to practice as of the filing date, the patent will be denied on the grounds of non-enablement. While it is unclear what type and amount of corroborating evidence will suffice to prove enablement as of the filing date, the practical importance of the standard for corroborating evidence is immense.

b. Corroborating Evidence

The Lundak decision permits an applicant to submit a necessary deposit after the filing date of the written application. In order to guarantee actual/constructive reduction to practice on or before the filing date, late deposits will require corroborating evidence of the chain of custody from private depositories to the ATCC. The PTO has not yet established the standard for such corroborating evidence. The PTO Board of Appeals recently applied

65. See infra note 71 and accompanying text.
66. Bright lines in patent law assist competitors and courts in objectively determining the bounds of patent protection, and indicate to applicants the proper conduct necessary to obtain the broadest scope of protection. Prior to Lundak, determination of whether a deposit evidenced reduction to practice as of the filing date was straightforward. If the biological material was placed in an independent depository on or before the filing date, the deposit was presumed to demonstrate actual and constructive reduction to practice, and to be sufficient for an enabling disclosure. After Lundak, a late depositor will continue to receive a presumption of actual and constructive reduction to practice as of the filing date, but enablement on the filing date must be affirmatively established by adequate corroborating evidence of the chain of custody of the deposit.
67. For biological patents, this will require a showing of actual reduction to practice of the deposited material as of the filing date. See supra notes 26-34 and accompanying text (Part II.C.).
68. The PTO has recently issued draft policy guidelines for deposit of biological materials. Pat.Trademark & Copyright J. (BNA) No. 32, at 90 (May 22, 1986) [hereinafter Draft Guidelines]. These guidelines require a corroborating statement, but do not detail how much or what kind of evidence will be sufficient.

By analogy to case law on adequacy of corroboration in patent interferences, certain elements may
Lundak in _Ex parte Old_, a case involving private deposit in a research institute. However, in _Old_, the Board did not have to address the standard for corroborating evidence required to prove chain of custody, because the deposit had not been transferred from the Sloan-Kettering Institute for Cancer Research to an independent depository. Corroborating evidence was not reviewed in _Old_, so a biotechnological inventor still faces reasonable uncertainty as to what standard of corroborating evidence might be applied in instances of post-filing deposit of biological materials.

Case by case evaluation of corroborating evidence will also significantly affect the PTO itself. Federal Circuit approval of deposition after filing will lead, in practice, to an increased amount of paperwork and time for reviewing corroborating evidence on a case by case basis. In turn, the workload of examiners will be increased, and longer time periods from filing to issuance will likely result. Logically, for post-filing depositors, more extensive corroborating evidence may be required with increasing time periods from filing date to ATCC deposit date.

An advantage gained by inventors by postponing deposit is elimination of the cost and effort of depositing with an independent depository before receiving assurance that a patent will issue. However, inventors who


70. As in _Lundak_, _Old_ resulted in reversal of a section 112 rejection for non-enablement. The applicants in _Old_ filed declarations that several hybridoma cell lines had been deposited prior to the filing date at Sloan-Kettering Institute for Cancer Research, asserting that the maintenance practiced at Sloan-Kettering is substantially the same as that practiced by the ATCC. However, in contrast to _Lundak_, the applicants stated that they had no intent to transfer the deposits to the ATCC until after receipt of a notice of allowance.

The Board interpreted _Old_ in light of _Lundak_, and was similarly convinced that the applicants had demonstrated reduction to practice prior to filing. In addition, public access to the invention was believed assured by the “renown and integrity” of Sloan-Kettering and its professed maintenance procedures. _Old_, 229 U.S.P.Q. (BNA) at 199. The PTO Board of Appeals apparently read _Lundak_ as approving private deposit until notice of allowance was sent. The difficulty presented by this reading is that the type and quantity of corroborating evidence required to support storage in private depositories remains an unknown parameter.

71. At the time this Note was prepared, the costs for depositing with ATCC in compliance with international requirements, for example, include: $570 for storage and maintenance for 30 years plus 5 years after the most recent request for a sample of the deposit; $100 for viability testing (optional); $300
choose to exercise the option to deposit after filing are exchanging the ease and certainty that was provided by a pre-filing enabling deposit for the unpredictability of case by case analysis that accompanies post-filing deposits. If a late depositor’s corroborating evidence is found to be insufficient, the section 112 rejection for non-enablement will stand and no patent will issue.

2. Potential for Sham

The Federal Circuit discounted any increased potential for sham applications in the wake of Lundak. A distinct possibility, however, is that Lundak might open the door for deposit of improved or switched samples during pendency, rather than deposit of the sample in the inventor’s hands at filing. This consequence may arise after Lundak because the deposit can remain solely in the applicant’s hands up to the time the patent issues.

If a new or improved biological sample is deposited after the filing date, the deposit adds new information to the specification and would be barred as new matter under 35 U.S.C. § 132. Deposit in independent domestic or foreign depositories as of the filing date circumvented any temptation to stretch the definition of what was “in the inventor’s hands at filing” because compliance with the pre-Lundak procedure meant that the deposit was out.

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72. The eventual result of extended time for deposit and uncertainty arising from case by case adjudication might lead to pursuit of trade secret protection instead of patent protection for biotechnology inventions, in a manner analogous to computer software protection.

73. See supra notes 61–62 and accompanying text.

74. Pre-Lundak procedures entailed a matching of the strain or cell line described in the specification to a specific deposit; improved strains or cell lines could not be added because they would be barred as new matter under 35 U.S.C. § 132 (1982). However, it should be noted that, before Lundak, independent depositories did not examine or characterize materials deposited with them, either for viability or content. After Lundak, the inventor conceivably could later deposit a biological material that was not in the inventor’s hands on the filing date, if the biological material was adequately described in the written specification. The Lundak decision might encourage filing of applications for inventions conceived, but not actually or constructively reduced to practice, in order to obtain a United States priority date. In actuality, however, any material reduced to practice after the filing date may be difficult, if not impossible, to identify as the biological material that was in the inventor’s hands on the filing date. Further, most inventors would not risk potential loss of patent rights due to insufficient evidence of reduction to practice on the filing date.

75. New matter may include the addition of inherent characteristics, such as chemical or physical properties, a new structural formula, or a new use. MPEP § 608.04(a) (relying on 37 C.F.R. § 1.118 (1985)).
Biological Deposits and Patents

of the inventor's hands at filing. A procedure that opens the door to fraud on the PTO may lead to abuse, especially in light of increasing commercial and financial pressures placed on biological inventors and enterprises to obtain patent protection for technology developed in the laboratory.76

3. International Implications/Complications

Foreign patent protection for an invention dependent on a new or unavailable biological material may be precluded by the depositing procedure accepted in Lundak.77 The Federal Circuit decision provides a liberal deposit procedure sufficient for receipt of United States patent protection, but the court did not address potential problems in obtaining foreign patent protection.

Although independent deposit by an inventor after the filing date, when accompanied by sufficient corroboration of the chain of custody, will now allow enablement of domestic patent applications, foreign filing procedures that require the pre-Lundak protocol of deposit on or before the filing date will not be met by post-filing deposits.78 Accordingly, if an applicant for a domestic patent perceives any possibility that foreign patent protection might be sought, the required domestic biological deposit should still be made according to the pre-Lundak procedure. Inventors might not elect to follow the more liberal deposit procedures permitted by Lundak, in the realization that by taking advantage of such procedures they may be sacrificing potential world-wide patent protection. Commercial realities may therefore limit the practical impact of the Lundak decision.

Additionally, the door has been opened for some foreign applicants to obtain domestic patent protection for inventions where foreign patents were

76. Sanctions resulting from fraud on the PTO are discussed at 4 D. CHISUM, PATENTS § 19.03[6] (rev. 1986). Proof of fraud may result in removal of a patent application from PTO files, or in invalidity or unenforceability of a patent.
77. Issuance of a domestic patent only grants patent rights enforceable in the United States. To exclude others from making, using, and selling the invention outside the United States, foreign patent protection must be obtained.
not available because of deposit after filing. A foreign inventor who inadvertently or intentionally deposited after filing might now use a foreign filing date for domestic priority, if the domestic application is filed within a year of foreign filing.\textsuperscript{79}

Finally, the \textit{Lundak} decision makes the determination of international priority dates of filing much less clear. After \textit{Lundak}, a late deposit is not barred as new matter, and therefore the filing date of the application is the domestic priority date. Although at present a domestic patent application accompanied by a post-filing deposit would preclude use of a United States filing date as a priority date for foreign patent applications, several options might arise. Under one option, in cases of post-filing deposit, foreign filing procedures might assign a priority date of the date of deposit, rather than of the domestic filing date. Second, foreign patent authorities might defer to the domestic patent priority date, and grant that date priority for foreign purposes.\textsuperscript{80} Third, foreign filing procedures might be amended to conform with the \textit{Lundak} decision, for achievement of deposit uniformity throughout the world. At present it remains unknown which, if any, of these results will follow from \textit{Lundak}.

\textbf{B. Future of the Deposit Requirement}

Although \textit{Lundak} permits a liberalized deposit procedure, an applicant can avoid submission of corroborating evidence documenting the chain of custody of the deposit by continuing to satisfy the pre-\textit{Lundak} requirements. Fulfilling pre-\textit{Lundak} requirements eliminates the uncertainty and the associated risk of insufficient corroboration. In addition, the temptation to assert in the future that later improvements were known at the time of filing would thereby be avoided. Finally, compliance with foreign patenting requirements may be ensured by depositing on or before the filing date. Therefore, the potential hazards associated with post-filing deposits would appear to outweigh the monetary and practical benefits that may be derived by postponing deposit with an independent depository.

By depositing after the filing date of the application, an applicant loses a presumption of enablement that accrued under the pre-\textit{Lundak} depositing procedure. After \textit{Lundak}, an applicant who chooses to deposit after the filing date must take active steps to establish enablement as of the filing date. In contrast, a deposit on or before the filing date gives rise to a

\textsuperscript{79} 35 U.S.C. § 119 (1982) describes in more detail the effect of an earlier foreign filing date on a U.S. patent application filed within 12 months from the earliest such foreign application.

\textsuperscript{80} However, in the reverse circumstance, the United States will not give an applicant benefit from foreign priority documents unless the foreign application complies with the requirements of United States patent law. See 3 D. \textsc{Chisum}, \textsc{Patents} § 14.03[3] n.19 (rev. 1986).
presumption of enablement, which may be overcome only by a prima facie showing to the contrary.

The *Lundak* court granted the late depositor benefit of the filing date only after concluding that Lundak's written specification, plus corroborating evidence of actual reduction to practice, sufficed to meet the section 112 requirement for enablement.81 Lundak thus received a presumption (and the benefit) of a priority date as of filing, because he was able to demonstrate that he had actually reduced the invention to practice as of the filing date. The possibility of mere constructive reduction to practice as of the filing date for any biotechnological patent application that currently requires an accompanying deposit apparently continues to be foreclosed after the *Lundak* decision.

The deposit requirement assures that a particular end product may be reproducibly obtained. However, in light of rapid advances in biotechnology, commentators currently debate whether a deposit is indeed necessary in every case of biotechnological invention.82 If certain types of patentable subject matter are relieved of the deposit requirement, constructive reduction to practice of biotechnological inventions could conceivably occur.83 At present the deposit procedure for biological materials has been modified, and in the future deposits may even be eliminated for

81. Although Lundak did not deposit in an independent depository on or before the filing date, Lundak's 10 pages of written description were held to be more than adequate to demonstrate reduction to practice (possession of the invention), even in the absence of a prefiling deposit. Reduction to practice was further supported with declarations by the inventor and his colleagues, filed during the period between the Board decision and argument before the Federal Circuit, that the cell line was in their hands at filing and was the same as the sample deposited one week later with ATCC.

Although a hybridoma, according to Lundak's second claim, may not have been actually reduced to practice on the filing date, the hybridoma is a type of biological material that did not require deposit, and thus might be constructively reduced to practice. See supra note 36. However, the PTO Board of Appeals discussion in *Old*, directed to hybridomas and obviousness, suggests that hybridomas may not be amenable to constructive reduction to practice. See *Old*, 229 U.S.P.Q. (BNA) at 200.


83. For example, a hybridoma according to Lundak's second claim did not require a separate deposit, because the necessary starting materials were known and readily available. See supra note 36. A hybridoma useful for production of a specific monoclonal antibody would likely require a deposit, however, since the hybridoma would not be known or readily available. With the sophisticated and reproducible techniques utilized in molecular biology today, a strong argument can be made for the superfluosity of a deposit for selected inventions (for example, plasmids and peptides encoded by a known DNA sequence), where one skilled in the art could reproduce the invention from a written description only. In the future, an inventor might successfully file a biotechnical patent application that does not require a deposit on the basis of constructive, rather than actual, reduction to practice. See generally note 82.
certain types of biological inventions. Lundak, however, has not yet obviated the legal necessity, arising out of 35 U.S.C. § 112, para. 1, for actual, rather than constructive, reduction to practice for biological inventions that require a deposit for enablement. Therefore, Lundak will continue to have a significant impact on procedures necessary to obtain patent protection for certain classes of biological material, because proof of actual reduction to practice, either through a pre-filing deposit or a post-filing deposit with proper corroborating evidence of chain of custody, will still be required.

C. PTO Draft Policy Guidelines

The Lundak decision has prompted the PTO to draft new policy guidelines covering all biological deposits. As with the previous guidelines, an enabling disclosure under 35 U.S.C. § 112, para. 1 may now be satisfied either by a demonstration that a necessary biological material is “known and readily available” to the public, or by a deposit according to the PTO draft guidelines. Reflecting Lundak, the draft guidelines require deposit in a recognized or permanent depository “not under the control of the depositor or patent owner,” prior to or at the time of payment of the

84. Inventors might benefit from the requirement for corroborating evidence that the patentable biological material was in the inventor’s hands as of the filing date. In the future the PTO could conceivably derive essentially pre-Lundak results (deposit on or before filing) by utilizing tension between 35 U.S.C. §§ 112 and 103 (1982). Section 103 requires that an invention be non-obvious: “A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made.”

If Lundak had permitted constructive reduction to practice of biological materials, reduction to practice through a written disclosure alone by one skilled in the art might be predictable in light of prior art. This level of predictability, in light of knowledge at the time of constructive reduction to practice, might in turn make the invention obvious. In this context, sections 112 and 103 might be pictured as opposite points on a continuum—the more vigorously a biological inventor argues that a deposit is not required to provide an enabling disclosure, the more the specification will be drawn toward a section 103 rejection for obviousness.

85. Draft rules for deposit of biological materials after Lundak were released on May 2, 1986. See Draft Guidelines, supra note 68.

86. See supra notes 2, 20.

87. Draft Guidelines, supra note 68, at 90. To provide an enabling disclosure without an accompanying deposit, any necessary biological material must be known and readily available to the public, with no question of continued availability beyond the life of the patent monopoly. See id. Factors supporting a demonstration of public accessibility, either alone or in combination, include: (1) commercial availability of the biological material through suppliers that are not controlled by a party/parties with an interest in the patent; (2) reference to the biological material in printed publications; (3) declarations of accessibility to the biological material by disinterested persons in the field of the invention; (4) abundance of the biological material in nature, either in useful form or coupled with a reliable screening procedure; and (5) previous deposit of the biological material according to these guidelines. See id. at 91 (1.1-5).

88. Without this limitation, it would be foreseeable that large and then small biotechnology
issue fee. The PTO apparently is not ready to accept continued deposit after issuance in individual inventors' laboratories, even though certain standards for permanence and access are met. By foreclosing the possibility of fulfilling the enablement requirement of section 112 through in-house deposits after issuance, the PTO has at least avoided case by case subjective determination of enablement, and, to the extent possible, minimized the opportunity for abuse and sham.

Other proposed changes from the pre-Lundak PTO guidelines include: (1) requirement for a viability statement; (2) assurance of public accessibility to the deposit for at least five years after the most recent request for a sample, or for thirty years, whichever period is longer; and (3) if a deposit is made after the filing date, a requirement for corroboration that the biological material described in the application is the same as that deposited in a recognized depository.

The procedural guidelines for biological deposits drafted by the PTO after the Lundak decision are somewhat confusing. If an inventor elects to deposit in a recognized depository on or before the filing date, much of the confusion may be avoided.

In instances of independent deposit after the filing date, the following steps have been envisioned by the PTO. An applicant who has not placed a necessary biological material in a recognized depository on or before the filing date would first receive a rejection under 35 U.S.C. § 112, para. 1 for non-enablement. The applicant could avoid the rejection either (1) by showing that the biological material is "known and available," or (2) by making a deposit and showing a corroborating chain of custody. If the applicant takes neither of these steps, the applicant must assure the PTO that deposit and corroboration will be provided prior to or concurrent with payment of the issue fee. In all instances, and as required before Lundak, an applicant must provide the PTO access to the deposit during pendency. If companies would develop institutional depositories which meet PTO standards. These companies could then file for and receive patent protection strictly on the basis of in-house deposits fully within their control.

89. The depository must be an International Depositary Authority, recognized by the Budapest Treaty, see supra note 78, or the sample must be placed in a permanent depository that meets the requirements of a Budapest Depository and is not controlled by the depositor or patent owner.

90. Private deposition could result in denial of public access to the patented subject matter, which would not support the quid pro quo of the patent monopoly system.

91. Draft Guidelines, supra note 68, at 91–92 (II.3). A viability statement was previously required for deposits made under the Budapest Treaty. See supra note 78.


93. "Id. at 92 (II.5).

94. The Draft Guidelines do not expressly state what biological materials are covered. For each biotechnical application requiring a deposit, the PTO will likely request a deposit. Before Lundak, the PTO had the burden of making a prima facie showing of non-enablement before requiring a deposit.

95. Draft Guidelines, supra note 68, at 92.
either assurance of deposit or deposit itself supported by corroboration is provided, and the subject matter of the application is determined to be patentable, the PTO will mail a notice of allowance of the patent and the rejection for non-enablement will be withdrawn. If the applicant has neither deposited nor provided assurance of deposit before issuance, a request for appropriate deposit under 35 U.S.C. § 132 will be issued by the PTO. The applicant then has a three-month, nonextendable period in which to deposit; otherwise the section 112 rejection will be maintained.

Although procedurally the PTO has accepted declarations of inventors in the past, to ensure prompt public access to the invention, a notice of allowability would be sent. The official notice of allowance could then be reserved until the PTO has received two items: (1) documentation of an ATCC deposit, and (2) sufficient corroborating evidence that the cell line(s) deposited with the ATCC are identical to those in the hands of private depositories or laboratories at the time of filing. The applicant could be given three months to document independent deposit, and failure to do so would result in final 35 U.S.C. § 112, para. 1 rejection for non-enablement. Demanding independent deposit before mailing of a notice of allowance would institute an objective deadline for all post-filing deposits analogous to the pre-Lundak requirements for deposit on or before the filing date, and would circumvent the need to subjectively review applicant’s

96. Id.
97. Under section 132, if omitted requirements are found by the PTO during prosecution, the Commissioner must notify the applicant of the requirement.
98. Reliance on personal assurances might lead to a type of "worst-possible scenario." For instance, assume that after receipt of the PTO notice of allowance, the applicant gives assurance of deposit and pays the required issuance fee. The patent then issues "in regular course." A deposit is now inadvertently made after issuance, in a situation analogous to Lundak's late filing. The courts might have to invalidate the newly-issued claims, after the time, expense, and effort of a complete PTO examination, because the disclosure would not be enabling upon issuance. If the PTO permitted deposit after issuance when supported by an abundance of corroborating evidence, relying on an applicant being in a position to deposit as of issuance, this would signal entrance to an even more dangerous "slippery slope." Another "bright line" will be exchanged for a "slippery slope" case by case analysis, but this time at a very real and great risk of loss to the public of benefits to be derived from the patented invention.

Alternatively, an applicant might request a deferral of issuance under 37 C.F.R. § 1.314 (1985) upon showing of necessity, or might extend the three month period for independent deposit through a process of abandonment and revival of the application under 37 C.F.R. § 1.137 (1985) or 35 U.S.C. §§ 133, 151 (1982). The PTO would be likely to freely permit deferrals to allow deposit before issuance, guaranteeing public access to an enabling disclosure, but at the same time pushing back in time the 17-year grant of a patent monopoly. The buffer zone of pendency available in Lundak would be diminished or extinguished.

99. Deferring receipt of official PTO notice of allowance may have tax consequences for the inventor. Prior to receipt of a notice of allowance, patent applications are assignable and nondepreciable. Upon receipt of a notice of allowance, patent applications are treated as patents, i.e., as depreciable property under I.R.C. § 1239 (CCH 1985). See Myers v. United States, 613 F.2d 230, 205 U.S.P.Q. (BNA) 591 (9th Cir.), cert. denied, 449 U.S. 826 (1980).
assurances to the PTO. For many biotechnology inventors, cost/benefit analysis and a desire for preservation of possible foreign patent rights will limit the use of the procedure approved in _Lundak_, at least until both United States and foreign responses to _Lundak_ offer more certainty to biological inventors.

V. CONCLUSION

Prior to _Lundak_, the PTO required evidence of deposit in an independent depository on or before the filing date of the patent application, but the inventor could restrict access to the deposit until assured of patent issuance. In _Lundak_, the Federal Circuit placed a stamp of approval on biological deposits placed in recognized independent depositories after the filing date of written patent application materials. In the wake of _Lundak_, an inventor may retain control of a biological material necessary for enablement during prosecution of the patent application. The _Lundak_ court may have underestimated the possibility that inventors might abuse this retention of control over deposits. Rather, the court viewed post-filing deposits as part of a rational progression from restricted access to domestic and foreign independent prefiling deposits approved in _Argoudelis_ and _Feldman_. Moreover, the _Lundak_ court did not address the apparent conflict between post-filing deposits and foreign filing requirements.100

The PTO has responded to the _Lundak_ decision with new depositing guidelines that permit an inventor to satisfy the section 112 enablement requirement without an independent deposit on or before the filing date. However, the procedure described by the new PTO guidelines may insert uncertainty into procedures for biological deposits. The danger associated with this uncertainty is the possible loss of patent protection in instances of post-filing deposit, due to insufficient evidence to overcome a section 112 rejection for non-enablement. The risk of sacrificing potential patent rights, both domestic and foreign, outweighs any potential benefit derived from depositing in an independent depository upon receipt of PTO assurance that patent protection is forthcoming. Therefore, the safest and most certain course to assured enablement and subsequent issuance of a patent is to disregard the expanded permissible deposit procedure approved by the Federal Circuit in _Lundak_, and to continue to follow the depositing procedures instituted before the _Lundak_ decision.

_Dèbra K. Leith_

100. Perhaps the court realized that foreign patent requirements would act to moderate the practice of depositing after the filing date, thus reducing reliance on the liberal post- _Lundak_ procedure.