CASE UPDATE

The *Case Update* is a survey of recent state and federal court decisions that significantly relate to high technology. Cases are included either because they introduce new substantive law in areas which are important to a technology practice, or because they illustrate a new application of other areas of law to technology. The cases are organized below under appropriate headings. As many of the cases are quite complex or ongoing, the decisions reported herein are not necessarily final dispositions. This issue's *Case Update* covers cases decided from January through August, 1991.

Table of Contents

CIVIL PROCEDURE

Amendment to § 1391(c) of the Venue Chapter Redefines the Term "Resides" in § 1400(b); Venue is Proper in Any Judicial District Where a Corporation is Subject to Personal Jurisdiction.

VE Holding Corp. v. Johnson Gas Appliance Co., 917 F.2d 1574 (Fed. Cir. 1990), *cert. denied*, 111 S. Ct. 1315 (1991).

Plaintiff VE Holding filed a civil action for patent infringement in the District Court of the Northern District of California. Defendant Johnson Gas Appliance moved to dismiss for improper venue, because it was an Iowa corporation with no regular and established place of business in the Northern District of California. Plaintiff argued that the 1988 amendment to 28 U.S.C. § 1391(c) redefined the term "resides" as it is used in 28 U.S.C. § 1400 (b). Under the new definition, venue for a corporation in a patent infringement action is proper in any judicial district where it is subject to personal jurisdiction. The district court rejected this argument and granted the defendant's motion to dismiss.

The Court of Appeals for the Federal Circuit reversed, holding that Congress by its amendment of § 1391(c) did mean to change the definition of the term "resides" as it is used in § 1400(b). The court came to this conclusion even though Congress had not given any clear

indication of whether it intended to change the scope of venue in § 1400(b). The court found support for its holding in the first sentence of amended § 1391(c), which states "[f]or purposes of venue under this chapter" a corporation resides in any judicial district where it is subject to personal jurisdiction. The phrase "this chapter" refers to Chapter 87 of title 28 that encompasses §§ 1391-1412, and therefore includes § 1400(b). Thus, the court argued that Congress was aware that the amendment of § 1391(c) would affect § 1400(b).

Additionally, the appellate court argued that there was no reason for venue in patent infringement actions to be different from venue in other civil cases. The court rejected the defendant's use of *Fourco Glass Co. v. Transmirra Prods. Corp.*, 353 U.S. 222 (1957) which held that the meaning of the terms used in § 1400(b) were not to be altered or supplemented by other provisions found in the venue statutes. The court argued that *Fourco Glass* was no longer applicable because it was decided before the 1988 amendment to § 1391(c). The Supreme Court denied certiorari.

FDA Regulation That Allowed Parties to Withdraw Information that was Not Exempt From Disclosure Under FOIA Held Invalid.

Teich v. Food and Drug Admin., 751 F. Supp. 243 (D.D.C. 1990).

Plaintiff Teich made a Freedom of Information Act ("FOIA") request for information on silicone gel breast implants submitted to the Food and Drug Administration ("FDA") by Dow-Corning. The requested information consisted of animal studies and a summary of consumer complaints. Dow-Corning contended that the FDA was not allowed to disclose the information because it was submitted to the FDA pursuant to the agency's presubmission review regulation, 21 C.F.R. § 20.44.

The regulation provides that information submitted to the FDA is to be held "confidentially and separately," and specifically states the information "is not received as part of FDA's files." If the FDA concludes that some or all of the information cannot be protected under one of the exemptions of the FOIA, the party can withdraw the information. If withdrawn, no copies or summaries of the information are retained by the FDA.

The district court rejected Dow-Corning's reliance on the FDA's presubmission review regulation, holding the regulation was invalid because it violated the FOIA. The FOIA requires disclosure of records when properly requested, unless they are specifically exempt under one of the nine FOIA exemptions. Agencies cannot construe the language of the FOIA or pass regulations to frustrate the goal of providing public access to all nonexempt information received by an agency. The court maintained that invalidating the FDA's regulation may impair voluntary

cooperation, but the FDA can and should use compulsion to obtain necessary information.

COPYRIGHTS

Course Readers No Longer Considered Fair Use.

Basic Books, Inc. v. Kinko's Graphics Corp. 758 F. Supp. 1522 (S.D.N.Y. 1991).

Various book publishers brought suit alleging copyright infringement against Kinko's, a national chain of photocopying centers that was sold college "course anthologies" or "course readers" to students based on lists of copyrighted sources from professors. In defense, Kinko's claimed fair use under the 1976 Copyright Act, 17 U.S.C. §§ 101-119.

The district court analyzed four factors:

1. The purpose and character of the use.

Kinko's argued that its selling of anthologies was educational and thus a fair use. But the court held that Kinko's exploited the copyrighted material without paying the customary price of permission from the publishers. The court stated that financial gain did not preclude Kinko's from establishing fair use, but that here Kinko's intended to supplant the copyright holders' commercially valuable rights.

2. The nature of the copyrighted work.

Kinko's, in its favor, copied factual works which have greater public value than non-factual works and need less copyright protection.

3. The amount and substantiality of the portion used.

The court inferred that the excerpts put into the course readers were critical parts of the copied works since the fact that the professors had them included indicated they were the most important parts. This inference, combined with the fact the excerpts were often entire chapters, led the court to state that the amount copied was "grossly out of line with accepted fair use principles." 758 F. Supp. at 1534.

4. The effect of the use upon the potential market.

This factor must be weighed most heavily. A fair use defense can be negated by showing that if the use became widespread, it would adversely affect the potential market for the copyrighted work. Here, Kinko's admitted to having 200 stores nationwide that serve hundreds of colleges and thousands of students, thus adversely affecting the potential market for the works. Further, the students' purchase of the course readers obviates their need to purchase the full text, directly affecting the income to the copyright holders.

Since three out of the four factors, including the most important one, weighed against Kinko's, the court held for the publishers.

EVIDENCE

FBI DNA Profiling Results Held Admissible Under Relevancy Test.

United States v. Jakobetz 747 F. Supp. 250 (D. Vt. 1990).

The United States District Court for the District of Vermont held that DNA profiling evidence was admissible to prove the identity of a defendant charged with kidnapping. Following the relevancy test advanced in *United States v. Williams*, 583 F.2d 1194 (2d Cir.), *cert. denied*, 439 U.S. 1117 (1978), the court concluded that DNA profiling was a reliable scientific technique that was properly applied and that the probative value outweighed the risk of prejudice.

The court found the testimony indicated the techniques were properly applied in this case. Furthermore, FBI and other expert witnesses convinced the court that there were sufficient fail-safe measures to minimize the possibility of a false positive and to underestimate the significance of a match, thus resolving doubt in the benefit of defendant. Sample degradation or failure to adhere to protocols would result in inconclusive results or a false negative. Protocols were designed to disallow marginal data. The statistical methods used by the FBI were found to be overly stringent and therefore would likely account for racial substructures not otherwise accommodated in the data.

Inadequate Statistical Support Blocks DNA Profiling Evidence.

Commonwealth v. Curnin, 565 N.E.2d 440 (Mass. 1991).

Defendant, convicted of the rape of a child and other offenses, appealed on grounds that the admitted DNA profiling evidence was prejudicial and therefore constituted reversible error. The Massachusetts Supreme Judicial Court found that the prosecution did not introduce sufficient evidence to support the testing company's conclusion that defendant's DNA profile occurs one in 59 million times for his racial group. Indeed, the prosecution's expert witness admitted some of the assumptions made to determine population statistics were subject to uncertainty. The defense emphasized the possibility of racial sub-groupings not accounted for by the testing company. The court concluded there was no demonstrated general acceptance of, or inherent rationality in, the methods used by the testing company to determine the chance of a matching profile, and therefore the evidence was improperly admitted.

MEDICINE

Administration of Non-Approved Drugs to Active Duty Military Personnel Ruled Military Decision Not Subject to Judicial Review.

Doe. v. Sullivan, 938 F.2d 1370 (D.C. Cir. 1991).

Plaintiffs brought suit to enjoin the Department of Defense from administering drugs, which had not been approved by the Food and Drug Administration ("FDA") for human use, to military personnel in Saudi Arabia and Iraq to protect them from chemical and biological warfare agents. The District Court for the District of Columbia dismissed the suit.

On appeal, the D.C. Circuit Court of Appeals held that the FDA rule, which permitted exemptions for the informed consent requirements normally in effect when administering non-approved drugs in specific situations involving combat, was within the agency's discretion. The Court also held that a decision to use non-approved drugs in time of war was a non-justiciable military decision.

Drug Manufacturers Exempt From Strict Liability for Design Defects in Utah.

Grundberg v. UpJohn Co., 813 P.2d 89 (Utah 1991).

Plaintiff filed a civil action against UpJohn Co. in U.S. District Court. Plaintiff had killed her mother and attributed it to UpJohn's failure to adequately warn her about the drug Halcion's side effects and a defect in its design. UpJohn moved for summary judgment, arguing that Halcion falls under the category "unavoidably unsafe" and thus Upjohn cannot be held strictly liable.

The case was sent to the Supreme Court of Utah to determine whether Utah adhered to the "unavoidably unsafe products" exception of strict products liability from the Restatement (Second) of Torts ("comment k").

The Utah Supreme Court adhered to comment k, holding that "unavoidably unsafe" drugs are immune from strict liability claims for design defects. The court also held that all prescription drugs approved by the Food and Drug Administration are "unavoidably unsafe" in design. The court based this decision on the risk of side effects inherent in all drugs.

The supreme court cited the public policy goal of available affordable drugs and reasoned that holding manufacturers liable for strict liability for design defects would make drug manufacturers hesitant to introduce new products.

Manufacturer of HIV-Contaminated Blood Product Not Strictly Liable for Recipient's Resulting AIDS.

Rogers v. Miles Lab., 802 P.2d 1346 (Wash. 1991).

A U.S. District Court in Washington certified to the state Supreme Court the question of whether strict liability for blood products applied to manufacturers not covered by the Washington blood shield statute. The statute grants immunity from civil liability, but is limited to manufacturers who do not compensate donors.

The supreme court held that absence of statutory immunity does not impose strict liability per se, but liability exists in accordance with the common law. Applying comment k of the Restatement (Second) of Torts which concerns unavoidably unsafe products, the court limited manufacturer liability to cases of negligence or failure to provide adequate warning.

Modified Market Share Alternate Theory of Liability for DES Claims Adopted by Florida.

Conley v. Boyle Drug Co., 570 So. 2d 275, (Fla. 1990).

Plaintiff had been exposed to diethylstilbestrol ("DES") in utero. At the age of twenty-one, she underwent a hysterectomy for cancer of the uterus. She brought suit against eleven defendants who manufactured DES, alleging a link between her cancer and her mother's ingestion of the drug.

On appeal, the Supreme Court of Florida remanded, holding that a modified market share alternate theory of liability should be applied to DES cases. The theory 1) allows defendants to exculpate themselves by demonstrating that they were not members of the market at the time of the drug's manufacture, 2) requires the market to be as narrowly drawn as the evidence will permit, and 3) does not permit joint and several liability. The Court also held that the defendants over whom personal jurisdiction could not be established should be dismissed from the suit.

The Validity and Necessity of a Non-Standard Diagnostic Procedure (Thermography) Must Be Determined In View of the Medical Condition of Each Patient.

Sabatier v. State Farm Mutual Life Ins. Co., 592 A.2d 1098 (Md. Ct. App. 1991).

Plaintiff, a physician, sued for fees allegedly payable for his performance of thermography while caring for the defendant's insureds. The trial court ruled that the *Frye-Reed* test for admissibility of scientific evidence in a criminal trial, which requires "the underlying principle to have gained general acceptance in the particular field in which it

belongs," should apply. On that basis, the trial court found for the insurer.

The Maryland Court of Appeals remanded, ruling that this is too stringent a standard where the statute only requires that medical care provided by licensed physician be "reasonable" and "necessary." Instead of determining if thermography is fundamentally and generally valid, the trial court should have determined whether it is necessary in view of the medical condition of the individuals for whom reimbursement is at issue.

Third Generation DES Liability Not Allowed Under New York Law.

Enright by Enright v. Eli Lilly & Co., 570 N.E.2d 198 (N.Y. 1991).

Plaintiffs Karen Enright, an infant with birth defects, and her parents brought an action to recover damages from manufacturers of diethylstilbestrol ("DES"). Plaintiffs claimed that the Karen's injuries were caused by her premature birth, which resulted from damage to her mother's reproductive system caused by the mother's in utero exposure to DES. Defendants moved for summary judgment contending that claims of a pre-conception tort presented no cognizable cause of action.

The trial court granted the defendants' motion, relying principally on *Albala v. City of New York*, 429 N.E.2d 786 (N.Y. 1981). The *Albala* court held that there was no cause of action for a child deformed due to an injury to the mother's uterus caused by medical malpractice during surgery performed four years before the child's birth.

On appeal, the appellate division agreed that *Albala* foreclosed a cause of action for a pre-conception tort based upon negligence. However, the court held that a strict products liability cause of action was justified because of the policy concerns surrounding DES cases. The court of appeals reversed, holding that strict products liability of manufacturers of DES does not extend to third generation plaintiffs, but was limited to those who ingested the drug or were exposed to it in utero.

The court stated the public interest in providing a remedy for third generation plaintiffs injured by DES was no stronger than the interest in providing a remedy for those injured by medical malpractice, as in *Albala*. The court also stated that limiting liability would not impair any of the deterrence purposes of strict products liability. Thus, it found no reason why a cause of action should be extended in DES cases when not available in other contexts.

PATENTS

Best Mode Enablement of Genetically-Engineered Subject Matter Does Not Require a Deposit of the Material.

Amgen v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991).

Chugai, a licensee of Genetics Institute, appealed from a determination by the district court that Amgen's patent for the human hormone erythropoietin ("EPO") was not invalid under 35 U.S.C. § 112 (relating to enablement of the best mode of practice) or 35 U.S.C. § 102(g) (relating to prior invention).

The Court of Appeals for the Federal Circuit answered a question of first impression regarding the best mode requirement for genetically-engineered material. As long as the best mode has been disclosed and adequately enabled, failure to deposit biological material representative of the best mode will not invalidate the patent under 35 U.S.C. § 112. The court agreed with the district court's finding that there was sufficient information for one skilled in the art to prepare the patent material from known materials and the procedures described in the specification.

The court also held that when the DNA sequence of a gene is unknown, conception does not occur until reduction to practice. Amgen's patent was not invalidated by the work of Dr. Fritsch of Genetics Institute toward isolating the gene for the human hormone erythropoietin and possible means for its isolation. Conception did not occur because he did not know the sequence of the gene and thus could not distinguish it from other materials, nor did he know if his method for obtaining it was viable.

Drawings Alone May Be Sufficient to Meet the "Written Description" Requirement of 35 U.S.C. § 112.

Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991).

Plaintiff Vas-Cath filed a suit seeking declaratory judgment that its duel-lumen hemodialysis catheters did not infringe defendant's patents. In March, 1982, the defendant filed a U.S. design application, no. 356,081 ('081), which was later abandoned. At that time, the defendant also filed a Canadian Industrial Design application. This application contained the same drawings as the '081 design application plus some additional textual description. A Canadian patent issued on this application in August, 1982. More than one year later, defendant filed two U.S. utility patent applications, claiming the benefit of the filing date of the '081 design application. Patents nos. 4,568,329 ('329) and 4,692,141 ('141) issued in 1986 and 1987, respectively.

Plaintiff claimed that the '329 and '141 patents were not entitled to the filing date of the '081 design application because the drawings in the

'081 application failed to provide an adequate "written description" of the claimed invention as required by 35 U.S.C. § 112. Therefore, plaintiff argued that the '329 and '141 patents were anticipated by the Canadian patent and were thus invalid under 35 U.S.C. § 102(b). The question before the district court was whether the drawings in the '081 design application by themselves met the "written description" requirement of § 112. The district court held that the drawings alone were not enough to satisfy the "written description" requirement. Thus, it ruled that both of the defendant's patents were invalid.

The Court of Appeals for the Federal Circuit ("CAFC") reversed, holding that drawings alone *may* be sufficient to meet the "written description" requirement of § 112. To satisfy the written description requirement "the applicant must convey with reasonable clarity to those skilled in the art that, as of the filling date they were in possession of the invention." 935 F.2d at 1563. The CAFC stated that in some situations drawings alone could be sufficient to meet this standard. The court remanded the case to the district court to decide whether the drawings of the '081 design application satisfied the written description requirement for each of the claims in the defendant's patents.

Licensee of a Federally-Owned Patent Can Maintain an Infringement Action Without the United States as a Party.

Nutrition 21 v. United States, 930 F.2d 862 (Fed. Cir. 1991).

Plaintiff Nutrition 21, an exclusive licensee of a federally-owned patent, invited the United States to join its planned infringement suit against Thorne Research, Inc. When the United States refused, Nutrition 21 filed suit against Thorne and named the United States as a party defendant pursuant to Rule 19(a) of the Federal Rules of Civil Procedure. The United States moved to be dismissed from the case under Rule 19(b), arguing that Nutrition 21 could maintain the suit without its participation. Nutrition 21 opposed this motion fearing their infringement action might be dismissed on appeal for lack of an indispensable party. The district court denied the United States' motion and realigned the United States as an involuntary plaintiff.

The Court of Appeals for the Federal Circuit ("CAFC") reversed the district court's order, holding the words "right of enforcement" in 35 U.S.C. § 207(a)(2) authorized federal agencies to grant enforcement rights to licensees. Furthermore, the court held that the United States' authority to grant enforcement rights included the authority to grant licensees the right to maintain actions without the United States as a party. Applying its holding, the court ruled that Nutrition 21 could maintain its action without the United States because the license agreement between Nutrition 21 and the United States provided the "LICENSEE is

empowered . . . to bring suit in its own name, at its own expense, and on its own behalf for infringement . . . ." 930 F.2d at 864.

Federal Circuit Rejects Challenge to PTO Rule on Patenting Life.

Animal Legal Defense Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991).

Plaintiffs, assorted individual farmers and animal rights organizations, brought a challenge to a rule promulgated by the Patent and Trademark Office ("PTO") confirming the patentability of multicellular living organisms and sought to enjoin the PTO from approving or issuing any patents under the rule. Plaintiffs alleged that the Commissioner of Patents had violated the Administrative Procedure Act ("APA") by promulgating the rule without any period for public notice and comment, and had exceeded his authority under the Patent Act.

The rule in question, *see* 1077 OFF. GAZ. PAT. OFFICE 23 (Apr. 21, 1987), interpreted the decision of the Supreme Court in *Diamond v. Chakrabarty*, 477 U.S. 303 (1980) (live, non-naturally occurring microorganisms are patentable subject matter under 35 U.S.C. § 101), to extend the scope of patentable subject matter under 35 U.S.C. § 101 to include man-made multicellular living organisms but not human or naturally occurring organisms. The Commissioner therefore proclaimed the PTO's intention to examine such claims and stated they would not be rejected as nonstatutory subject matter.

The District Court dismissed the suit and the Court of Appeals for the Federal Circuit ("CAFC") affirmed. A five-judge panel held that the plaintiffs lacked standing to sue and that the rule was "interpretative" of prior decisional law, and therefore was not subject to the APA's notice and comment requirement, 5 U.S.C. § 533(b)(A). The CAFC noted the rule was simply an agency interpretation of the *Chakrabarty* decision and thus fit into the exception in § 553(b)(A), so the plaintiffs could not allege injury based upon the PTO's failure to allow for notice and comment.

The CAFC was also unconvinced by the plaintiffs' arguments that they were injured by the rule because of an increase in cruelty to animals which plaintiffs alleged would follow the issuance of "animal" patents. Here, the CAFC found no grounds for finding that the PTO rule caused such injury to the plaintiffs, even if the injury was real, because there was no indication that the issuance of such patents would encourage researchers to violate existing animal protection laws.

TRADE/ANTITRUST

Software Considered Goods Under U.C.C.

Advent Systems Ltd. v. Unisys Corp., 925 F.2d 670 (3d Cir. 1991).

Unisys appealed from a judgment of breach of contract with Advent Systems. Unisys contended on appeal that its agreement with Advent for special software was for goods and the Uniform Commercial Code ("UCC") provisions for the statute of frauds applied, making the agreement unenforceable.

The Court of Appeals for the Third Circuit, applying Pennsylvania's traditionally broad interpretation of goods under its UCC law, found that while the creation of software was intellectual property, once it is put on media such as magnetic disc, it can be widely distributed. Since a good is anything which is movable at the time of the identification for sale, the court held that software becomes a good when it is put on a disc because it is identified for sale, tangible, moveable, and available in the marketplace.

The court analogized software to a musical performance which is intellectual property but which becomes a good when it is recorded on a compact disc. Further, the UCC applied despite the fact that the software was specially designed to convert engineering documents into a database. The UCC contemplated specially manufactured goods and thus specialized software was included.