



THE NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION

BULLETIN

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Number 4

PRESIDENT'S CORNER

I am pleased to report in this newsletter the completion of another successful Annual Dinner in Honor of the Federal Judiciary. Our dinner continues to expand in size each year, setting again a new record with over 2600 members and guests in attendance.

Our guest speaker, Marlin Fitzwater, was both entertaining and informative about recent public events and activities in the White House. During the course of the evening he requested our official photographer to give him a photograph of the filled Grand Ballroom. He explained to me that he had been in the Grand Ballroom numerous times with both Presidents Reagan and Bush and had never seen it fully occupied. He plans to send the picture to President Bush with a note explaining that he was able to fill the Grand Ballroom while the President was not.

As part of our Association's commitment to representing our members' views on matters affecting the profession, we are continuing to make our Association's views known to the Patent and Trademark Office. We recently submitted a very detailed response to the PTO's request for comments on 18-month publication. The response, prepared through the efforts of our Committee on Legislative Oversight and our Foreign Patent Law and Practice Committee, is too extensive to include in the *Bulletin*. However, if anyone would like a copy, please let me know.

We look forward to the publication of the second edition of the *NYIPLA Annual*. As a result of the continuing efforts of Greg Battersby and the noteworthy contributions of a prestigious group of authors, you will shortly be receiving the next edition of this yearly publication of our Association.

I ask that you all place two important dates on your calendars. First, the Annual Meeting has been scheduled for May 17, 1995 at The University Club. More detailed announcements will be forthcoming. Also, again through the efforts of Greg Battersby, we plan to reinstitute our golf outing. This is presently scheduled for Tuesday, May 23, 1995, at a golf course in Stamford, Connecticut. An announcement is included in this *Bulletin*.

— Pasquale A. Razzano



CALENDAR OF EVENTS

- | | |
|------------------------|---|
| April 18-21, 1995 | American Intellectual Property Law Association, Spring Stated Meeting, Seattle Four Seasons, Seattle, Washington |
| April 20-21, 1995 | "International Intellectual Property Law and Policy," sponsored by Fordham University School of Law, McNally Amphitheater, New York, New York |
| April 29 - May 3, 1995 | International Trademark Association's 117th Annual Meeting, The Walt Disney World Dolphin and Swan, Orlando, Florida |
| May 17, 1995 | NYIPLA Annual Meeting, The University Club, New York, New York |
| May 23, 1995 | NYIPLA Golf Outing, E. Gaynor Brennan Golf Course, Stamford, Connecticut |
| June 7 - July 28, 1995 | Ninth Annual Intellectual Property Summer Institute, Franklin Pierce Law Center, Concord, New Hampshire |

THE SELF-EVALUATIVE PRIVILEGE PROTECTS FDA DOCUMENTS FROM DISCOVERY

by Thomas H. Beck

The "self-evaluative" privilege is a little-known but important privilege which may protect certain highly sensitive internal documents from discovery. This privilege has now been applied in a patent case, where FDA regulations and procedures were raised in the context of the exemption from patent infringement for potentially infringing activities reasonably related to an FDA application, under 35 U.S.C. § 271(e)(1).

THE THREE-PRONG TEST

The self-evaluative privilege in general has a three-prong test: (i) there is an internal evaluation or critique, (ii) the evaluation should be encouraged as a matter of public policy, and (iii) disclosure of the evaluation would result in the termination or curtailment of future self-evaluations.

BACKGROUND OF THE CASE

In *NeoRx Corp. v. Immunomedics Inc.*, 28 USPQ 2d 1797 (D.N.J. 1993), the self-evaluative privilege was held to protect from discovery the accused infringer's internal evaluations of its own pending FDA applications, referred to as Good Clinical Practice (GCP) audits. The second and third prongs were demonstrated by the FDA's own Compliance Policy Guide which expressly sought to "encourage firms to conduct quality assurance program audits and inspections that are candid and meaningful," and which provided that the FDA would not ordinarily "review or copy reports and records that result from audits and inspections of a written quality assurance program."¹

The patent owner NeoRx sought the GCP audits to show that the § 271(e)(1)

exemption from infringement did not apply because of alleged material violations of FDA regulations including fraud on the FDA. The Court held that the patent owner's assertions of a strong public interest in ensuring that data submitted to the FDA are not fraudulent was overridden by the FDA's stated goal of encouraging the GCP audits. The Court also rejected the patent owner's demand for the non-privileged "facts" contained in the GCP audits, in part because the underlying FDA records had previously been provided.

OTHER CASES UPHOLDING THE SELF-EVALUATIVE PRIVILEGE

Application of this self-evaluation privilege on behalf of accused infringers may become more common in patent suits as more Courts are called upon to apply the § 271(e)(1) exemption. In addition, whenever there is an issue of a patent owner's unclean hands in the FDA, the patent owner's self-evaluative GCP audits (if they exist) are potentially relevant.

Other situations where the self-evaluative privilege has sometimes been upheld include: medical staff reviews of a hospital's own clinical practices, *Bredice v. Doctors Hospital, Inc.*, 50 F.R.D. 249 (D.C.D.C. 1970), *aff'd without op.*, 749 F.2d 920 (D.C.Cir. 1973); employer evaluations of whether equal employment goals are being attained, *Roberts v. National Detroit Corp.*, 87 F.R.D. 30 (D. Mich. 1980); portions of an Amtrak Investigation Committee Report regarding accident analysis, *Granger v. National R.R. Passenger Corp.*, 116 F.R.D. 507 (E.D.Pa. 1987). But see *Etienne v. Mitre*, 146 F.R.D. 145 (E.D.Va. 1993) (no privilege for internal investigations and reports concerning compliance with the Age Discrimination in Employment Act.)

The Federal Circuit has not addressed the application of the self-evaluative privilege. Pursuant to Rule 501, Fed. R. Evid., in a patent suit in Federal District Court, the law governing privilege would be federal common law. Further, under *Panduit Corp. v. All States Plastic Mfg. Co.*, 744 F.2d 1564, 1574-75 (Fed. Cir. 1984), the Federal Circuit will apply the law of the regional circuit to procedural matters that are not unique to patent law. In at least one case, *American Standard Inc. v. Pfizer Inc.*, 828 F.2d 734, 745 (Fed. Cir. 1987), the Federal

Circuit looked to regional circuit law in applying the attorney-client privilege to a patent-validity opinion letter. Whether there will be a separate Federal Circuit law regarding the self-evaluative privilege, or any practical differences between regional circuit law and such Federal Circuit law, remains to be seen.

¹FDA Compliance Policy Guide No. 7151.02; FDA Compliance Program Guidance Manual, Program 7348.810.

IN MEMORIAM JOHN T. KELTON

John T. Kelton, President of the NYIPLA from 1967-1968, died on March 4, 1995 in Essex, Connecticut at the age of 85. A memorial service was held at the First Congregational Church in Essex on March 11, 1995.

John Kelton was born in Bay City, Michigan on March 12, 1909. He graduated from Culver Military Academy in 1928 and earned a B.S. in chemical engineering in 1932 from the Massachusetts Institute of Technology and a law degree from Harvard Law School in 1935.

John Kelton worked with Watson Leavenworth Kelton & Taggart and its predecessor firms from 1935 until 1981. From 1981 to 1985 he was counsel to Darby & Darby. In addition to serving as NYIPLA president, he was president of the AIPLA in 1973.

John Kelton is survived by two daughters, Carol Kelton Ryland of Essex, Connecticut and Joy Kelton McIntyre of Bonita Springs, Maryland, and four grandsons. Contributions may be made in his memory to the Parkinson's Disease Foundation, 650 West 168th Street, New York, New York 10032-9982.

ANNUAL NYIPLA GOLF OUTING

The annual NYIPLA golf outing will be held Tuesday, May 23, 1995 at E. Gaynor Brennan Golf Course in Stamford, Connecticut. The event is scheduled to begin with a 12:00 tee time for eighteen holes

of golf, followed by cocktails, a buffet-dinner and an awards ceremony at The 19th Hole restaurant on the golf course grounds in Stamford. The fee for this event is \$80 per person for NYIPLA members and their guests. The fee includes greens fees, golf carts, cocktails, appetizers, dinner and dessert.

Space is limited for this event, so NYIPLA members and their guests are strongly urged to reserve their space before May 12, 1995. Members may contact Greg Battersby, Grimes & Battersby, (203) 324-2828 for more information. There is also a reservation form included in this *Bulletin*. ■

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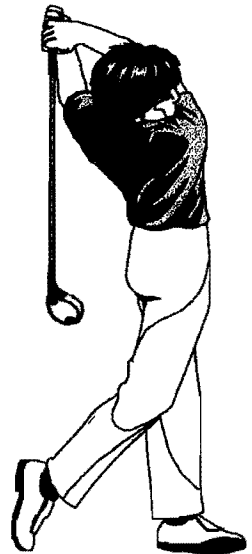
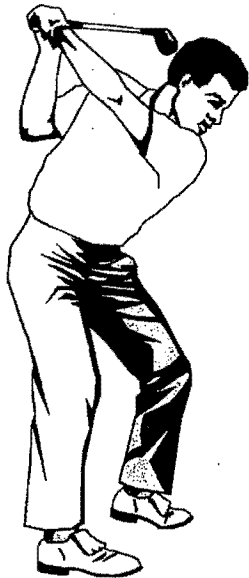
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Tuesday, May 23, 1995

E. Gaynor Brennan Golf Course
Stamford, CT

12:00 noon Tee Time

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buffet-dinner and awards ceremony
at The 19th Hole
5:30 - 7:30 p.m.



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NEWS FROM THE BOARD OF DIRECTORS

by William H. Dippert

The Board of Directors met on January 10, 1995. Pasquale Razzano presided. Reading of the minutes of the December 13, 1994, meeting was waived. An amendment to the proposed minutes concerning the Judges Dinner prices was discussed, and upon motion the minutes as amended were unanimously approved.

Howard Barnaby gave the Treasurer's Report. He commented that the Association's bank account was declining slowly but that he expected an influx in connection with the Judges Dinner. Upon motion, the Treasurer's Report was approved.

Neither Edward Blocker nor Edward Filardi was able to attend the meeting. Therefore, a report from them concerning ways to increase membership was postponed until the next meeting.

Mr. Razzano reported that the USPTO had requested comments regarding 18-month publication, with oral presentations set for February 15 and written responses to be filed by February 18. Jack Sinnott and Sam Helfgott will be preparing a draft NYIPLA response, copies of which will be circulated to Board Members. Board Members will be asked to forward comments about the draft response to Mr. Razzano. There was discussion whether the Association should make an oral presentation. Mr. Creel commented that if the Association had something substantially different to say, an appearance was warranted. It was agreed that Mr. Razzano would have the authority to request an oral hearing by February 13, the final decision to be made at the next Board Meeting.

Mr. Razzano read the names of four candidates for membership: John M. Delehanty, Kim J. Landsman, Carroll E. Neesemann, and Karen G. Horowitz. A motion for approval of the candidates passed unanimously.

There was brief a discussion of ways to increase membership. In the course of this discussion it was suggested that the admis-

sion procedure, including the admission form, be simplified.

Mr. Razzano and Martin Goldstein reported on the selection of a speaker for the Judges Dinner. Mr. Razzano reported that a non-judicial speaker is being considered. ■

RECENT DECISIONS OF INTEREST

by Thomas A. O'Rourke

PATENT INFRINGEMENT

In *High Tech Medical Instrumentation, Inc. v. New Image Industries*, 1995 U.S. App. Lexis 4290 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit reviewed an order of the district court granting a patent holder's motion for a preliminary injunction in a patent infringement suit. The Court found that the district court committed legal errors requiring reversal of the preliminary injunctive relief.

The appellee, High Tech Medical Instrumentation, Inc. (HTMI), was the assignee of all rights to Patent No. 4,858,001 (the '001 patent) relating to a miniature imaging device used in dental work. The principal claim in issue, claim 24, recited an endoscopic optical device comprising a body member and a camera where "said camera being rotatably coupled to said body member."

In November, 1993, HTMI moved for a preliminary injunction to prevent the appellant, New Image Industries, Inc. (New Image), from selling its "AcuCam," an intra oral endoscope which HTMI alleged infringed the '001 patent. The "AcuCam" camera was similar to the camera claimed in the '001 patent, but, as manufactured, did not rotate within its housing. In granting HTMI's motion for a preliminary injunction, the district court applied the familiar four-part test: (1) whether the mov-

ing party is likely to succeed on the merits; (2) whether the moving party will suffer irreparable harm if a preliminary injunction is not granted; (3) whether the balance of hardships tips in favor of the moving party or the opponent; and (4) whether the grant of preliminary injunctive relief will adversely affect the public interest. The Court found that the district court committed legal errors in the course of disposing of two of the issues before it: HTMI's likelihood of success on the merits and HTMI's claim that it would suffer irreparable harm if it was denied injunctive relief.

The district court found that when two sets of screws on the AcuCam camera were loosened, the camera could rotate within the housing. The district court acknowledged that the AcuCam camera was not intended to rotate within the housing and that the set screws prevent such rotation when they were tightened. Nonetheless, because the camera could rotate when the screws were loosened, the court concluded that the AcuCam infringed the '001 patent and that "the addition of two easily removable set screws ... does not preclude a finding of infringement."

The Federal Circuit reversed the district court and stated that:

The fact that it is possible to alter the AcuCam so that the camera becomes "rotatably coupled" to its housing is not enough by itself to justify a finding that the manufacture and sale of the AcuCam infringe HTMI's patent rights. Of course, if a device is designed to be altered or assembled before operation, then the manufacturer may be held liable for infringement if the device, as altered or assembled, infringes a valid patent. *Id.* at 10.

Since HTMI did not establish that the AcuCam was "rotatably coupled" in spite of the set screws, the Court disagreed with the district court that HTMI was likely to succeed in proving that the AcuCam infringed the '001 patent.

According to the Federal Circuit, the district court based its finding of irreparable harm not on any affirmative showing of prospective harm to HTMI, but on a presumption of irreparable harm stemming from the strength of HTMI's showing on the merits. However, the Federal Circuit found that the presumption of irreparable harm was unavailable because HTMI was not likely to succeed in proving infringement.

In addition, the Federal Circuit found that there was no indication in the record that HTMI needed an injunction to protect its rights. HTMI did not contend that New Image would be unable to respond in damages for any infringement that may be found at trial. Also, HTMI's 17 month delay in bringing the action militated against the issuance of a preliminary injunction by demonstrating that there was no apparent urgency to the request for injunctive relief.

THE ON SALE BAR

In *Ferag AG v. Quipp Inc.*, 33 USPQ 2d 1512 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit reversed the district court, finding that the district court misapplied the on sale bar provision of section 102(b). The Court of Appeals found two independent reasons for concluding that Ferag AG had placed the invention on sale before the critical date.

Plaintiff Ferag AG, a Swiss Corporation, charged the defendant with infringing its patent on a conveyor apparatus. Ferag AG filed the application on January 15, 1981. Prior to March 31, 1979, Ferag AG owned all the outstanding 100,000 shares of stock in Ferag, Inc., a Pennsylvania Corporation. Then Ferag AG sold 100,000 additional shares of stock to Smallacombe, and Smallacombe became chief executive officer and president of Ferag, Inc. and a member of the board of directors.

Early in 1979, Ferag AG entered into discussions with the Bergen Evening Record (Bergen) about installing Ferag equipment. In March, Ferag AG, Bergen and Ferag, Inc. entered into a three-way agreement which provided for installation of two Ferag inserting systems. The agreement did not provide specific details about the system, but it did spell out general performance criteria. On November 23, 1979, Ferag AG sent Ferag, Inc. a document confirming a Ferag, Inc. order of an inserting system destined for Bergen.

The district court declined to invalidate the patent based on the transaction between Ferag AG and Ferag, Inc. reflected in the November, 1979 order confirmation. The district court found there was no on sale bar because Ferag, Inc. was not a separate entity from Ferag AG. *See id.* at 1515. The Court of Appeals disagreed and stated that whether there is a statutory bar

depends on whether the seller so controls the purchaser that the invention remains out of the public's hands. The Court held that the two companies were separate. According to the Court, the terms of the agreement between Smallacombe and Ferag AG reflected shared control. Furthermore, Ferag AG gave Smallacombe complete management authority over the operations of Ferag, Inc. The Court held that: "because Ferag could not control Ferag, Inc.'s marketing of the invention, the two companies were separate entities for section 102(b) purposes and the transaction between them gives rise to a statutory bar." *Id.*

The Court found that the sale of a Ferag system to Bergen independently supported the conclusion that Ferag AG had placed the invention on sale before the critical date. The Court held that the district court mistakenly relied on the seller's intent and the purchaser's understanding and stated that:

the key question in the case before us today, is whether, under the totality of the circumstances, the inventor placed his invention on sale, objectively manifested by a sale or offer for sale of a product that embodies the invention claimed in the patent. We emphasize that this is an objective test, and that at its heart lies the inventor's attempt to commercialize the invention. *Id.* at 1516.

The Court found that by November of 1979 Ferag AG had decided to supply the patented conveyor to Bergen. The Court held that the terms of the March agreement:

clearly include a contract for sale of a conveyor system, but it is not clear just what conveyor Ferag would supply. Indeed, the record suggests Ferag had not even begun development of the patented conveyor by that time. But the agreement did set forth functional specifications that the conveyor would meet. An existing prior art conveyor could have met these specifications, but the claimed conveyor, when it was developed, met them as well. *Id.* at 1517.

Therefore, under the totality of the circumstances, the Court concluded that Ferag AG placed the invention on sale before the critical date. *See id.*

REDUCTION TO PRACTICE

In *In re Asahi/America, Inc.*, CAFC No. 94-1249, decided February 24, 1995, the U.S. Court of Appeals for the Federal

Circuit held that for a simple invention, proof of actual reduction to practice does not require a showing that the invention existed and worked for its intended purpose. The Court found that a photograph in a trade journal, coupled with the entirety of a Rule 131 declaration, established that the invention was constructed and therefore reduced to practice.

During a reexamination proceeding Asahi filed a Rule 131 declaration to show reduction to practice for its U.S. Patent No. 4,393,544 (the "Ziu" patent) prior to the filing date of U.S. Patent No. 4,779,652 to Sweeney, a patent which had been cited against the Ziu patent. Asahi presented evidence that the claimed coupling was manufactured by an outside vendor and shown and described in two trade publications as part of commercial offerings prior to the April 9, 1987, filing date of the Sweeney patent. The patents of both Asahi and Sweeney contemplated double pipe systems where an inner "carrier" pipe carries the fluid while an outer "contaminated" pipe surrounds the pipe and contains the leaks. The Board of Patent Appeals and Interferences affirmed the examiner's rejection, holding that proof of actual reduction to practice requires a showing that the invention existed and worked for its intended purpose.

The Court of Appeals for the Federal Circuit noted that where a reference cited in support of a rejection "substantially shows or describes but does not claim" the subject matter of the invention in question, §131 allows the patent owner to overcome the reference by showing that the invention in question was reduced to practice prior to the filing date of the reference.

The Court noted that in prior cases the Court has held that "some devices are so simple that a mere construction of them is all that is necessary to constitute reduction to practice." The Court held that upon close examination of a photograph of the pipe fittings published in trade journals, the crucial length relationships required by the Ziu patent could be determined.

The Court reversed the Board and remanded the case, concluding as follows:

[T]he restraint coupling is so simple a device that mere construction of it is all that is necessary to constitute reduction to practice. The photograph, coupled with the entirety of the 131 declaration, establishes that the cou-

pling was constructed and therefore reduced to practice prior to the filing date of the Sweeney '652 patent. Accordingly, we reverse the Board's finding that the 131 declaration did not establish reduction to practice of the invention claimed in the Ziu '544 patent and remand for further proceedings consistent with this opinion.

COPYRIGHT INFRINGEMENT

In *NLFC Inc. v. Devcom Mid-America Inc.*, 33 USPQ 2d 1629 (7th Cir. 1995), the Court of Appeals affirmed the district court's grant of summary judgment for the defendant who was charged with copyright infringement, misappropriation of trade secrets, tortious interference with contract and unfair competition.

The plaintiff, NLFC, owned the copyright to a computer program for use in pathology laboratories. The software contained many bugs, and the labs which used it experienced great difficulty with NLFC in getting the program to run. An outside consulting firm, Devcom, contracted with the labs to remove the bugs from the NLFC software. In order to assist them in making the necessary changes, a viewable copy of the source code of the NLFC software was printed at Devcom's offices. Devcom marketed its expertise to other labs which used the NLFC software.

On appeal, NLFC contended that the district court erred in holding, as a matter of law, that its exclusive rights to the NLFC software under section 106 of the Copyright Act were not violated. Under §106, the owner of a copyright is given the exclusive right to (among other things) reproduce the work in copies, prepare derivative works based on the copyrighted work and distribute copies of the work to the public. *See id.* at 1630-31. NLFC claimed that Devcom violated its rights by (1) copying the software in the process of its activities and (2) marketing the NLFC software as modified. *See id.* at 1631.

With regard to NLFC's first claim, the Court of Appeals held that NLFC did not come forward with persuasive evidence that Devcom copied the NLFC software. According to the Court, the testimony offered at trial:

or dedicated phone lines and the use of dumb terminals [T]herefore the district court was correct in granting summary judgment in favor of Devcom on this allegation. *Id.* at 1632.

In addition, the Court of Appeals found that the district court did not err in concluding that the evidence did not support NLFC's claim that Devcom marketed an enhanced version of the NLFC software to other current NLFC software users. To support that claim, NLFC introduced into evidence a Devcom letter which contained highlights of consulting work with NLFC programs. The Court found that there was nothing in Devcom's letter which could be "reasonably interpreted as marketing anything but Devcom's expertise in working with this software." *Id.*

Finally, the Court held the district court did not err in dismissing NLFC's three state law claims for lack of supplemental jurisdiction. The Court noted that if all federal law claims dropout before trial, the district court may dismiss any pendant state law claims. *See id.* at 1632-33. The Court held that it was not an abuse of the district court's discretion to dismiss the three state claims after properly granting summary judgment on NLFC's federal copyright claim. *See id.* at 1633.

LANHAM ACT

In *Versa Products Co. v. Bifold Co.*, 1995 U.S. App. LEXIS 2838 (3rd Cir. 1995), the Court of Appeals for the Third Circuit held that the likelihood of confusion standard in product configuration trade dress infringement cases requires less emphasis on similarity of appearance, strength of the mark and the defendant's intent, and more emphasis on product labeling and the exercise of ordinary care by consumers.

Section 43(a) of the Lanham Act requires a showing of non-functionality, acquired or inherent distinctiveness and likely confusion. The Court noted that while most courts apply the "likelihood of confusion" standard, some courts apply the less demanding test of "possibility of confusion" where the plaintiff was well established in an area and the alleged infringer was new. The Court stated that the rationale for applying the less demanding standard for confusion is diminished in product packaging infringement cases.

First, the mere copying of product configurations does not suggest that the copier was necessarily trying to capitalize on the goodwill of the source of the original product.

Second, although a product's trade dress in the form of its configuration could function as an indicator of the product's source, product configurations in general are not reliable as source indicators, for functional configurations are not protected and thus may be freely copied, and inherently distinctive configurations will be rare. *Id.* at *31 (citations omitted)

The Third Circuit examined the factors which establish likelihood of confusion. The Court examined the similarity of appearance of goods. However, the Court stated that similarity of appearance by itself does not strongly suggest likely confusion in product configuration cases. The Court also stated that the strength of a trademark or product packaging does not translate literally into the product configuration context. The Court held that strength of product configuration as relevant to determining likelihood of confusion on the part of ordinary careful consumers should be found only if consumers rely on the configuration to identify the producer.

The Court noted that the care exercised by consumers takes on enhanced importance in product configuration cases. The Court held that clarity of labeling and marketing must be taken into account in considering whether there is likelihood that consumers exercising ordinary care will be confused as to the source of substantially identical products.

The Court of Appeals concluded that the district court erred in finding that strong similarity of appearance established likely confusion. According to the Court, the greatest weight must be given to packaging, trademarks and advertising. The district court also erred by relying on the strength of the plaintiff's trade dress to find likely confusion because here, customers did not rely on the appearance of the goods for identification and ordering, but instead used model numbers. The Third Circuit also found that the district court gave too much weight to the price of the goods and other factors relating to the care exercised by purchasers. Thus, the district court's judgment was reversed and the injunction was vacated. ■

indicates that Devcom did not, during its course of business with either lab, download the software onto its computers in order to work on it. Instead, Devcom directly accessed the laboratory computers via leased

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by Jack Revoyr

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