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Eli Lilly & Co. v. American Cyanamid Co.: A "Patent Case" of Dangerous Dicta in the Federal Circuit?

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CASENOTE

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I. INTRODUCTION

Although today more law exists in statutory form rather than in common law, courts do not have clear-cut guidelines for interpreting statutes. Courts must, therefore, interpret statutes in light of the particular facts of each case, generally through consideration of legislative intent as evidenced by the purpose, text, and legislative history of the statute. This Note analyzes a recent Federal Circuit interpretation of a statute enacted to enhance protection for U.S. process patent holders. Unfortunately, that court’s interpretation of the statute has returned a certain group of those patent holders to the position they held before enactment of the statute—with no protection against foreign infringers importing products made using U.S.-patented processes.

Analyzing the statute through several leading statutory interpretation techniques casts doubt on the Federal Circuit's decision to interpret the statute by examining its legislative history. Using this approach, the Court applied a test set forth in *one* committee report. This test is not uniformly applicable in the field of chemical processing, however, due to the nature of chemical reactions on various materials' physical and chemical properties. Additionally, it is unclear why the Federal Circuit examined the statute in such detail when it could have reached the same result under the facts of the case without interpreting vague statutory language.

II. STATUTORY INTERPRETATION GUIDELINES

Although Congress is responsible for drafting and enacting legislation in the form of statutes and thus, has "the central responsibility for the statutory management of social policy in the substantive areas allocated to it under the applicable constitution,"¹ courts are responsible for interpretation of statutes. Statutes are now "our primary source of law . . . [and] statutory interpretation has reemerged as an important topic of academic theory and discussion."² At least one commentator has suggested that "[t]he standard criterion for proper interpretation of a statute is to find 'the intention of the legislature.'"³ As Professor Radin contended, however, a legislative *body* has no intent and, even if it did, "the intent would not govern application of the statute."⁴

Courts have taken various approaches to statutory interpretation. In order to adequately advise their clients, lawyers must have some sense of which approach a particular court will take.⁵ Professors Eskridge and Frickey analyzed various approaches to statutory interpretation used by courts today: "foundational; . . . theor[ies] that identif[y] a single primary legitimate source of interpretation . . . and adhere[] to the statutory meaning that source suggests, regardless of the circumstances or conse-

1. Reed Dickerson, *Statutory Interpretation: Dipping into Legislative History*, 11 HOFSTRA L. REV. 1125, 1125 (1983).

2. William N. Eskridge, Jr. & Philip P. Frickey, *Statutory Interpretation as Practical Reasoning*, 42 STAN. L. REV. 321, 321 (1990). *But see* RICHARD A. POSNER, *THE FEDERAL COURTS: CRISIS AND REFORM* 262 (1985) ("[T]he interpretation of statutes is an extremely important function of the federal courts and one that . . . does not receive the systematic scholarly attention it deserves.").

3. JAMES WILLARD HURST, *DEALING WITH STATUTES* 32 (1982).

4. *See id.* (citing Max Radin, *Statutory Interpretation*, 43 HARV. L. REV. 863 (1930)).

5. *See id.* at 31-32 ("Few of the multitude of choices people make everyday affected by what they find in statute books ever come before a court; what judges do is important, but it is outreached by the vast number of occasions on which laymen, lawyers, and executive and administrative officers make final decisions on the meaning of legislation. . . . Statutory texts . . . derive much of their impact from the uses others than legislators make of them.").

quences.”⁶ Three of the “foundational” statutory interpretation theories analyzed involve the use of: (1) statutory purpose (purposivism); (2) statutory text (textualism); and (3) legislative intent (intentionalism).⁷ The authors point out that each of these approaches to statutory interpretation “rests upon questionable premises about the nature of interpretation and the legislative process. . . . [N]one . . . systematically produce[s] determinate results in the ‘hard cases,’ which undermines their claims to ‘objectivity.’”⁸ In practice, the authors found that the Supreme Court uses all three approaches, reaching final statutory interpretations by comparing results under each approach and determining which best accomplishes the goal of the statute at issue in light of circumstances that may not have been anticipated when the statute was enacted.⁹

A. Purposivism

Purposivism requires identifying the purpose or objective of the statute, and “deducing the interpretation with which it is most consistent.”¹⁰ Also referred to as the “mischief rule” (what mischief was the legislature trying to correct when it passed the statute?),¹¹ this approach assumes the statute “must be read in the light of some assumed purpose. A statute merely declaring a rule, with no purpose or objective, is nonsense.”¹² The purpose of the statute may be gleaned from a variety of sources including any purpose stated therein, the circumstances under which the statute was enacted, and its legislative history.¹³ The statute should be given meaning in light of this purpose.¹⁴

An example of purposivism is found in *Church of the Holy Trinity v. United States*.¹⁵ There, the Court analyzed a statutory provision imposing a penalty for importation of aliens into the United States for the purpose of performing any labor or service. The church wished to

6. Eskridge & Frickey, *supra* note 2, at 321 n.2.

7. *See id.* at 322.

8. *Id.*

9. *See id.* at 345-62.

10. *Id.* at 333.

11. *See* WILLIAM P. STATSKY, LEGISLATIVE ANALYSIS AND DRAFTING 77 (John F. O’Connell & Bruce Comly French eds., 2d ed. 1984).

12. Karl N. Llewellyn, *Remarks on the Theory of Appellate Decision and the Rules or Canons About How Statutes Are To Be Construed*, 3 VAND. L. REV. 395, 400 (1950).

13. *See* STATSKY, *supra* note 11, at 78.

14. *See* HENRY M. HART, JR. & ALBERT M. SACKS, THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW 1169 (1994) (positing that, in interpreting a statute, the court should “[d]ecide what purpose ought to be attributed to the statute” and “[i]nterpret the words of the statute . . . so as to carry out the purpose as best it can”).

15. 143 U.S. 457 (1892).

bring a minister into the country from England to become its pastor.¹⁶ Although the Court found the contract between the church and the pastor fell within the letter of the statute, it also concluded that the statute was intended to prohibit the importation by contractors of unskilled labor in order to prevent the degradation of American labor.¹⁷ In overturning the lower federal court ruling that the church had violated the statute, the Court "prefer[red] what [it] deem[ed] to be the substantive ends of a statute over its text."¹⁸ The Court thus interpreted the statute in light of its *purpose* over its *text*.

The fiction that the legislature can be of one mind, and have one purpose, has many weaknesses. As Judge Mikva pointed out:

[T]he real problem is that we start out with 435 prima donnas in the House and 100 prima donnas in the Senate, and the name of the game is to get them to agree on a single set of words

Those 535 people . . . are going to find it difficult to agree on an agenda, let alone on the words to describe whatever consensus they reach. The consensus that is reached to get a bill passed in the first place is a tenuous and confused one. Is it any wonder that the words they do finally choose tend to have diffuse and ambiguous meanings?¹⁹

Problems with using purposivism as a foundational theory of statutory interpretation include assumptions that "the legislature is filled with reasonable people who will reach reasonable, purposive results by following established procedures"²⁰ and that various purposes of the range of interest groups in the legislature can "be aggregated into a *public* purpose."²¹ For example, examining the purpose behind the enactment of a portion of the Civil Rights Act of 1964 reveals that:

Title VII seems to be one of the most purposive statutes . . . adopted in [recent] years. . . . Yet [its] purpose [of nondiscrimination] is compromised in many ways by statutory exceptions for small businesses, union seniority arrangements, and so forth. Thus it is not a principle that Congress was willing to implement at any price. How, then, can the overall purpose control statutory interpretation, when it is clear that Congress itself did not believe in it without reservation?²²

"Moreover, [m]odern political theory, especially public choice theory, renders the political theory assumptions of purposivist statutory

16. *See id.* at 458.

17. *See id.* at 458, 459, 463-65.

18. HURST, *supra* note 3, at 48.

19. Abner J. Mikva, *A Reply to Judge Starr's Observations*, 1987 DUKE L.J. 380, 380.

20. Eskridge & Frickey, *supra* note 2, at 334.

21. *Id.* at 335 (emphasis added).

22. *Id.* at 336 (footnote omitted).

interpretation highly controversial.”²³

Using purposivism as the sole technique of statutory interpretation also presents a problem because “*text* is the only thing enacted into law, [and] is formally the most legitimate expression of legislative intent or purpose.”²⁴ Purposivist theory can potentially defeat the goal that citizens “be able to open up the statute books and have a good idea of their rights and obligations. When the statute seems plainly to say one thing, courts should be reluctant to alter that directive.”²⁵

B. *Textualism*

Textualism, also called the “plain meaning rule,”²⁶ is based on the premise that “[t]he beginning, and usually the end, of statutory interpretation should be the apparent meaning of the statutory language.”²⁷ As Justice Holmes said, “We do not inquire what the legislature meant; we ask only what the statute means.”²⁸ Interpretation of the text of a statute, however, requires more than merely reading the words of the statute. While, in the absence of textual ambiguity, courts should enforce a statute according to its terms, “[t]he meaning of language is derived from its context. . . . [T]he meaning of words cannot be conclusively established in the abstract.”²⁹ Accordingly, the *meaning* of the words in a statute must be determined from the *purpose* of the statute.³⁰ Justice Frankfurter explained that, “[t]he notion that because the words of a statute are plain, its meaning is also plain, is merely pernicious oversimplification.”³¹

The Court’s interpretation of the Mann Act in *Caminetti v. United*

23. *Id.* at 335; see also Daniel A. Farber & Philip P. Frickey, *Legislative Intent and Public Choice*, Working Paper No. 39, at 2-3 (Nov. 1987) (discussing questions concerning the extent to which legislation reflects a coherent congressional view of the public interest due to the perception that congressional enactments are not motivated by conceptions of the public interest but rather reflect private-interest deals, re-election posturing, or arbitrary outcomes. Based on this view, it has been suggested that judges should enforce a statute only within the domain of the plain meaning of its words and abandon interpretation based upon the legal fictions of legislative intent and statutory purpose).

24. Eskridge & Frickey, *supra* note 2, at 337 (emphasis added).

25. *Id.* at 339.

26. See STATSKY, *supra* note 11, at 75.

27. Eskridge & Frickey, *supra* note 2, at 340.

28. Oliver Wendell Holmes, *The Theory of Legal Interpretation*, 12 HARV. L. REV. 417, 419 (1899).

29. STATSKY, *supra* note 11, at 75; see also Radin, *supra* note 4, at 868 (defining ambiguous as meaning that a statute has any two possible meanings, whether or not these meanings are contradictory, and that any statute that describes “a group of possible events within a situation . . . is essentially ambiguous”).

30. See STATSKY, *supra* note 11, at 76.

31. *United States v. Monia*, 317 U.S. 424, 431 (1943) (Frankfurter, J., dissenting).

*States*³² presents an example of strict textualism. Caminetti had been found guilty of violating the Act by transporting a woman in interstate commerce for the “immoral purpose” of becoming his concubine or mistress. The court reasoned that a married man who took an unmarried woman out-of-state and slept with her had an immoral purpose, and thus Caminetti was in plain violation of the statute.³³ This strict textualist approach is “rarely followed today”; courts go outside the “four corners of the statute” to determine *if* the language in the statute is plain and unambiguous.³⁴

Judge Wald noted that, in the 1981 Term, “although the Court still refer[red] to the ‘plain meaning’ rule, the rule has effectively been laid to rest. . . . When the plain meaning rhetoric is invoked, it becomes a device . . . for shifting onto legislative history the burden of proving that the words do not mean what they appear to say.”³⁵ However, in the 1988-89 Term, she noted that the Court was again relying on text: she found only five cases in which the Court used outside materials in interpreting a statute.³⁶ Justice Scalia has been called the “spiritual leader” of the Court’s return to a textualist approach to statutory interpretation.³⁷ Gregory Maggs credits Justice Scalia with the growing trend toward decreased reliance on legislative history in statutory interpretation, as Justice Scalia “has adopted an almost absolute stance against deciding cases on the basis of anything other than the statutory text.”³⁸

Textualist theory supports the argument that citizens should “be able to read the statute books and know their rights and duties;”³⁹ however, “when contextual arguments strongly cut against the textual ones” the Court sometimes refuses to rely on textualism.⁴⁰ Thus, when “current values and historical context strongly support an interpretation, a

32. 242 U.S. 470 (1917).

33. *See id.* at 486.

34. *See* STATSKY, *supra* note 11, at 5.

35. Patricia M. Wald, *Some Observations on the Use of Legislative History in the 1981 Supreme Court Term*, 68 IOWA L. REV. 195, 195 (1983).

36. *See* Patricia M. Wald, *The Sizzling Sleeper: The Use of Legislative History in Construing Statutes in the 1988-89 Term of the United States Supreme Court*, 39 AM. U. L. REV. 277, 294 (1990).

37. *See id.* at 281; *see also id.* at 281-82 (explaining that “the Scalia view has as its bedrock principle a most unexceptional notion: the role of the courts in interpreting statutes is to ascertain and effectuate the ‘intentions’ of Congress as they are expressed when it passes legislation. . . . Justice Scalia’s ‘textualist’ view departs from th[e] norm,” however, because he advocates determining the meaning of terms in statutes by context, ordinary usage, and compatibility with the surrounding body of law, as opposed to the frequent practice of resorting to extra-statutory materials only to explain language that is ambiguous or seemingly contradictory).

38. Gregory E. Maggs, *The Secret Decline of Legislative History: Has Someone Heard a Voice Crying in the Wilderness?*, 1994 PUB. INTEREST L. REV. 57, 58.

39. Eskridge & Frickey, *supra* note 2, at 340.

40. *See id.* at 344.

determinate text will not stand in the way.”⁴¹

Textualism as the sole source of statutory interpretation suffers from several deficiencies: it “oversimplif[ies] the meaning of statutory texts, [is] not so determinate as [it] sound[s], and ignore[s] other values our polity considers important.”⁴² If a statute must be interpreted by an appellate court, the textualist approach is inappropriate. Judge Wald points out that “[d]isputes that are resolved by plain statutory language usually settle long before they make their way into the federal appellate courts.”⁴³ If the plain meaning of a statute can be easily interpreted from its text, the trial court should be able to resolve the issue. Only those statutes where the meaning is not clear from the text should thus be interpreted by higher courts.

C. *Intentionalism*

A third, somewhat controversial approach to statutory interpretation requires an examination of legislative history to ascertain the intent of the legislature in enacting the statute. Under this approach, the Court seeks to determine whether “specific facts currently in controversy were ever discussed by the legislature while it was considering the proposed statute” and “the broad or narrow purpose that prompted the legislature to enact the proposed statute.”⁴⁴ As compared to a purposivism approach, in which the Court may review the legislative history to ascertain the *purpose* of the enactment of the statute, under this approach, the Court looks for discussions of specific fact situations to determine how the legislature wanted these situations resolved.⁴⁵

Judge Wald found that, in the 1981 Term, “[n]o occasion for statutory construction . . . exist[ed] when the Court [did] *not* look at the legislative history,”⁴⁶ whereas “[e]arly American courts . . . used legisla-

41. *Id.* at 343.

42. *Id.* at 341.

43. Wald, *supra* note 36, at 301.

44. STASKY, *supra* note 11, at 99.

45. See HART & SACKS, *supra* note 14, at 1379:

The history should be examined for the light it throws on *general purpose*. Evidence of specific intention with respect to particular applications is competent only to the extent that the particular applications illuminate the general purpose and are consistent with other evidence of it Effect should not be given to evidence from the internal legislative history if the result would be to contradict a purpose otherwise indicated and to yield an interpretation disadvantageous to private persons who had no reasonable means of access to the history.

(emphasis added).

46. Wald, *supra* note 35, at 195 (emphasis added). *But see* Maggs, *supra* note 38, at 58 (noting that, during the 1992-93 Term, the Court appeared to be cutting down on reliance on legislative history); Wald, *supra* note 36, at 281 (reporting that, during the 1988-89 Term, there

tive history sparingly.”⁴⁷ “The Canadians came to joke that the American rule was: ‘whenever the legislative history is ambiguous it is permissible to refer to the statute.’”⁴⁸ In contrast, English courts “refus[e] to consider legislative history.”⁴⁹

*Massachusetts v. Morash*⁵⁰ exemplifies the use of legislative history to interpret a statute contrary to its text even though the meaning of the statute appears clear on its face. The Court there interpreted regular employer-provided vacation benefits as not covered under ERISA as an “employee welfare benefit plan.” Although ERISA specifically refers to vacation benefits when defining an “employee welfare benefit plan,”⁵¹ the Court concluded after examining the legislative history of ERISA that *conventional* vacation benefits were not included.⁵² The Court explained in part that “in expounding a statute, we [are] not . . . guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.”⁵³

Even though the use of legislative history in statutory interpretation presents a variety of problems, many disagree with Justice Scalia’s rigid stance against its use.⁵⁴ One argument against the use of legislative history “attacks reliance on materials other than statutory text because Congress has a voice as a constitutional player only through its finally enacted statutes, not through any supplementary explanation thereof.”⁵⁵

was “a fully articulated and quite aggressive assault in the Supreme Court on the use of legislative history in construing statutes”).

47. Wald, *supra* note 35, at 196.

48. *Id.* at 197.

49. See William S. Jordan, III, *Legislative History and Statutory Interpretation: The Relevance of English Practice*, 29 U.S.F. L. REV. 1, 2 (1994).

50. 490 U.S. 107 (1989).

51. 29 U.S.C. § 1002(1) (1994).

52. See *Massachusetts v. Morash*, 490 U.S. at 114-15.

53. *Id.* (alteration in original) (quoting *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51 (1987)).

54. See Posner, *supra* note 2, at 269 (“It is tempting to argue that because legislators vote on the statutory language rather than on the legislative history, they cannot be presumed to have assented to all that has been said, either in the committee reports or on the floor, about a bill that becomes law. But if legislators know that courts look to legislative history in interpreting statutes—and they do know this—then when they vote for a bill they are assenting, in a sense, to at least some of what is in that history.”); Farber & Frickey, *supra* note 23, at 32-33 (“The Scalia-Easterbrook arguments might seem to apply with some force when a statute is unambiguous on its face. . . . But where a reader could reasonably attribute more than one meaning to the statute, the Scalia-Easterbrook arguments misfire. When statutory language could have one of several meanings, the ideal of ‘government by laws’ is irrelevant, because our problem is precisely that we don’t know what the ‘laws’ require.”); Wald, *supra* note 35, at 200-01, 202 (“[I]t is unrealistic to say . . . that courts should only consider certain items. . . . Committee reports indeed remain the most widely accepted indicators of Congress’ intent. . . . Courts can benefit, however, from access to more information concerning those stages of the legislative process that are most critical. For example, committee and subcommittee markups are key points in the process.”).

55. Wald, *supra* note 36, at 285; see also *In re Sinclair*, 870 F.2d 1340, 1343-44 (7th Cir.

Another argument contends that *silence* in the form of absence of objection by legislators in the materials is interpreted as *consent* by legislators.⁵⁶ Additionally, “[w]hen courts and agencies use legislative history to find a more specific intent than the statute expresses, legislators have an incentive to ‘manufacture’ legislative history on points of interest to them.”⁵⁷

Manufacturing legislative history offers two advantages over amending [a bill]. . . . [I]t is quicker and easier than drafting, debating, and voting on an amendment . . . [and] increases the chances that the member’s intentions will become law if they are controversial. Other members of Congress may never learn of the legislative history. This is especially true if it is manufactured in the house that is considering the bill *after* the other house has completed its consideration.⁵⁸

Another objection is that because legislative history can be created after legislation has left one house, its use violates the presentment and bicameralism requirements of the Constitution, similar to the legislative veto at issue in *INS v. Chadha*.⁵⁹ In response to this argument, Professors Farber and Frickey counter that “Article I procedural requirements are fully satisfied” because “the materials on which judicial interpretation is based are available to both Houses of Congress and to the President,” and “the decision by each entity as to whether to approve a bill can be based on an appraisal of the bill’s probable judicial interpretation.”⁶⁰ However, this argument fails to consider the amount of time required by the legislative and executive branch members to fully consider all pieces of what might be considered relevant material to deduce how the judiciary may interpret a bill. “[D]ocuments of legislative history . . . are still generally inaccessible,” and the cost of researching these documents can be substantial.⁶¹

Several commentators have noted that legislative history should

1989) (discussing the fact that legislative history is not subject to vote or veto, and therefore, resort to intent is no more forceful than resort to an opinion poll revealing the wishes of Congress, which does not translate to legal rules).

56. See W. David Slawson, *Legislative History and the Need to Bring Statutory Interpretation Under the Rule of Law*, 44 STAN. L. REV. 383, 396 (1992) (“The assumption is that if the other legislators had not agreed with what any particular legislator said, some of them, at least, would have voiced their own opinions, and these contrary expressions would also be in the record. Their absence therefore implies unanimous agreement.”).

57. *Id.* at 397.

58. *Id.* (emphasis added).

59. 462 U.S. 919 (1983).

60. Farber & Frickey, *supra* note 23, at 33.

61. STASKY, *supra* note 11, at 106; see also Kenneth W. Starr, *Observations About the Use of Legislative History*, 1987 DUKE L.J. 371, 378 (“[T]he costs extend beyond the bar and its clients: the judiciary must also devote time searching through mountains of material.”).

only be consulted if the statute is ambiguous.⁶² However, ambiguity must be distinguished from vagueness. Professor Slawson contends that vagueness in a statute is not a mistake but rather “measures the length to which the legislature chose to go in determining the outcomes of future cases,” and thus legislative history should never be used to reduce vagueness.⁶³

If legislative history is to be consulted in statutory interpretation, which particular “parts . . . actually cast light on [the statute’s] meaning?”⁶⁴ The various types of legislative history include study group recommendations, committee hearings and reports, floor debates, the adoption, non-adoption, or rejection of interim amendments, and post-enactment developments.⁶⁵

Many commentators consider committee reports the most reliable source of legislative history,⁶⁶ and post-enactment history the least reliable.⁶⁷ However, in a Congressional Research Service report prepared to “assist Members and staff in determining where their best chance (short of amendment) is to influence interpretation of legislation,”⁶⁸ the author noted that conference committee reports are “especially persuasive evidence of congressional intent” because conference committee action is

62. See, e.g., HART & SACKS, *supra* note 14, at 1236-37 (suggesting that the plain meaning rule calls for no analysis by the court if the meaning is plain on the face of the statute, but if the words seem ambiguous to the court, alternative arguments as to meaning might be required, which would take account of outside aids); HURST, *supra* note 3, at 55 (“Judges in the United States routinely stipulate that before they will consider evidence of legislative intent outside the words of the statute they must be persuaded that the words taken in themselves are of uncertain meaning. . . . [T]he rule makes a showing of uncertainty on the face of the statute an absolute prerequisite to looking beyond the face.”); see also *supra* note 29 and accompanying text.

63. Slawson, *supra* note 56, at 423.

64. POSNER, *supra* note 2, at 269.

65. See Dickerson, *supra* note 1, at 1130-33.

66. See, e.g., STASKY, *supra* note 11, at 108-09 (“Perhaps the most reliable documents of legislative history are the committee reports These reports often have two main components. [T]hey state the purpose of the bill. They will often include discussions of prior law on the subject of the bill . . . [and] the reports contain a section-by-section summary of the bill.”); Mikva, *supra* note 19, at 385 (“I always find that the committee report is the most useful device; it is what I use to try to resolve some of those ambiguities. Most of the time . . . the committee report represents the synthesis of the last meaningful discussion and debate on the issue.”); cf. Dickerson, *supra* note 1, at 1131 (“Committee reports are the second most reliable kind of legislative history. Their main value is in showing (if they do) the ulterior purposes that the respective bills are intended to advance.”).

67. See, e.g., POSNER, *supra* note 2, at 270 (“Postenactment statements . . . as to what the legislation meant should . . . be given little or no weight in general.”); Dickerson, *supra* note 1, at 1133 (“Post-enactment developments should be disregarded for purposes of cognition, simply because at enactment they were taken into account by neither the authors of the statute nor its audience.”).

68. GEORGE A. COSTELLO, SOURCES OF LEGISLATIVE HISTORY AS AIDS TO STATUTORY CONSTRUCTION CRS-1 (Jan. 27, 1989).

“frequently the critical stage in shaping legislation.”⁶⁹ He cautioned, however, that the explanations therein “are often brief, cryptic; or totally absent,” in which case “courts may attempt to read the resulting language as not expanding the scope of the reconciled House and Senate versions.”⁷⁰ The author recognized that “[o]rdinarily, committee reports are considered the most reliable and persuasive element of legislative history,”⁷¹ although “[t]he Court is wary of efforts in committee reports to spell out specific results in future litigation if those results do not necessarily follow from statutory language.”⁷² Where the committee report explanations of the two houses are different, a court may favor one explanation over the other as better reflecting its own reading of the statute; where equally plausible explanations are contradictory between the two reports, a court may rely upon whichever report was before both houses.⁷³

D. *Statutory Interpretation by “Practical Reasoning”*

The debate continues on the proper guidelines to follow in statutory interpretation. Canons of construction suffer from the reality that there are two opposing canons on almost every point.⁷⁴

Professors Eskridge and Frickey found that the Supreme Court’s approach to statutory interpretation “is largely grounded in practical reasoning,”⁷⁵ a theory they derived from “an analysis of the Court’s actual practice in statutory interpretation cases . . . and from [an] interpretation of the pragmatic and hermeneutical traditions in philosophy.”⁷⁶ They point out that:

[S]tatutory interpretation involves creative policymaking by judges and is not just the Court’s figuring out the answer that was put ‘in’ the statute by the enacting legislature. . . .

. . .

. . . [C]reation of statutory meaning is not a mechanical opera-

69. *Id.* at Summary to CRS-6.

70. *Id.* at Summary to CRS-7.

71. *Id.* at CRS-3.

72. *Id.*

73. *See id.* at CRS-4.

74. KARL N. LLEWELLYN, *THE COMMON LAW TRADITION: DECIDING APPEALS* 521 (1960); *see also* STASKY, *supra* note 11, at 83-95 (“Rules of interpretation are commonly called ‘canons of construction.’ In fact, however, they are not rules or laws in the technical sense of this word. . . . No court is required to apply a canon.”); POSNER, *supra* note 2, at 276-86 (discussing various canons of construction and noting that “[a] realistic understanding of legislation is devastating to the canons of construction”).

75. Eskridge & Frickey, *supra* note 2, at 383.

76. *Id.* at 345. “Hermeneutics suggests that the text lacks meaning until it is interpreted.” *Id.* at 346. “American pragmatism . . . complements this . . . insight. Reasoning in human affairs does not seek abstract answers, but concretely useful results.” *Id.*

tion, [and] often involves the interpreter's choice among several competing answers. . . .

. . . .

. . . [S]tatutory interpreters . . . are normally not driven by any single value . . . but are instead driven by multiple values.⁷⁷

Eskridge and Frickey suggest that, in hard cases, "the evidence points in different directions, and the Court critically analyzes each textual or historical or evolutive argument, both as to its own cogency and as to its cogency in light of the other evidence."⁷⁸ Judge Wald's observations of the 1981 Supreme Court Term agree with this analysis:

I cannot conclude that any ideological wing of the Court uses an 'intent' analysis more than 'purpose' or gives greater weight to plain language and canons than to legislative history. Frankly, the same Justices who rely on plain language and repudiate thirty years of contrary judicial interpretation in one case say in another that they must look to the broad purposes of the act and not to any cramped phraseology. . . . [I]n the present state of the law, the various approaches to statutory construction are drawn out as needed. . . .⁷⁹

Likewise in her analysis of statutory interpretation cases by the Supreme Court in 1988-89, Judge Wald found that,

"[i]n eighteen cases, the Court referred to legislative history to confirm its reading of statutory language,"⁸⁰ in eight cases, "legislative history was able to shed some light on the particular issue for decision,"⁸¹ "in twenty-four cases, the Court failed to find specific answers to the legislative history questions before it but did glean important understandings of the fundamental purposes of the Act,"⁸² and "[i]n only five cases . . . did the Court use legislative materials to come to a different result from that derived from the arguably 'plain' language of the statute."⁸³

Although Judge Wald analyzed the use of textualism versus legislative history in statutory interpretation by the Court, her results confirm that the Court does not follow any one approach to statutory interpretation. Rather, it reaches its decisions by utilizing a variety of interpretive techniques.

An example of the results reached by the use of various interpretive techniques is seen in *Watt v. Western Nuclear, Inc.*⁸⁴ There, the

77. *Id.* at 345-48.

78. *Id.* at 323.

79. Wald, *supra* note 35, at 215.

80. Wald, *supra* note 36, at 289.

81. *Id.* at 292.

82. *Id.* at 293.

83. *Id.* at 294.

84. 462 U.S. 36 (1983).

Court interpreted a statutory provision to determine if Congress had intended that gravel be considered a mineral for purposes of the statute.⁸⁵ The majority interpreted the section, which read “all the coal and minerals” to include gravel.⁸⁶ The Court used the principles of purposivism and textualism to reach this result, and considered alternative interpretations that produced results at odds with the purpose of the statute.⁸⁷ The dissent interpreted the statute by considering the intent of Congress at the time the statute was written⁸⁸ and concluded that all gravel was *never* intended by Congress to be classified as a mineral.⁸⁹ Both sides determined that the definition of mineral was not clear on the face of the statute. However, each used the same interpretative techniques—

85. See *id.* at 37-38.

86. See *id.* at 56.

87. See *id.* at 42-60. The Court considered a variety of definitions of “mineral” and determined that the legal understanding of the term “minerals” prevailing when the statute was enacted did not indicate whether Congress intended the mineral reservation in the statute to include gravel. See *id.* at 42-44. The Court also reviewed an administrative decision by the Secretary of the Interior indicating that “land containing deposits of gravel and sand useful for building purposes was not mineral land beyond the reach of homestead laws” *Id.* at 45. The Court concluded that the purpose of the Act was “that the mineral reservation . . . includes gravel,” *Id.* at 47, because “Congress intended to facilitate development of both surface and subsurface resources, [so] the determination of whether a particular substance is included in the surface estate or the mineral estate should be made in light of the use of the surface estate that Congress contemplated.” *Id.* at 52. Legislative history revealed “Congress’ understanding that the mineral reservation would ‘limit the operation of this bill *strictly to the surface of the lands.*’” *Id.* at 60 (quoting H.R. REP. NO. 64-35, 18 (1916)). “Given Congress’ understanding that the surface of [the] lands would be used for ranching and farming, we interpret the mineral reservation in the Act to include substances that are mineral in character, . . . that can be removed from the soil, and that can be used for commercial purposes, and that there is no reason to suppose were intended to be included in the surface estate.” *Id.* at 53. Noting that the statutory language was ambiguous, the majority found that an interpretation that “convey[ed] gravel deposits to the farmers and stockmen” would “produce a result at odds with the purposes underlying the statute. Instead, we interpret the language of the statute in a way that will further Congress’ overriding objective of facilitating the concurrent development of surface and subsurface resources.” *Id.* at 56. The Court found its decision was “supported by the treatment of gravel under other federal statutes concerning minerals,” *id.* at 56, and under “the established rule that land grants are construed favorably to the Government . . . and that if there are doubts they are resolved for the Government, not against it.” *Id.* at 59 (quoting *United States v. Union Pac. R.R. Co.*, 353 U.S. 112, 116 (1957)).

88. See *id.* at 62-72 (Powell, J., dissenting). The dissent cited an Interior Department rule and noted that “[a] search of the standard American authorities has failed to disclose a single one which classifies a deposit such as claimed in this case as a mineral.” *Id.* at 64 (quoting *Zimmerman v. Brunson*, 39 Pub. Lands Dec. 310, 312 (1910)). The dissent interpreted the legislative history as silent on the definition of mineral, see *id.* at 65-66, remarked that Congress removed gravel from the purview of general mining laws, see *id.* at 69, and concluded that the legislative history indicated “[c]ongressional interest in stockraising and mineral development was subordinate to the ultimate congressional purpose of settling the West.” *Id.* at 71. “Congress surely did not intend to destroy that sovereignty by reserving the commonplace substances that actually constitute much of that soil.” *Id.* at 71-72.

89. See *id.* at 70 (Powell, J., dissenting).

purposivism, textualism, related statutes, and prior administrative rulings—and reached opposite conclusions.

When interpreting a statute, courts should consider all the techniques discussed above and “decide what attribution of meaning to the statute will yield the most reasonable result in the case at hand. . . .”⁹⁰

III. STATUTORY INTERPRETATION OF THE PROCESS PATENT AMENDMENTS ACT OF 1988

The problems of statutory construction and resulting interpretation by the courts are illustrated in two cases brought under a statute enacted as part of the Omnibus Trade and Competitiveness Act of 1988. That statute, the Process Patent Amendments Act of 1988, was enacted with the express purpose of protecting the economic value of U.S.-patented processes and “provid[ing] meaningful protection to owners of patented processes”⁹¹ by allowing a cause of action in federal court by U.S. process patent holders against persons who use the patented process in another country and subsequently import a *product* of that process into this country. Prior to passage of the Act, such activity did not offend U.S. patent law because only infringing acts occurring within U.S. territory were prohibited; patent laws are territorial and the United States had no authority in foreign locales where alleged infringing activity occurred.

A. *Background of the Act*

Because intellectual property laws vary in significant respects among various countries, some countries have attempted to harmonize intellectual property protection by participating in the Paris Convention and the recent TRIPS agreement (part of the Uruguay Round of GATT). The Paris Convention has been the underlying source of international industrial property protection for the past century.⁹² Under the Paris Convention, “Article 5 *quater* mandates that each member nation must treat imported products manufactured by processes patented in the country of importation as if those products were manufactured in that country.”⁹³ Consequently, U.S. law did not comply with this provision before passage of the Act because an action for infringement could lie only if the infringing act took place in U.S. territory; the Paris Convention calls for infringement in such cases *despite* the location of the

90. POSNER, *supra* note 2, at 287.

91. H.R. REP. NO. 100-60, 100th Cong., 1st Sess. 3 (1987).

92. See Glenn E.J. Murphy, Note, *The Process Patent Amendments Act of 1988*, 9 J.L. & COM. 267, 280 (1989).

93. *Id.* at 293.

infringing act.⁹⁴ Passage of the Act thus brought U.S. law into compliance with the Paris Convention in the protection of *products* of patented processes.

Similar to the Paris Convention, the recent TRIPS agreement sets out *minimum standards* of intellectual property protection which member nations must implement.⁹⁵ TRIPS "standards are set at a level comparable to those in the major industrial countries today. . . . The Agreement sets these standards by requiring . . . compliance with the substantive obligations of the main WIPO conventions, the Paris Convention, and the Berne Convention. . . ." ⁹⁶ Under TRIPS, the United States is compelled to comply with the Paris Convention for protection of products of patented processes. Passage of the Act also brought U.S. law into compliance with TRIPS.

A WIPO committee in 1986 noted that eleven countries (including Japan and most of the EC) provided patent protection to *direct* products of patented processes, whereas seven countries (including the United States) did not.⁹⁷ Thus, the Act brought U.S. law into conformity with the laws of these other industrialized nations.

The Senate recognized that the sovereignty of other countries must be respected, noting that:

The bill does not attempt to prevent the use of the process in another country. . . . If the U.S. process patentholder has not obtained a similar patent in the other country, he has no right by virtue of his U.S. patent to prevent anyone from using the process in that country. . . . [The bill] protect[s] against the entry into the U.S. marketplace of goods made abroad without authorization from the inventor who has a process patent in this country. The patent is on the process alone, but the entry of the goods made elsewhere by that process clearly encroaches on the rights of the patent owner.⁹⁸

The Act does not invade the sovereignty of other nations' patent laws (at least those who are members of the Paris Convention), and is no more invasive on non-members' patent laws than the laws of those

94. See *id.* at 282 (arguing that Article 5 *quater* is enforceable in federal courts due to a Supreme Court ruling that "the Paris Convention is self-executing and its provisions are immediately applicable by the Patent Office or Federal courts. However, . . . no Federal court has applied its provisions . . . [and] while it appears that Federal courts would be willing to enforce Article 5 *quater*, no U.S. process patentees have opted to take that chance.").

95. Adrian Otten & Hannu Wager, *Compliance With TRIPS: The Emerging World View*, 29 VAND. J. TRANSNAT'L L. 391, 394 (1996); Monique L. Cordray, *GATT v. WIPO*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 121, 125 (1994).

96. Otten & Wager, *supra* note 95, at 396.

97. See *Intellectual Property and Trade: Hearings Before the Subcomm. on Courts, Civil Liberties, and the Admin. of Justice of the House Comm. on the Judiciary*, 99th Cong., 2d Sess. 520 (1986) [hereinafter *Hearings*], Memorandum by the Int'l Bureau of WIPO.

98. S. REP. NO. 100-83, 100th Cong., 1st Sess. 30 (1987).

members of the Paris Convention who already protect the products of patented processes. Certain less-developed countries (LDCs) have complained that such provisions are an invasion of their sovereignty,⁹⁹ however, due to the "general lack of consensus among LDCs regarding process patents . . . [and] the peripheral participation of LDCs in the international patent system, . . . U.S. efforts at harmonization with world patent laws give little consideration to LDC patent systems."¹⁰⁰

The express congressional intent in passage of the Act was to protect the economic value of U.S. patented processes and to preserve American jobs. The Senate Committee on the Judiciary recognized that "[i]mportation, use and sale in the United States of products produced by processes patented in this country severely diminishes the value of such patents."¹⁰¹ Similarly, the House Committee on the Judiciary observed that "the unfettered ability of others to import, sell or use a product made by the patented processes, severely diminishes the value of a U.S. process patent. It also results in the loss of American jobs, particularly in new technology areas."¹⁰²

The Act makes it easier for U.S. process patent holders to obtain relief from an infringing foreign manufacturer, as compared to actions for relief under the prior law. Prior to passage of the Act, U.S. process patent owners were required to bring actions against an infringer either through Articles 5 and 28 of the Paris Convention, GATT, or section 337 of the Tariff Act of 1930.¹⁰³ Each of these actions has drawbacks compared to a suit in federal court, however, where a party can obtain damages and injunctive relief against an infringer,¹⁰⁴ also, actions under these alternatives are time consuming, expensive, and can be difficult to prove.¹⁰⁵ However, Congress added two exceptions to the Act in section 271(g) concerning what constitutes an infringing product made from a U.S. patented process, which exceptions have caused difficult interpretive questions: if the product of the patented process (a) is materially changed by subsequent processes, or (b) becomes a trivial and nonessential component of *another* product, the imported product will not be considered infringing.¹⁰⁶

99. See Murphy, *supra* note 92, at 296-97. Brazil, in particular, has complained that under section 301 of the Trade Act of 1974, the United States has no right to exclude Brazilian pharmaceutical products as products of piracy. See *id.*

100. *Id.* at 295.

101. S. REP. NO. 100-83, at 31 (1987).

102. H.R. REP. NO. 100-60, at 3 (1987).

103. See Murphy, *supra* note 92, at 280-89.

104. See S. REP. NO. 100-83, at 2 (1987).

105. See Murphy, *supra* note 92, at 283-89.

106. See 35 U.S.C. § 271(g) (1995 Supp.). This section reads:

Whoever without authority imports into the United States or offers to sell, sells

As noted above, most foreign patent laws limit patent protection to “direct” products of the patented process.¹⁰⁷ Notably, the statutory exceptions do not contain the “direct” product language found in the laws of other countries; however, this difference should not be construed as giving federal courts *more* flexibility than their foreign counterparts in finding products infringing. Rather, the word “direct” was replaced with the phrase “materially changed” because of the constraints Congress believed such language could cause in judicial interpretation.¹⁰⁸ The Senate Subcommittee on Courts, Civil Liberties, and the Administration of Justice hesitated to use the term “directly” in the wording of the Act because “words like these take on . . . legal connotations.”¹⁰⁹

To determine the extent of protection provided by use of the word “directly,” the U.S. delegation raised the question at a WIPO committee meeting of how to distinguish between products “obtained directly” and those not “obtained directly” from a patented process. In reply, the WIPO final report states that “until the resulting product ha[s] been materially changed, it should be considered to have been obtained directly from the patented process.”¹¹⁰

The use of the term “materially changed” thus should not be considered an expansive departure from comparable countries’ patent protection for products of patented processes. Rather, this term was used

or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

- (1) it is materially changed by subsequent processes; or
- (2) it becomes a trivial and nonessential component of another product.

107. *See* S. REP. NO. 100-83, at 36, 49 (1987). Discussing the differences between U.S. patent law and that of foreign nations, the Senate Report points out that most industrialized nations limit process patent laws to products made directly from the process and that Congress decided against including the word “directly” in the statute out of concern that the term might be construed too broadly and possibly exempt too many products that have been altered in insignificant ways after manufacture by the patented process. *See id.* at 49; *see also supra* note 97 and accompanying text.

108. *See* S. REP. NO. 100-83, at 36, 49 (1987) (noting that the “materially changed” wording is to “serve the same general purpose of restricting the scope of the bill to exclude ultimate products that, because of intervening manufacturing steps, cease to have a reasonable nexus with the patented process”).

109. *Hearings, supra* note 97, at 280 (statement of David Mallino, Legislative Director, Industrial Union Department, AFL-CIO).

110. *Id.* at 528 (report by the Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions. The report also included a request for examples from participants to illustrate application of this term.) *See id.*

because the word "directly" has legal connotations peculiar to the U.S. judicial system which could result in more *restrictive* results than in other countries.

As written, the Act exhibits opposing purposes. The first purpose is to give a U.S. process patent holder legal protection against foreign manufacturers who use a patented process and subsequently import a product of that patented process.¹¹¹ The second purpose is to protect foreign manufacturers whose final imported products are too far removed from the final product of the patented process to be considered infringing.¹¹² Between these two extremes, of course, lie the most difficult cases—cases that require courts to apply the exceptions and draw a line where an imported product is "materially changed" from the product of a U.S. patented process. Courts must walk a tightrope in these cases. They cannot be too protective of process patent holders, as this could negatively affect international trade and provide a disincentive for U.S. patent process holders to obtain foreign patents. Alternatively, the reason for enactment of the statute was to *protect* these process patent holders. Courts should consider these issues when interpreting the Act.

Congress specifically recognized the importance of protecting process patents in the pharmaceutical industry,¹¹³ and representatives of the industry played significant roles in the hearings on the passage of the Act. The positions of both U.S. process patent holders (name-brand drug companies) and foreign manufacturers (generic drug companies) were in conflict because the name-brand drug companies desired the protection being offered, while some generic drug companies felt they might experience higher costs because the active ingredients imported as raw materials might be manufactured overseas in violation of U.S. process patents.¹¹⁴

Disputes have arisen over what is included under the two exceptions. Not surprisingly, drug companies have taken opposite views on what constitutes a "material change" in a product for the purpose of exclusion from infringement under the statute. Two federal court cases, one involving an appellate decision, both of which centered around generic drug importation, have formed the basis for judicial interpretation of the two exceptions included in the Act by Congress.

In the following sections, the Act will be analyzed using standard statutory interpretative techniques to demonstrate how the statutory lan-

111. See *supra* notes 91, 101, 102, and accompanying text.

112. See H.R. REP. NO. 100-60, at 13-14 (1987); S. REP. NO. 100-83, at 49-50 (1987).

113. See S. REP. NO. 100-83, at 30 (1987).

114. See *Hearings, supra* note 97, at 163 (statement of Dee Fensterer, President, Generic Pharmaceutical Industry Association).

guage responds to different approaches in the interpretation of the phrase "materially changed." Next, these cases will be analyzed to illustrate how the courts responded to this interpretation problem. Comparison of the results leads one to wonder whether the courts were protective enough of certain U.S. process patent holders, perhaps opening the door to substantial economic loss for the chemical process industry.

B. *Purposivism*

Under purposivist theory, the phrase "materially changed" should be interpreted in light of the mischief the legislature was trying to correct when it passed the statute. That mischief is the loss in value to U.S. process patents due to importation of products made by the process. However, the statute's primary purpose—to provide meaningful protection to owners of patented processes—is clearly limited by the statutory exceptions. Courts must determine whether a product of a U.S. patented process has been "materially changed" by intervening processes such that the infringement does not severely diminish the value of the process patent¹¹⁵ in light of the statute's *other* purpose—the protection of foreign manufacturers whose imported products "cease to have a reasonable nexus with the patented process."¹¹⁶

The surrounding body of law—the patent laws—should also be considered in this interpretation. The constitutional purpose of the patent system is to "promote the progress of science and useful arts . . .," and Congress is empowered to pass all laws to enact the patent system.¹¹⁷ The patent system "was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge."¹¹⁸ The Act must also be interpreted in light of this purpose; the result should support the promotion of technology by inducing further invention and disclosure in the field of art of the patented process.

C. *Textualism*

The textualist approach emphasizes the words in the statute rather than the "more abstract and judicially malleable interpretive sources."¹¹⁹ Textualism is not a preferred mode of analysis in this case because

115. See *supra* notes 101, 102, and accompanying text.

116. S. REP. NO. 100-83, at 36 (1987).

117. See U.S. CONST. art. I, § 8, cl. 8.

118. *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1966). The Court noted that the grant of a patent monopoly, despite early American aversions to such, was for the purpose of "weeding out those inventions which would not be disclosed or devised but for the inducement of a patent." *Id.* at 11.

119. Eskridge & Frickey, *supra* note 2, at 340.

"[t]extualism can control statutory interpretation only if the text itself offers a complete and reasonably determinate source of meaning."¹²⁰ The phrase "materially changed" can have several meanings, and must be interpreted according to context.¹²¹ Even in a contextual sense, this provision of the statute eludes determinative interpretation, as evidenced by the difficulty the Congress experienced in explaining the concept. Here, the *language* of the statute is plain and unambiguous. The language may be *vague*, but vagueness "measures the lengths to which the legislature chose to go in determining the outcomes of future cases."¹²² Textualism does not provide a clear answer to the interpretation of the phrase "materially changed" because the text does not define the term.

D. *Intentionalism*

Because actual intent of legislators is difficult to determine, at best, under this approach courts look to what Eskridge and Frickey call "conventional" legislative intent.¹²³

In this instance, a joint conference committee report as well as reports by committees of both houses are available for study. The joint conference committee report reconciles the language of the second exception between the bills passed by each house which resulted in section 271(g). In the House bill,¹²⁴ the second exception was described as applying when a product "becomes a minor or nonessential component of another product,"¹²⁵ whereas in the Senate bill,¹²⁶ it was described as applying when a product "becomes a trivial and nonessential component of another product."¹²⁷

The House receded to the Senate version of the bill, with the only explanation being that, since neither version of the bill "proposed changes to the concept of apportionment of damages, House recession

120. *Id.* at 341.

121. *See supra* notes 29-30 and accompanying text.

122. *See supra* note 63 and accompanying text.

123. *See* Eskridge & Frickey, *supra* note 2, at 326. "Statements made in committee reports and floor statements by sponsors or floor managers of legislation presumably represent the legislature's views on specific issues. . . . [This approach is] legitimated . . . only if legislators in general agree with, or at least acquiesce in, the views of the few actively involved in the passage of legislation." *Id.* at 327. Other problems include the facts that committee members may not represent a cross-section of the legislature and that interest groups may have their legislative allies "pack committee reports and stage planned colloquies to suggest a meaning for the statute that they cannot place in the statutory language." *See id.*

124. Process Patent Amendments Act of 1987, H.R. 1931, 100th Cong. (1987). *See* H.R. REP. NO. 100-60, at 1 (1987).

125. H.R. REP. NO. 100-60, at 1 (1987).

126. Process Patent Amendments Act of 1987, S. 1200, 100th Cong. (1987). *See* S. REP. NO. 100-83, at 1 (1987).

127. S. REP. NO. 100-83, at 13 (1987).

. . . does not signify a modification of this important patent law concept."¹²⁸ No discussion of the proposed tests suggested in the House and Senate committee reports to determine when a product is materially changed was contained in the conference report, however, and thus no guidance to interpretation is available from this source. The House and Senate committee reports both address the issue of when products are materially changed; however, proposed tests to determine when a product is materially changed from the product of the patented process vary between the two.

Both reports contain identical wording in the first exception, the "materially changed" limitation.¹²⁹ The Senate committee report recognized that "the courts may frequently find themselves in a quandary on this most important phrase,"¹³⁰ and stated that the committee "intends a specific two-phase test to be implemented."¹³¹ The test is as follows:

1. A product will be considered made by the patented process regardless of any subsequent changes if it would not be possible or commercially viable to make that product but for the use of the patented process. In judging commercial viability, the courts shall use a flexible standard which is appropriate to the competitive circumstances.

2. A product will be considered to have been made by a patented process if the additional processing steps which are not covered by the patent do not change the physical or chemical properties of the product in a manner which changes the *basic utility* of the product by the patented process. However, a change in the physical or chemical properties of a product, even though minor, may be "material" if the change relates to a physical or chemical property which is an important feature of the product produced by the patented process. Usually, a change in the physical form of a product (e.g., the granules to powder, solid to liquid) or minor chemical conversion (e.g., conversion to a salt, base, acid, hydrate, ester, or addition or removal of a protection group) would not be a "material" change.¹³²

The House report includes identical language concerning the first part of this two-part test respecting commercial viability of making the

128. See H.R. CONF. REP. NO. 100-576, at 1087 (1988), reprinted in 1988 U.S.C.C.A.N. 1547, 2119, 2120. Apparently, the only concern of the House in receding to the Senate was that, when a product is made directly from a U.S. patented process but "injunctive relief might not be appropriate under [the] circumstances, some damage relief would be appropriate, based, for example, on an apportionment of the contribution of the infringing part to the value of the whole product in which it is incorporated." See S. REP. NO. 100-83, at 51 (1987).

129. See H.R. REP. NO. 100-60, at 1 (1987); S. REP. NO. 100-83, at 13 (1987).

130. S. REP. NO. 100-83, at 50 (1987).

131. *Id.* at 49.

132. *Id.* at 50 (emphasis added).

imported product using the patented process at issue.¹³³ In this part of the test, both houses explicitly agreed the courts should have flexibility in adjudging when a patented process is either vital or commercially necessary to make a product. Several factors can make a process commercially viable, such as the steps involved in production (whether they are energy-intensive or whether a manufacturer has equipment available that can be adapted for use in the process) and the cost of raw materials (whether there is an advantage to using a specific raw material). In its committee report, the House recognized that a "new process may permit [a] product to be made much more economically."¹³⁴

The second part of the Senate's two-part test, the "basic utility" test, is not contained in the House committee report, however. Applying the second part of the Senate test is thus questionable,¹³⁵ because the Senate committee report was not issued until after the initial House vote on the bill,¹³⁶ and therefore, was not considered in the House deliberations. Additionally, the inclusion of specific examples in the House and Senate reports may be construed as attempts to dictate specific results in future litigation, reducing reliability of these examples as interpretive guides.¹³⁷ Interpretation through use of legislative history is accordingly inconclusive as to determining whether or not a product is "materially changed" from the product of a patented process.

Using legislative history as his guide, one student commentator pointed out that "[t]he 'made by' language [in the statute] . . . determine[s] the extent to which foreign activity leads to infringement liability in the United States. The true scope of the statute, however, is not apparent on its face."¹³⁸ He argued that the conjunctive "or" used in the statutory caveats has been misused; according to the committee reports, this "or" should have been an "and," which would call for a product to satisfy *both* limitations in order to be considered non-infringing.¹³⁹ As the statute is written, a product need only satisfy one of the provisions to be considered "materially changed." The author concluded that:

In deciding whether a change is material, the inquiry should focus on the conventionality of the process for making the change, rather than on the physical transformation of the product itself. This

133. See H.R. REP. No. 100-60, at 13-14 (1987).

134. *Id.* at 3.

135. See *supra* notes 68-73 and accompanying text.

136. The House considered and passed H.R. 1931 on April 30, 1987, prior to issuance of the Senate committee report on June 23, 1987.

137. See *supra* notes 68-73 and accompanying text.

138. Glenn Law, Note, *Liability Under the Process Patent Amendments Act of 1988 for the Use of a Patented Process Outside the United States*, 60 GEO. WASH. L. REV. 245, 248 (1991) (footnote omitted).

139. See *id.* at 257-59.

interpretation of section 271(g) gives effect to Congress' desire to provide effective protection for processes that are patented in the United States.¹⁴⁰

In other words, when considering whether a product has been materially changed, the court should look closely at the *process* by which a product is changed, rather than comparing the properties of the product of the patented process to the final imported product.

E. "Practical Reasoning" Approach

As seen in *Watt v. Western Nuclear, Inc.*,¹⁴¹ a court may use a variety of techniques in its analysis and weigh the results against each other.¹⁴² As also seen in *Watt*, different judges reach different answers using the same techniques and materials. Courts should interpret the Act using each of the two techniques (purposivism and intentionalism) and compare the results. If both approaches reach the same result, the decision is likely the proper one. If different results are reached, however, the court must then determine which values it believes are the most important to uphold in its decision.

IV. JUDICIAL INTERPRETATION OF THE PROCESS PATENT AMENDMENTS ACT OF 1988

Two district courts and the Federal Circuit have interpreted the "materially changed" provision of the Act in two separate cases. This note analyzes the reasoning and results of each court—and concludes that two of the courts included "dangerous dicta" in their opinions which may be relied upon in future cases brought by U.S. process patent holders against allegedly infringing foreign manufacturers.

A. A Background Case:

Marion Merrell Dow, Inc. v. American Cyanamid Co.

The District Court for the District of New Jersey interpreted the "materially changed" exception in a suit brought by Marion Merrell Dow, Inc. ("MMD") and Tanabe Seiyaku Co. Ltd. against Abic, Ltd. ("Abic") and American Cyanamid Co. ("Cyanamid") for infringement of MMD's U.S. process patent.¹⁴³ Abic, in turn, sought a declaration via summary judgment of non-infringement for the accused product, dil-

140. *Id.* at 267.

141. 462 U.S. 36 (1983).

142. See *supra* notes 84-89 and accompanying text.

143. *Marion Merrell Dow, Inc. v. American Cyanamid Co.*, 36 U.S.P.Q.2d 1036, 1036-37 (D.N.J. 1994).

tiazem hydrochloride.¹⁴⁴ Abic is the foreign manufacturer and Cyanamid is the reseller of the imported generic product.¹⁴⁵ Abic argued that since it further processed the *direct* product of the patented process to make the final imported product, under section 271(g), the final product was materially changed from the product of the patented process and thus non-infringing.¹⁴⁶

The court compared diltiazem precursor (one of the products of the patented process) and diltiazem hydrochloride (the imported product, Cardizem) by the amount of their vasodilatory properties. The court found that Claim 1 of the subject patent covers N-alkylation, which is the step that activates this cardioselective activity. Ultimately, the acetylation and hydrochlorination steps which Abic relied upon as producing the material change in the product of the process were found to be minor chemical conversions which affect only the toxicity and adverse side effects and not the vasodilatory properties.¹⁴⁷

The court looked to the legislative history of the Act for guidance in interpreting the statutory exceptions to infringement.¹⁴⁸ It also considered the stated statutory purpose—to provide “meaningful” protection to process patentees—and decided that “[m]eaningful protection will not be provided if an accused infringer can avoid liability under section 271(g) when it uses a patented process to produce an intermediate, converts the intermediate to the only commercially saleable drug product of the process using conventional techniques, and imports that final product.”¹⁴⁹

The commonality of vasodilatory properties between the chemical intermediate product of the patented process and the final imported product, together with the fact that diltiazem hydrochloride is the “only commercial saleable drug product of the process using conventional

144. *See id.* at 1036-37. MMD is the licensee of the subject patent and markets diltiazem hydrochloride under the trademark “Cardizem.” *See id.* Cardizem is a coronary vasodilator. *See id.* at 1037. A coronary vasodilator dilates the blood vessels of the heart. *See* Eli Lilly & Co. v. American Cyanamid Co., 896 F. Supp. 851, 858 (S.D. Ind. 1995).

145. *See* *Marion Merrell Dow*, 36 U.S.P.Q.2d at 1037.

146. *See id.* at 1038. Claim 1 of the subject patent covers two situations: where the starter material is hydroxyl or acetyl. *See id.* at 1037-38. If the starter material is hydroxyl, the product resulting from the claim process is diltiazem precursor, and acetylation is further required to produce diltiazem. *See id.* at 1037. However, if the starter material is acetyl, diltiazem is produced directly under the patented process. *See id.* at 1038. Abic argued that since it starts with hydroxyl starter material, *see id.* at 1040, and since acetylation is not included in the claim, it is not infringing the claim. *See id.* at 1038. Although diltiazem is converted to diltiazem hydrochloride by hydrochlorination, the court regarded this step as a minor chemical conversion, and thus, not a material change. *See id.* at 1041.

147. *See id.* at 1040-41.

148. *See id.* at 1038-39.

149. *Id.* at 1041.

techniques," provided a basis for the court to find the accused product was *not* materially changed from the product of the patented process, and thus Abic's motion for summary judgment was denied.¹⁵⁰ The court used two different statutory interpretation techniques—purposivism and intentionalism—and under both approaches reached the same conclusion. Under the practical reasoning approach, since the two approaches reached the same conclusion, the result was likely proper.

B. *District Court Opinion in Eli Lilly and Co. v. American Cyanamid Co.*

One year later, a second district court interpreted the "materially changed" exception of section 271(g) in *Eli Lilly & Co. v. American Cyanamid Co.*¹⁵¹ As in *Marion Merrell Dow*, the case centered around the importation of a generic drug, the issue being whether the drug was manufactured in violation of a U.S. process patent and thus infringing under section 271(g).

Eli Lilly and Company ("Lilly") brought suit in the Southern District of Indiana against the importers and the foreign manufacturer of the generic drug cefaclor alleging infringement of its patented process in producing cefaclor, an antibiotic, and seeking a preliminary injunction against the drug's importation.¹⁵² Cefaclor is part of a general class of antibiotics that all have as a common core the "cephem nucleus." Although numerous compounds have this common nucleus, few have been used as antibiotics, and fewer have been sold commercially. Lilly produces cefaclor by a different process than that covered by the patent at issue, but in both the process used by Lilly and the process in suit, the enol cephem intermediate is produced, which is then chlorinated and subjected to subsequent processing steps to produce cefaclor.¹⁵³ The processes start with different raw materials, but both ultimately produce the same intermediate compound: the enol cephem.¹⁵⁴ The Italian manufacturer, Biochimica Opos, S.p.A. (Opos), utilizes a process which transforms an intermediate compound (compound 5) via a cyclization reaction into compound 6 (the enol cephem), a step which is covered by Claim 5 of the Lilly patent.¹⁵⁵

150. *See id.*

151. 896 F. Supp. 851 (S.D. Ind. 1995).

152. *See id.* at 852, 853, 854.

153. *See id.* at 853. Lilly markets the drug under the name "Ceclor." In the Lilly process, the intermediate compound exomethylene is converted into the enol cephem, whereas in the patent at issue, the enol cephem is produced by a cyclization process. *See id.*

154. *See id.*

155. *See id.* at 852, 853. Claim 5 of the patent in suit describes a cyclization reaction of various raw materials to produce the enol cephem intermediate, which can then be processed to make cefaclor as well as other cephem antibiotics. Subsequent processing steps convert the enol

In deciding Lilly's request for a preliminary injunction, the court considered two factors critical to issuance: the reasonable likelihood of Lilly's success on the merits and irreparable harm to Lilly if the injunction were not granted.¹⁵⁶ Likelihood of success on the merits requires a showing of validity and infringement,¹⁵⁷ and the court concluded validity of the patent was established.¹⁵⁸ In its analysis of Lilly's reasonable likelihood of success in proving infringement, the court focused on the subsequent processing steps which converted enol cephem into cefaclor and defined the issue as whether the imported generic product was "materially changed by subsequent processes" to remove it from the Act's definition of an infringing product.¹⁵⁹ The court alternatively stated the issue as "whether the end product of cefaclor represents a material change to intermediate compound 6."¹⁶⁰

Using guidelines from congressional committee reports, the court concluded that "the differences between compound 6 and cefaclor are manifest."¹⁶¹ Describing the subsequent processing steps used to convert compound 6 into cefaclor as "fairly complex process steps"¹⁶² and comparing the biological (antibiotic) properties of compound 6 and cefaclor, the court concluded that compound 6 had been materially changed within the meaning of section 271(g) and that Lilly was unlikely to succeed on its infringement action.¹⁶³ The court rejected Lilly's arguments (that the "basic structure of compound 6 is unchanged by the subsequent processing steps"¹⁶⁴ and that the subsequent processing steps are "common, conventional, and routine reactions that are well known to organic chemists"¹⁶⁵) as unconvincing, and reconciled its holding as consistent with *Marion Merrell Dow*.¹⁶⁶ Noting that the chemical intermediate produced by the patented process at issue in *Marion Merrell Dow* could only be converted into one commercially

cephem into cefaclor. *See id.* at 853. The litigants stipulated that Claim 5 of the patent in suit is the same as step 5 of the Opos process. *Id.* at 856.

156. *See id.* at 854-61.

157. *See id.* at 854 (citing *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir. 1994)).

158. *See id.* at 855.

159. *See id.* at 856 (quoting 35 U.S.C. § 271(g) (1995 Supp.)).

160. *See id.*

161. *Id.*

162. *Id.* (Lilly argued that the subsequent processing steps were "common, conventional and routine reactions that are well known to organic chemists." *See id.* at 858. Lilly's expert testified that these steps result in "rather simple derivatives" because the transformations are "quite obvious and standard"). *See id.* at 858 n.8.

163. *See id.* at 856-59.

164. *Id.* at 857.

165. *Id.* at 858.

166. *See id.*

saleable drug product and that the two chemicals exhibited similar activity and efficacy, the court distinguished the case at bar by looking at the variety of products that could be manufactured from compound 6 and the significantly different *biological* properties of cefaclor from compound 6.¹⁶⁷ The court noted that Congress chose “to restrict the scope of section 271(g) to exclude downstream products that, due to intervening processing, cease to have a strong nexus to the patented process.”¹⁶⁸ The court further noted that:

Whereas cefaclor is a medicine, compound 6 is merely a raw material that can be used for making medicines. Cefaclor, then, is like a finished automobile, while compound 6 is the iron ore that must be refined and alloyed with carbon to make the steel to make the components of the automobile.¹⁶⁹

The court also found that Lilly did not establish the requisite irreparable harm that would result if the injunction did not issue, suggesting that “an award of money damages would be an adequate remedy in the event that Lilly ultimately establishe[d] that the Opos process infringes the [subject] patent.”¹⁷⁰ The preliminary injunction was denied.¹⁷¹

The court relied heavily upon legislative history in interpreting the statute. Considering the purpose of the Act and noting that “in some circumstances, infringement liability will lie even though the imported product is subjected to further processing steps that alter its appearance or structure,”¹⁷² the court decided that, by following guidelines set out in the committee reports, the final product in this case *was* materially changed from the product of the patented process and thus noninfringing. Specifically, the court found that the additional processing steps “change the physical or chemical properties of the product in a manner which changes the basic utility of the product.”¹⁷³

167. *See id.* at 859. Lilly argued that cefaclor is the only drug that can be *conveniently* manufactured from compound 6, although other cephalosporins can be manufactured from it as well. *See id.* at 859 n.11. The court determined that convenience in manufacture was not material except to the extent of the importance of the change generated by those processes. *See id.* The antibiotic properties of cefaclor are mainly attributable to subsequent processing steps, as opposed to properties inherently present in the intermediate, as in *Marion Merrell Dow*. *See id.* at 859. The court noted that the subsequent processing steps altered the “*basic utility*” of the final product, cefaclor, from that of the chemical intermediate. *Id.* at 857 (quoting S. REP. NO. 100-83, at 70 (1987)).

168. *Id.*

169. *Id.* at 857.

170. *Id.* at 860.

171. *See id.* at 861.

172. *Id.* at 856.

173. *Id.* at 857 (quoting S. REP. NO. 100-83, at 70 (1987)).

C. *Appellate Court Opinion in Eli Lilly & Co. v. American Cyanamid Co.*

Lilly appealed the denial of its request for a preliminary injunction to the Federal Circuit.¹⁷⁴ Judge Bryson wrote the opinion of the court, which upheld the lower court ruling,¹⁷⁵ and Judge Rader filed a concurring opinion which joined in the denial of the injunction but disagreed with “the court’s reasoning and conclusion about the ‘material change’ standard under 35 U.S.C. § 271(g).”¹⁷⁶

The majority noted that the statutory language of the two exceptions to infringement is “not very precise.” Recognizing that the case is a close one for application of that language, the majority acknowledged the “considerable appeal” of Lilly’s argument that the “materially changed” clause of section 271(g) must be construed in light of its underlying purpose—to protect the economic value of U.S. process patents to their owners.¹⁷⁷ The court examined the legislative history of the statute and found that it provided something for each side: “characterizations of the legislation as creating process patent protection that is ‘meaningful and not easily evaded,’”¹⁷⁸ and on the other side, “language of the statute [that] refers to changes in the product,” and “purpose cannot displace language.”¹⁷⁹

The majority declined to “stretch the term ‘materially changed’ as far as Lilly’s argument would require,” explaining that the statutory language “refers to changes in the product”¹⁸⁰ whereas “Lilly’s proposed test . . . turns on the quite different question of whether the use or sale of the imported item impairs the economic value of the process patent.”¹⁸¹ The court interpreted Lilly’s argument as depending “on whether there are other products of the first compound that have economic value,” and “look[ed] instead to the *substantiality of the change* between the *product* of the patented process and the *product* that is being imported” in

174. *See* *Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568 (Fed. Cir. 1996).

175. *See id.* at 1569-79.

176. *See id.* at 1579-81 (Rader, J., concurring).

177. *Id.* at 1572.

178. *Id.* at 1573 (quoting H.R. REP. NO. 100-60, at 13 (1987)).

179. *Id.* at 1572.

180. *Id.*

181. *Id.* at 1572-73. Lilly argued that “the product of a patented process . . . should not be considered ‘materially changed’ if the principal commercial use of that product lies in its conversion into the product that is the subject of the infringement charge.” *Id.* at 1572. Interpreting the purpose of the statute as protection against subversion of protected economic rights, Lilly argued that the statute should be applied to any scheme that undercuts the commercial value of a U.S. process patent. It contended that, since cefaclor is the only commercial product of compound 6 sold in the U.S. market, any change thereto resulting in cefaclor should not be considered a material change under section 271(g). *See id.*

upholding unlikelihood of success by Lilly on its infringement claim.¹⁸² Looking at the *chemical* and *biological* properties of compound 6 and cefaclor,¹⁸³ and conceding that the legislative history does not provide a “conclusive answer to the question of how the ‘materially changed’ clause should be construed in general, and how it should be applied to the facts of this case in particular,” the court upheld the lower court’s decision “that compound 6 is likely to be found to have been ‘materially changed’ in the process of its conversion into cefaclor, and that the importation and sale of cefaclor is therefore not likely to be held to infringe Lilly’s rights under claim 5 of the [subject] patent.”¹⁸⁴ Recognizing that the lower court found that “the processing steps necessary to convert compound 6 to cefaclor ‘change the physical or chemical properties of the product in a manner which changes the *basic utility* of the product,’”¹⁸⁵ the court also noted that “with respect to chemical products, as to which simple, routine reactions can often produce dramatic changes in the products’ structure and properties . . . a grudging construction of the statute *could* significantly limit the statute’s effectiveness.”¹⁸⁶ The majority agreed with the lower court, however, that a change in chemical structure and properties as significant as that between compound 6 and cefaclor “cannot lightly be dismissed as immaterial.”¹⁸⁷ The majority also held that the district court “did not commit clear error in finding that Lilly failed to prove irreparable harm,”¹⁸⁸ and did not abuse its discretion in declining to grant the requested injunction.¹⁸⁹

Judge Rader concurred that Lilly did not show it would suffer irreparable harm if the preliminary injunction were not granted, but he “depart[ed] from the court’s reasoning and conclusion about the ‘material change’ standard under 35 U.S.C. § 271(g).”¹⁹⁰ Recognizing that none of the parties who fought to influence the statutory language during enactment were successful in convincing Congress to pass an amendment clearly favorable to either side, and that each side had “lobbyists . . . lace the reports with tutorials to the courts about applying the ambiguous provisions of section 271(g) in future litigation,”¹⁹¹ Judge Rader found the legislative history concerning the meaning of “material

182. *See id.* at 1573 (emphasis added).

183. *See id.* at 1577.

184. *Id.* at 1578.

185. *Id.* at 1571 (quoting *Eli Lilly & Co.*, 896 F. Supp. at 857) (emphasis added).

186. *Id.* at 1572 (emphasis added).

187. *See id.* at 1573.

188. *Id.* at 1578.

189. *Id.* at 1579.

190. *Id.* (Rader, J., concurring).

191. *See id.*

change" in the enactment history unenlightening, and stated that "this court should interpret this language in light of the overriding purpose of the statute . . . to afford meaningful protection to owners of United States process patents."¹⁹² The judge noted that "[i]n view of the purpose of the statute, compound 6 and cefaclor are essentially the same product"¹⁹³ as no other current commercial uses of compound 6 were shown in the record. He also noted that this decision "will create another massive loophole in the protection of patented processes" and "deny protection to holders of process patents on intermediates as opposed to 'final' products."¹⁹⁴

V. ANALYSIS OF THE *LILLY* COURTS' INTERPRETATIONS OF THE PROCESS PATENT AMENDMENTS ACT OF 1988

The *Lilly* courts decided the issue of whether the Act covered a process patent for an intermediate product that was not itself commercially saleable and that *could* be produced by other processes in favor of non-infringement by a foreign manufacturer who imported a product made by the further processing of the U.S. process patent product. In doing so, both the district court and the Federal Circuit considered the purpose and the legislative history of the Act. Unlike the situation in *Marion Merrell Dow*, the two approaches did *not* reach the same result, and the *Lilly* courts, therefore, adopted the result reached using the legislative history approach (unlike the Court in *Watt*).

A. Purposivism

Although both courts in *Lilly* considered the *purposes* of the Act as stated in the committee reports, which are to "provide meaningful protection to owners of [U.S.] patented processes,"¹⁹⁵ and "to improve the rights of patent owners,"¹⁹⁶ neither considered the underlying purpose of the patent system—to "bring forth new knowledge."¹⁹⁷ From a *purposivist* approach, the result reached by the courts in this case contravenes both protection of the economic value of a process patent and disclosure of new knowledge.

The result in this case does not protect the *economic value* of certain U.S. process patents (namely those that cover production of sophisticated chemical intermediates that could make final products cheaper to

192. *Id.* at 1581.

193. *Id.*

194. *Id.*

195. H.R. REP. NO. 100-60, at 3 (1987).

196. S. REP. NO. 100-83, at 2 (1987).

197. See *supra* notes 117, 118, and accompanying text.

manufacture but where the intermediate does not share similar chemical properties to the imported product), because the courts did not consider whether the patent in suit made enol cephem production commercially viable to the foreign manufacturer. U.S. patent law requires that the utility of an invention be shown prior to issuance of a patent; the patent at issue here stated its utility as “provid[ing] the higher yielding and simpler process from *less expensive* penicillins to give valuable key intermediates, the 3-hydroxy-3-cephem compounds.”¹⁹⁸ The patent thus covers a process to make a valuable chemical intermediate from *less expensive* raw materials than those used in prior known processes.

The district court acknowledged testimony that “the invention . . . would not have been obvious to a person of ordinary skill in the art” and that “the process . . . seemed to go against the grain of what . . . a lot of people . . . had been thinking about the way to make the enol cephem.”¹⁹⁹ This testimony was considered for the *validity* of the patent but not for the patent’s *economic value*. The courts never considered *why* an inventor would try to find an alternative route to produce an intermediate which itself has no commercially saleable value. Such reasons could include cheaper raw materials, less energy-intensive processing steps, and fewer processing steps, all factors which relate to the economic value of the patent as compared to the other known way Lilly produces the enol cephem.²⁰⁰ The Federal Circuit discounted Lilly’s argument of reduced economic value as depending on whether there are other known uses for the product of the patented process, and concluded that under Lilly’s theory the intermediate product at issue (the enol cephem) would become materially different from cefaclor “if and when [the enol cephem] came to have other commercial uses in the United States, even though the respective structures and properties of the two compounds remained unchanged.”²⁰¹ However, the court’s reasoning does not reflect a flexible standard to be used in judging commercial viability, as suggested by the congressional committee reports, because the court never discussed *why* the foreign manufacturer uses the patented process rather than the other known process that is in the public domain. This question is vital to determine whether it “would not be . . . commercially viable to make [the imported cefaclor] but for the use of the patented process.”²⁰²

The result also fails in promoting the disclosure of new knowledge. Now, owners of such U.S. patented processes must decide whether to

198. U.S. Patent No. 4,160,085 (1979) (emphasis added).

199. *Eli Lilly & Co.*, 896 F. Supp. at 855 (internal quotations omitted).

200. *See supra* notes 153-55 and accompanying text.

201. *Eli Lilly & Co.*, 82 F.3d at 1573.

202. S. REP. NO. 100-83, at 50 (1987).

fully disclose the results of their research in a patent, knowing that a foreign manufacturer may use that knowledge without fear of an infringement action brought in federal court, or to keep the information private as a trade secret.

B. *Intentionalism*

The *Lilly* courts found support in the legislative history of the Act in reaching their decisions denying Lilly's request for a preliminary injunction. The use of legislative history in statutory interpretation is the most controversial approach of the three foundational approaches discussed above, and its use in this case demonstrates why it is controversial. In interpreting the "materially changed" provision, the courts used language from the committee reports that is not included in the statute, as well as guidelines found in only one committee report.

The Federal Circuit looked to both the House and Senate committee reports to reach its decision, stating that "under the test set forth in the Senate report, it is enough to defeat the claim of infringement that there is another way of producing the intermediate, even if the alleged infringer does not use that alternative process."²⁰³ Two problems arise with this approach. First, the test is not apparent from the text of the statute, defeating the goal of citizens being "able to read the statute books and know their rights and duties"²⁰⁴; those lacking the time or resources to research the Act's legislative history would not know of this test simply from reading the statute.

Second, the Federal Circuit's *interpretation* of the test does not logically follow from its *text*. The Senate committee report states that *if* the patented process *must* be used (i.e., it is the only possible or commercially viable way) to make a product, that product will be infringing *regardless* of any subsequent changes. In other words, the court will look no further into the nexus between the imported product and the patented process. The court *interpreted* the Senate test to mean that "the end product will be deemed to be made by the patented process *if (and only if)* it would not be commercially feasible to make the end product *other than* by using the patented process."²⁰⁵ The Federal Circuit then looked at the existence of an alternate production route as a break in the nexus between the intermediate and the final product. The court's *interpretation* of the test does not follow from its *text*. The Senate test states that "[a] product *will be considered* made by the patented process regardless of any subsequent changes if it *would not be possible* or com-

203. *Eli Lilly & Co.*, 82 F.3d at 1577.

204. See *supra* notes 25, 39, and accompanying text.

205. *Eli Lilly & Co.*, 82 F.3d at 1575 (emphasis added).

mercially viable to make that product *but for* the use of the patented process.”²⁰⁶ The court interpreted the test as stating that a product *will not be considered made* by the patented process if it *would be possible* to make that product by another method. The test states, “A, if B;” the interpretation is, “not A, if not B;” this is an error in reasoning.

The court’s *interpretation* of the test derives from the Senate committee report, which states that “[i]f there are commercially viable non-infringing processes to have arrived at X, the connection between the patented process for producing chemical X and the ultimate product, chemical Y, is broken, and Y would be a non-infringing product having satisfied both phases of the test.”²⁰⁷ The House committee report does not contain this example. The Federal Circuit, thus, partly based the *Lilly* decision on an interpretation of a committee report test found in the legislative history of only one house and which does not logically follow from the text of the test.

George Costello warns that “[t]he Court is wary of efforts in committee reports to spell out specific results in future litigation if those results do not necessarily follow from statutory language.”²⁰⁸ Presumably, if Congress had intended the Senate test to be the law, it would have included it in the statute. Additionally, the Federal Circuit seized upon an explanation of the test, which is found *only* in the Senate committee report.²⁰⁹ The use of legislative history found only in one report is controversial. Using a test not apparent on the face of the statute (which looks like an attempt to resolve future litigation), and interpreting that test using language found in *only one* committee report demonstrate two of the problems with such strong reliance on legislative history: it is very tedious and time-consuming for citizens to research statutes in such detail, and no one can predict which portions a court will find influential.

Both courts also point to language set out in the second part of the Senate test, which analyzes the term “material change” as a change in the “basic utility of the product [produced] by the patented process.”²¹⁰ The problem is that this “basic utility” test is *only* found in the Senate committee report, which was issued *after* the debate and vote on the House bill (the final consideration by the House before the joint confer-

206. S. REP. NO. 100-83, at 50 (1987) (emphasis added). *See also supra* note 132 and accompanying text.

207. *See id.* at 51.

208. *See COSTELLO, supra* note 68, at CRS-3.

209. *See S. REP. NO. 100-83*, at 51.

210. *Id.* at 50; *see Eli Lilly & Co.*, 896 F. Supp. at 857; 82 F.3d at 1577. *See also supra* note 132 and accompanying text.

ence committee report).²¹¹ As discussed above, the use of legislative history from only one house could violate the presentment and bicameralism requirements of the Constitution.²¹² Additionally, as Professor Slawson points out, this method of manufacturing legislative history is easier than amendment.²¹³ The *Lilly* courts took legislative history from the Senate, the second house to consider the bill, and made this "legislative history" law.

Another problem with the Senate "basic utility" test is in the court's definition of utility. Comparing two chemicals' utilities by their chemical properties can be problematic, particularly in the chemical intermediates field. The Federal Circuit majority noted that "simple, routine reactions can often produce dramatic changes in [chemical] products' structure and properties"²¹⁴; thus, under this court's interpretation, a chemical product's *utility* can be easily altered in contradiction of the Act's purpose to provide protection that is "not easily evaded."²¹⁵ Much of the chemical process industry is centered around the production of chemical intermediates which might be susceptible to this flaw in the "basic utility" test under the Federal Circuit's interpretation.

The Federal Circuit recognized that Congress "purports to identify some products that can 'materially be changed' without being 'materially changed.'"²¹⁶ An example cited by the House committee report is a polymer, which can be easily changed by conventional processes to make an end product.²¹⁷ Obviously, the intermediate and the end product have different properties and utilities, but the House committee did not think the final product in this example should be considered "materially changed" from the intermediate. Applying the Federal Circuit's interpretation of the Senate test to the House example would result in a finding of non-infringement, further illustrating why specific tests and examples from the legislative history of only one house should not be relied upon in statutory interpretation.

Both courts found that the differences in the properties of the encephem and cefaclor constituted a material change in the product of the patented process, and the Federal Circuit pointed out that the statutory language "refers to changes in the product."²¹⁸ It further stated that "while the general purpose of the statute informs the construction of the

211. See *supra* note 136.

212. See *supra* notes 59-61 and accompanying text.

213. See Slawson, *supra* note 56, at 397.

214. *Eli Lilly & Co.*, 82 F.3d at 1572.

215. See *id.* at 1573 (quoting H.R. REP. NO. 100-60, at 13 (1987)).

216. *Id.* at 1575.

217. See H.R. REP. NO. 100-60, at 13 (1987). The end product would likely be a plastic.

218. *Eli Lilly & Co.*, 82 F.3d at 1572.

language Congress chose, purpose cannot displace language, and we cannot stretch the term 'materially changed' as far as Lilly's argument would require."²¹⁹

Glenn Law analyzed this statutory provision years prior to the *Lilly* case, however, and concluded that the inquiry into whether a change is material should "focus on the conventionality of the process for making the change, rather than on the physical transformation of the product itself,"²²⁰ based on the assumption that the statutory exceptions should be interpreted conjunctively rather than separately.²²¹ He found that "[a] direct conflict exists . . . between the intention of Congress, as gleaned from the committee reports, and the literal language of the statute,"²²² and that "[t]he Supreme Court has recognized that in cases where a literal application of conjunctive or disjunctive language in a statute would produce results demonstrably at odds with the intent of its drafters, the intent of the drafters should be given effect."²²³ He argued that the examples cited in the House and Senate committee reports "indicate that a determination of whether a change is material requires a focus not on the actual physical transformation of the product, but instead on the conventionality of the process required to accomplish the changes."²²⁴ Here, the courts focused instead on the "substantiality of the change between the product of the patented process and the product that is being imported,"²²⁵ which, as discussed above, is a problematic approach in the field of chemical intermediates. The courts here could have followed the precedents cited by Law in which courts have "interpret[ed] statutes in a manner contrary to their literal language to remedy legislative carelessness in the use of conjunctive and disjunctive terms,"²²⁶ and found that the "materially changed" provision was not meant to exclude from the Act's protection a process patent that, due to competitive circumstances, might make it commercially viable for the foreign manufacturer to produce cefaclor.

The legislative history was not used in this case "to confirm [the Court's] reading of statutory language,"²²⁷ or to clear up ambiguous language.²²⁸ Rather, it was used to reduce vagueness, a use Professor

219. *Id.*

220. See Law, *supra* note 138, at 267.

221. See *supra* notes 138, 139, and accompanying text.

222. Law, *supra* note 138, at 259.

223. *Id.*

224. *Id.* at 262.

225. *Eli Lilly & Co.*, 82 F.3d at 1573; see *Eli Lilly & Co.*, 896 F. Supp. at 857.

226. Law, *supra* note 138, at 261.

227. Wald, *supra* note 36, at 289; see also *supra* notes 28-31 and accompanying text.

228. See *supra* notes 62, 63, and accompanying text.

Slawson argues is not justified.²²⁹ Vagueness “measures the length to which the legislature chose to go in determining the outcome of future cases.”²³⁰ The *Lilly* courts adhered to many constraints found in the legislative history but failed to acknowledge the flexibility granted in “judging commercial viability,”²³¹ which grant could be interpreted as allowing courts to interpret the “materially changed” provision *without* the severe constraints to which the courts here adhered.

C. “Dangerous Dicta”

Further consideration of the *Lilly* courts’ decisions leads to the description of the opinions as “dangerous dicta.” The issue involved was whether a preliminary injunction against importation of foreign-manufactured cefaclor should be granted to Lilly. The district court cited four factors to be considered in a preliminary injunction request: (1) reasonable likelihood of success on the merits; (2) irreparable harm to the movant if the injunction were not granted; (3) the balance of hardships tipping in the movant’s favor; and (4) the impact of the injunction on the public interest.²³² The Court noted, however, that it need not articulate its findings on the final two factors if a “party fails to establish *either* of the [first] two . . . factors.”²³³ “[A] movant cannot be granted a preliminary injunction without findings by the district court that the movant carried its burden on *both* factors”²³⁴; the movant must prove *both* reasonable likelihood of success on the merits *and* irreparable harm. Irreparable harms “are those that are impossible to measure in monetary terms.”²³⁵

In *Lilly*, the district court found that “an award of money damages would be an adequate remedy in the event that Lilly ultimately establishes that the Opos process infringes the [subject] patent,”²³⁶ and thus Lilly “failed to establish the requisite irreparable harm.”²³⁷ The Federal Circuit agreed, finding that “Lilly’s . . . claims of irreparable injury . . . [are not] sufficiently compelling to justify overturning the district court’s conclusion on the issue of irreparable harm.”²³⁸ Thus, the courts concluded that Lilly could not establish irreparable harm and was not

229. See Slawson, *supra* note 56, at 423.

230. *Id.*

231. S. REP. NO. 100-83, at 50 (1987); H.R. REP. NO. 100-60, at 13 (1987).

232. See *Eli Lilly & Co.*, 896 F. Supp. at 854.

233. See *id.* at 861 (emphasis added).

234. *Reebok Int’l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994) (emphasis added).

235. *Eli Lilly & Co.*, 896 F. Supp. at 859 (citing *Atlas Powder Co. v. Ireco Chems.*, 773 F.2d 1230, 1233 (Fed. Cir. 1985)).

236. *Id.* at 860.

237. *Id.* at 861.

238. *Eli Lilly & Co.*, 82 F.3d at 1578.

entitled to a preliminary injunction *regardless* of their findings concerning Lilly's reasonable likelihood of success on the merits.

"[A] presumption of irreparable harm arises when a patentee makes a strong showing that its patent is both valid and infringed";²³⁹ however, this presumption is rebuttable.²⁴⁰ The greatest benefit that Lilly could have received from a favorable judgment by the courts concerning the reasonable likelihood of its success on the merits was thus a rebuttable presumption of irreparable harm, a presumption which was successfully rebutted as both courts decided that Lilly's harm was compensable with money.²⁴¹ The dicta concerning the interpretation of "materially changed" was unnecessary, as it was not essential to the judgment. However, this "dangerous dicta" can be cited by future foreign manufacturers wishing to avoid infringement charges in similar situations.

VI. CONCLUSION

The *Lilly* courts engaged in extensive, unnecessary, and "dangerous dicta" for potential use *against* holders of U.S. process patents which produce chemical intermediates that are themselves not commercially saleable, that can be produced in other ways, and that do not have the same chemical properties as the final products made therefrom. The denial of Lilly's request for a preliminary injunction could have been based on Lilly's failure to show irreparable harm, without the Courts' intricate analyses of the statute as applied to the facts.

The Federal Circuit recognized that "simple, routine reactions can often produce dramatic changes in [chemical] products' structure and properties," and that "a grudging construction of the statute could significantly limit the statute's effectiveness."²⁴² The court nevertheless affirmed the district court's decision despite the lower court's reliance on comparison of the molecular structure, biological properties, and pharmacological purposes of the intermediate chemical and the final imported product.²⁴³ The courts relied extensively on legislative history to reduce vagueness, not ambiguity, and interpreted the statute in a way that is contrary to its plain language. The *Lilly* decisions demonstrate that the average citizen—or lawyer—has no clue as to what may sway a court relying on legislative history to interpret a statute.

Another troublesome area of dictum in the decisions is the compari-

239. *Eli Lilly & Co.*, 896 F. Supp. at 859 (citing *High Tech Med. Instrumentation v. New Image Indus., Inc.*, 49 F.3d 1551, 1556 (Fed. Cir. 1995)).

240. *See Reebok Int'l Ltd.*, 32 F.3d at 1556.

241. *Cf. id.* at 1558 (noting that since any harm Reebok suffered was fully compensable by money damages, the presumption of irreparable harm had been successfully rebutted).

242. *Eli Lilly & Co.*, 82 F.3d at 1572.

243. *Eli Lilly & Co.*, 896 F. Supp. at 858.

son of the sophisticated chemical intermediate, which required extensive research to manufacture in the patented manner, with a raw material such as iron ore, which must be refined to make the final product; this view completely overlooks the technological advancement contributed by disclosure of the patented process.²⁴⁴

Glenn Law has proposed a workable solution to determine when a final product in the chemical field has been "materially changed" from an intermediate. As he found in his analysis of the examples given in the House and Senate committee reports, congressional intent in the use of the term "materially changed" seemed to focus on the process making the change, *not* the difference or similarity in properties of the final product resulting from the change. Under *Lilly*, a foreign manufacturer who subjects a chemical intermediate made by the use of a U.S. patented process to *conventional processing steps* may be guilty of infringement *only if* the intermediate and the final product share similar chemical and physical properties and "utility" *or if* the patented process is the only commercially viable method to produce the intermediate. The *Lilly* courts overlooked the flexibility they were granted to determine when a process makes the manufacture of a product commercially viable. The *nexus* between the intermediate and the final product should be determined by the nature of the processing steps *producing* the change, not the resulting properties of the products. Courts will still have to determine when a *process* is conventional or unconventional, but this determination should be subject to less variation than attempted comparisons of the properties and utilities of chemicals. "Material change" must be determined as either in the *process* or the *product*, but in the chemical field, processes should be easier to classify as conventional or not, as opposed to comparison of chemical properties.

Consider the simple example of an individual who would like to patent a new process to manufacture methane gas that significantly reduces its production cost. The gas can be chlorinated to produce chloroform, but the reaction also produces methyl chloride and carbon tetrachloride.²⁴⁵ The chemical intermediates in both *Marion Merrell Dow* and *Lilly* were subjected to a chlorination step, which was considered a conventional processing step. In *Marion Merrell Dow*, this chlorination step was a part of a series of conversions that *did not* change the product's "utility," whereas in *Lilly*, the chlorination was a part of a series of steps that *did*. In the hypothetical, the chlorination step certainly changes the "utility" of methane gas, as chloroform and methane gas have very different purposes and properties. Under *Lilly*, a foreign man-

244. See *id.* at 857. See also *supra* note 169 and accompanying text.

245. See LOUIS F. FIESER & MARY FIESER, INTRODUCTION TO ORGANIC CHEMISTRY 33 (1957).

ufacturer would be able to freely use this new methane production technology which greatly reduces his costs in the manufacture of chloroform, and then import this cheaper chloroform into the United States without fear of patent infringement. The inventor would undermine his own claim of infringement against the foreign manufacturer by patenting the process because the foreign manufacturer would be able to claim as a defense that, since other viable ways to produce methane gas are available and since other commercially saleable products can be made from the intermediate, the nexus between methane and chloroform is broken due to the different "utilities." The economic value to the inventor of the patented process would be reduced. *Less* disclosure of new technology would thus result, contrary to the purposes of the patent laws to encourage disclosure for the advancement of the technological arts.

Under the test proposed by Glenn Law, however, the inventor would have some likelihood of success in an infringement suit because the chlorination step, being a conventional processing step, would not break the nexus between the methane gas and the chloroform, despite the differences in the final properties and "utilities" of the two. This approach would not subject the protection of the process patent to the unpredictability of the effects of conventional processing steps on the chemical properties of different materials.

By allowing foreign manufacturers to evade infringement liability, the court has done a disservice to the chemical processing industry. A foreign manufacturer can now infringe a U.S. process patent holder's invention by several methods with no liability in the United States by showing that a vital chemical intermediate for a final product *can* be produced in any commercially viable process other than the patented process, by showing that numerous final products may be made from that intermediate, or even by *developing* an alternative (possibly undesirable) method for making that intermediate. The result would be the same: the U.S. process patent would be diminished in value, and the United States would suffer a potential loss of American jobs. Courts may, by the terms of the Act, find some imported products are too far removed from the product of a patented process to be infringing. However, in the case of chemical intermediates where properties are easily altered by "simple, routine reactions," the courts' approach to the interpretation of "materially changed" leaves some process patent holders in the same unfortunate position as before passage of the Act, with no

recourse in U.S. courts against foreign manufacturers who make and import products using their patented processes.

NANCY J. FLINT*

* The author dedicates this Note to her children, Carolyn and Sandra Fortson, and to her mother, Ellenor Jo Flint, for all their support and patience. Also, the author expresses appreciation to Professor John Gaubatz for his guidance in transforming this piece from one written by an engineer, to one composed by a law student.