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OUTLINE:
Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320 (2000)

INTRODUCTION

A. The Federal Circuit's holding in *Purdue Pharma* and its reasoning.
B. Implication of the ruling—patent can be invalidated on inadequate written description grounds where the later amended claims are narrower in scope than what was disclosed in the specification as originally filed.
C. Thesis: Because the court failed to articulate a clear standard for how specific the written description must be to survive judicial scrutiny, the decision only adds uncertainty to the written description doctrine, which in turn is likely to discourage early disclosure. The decision also unduly limits the scope of pharmaceutical patents, where broad patent rights are crucial in ensuring innovation efforts.

I. BACKGROUND

A. The Evolution of the Written Description Doctrine
    a. 35 U.S.C. § 112: What the specification must convey
        i. enablement
        ii. written description
        iii. best mode
    b. Judicial Interpretation of the Written Description Requirement
        i. Written Description As a Separate Disclosure Requirement Independent of Enablement
        ii. Vas-Cath, Inc. v. Mahurkar
        iii. the vague "in possession" standard.
B. The Written Description Requirement in Biotechnology Patents
    a. The court has consistently invalidated biotechnology patents on written description grounds where the scope of the amended claims are broader than what is disclosed in the specification.
        i. Amgen v. Chugai Pharmaceutical
        ii. Fiers v. Revel
        iii. *Regents of the University of California v. Eli Lilly & Co*.
    b. The court seems to apply a heightened written description standard to biotechnology patents; together with a more stringent enablement requirement, they function to narrow the scope of biotech patents.

II. THE CASE

Purdue Pharma L.P. and the Purdue Frederick Company (collectively "Purdue Pharma") brought suit against Faulding Inc., Faulding Pharmaceutical Co., Faulding Services, Inc., and Purepac Pharmaceutical Co. (collectively "Faulding") in the United States District Court for the District of Delaware, alleging infringement of its United States Patent No. 5,672,360 ("the '360 patent").[1]

[1] Purdue Pharma, L.P. v. F.H. Faulding & Co., 48 F. Supp. 2d 420, 423 (D. Del. 1999).

Faulding challenged the validity of the '360 patent on the grounds of, *inter alia*, inadequate written description.[2] The district court held that the '360 patent was invalid for lack of written description.[3] On appeal, the Federal Circuit affirmed.[4]

A. Facts
B. The District Court Decision
C. The Federal Circuit Decision

III. DISCUSSION

In *Purdue Pharma*, the Federal Circuit fashioned a "defining quality" test, which requires that the specification, as originally filed, clearly identify each amended claim limitation as an important defining quality of the invention. This test is not only at odds with the court's written description precedent, but also unjustified by the purpose of the written description requirement. The decision may be the result of an incoherent written description jurisprudence. The court's continuing use of an unruly and often overly-harsh written description requirement leaves inventors with little incentive to disclose, and is likely to discourage inventors from seeking patent protection.

A. Purdue Pharma Adds Uncertainty to the Standard of Adequate Written Description
    a. The court's reasoning failed to provide guidance as to how specific the disclosure must be
        i. The court could have invalidate the patent for lack of enablement.
            a) By disclosing multiple "preferred embodiments" which do not all lead to the claimed "C submax / C sub24 > 2" ratio, the patent requires undue experimentation, and therefore can be invalidated on enablement grounds.
        ii. Nevertheless, the court chose to invalidate the patent for lack of adequate written description, yet was ambiguous about how to apply the "in possession" test.
            a) "C submax/C sub24 > 2" is an inherent physical characteristic of a process claim; if the court finds that the enablement requirement is met, then an enabling description of the claimed method should be sufficient to provide notice of possession.
            b) On the one hand, the court clings on to the notion that naming is not important, but the specification must encompass the claimed subject matter; if so, descriptions about the concentration curve, which records changes in blood morphine concentration over time, as an important parameter of the invention encompass the subject

[2] *Id*.

[3] *Id*. at 433.

[4] Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1322 (Fed. Cir. 2000).

matter, which in essence is the ratio of the blood concentrations at different time points.

c) On the other hand, the court insists on "blaze marks." Even if disclosure of an inherent physical characteristic of the invention is required as evidence of possession, the disclosure of a relative early T submax of 2 to 8 or 10 hours should suffice.

b. Purdue Pharma's defining quality test is inconsistent with the written description precedents
c. Purdue Pharma's defining quality test is unwarranted by the purpose of the written description requirement

B. The Origin: An Obscure Written Description Doctrine

The difficulty in finding a reasonable and well balanced test for adequate written description perhaps lies in the unfortunately cryptic and incoherent nature of the written description jurisprudence. The Federal Circuit has yet to clearly define what is "in possession." The written description doctrine, as it is developed, is inconsistent with some patent law doctrines, and redundant with others.

a. A Standardless "in Possession" Test
b. Incoherency Among the Doctrines
c. Redundancy and Confusion of a Separate Written Description Requirement

C. The Court's Decision Unduly Narrows the Scope of Pharmaceutical Patents
   a. The decision is consistent with the court's unwillingness to broaden the scope of biotechnology patents.
   b. While arguably narrow patent rights may be desirable for upstream biotech research, broad patent rights are crucial in promoting downstream pharmaceutical innovations.
      i. upstream vs. downstream research.
      ii. pharmaceutical industry: broad patent rights are necessary for a full appropriation of the economic rewards of the enormous research and development efforts.
      iii. bundling of rights rather than fragmenting them is a solution to the "anticommons tragedy."
   c. The uncertainty of the written description requirement is likely to eliminate the amendment practice, which may just be what the court intended; however, it will also undoubtedly discourage early disclosure, which is what the patent system sets out to promote.

D. The Harm of an Amorphous Written Description Doctrine May Extend to All Arts

IV. CONCLUSION