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UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NO. 94-5413

AMERICAN CYANAMID COMPANY,
Appellant

v.

FERMENTA ANIMAL HEALTH COMPANY,
a Delaware corporation

On Appeal From the United States District Court
For the District of New Jersey
(D.C. Civil Action No. 93-cv-04936)

ARGUED OCTOBER 28, 1994

OPINION VACATED APRIL 26, 1995

SUBMITTED PURSUANT TO LAR 34.1(a)
ON PANEL REHEARING MARCH 28, 1995

BEFORE: STAPLETON, HUTCHINSON and ROSENN, Circuit Judges

(Opinion Filed May 8, 1995)

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OPINION OF THE COURT

STAPLETON, Circuit Judge:

The issue in this case is whether a 1980 contract between the parties and a 1983 amendment thereto conveyed to American Cyanamid Company ("Cyanamid") perpetual rights to use the federal regulatory authority of Fermenta Animal Health Company ("Fermenta") to market an animal feed supplement. Cyanamid marketed the drug under the trademark Aureozol. Before the district court, both sides maintained that these documents are unambiguous, although each side differed on what was unambiguously stated therein. The district court held that "the

plain language of the 1980 agreement and the 1983 amendment," when read against the background of the parties' pre-contract negotiations and post-contract conduct, did not convey that right. We will affirm.

I.

This dispute arises from a contract that was signed between Cyanamid, a chemical and pharmaceutical conglomerate, and Diamond Shamrock Corporation ("Diamond Shamrock") in 1980. Fermenta, the defendant in this case, became the successor in interest to Diamond Shamrock through an acquisition in 1985. The purpose of the contract was to enable Cyanamid to produce and sell an animal feed drug that Diamond Shamrock had developed and was marketing. The drug was an antibiotic animal feed supplement consisting of chlortetracycline, sulfathiazole and penicillin, known as CSP 250. As consideration, Diamond Shamrock would receive an advance royalty and future royalties from Cyanamid's sales.

In order for Cyanamid to manufacture and sell Diamond Shamrock's product, the contract granted it two distinct rights. First, Cyanamid was given access to Diamond Shamrock's proprietary information about its animal feed drug for the purpose of manufacturing and selling it. Equally important, the agreement obligated Diamond Shamrock to seek federal regulatory authority to enable Cyanamid to sell the drug by applying for a "supplemental NADA" designating Cyanamid as a distributor of the drug.

The FDA licenses the sale in interstate commerce of animal drugs by approving a manufacturer's New Animal Drug Application (NADA), which remains on file with the FDA. Through the NADA, the FDA approves both the properties of the drug and its place and method of manufacture. See 21 U.S.C. § 360b(a). In 1971, Diamond Shamrock had obtained FDA approval of a NADA for its animal feed drug.¹

Obtaining a NADA can be an expensive and lengthy process because of the amount of resources that must be expended on researching and demonstrating the safety and efficacy of the proposed animal drug. However, a company may be able to avoid the costs associated with obtaining its own NADA if it wishes to market a drug identical to that already marketed by another company which has obtained federal regulatory approval for the sale of the drug. The company seeking to enter the market may request the current NADA holder to apply to the FDA for a "supplemental NADA" which designates the new market entrant as a distributor of the product. See 21 C.F.R. § 514.8(a)(4)(v).²

¹. When Fermenta became the successor in interest to Diamond Shamrock's animal drug business, it acquired Diamond Shamrock's NADA authority, as noted in 21 C.F.R. § 558.15(g)(1).

². 21 C.F.R. § 514.8(a)(4)(v) provides in part:

A communication proposing a change in a new animal drug application should provide for any one of the following kinds of changes:
. . . .

(v) Provision for outside firm to participate in the preparation, distribution, or packaging of a new animal drug (new

Cyanamid entered into this contract with Diamond Shamrock because its own animal drug, which competed in the market with Diamond Shamrock's CSP 250, was under scrutiny by the FDA for the possible carcinogenic effects of one of its components, sulfamethazine. Cyanamid sought to "insure" itself in the event the FDA took adverse action against its existing animal product by expanding its own product line to include Diamond Shamrock's animal feed supplement. Thus, in 1979, it entered negotiations with Diamond Shamrock, hoping to obtain the right to develop and sell Diamond Shamrock's product. Since Cyanamid could not sell Diamond Shamrock's drug without federal regulatory authority, the agreement required Diamond Shamrock to prepare and file a supplemental NADA establishing Cyanamid's facility as an alternate manufacturing site and designating Cyanamid as a distributor of the drug. In addition to pursuing an agreement with Diamond Shamrock, Cyanamid was formulating plans to obtain its own NADA for an animal product consisting of aureomycin, sulfathiazole and penicillin, a combination similar to CSP 250. This was reflected in a letter sent from Cyanamid to Diamond Shamrock during the course of negotiations in December of 1979.

Cyanamid and Diamond Shamrock executed their contract on July 23, 1980. Diamond Shamrock obtained the supplemental NADA in June of 1982 and the original five year contract period

(..continued)

distributor, packer, supplier, manufacturer,
etc.).

commenced on that date. Cyanamid thus enjoyed both commercial and regulatory rights to manufacture and sell the animal feed drug through June of 1987.

The contract also gave Cyanamid an option at the expiration of the agreement to purchase a perpetual license from Diamond Shamrock. Article 9.2 provides in part:

Upon expiration of the full term of this Agreement . . . CYANAMID shall have the right to obtain a perpetual, paid-up, non-exclusive license, without right to sublicense, under TECHNICAL INFORMATION as shall have been licensed hereunder to CYANAMID upon the payment of twenty-five thousand (\$25,000) dollars to DIAMOND SHAMROCK for such perpetual rights.

App. 158.

The option described in Article 9.2 was exercised prematurely by the parties in 1983 in the form of an amendment to the agreement. The amendment provides in part:

You will grant to us [Cyanamid] a perpetual paid-up nonexclusive license without right to sub-license under TECHNICAL INFORMATION as shall have been licensed under the Agreement upon our payment to you of \$87,500 for such perpetual rights. . . .

All other terms and conditions of the Agreement will remain in effect.

App. 165.

The dispute before the district court turned on whether this 1983 amendment, when read together with the original contract, gives Cyanamid a perpetual right to use the supplemental NADA to sell CSP 250. Cyanamid argued that the 1983

amendment gave it such a right, but Fermenta insisted that such a right ceased in 1987 with the expiration of the original contract.

Fermenta acquired Diamond Shamrock's interest in the contract in October of 1985, and from then through 1993, Fermenta monitored Cyanamid's regulatory compliance with the NADA. Prior to 1993, Fermenta never informed Cyanamid that its right to reference its NADA had expired with the termination of the original contract in 1987. Fermenta claims not to have realized that the contract expired in June of 1987 until 1993, when Fermenta more closely examined the entire contract because of Cyanamid's alleged regulatory breaches associated with the supplemental NADA. Fermenta thereupon demanded that Cyanamid pay it \$500,000, agree to pay a 10 percent royalty on all sales, and grant it a paid-up, royalty-free license under any patent or NADA which Cyanamid may have obtained on any related product. When Cyanamid refused to comply, Fermenta sent a letter to the FDA informing it that Cyanamid was no longer authorized to use the supplemental NADA that accessed Fermenta's NADA.

In response to Fermenta's action, Cyanamid filed a complaint in the U.S. District Court for the District of New Jersey seeking a preliminary injunction and a declaration that it held a perpetual, royalty-free license to use the supplemental NADA so that it could continue to sell the product. Fermenta counterclaimed, seeking a declaration that Cyanamid's right to use the supplemental NADA had expired in 1987. The jurisdiction of the district court was based on diversity, 28 U.S.C. § 1332.

After a one day evidentiary hearing at which it listened to extrinsic evidence of intent tendered by each side, the district court entered a declaratory judgment that Cyanamid "did not purchase a perpetual right to use the NADA or supplemental NADA." Dist. Ct. Order, No. 93-4936 (D. N.J., entered June 22, 1994). In its opinion, the district court analyzed the structure and text of the original agreement and the amendment and concluded that they could not reasonably be read to convey to Cyanamid a perpetual right to utilize Diamond Shamrock's regulatory authority. The court also concluded that the extrinsic evidence provided no basis for interpreting the scope of the rights conveyed by the agreements more broadly than the parameters of those rights as defined by its analysis of the structure and text.

We have conducted a plenary review of the district court's conclusions. Kroblin Refrigerated Xpress, Inc. v. Pitterich, 805 F.2d 96, 101 (3d Cir. 1986) (plenary review conducted of district court's conclusion that term of contract read against the background of the relevant extrinsic evidence was unambiguous). While our analysis of the structure and text of the agreement differs in one respect from that of the district court, that difference is not material for present purposes and our conclusions are the same as those reached by the district court.

The district court exercised its diversity jurisdiction. This means that the law to be applied is that of the forum state -- New Jersey. While the state law to which we look includes New Jersey's choice of law rules, Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496 (1941), neither party suggests any reason why a New Jersey court would apply other than its own law to this dispute and both, by the case law cited in their briefs, implicitly recognize New Jersey as providing the controlling law of contracts. The parties do not contend, moreover, that New Jersey's contract law differs in any material way from the generally accepted principles of contract law reflected in the Restatement (Second) of Contracts or from the "traditional rules of contract interpretation" that we described in Teamsters Indus. Emp. Welfare Fund v. Rolls-Royce Motor Cars, Inc., 989 F.2d 132, 135 (3d Cir. 1993). Cyanamid successfully urged the district court to follow the principles which we articulated in Rolls-Royce and Fermenta relies heavily on those principles before us. We there observed in the context of a collective bargaining agreement alleged to be ambiguous:

Although federal law governs the construction of collective bargaining agreements, traditional rules of contract interpretation apply when not inconsistent with federal law. To decide whether a contract is ambiguous, we do not simply determine whether, from our point of view, the language is clear. Rather, we "hear the proffer of the parties and determine if there [are] objective indicia that, from the linguistic reference point of the parties, the terms of the contract are susceptible of different meanings." Sheet Metal Workers, 949 F.2d at 1284 (brackets in original)

(quoting Mellon Bank, N.A. v. Aetna Business Credit, Inc., 619 F.2d 1001, 1011 (3d Cir. 1980)). Before making a finding concerning the existence or absence of ambiguity, we consider the contract language, the meanings suggested by counsel, and the extrinsic evidence offered in support of each interpretation. Id.; Mack Trucks, 917 F.2d at 111; see also Restatement (Second) of Contracts § 223 cmt. b (1981) ("There is no requirement that an agreement be ambiguous before evidence of a course of dealing can be shown. . . ."). Extrinsic evidence may include the structure of the contract, the bargaining history, and the conduct of the parties that reflects their understanding of the contract's meaning.

Id. at 135 (citations omitted).

These teachings appear to us to be consistent with those of New Jersey law. In Atlantic Northern Airlines, Inc. v. Schwimmer, 96 A.2d 652 (N.J. 1953), the Supreme Court of New Jersey summarized this area of the law in the following terms:

Evidence of the circumstances is always admissible in aid of the interpretation of an integrated agreement. This is so even when the contract on its face is free from ambiguity. The polestar of construction is the intention of the parties to the contract as revealed by the language used, taken as an entirety; and, in the quest for the intention, the situation of the parties, the attendant circumstances, and the objects they were thereby striving to attain are necessarily to be regarded. The admission of evidence of extrinsic facts is not for the purpose of changing the writing, but to secure light by which to measure its actual significance. Such evidence is adducible only for the purpose of interpreting the writing--not for the purpose of modifying or enlarging or curtailing its terms, but to aid in determining the meaning of what has been said. So far as the evidence tends to show, not the meaning of the writing, but an intention wholly unexpressed in the writing,

it is irrelevant. The judicial interpretive function is to consider what was written in the context of the circumstances under which it was written, and accord to the language a rational meaning in keeping with the expressed general purpose. Casriel v. King, 2 N.J. 45, 65 A.2d 514 (1949).

Id. at 656.

It is important for present purposes to note that extrinsic evidence of the negotiations, conduct and other circumstances of the parties is important to a court's analysis of whether an agreement is ambiguous only to the extent, if any, that such evidence provides "objective indicia that, from the linguistic reference point of the parties, the terms of the contract are susceptible of different meanings." Mellon Bank, N.A. v. Aetna Business Credit, Inc., 619 F.2d 1001, 1011 (3d Cir. 1980). That is, extrinsic evidence is permitted because the law recognizes that the meaning of words can depend on context, and what may seem unambiguous without context (or in the context that the judge may hypothesize, based on his or her own experience) may be ambiguous when understood from "the linguistic reference point of the parties." Id. See 3 Arthur L. Corbin, Corbin on Contracts § 542 (1960). Cf. 4 Samuel Williston & Walter H. E. Jaeger, A Treatise on the Laws of Contracts § 601, at 310-11 (3d ed. 1961). But the focus must remain on the language chosen by the parties, and a text unambiguous when accorded the commonly understood meaning of its words cannot be disregarded unless the extrinsic evidence is such as might cause a reasonable fact

finder to understand the text differently. See Mellon Bank, 619 F.2d at 1011 & 1012 n.13.

The point is well illustrated by Mellon Bank, N.A. v. Aetna Business Credit, Inc., a case to which we looked in Rolls-Royce for the "traditional rules of contract interpretation." Rolls-Royce, 989 F.2d at 135. There, Mellon Bank and Aetna Business Credit were commercial lending institutions. In the transaction giving rise to the dispute, Mellon was the construction lender and Aetna was the permanent lender. Mellon alleged that Aetna breached their contract by refusing to purchase the construction loan held by Mellon. Under the agreement, Aetna had "no obligation to acquire the construction loan from the construction lender in the event of . . . insolvency of the Borrower." Mellon Bank, 619 F.2d at 1006.

Mellon contended that the parties intended "insolvency" to mean that the borrower's liabilities exceeded its assets without reference to the liabilities or assets of the borrower that accrued from the particular project being financed. The district court heard extrinsic evidence and held, based on the conduct of the parties during their negotiations, that Mellon's reading was "required by the clear allocation of lending risks between" the contracting parties. Id. at 1008. We described the district court's reasoning and the issue before us in the following terms:

The district court found that Aetna in analyzing the security for its permanent loan did not consider the borrowers' cash flow, did not condition its obligation upon any occupancy level, and therefore concluded

"Aetna recognized that the financial transaction in question was not a basis for finding insolvency." The district court cited no basis in the contract document or wording of the insolvency clause for its conclusion. Our task is to decide if the district court permissibly used extrinsic evidence to interpret the contract and, if so, whether it drew the proper legal conclusions therefrom.

Id. at 1009.

We reversed, holding as follows: Although extrinsic evidence may be considered under proper circumstances, the parties remain bound by the appropriate objective definition of the words they use to express their intent. . . .

We have concluded that the district court here exceeded the permissible boundary of interpretation. . . . When the district judge received Mellon's evidence it should have rejected it as insufficient to vary the meaning of a commercial term as well established as "insolvent." In this case the district court added a term which made the condition a nullity. It ruled that, although the solvency of the borrowers was a condition in the written contract, the fact that the borrowers' solvency was not significantly considered by Aetna in evaluating the take-out loan minimized or nullified this clause of the contract.

. . . The fact that the insolvency of the borrowers was not significantly considered by Aetna in evaluating the take-out loan is immaterial given the expression of that concern in the written words of the contract.

Id. at 1013-14.

Our approach in Mellon Bank is consistent with the law of New Jersey. Although the New Jersey Supreme Court in Atlantic Northern Airlines extolled the use of extrinsic evidence to aid

in ascertaining the intent of the parties, even when the terms of the instrument are otherwise unambiguous, it cautioned that such evidence may not be used "for the purpose of modifying or enlarging or curtailing" the terms of the contract. With this understanding of the controlling law, we turn to examine the structure and text of the agreements and then to consider the extrinsic evidence offered by the parties.

III.

The preamble of the 1980 agreement clearly and tersely states Cyanamid's two objectives in entering the agreement -- access to Diamond Shamrock's proprietary information and the

right to sell the drug under a supplemental NADA:

DIAMOND SHAMROCK has developed or otherwise acquired certain proprietary information relating to the manufacture of an animal feed supplement and is the owner of an approved New Animal Drug Application (NADA) which permits the sale of such animal feed supplement; and

. . . CYANAMID desires to manufacture and sell such animal feed supplement and would like to obtain the right to utilize DIAMOND SHAMROCK's proprietary information and have DIAMOND SHAMROCK file supplemental NADA's to establish CYANAMID as an alternate manufacturing site and to designate CYANAMID as a distributor pursuant to 21 CFR 514.8.

App. 151.

Two separate sections of the contract implement the transfer to Cyanamid of the commercial and regulatory rights it

sought. The first is Article 2.1, which is the focal point of this controversy.

Article 2.1 provides:

DIAMOND SHAMROCK grants to CYANAMID a non-exclusive license to use TECHNICAL INFORMATION to practice the LICENSED PROCESS and to make, use and sell PRODUCT under its own name and trademarks.

App. 153-54. The terms used in Article 2.1 are defined in Article 1. "TECHNICAL INFORMATION" is defined as meaning "all information licensable by DIAMOND SHAMROCK as of the effective date of this Agreement and which relates to the practice of the LICENSED PROCESS or to the production and use of PRODUCT." "Licensed process" is defined as "DIAMOND SHAMROCK's process for the manufacture of an animal feed supplement presently sold under the trademark CSP 250 and comprising chlortetracycline, sulfathiazole and penicillin." The term "product" refers to CSP 250. App. 152. Thus, Article 2.1 grants commercial authority to Cyanamid to use Diamond Shamrock's proprietary information to manufacture, distribute and sell CSP 250.

Article 11.1, on the other hand, commits Diamond Shamrock to seek regulatory authority for Cyanamid to market CSP 250. That clause provides in part:

Promptly upon execution of this Agreement, DIAMOND SHAMROCK shall prepare and submit to the FDA supplemental new animal drug applications to establish CYANAMID's facility as an alternate manufacturing site and to designate CYANAMID as a distributor of PRODUCT under 21 CFR 514.8.

App. 160. This provision was, of course, a critical term of the agreement. If Diamond Shamrock failed to obtain a supplemental NADA by December 31, 1982, Article 11.2 entitled Cyanamid to terminate the agreement.

The dichotomy between commercial and regulatory rights reflected in the preamble and in Articles 2.1 and 11.1 is important for present purposes because the scope of the perpetual license Cyanamid claims to have received by virtue of the 1983 amendment is defined in that amendment and Article 9.2 of the original agreement solely by reference to the rights conferred by Article 2. As we have noted, Article 9.2 grants Cyanamid an option to obtain upon the termination of the agreement a perpetual "license . . . under TECHNICAL INFORMATION as shall have been licensed hereunder to CYANAMID." It was this perpetual license that Cyanamid acquired in 1983 when it was granted a perpetual "license . . . under TECHNICAL INFORMATION as shall have been licensed under the Agreement," i.e., a perpetual license to use "all information licensable by Diamond Shamrock as of [July 23, 1980] which relates to the practice of [its manufacturing process for CSP 250] or to the production and use of [CSP 250]."

The 1983 amendment provides that, save for the grant of this perpetual license of Diamond Shamrock's proprietary information, all other terms and conditions of the original agreement were to remain unchanged. Since one such term and condition was the five year limit on the rights originally conveyed, this meant that only the perpetual license of

proprietary information was to survive beyond June of 1987. It necessarily follows that any right Cyanamid had under the 1983 amendment after 1987 had to be a right conferred by Article 2.1.

Before the district court, Cyanamid insisted that, when Diamond Shamrock conveyed in Article 2.1 a "license to use TECHNICAL INFORMATION to practice the LICENSED PROCESS and to make, use and sell PRODUCT under its own name and trademarks," Diamond Shamrock conveyed a right to use the supplemental NADA.³ We agree with the district court, however. If the quoted words and those of the remainder of the agreement are given their commonly understood meaning, Article 2.1 simply does not make such a grant.

When the definitions of the defined terms are inserted in the grant evidenced by Article 2.1, one has a straightforward conveyance of a license to use Diamond Shamrock's proprietary information to practice its process and make, use and sell its product -- such proprietary information consisting of "all information licensable by Diamond Shamrock as of [July 23, 1980] which relates to the practice of [its manufacturing process for CSP 250] or to the production and use of [CSP 250]." This conveyance is consistent with the dichotomy we have previously

³. As we discuss in part V, *infra*, Cyanamid now argues that Article 2.1 conveys the commercial license to sell the product, and that once this right was perpetually conveyed through the 1983 amendment, Cyanamid enjoyed clear commercial and regulatory authority to sell the product, since only the FDA could terminate its right to use the supplemental NADA. However, Cyanamid did not argue before the district court that Fermenta could not terminate its right to use the supplemental NADA. Indeed, it proceeded on the contrary assumption.

identified in the preamble and between the grants made in Articles 2.1 and 11.1. As the district court stressed, if Article 2.1 gave Cyanamid not only a commercial license to make, use and sell CSP 250 using Diamond Shamrock's proprietary information, but also a right to use the supplemental NADA that Diamond Shamrock hoped to obtain for Cyanamid, Article 11 would serve no purpose. It is a well settled principle, however, that a court should read a contract so as to give all its terms their intended effect. J. L. Davis & Associates v. Heidler, 622 A.2d 923, 927 (N.J. Super. Ct. App. Div. 1993) (disapproving of a "reading of [a] contract [which] would nullify its very terms and render [a] provision useless"); Goldberg v. Commercial Union Ins. Co. of New York, 188 A.2d 188, 191 (N.J. Super. Ct. App. Div. 1963) ("Effect, if possible, will be given to all parts of the instrument"); 3 Corbin, supra, § 549, at 183 (stating that the "legal effects" of the terms of a contract are to be "determined as a whole").

Moreover, as the district court also noted, an understanding of Article 2.1 that includes a conveyance of regulatory rights as well as a commercial license to use proprietary information is inconsistent with its time focus. Article 2.1 effects a conveyance of rights Diamond Shamrock possessed as of July 23, 1980. As is recognized in Article 11, Diamond Shamrock had no authority on that date to give Cyanamid the right to legally sell CSP 250 in the United States. This could be accomplished only by Diamond Shamrock's taking the steps necessary to secure authority for Cyanamid from the FDA,

authority which, as the escape clause demonstrates, the parties knew might be obtained, if at all, only after the passage of a substantial period of time.

Cyanamid correctly points out that the reading of Article 2.1 which Fermenta champions and we adopt is not entirely consistent with the district court's reading of that provision. The district court interpreted Article 2.1 to convey two rights, a "license to use TECHNICAL INFORMATION to practice the LICENSED PROCESS" and a license "to make, use and sell PRODUCT under its own name and trademarks." As previously indicated, we, on the other hand, read both the "to practice" clause and the "to make, use and sell" clause as modifying "license to use TECHNICAL INFORMATION." The latter reading seems to us the more natural one since Cyanamid was going to use its own name and trademarks, Diamond Shamrock had no patent on CSP 250, and the only non-regulatory basis for excluding Cyanamid from competing in the CSP 250 market was the rights Diamond Shamrock possessed in its proprietary information. We do not, however, regard our difference with the district court as material in the present context. Even if there be an ambiguity as to what the "make, use and sell" clause modifies, that ambiguity does not render the text of the agreement and the 1983 amendment ambiguous as to whether Cyanamid possesses a perpetual right to use the supplemental NADA. As the district court's opinion demonstrates, this is so because the scope of the only perpetual license acquired by Cyanamid is defined solely by reference to the "TECHNICAL INFORMATION . . . licensed under the Agreement."

Thus, even if, like the district court, one breaks Article 2.1's conveyance up into two segments, it is only the first, TECHNICAL INFORMATION segment that is the subject of the perpetual license. TECHNICAL INFORMATION is a defined term and, as we have demonstrated, its meaning cannot be stretched to include a commitment on Diamond Shamrock's part to seek FDA authority for Cyanamid in the future.

IV.

The extrinsic evidence of intent heard by the district court does not transform Article 2.1's straightforward grant of a license to make, use and sell CSP 250 utilizing proprietary information into something else. Indeed, that evidence tends to support the reading of the agreements that accords the words their ordinarily accepted meaning.

When one who is unfamiliar with the background reads the agreement and the 1983 amendment, an important question arises: Why would Cyanamid want to pay for a perpetual license to use Diamond Shamrock's proprietary information concerning CSP 250 if it anticipated that its right to market CSP 250 under the supplemental NADA would expire in mid-1987? The extrinsic evidence supplies the answer. Cyanamid could apply for its own NADA and sell a product that was similar to CSP 250, and it intended to do so. Both the correspondence between the parties during the negotiation of the agreement and the testimony of Cyanamid's employees indicate that during the relevant period it was pursuing its own plan to secure independent marketing

authority from the FDA for a product consisting of aureomycin, sulfathiazole and penicillin. Thus, Cyanamid did not contemplate having to use the supplemental NADA indefinitely. It was buying time through these agreements insofar as regulatory authority was concerned, but it wanted continuing commercial authority to use the proprietary information regarding CSP 250 (which contained sulfathiazole, a component of the drug that Cyanamid was developing).⁴

The record also establishes that prosecution of an application for a NADA is time consuming and costs well in excess of \$1,000,000. Against this background, the structure of the consideration to be paid by Cyanamid provides further evidence that the agreement was deliberately drafted to treat the supplemental NADA as a right separate and apart from the TECHNICAL INFORMATION. The single most important part of the agreement was the commitment to seek regulatory authority, without which Cyanamid could terminate the agreement. Under Article 3 of the agreement, in addition to the \$150,000 advance royalty (which was creditable against 50 percent of earned royalties), Cyanamid was committed to pay earned royalties out of

⁴. Cyanamid's former manager of animal regulatory affairs testified that prior to 1980, Cyanamid had been selling a product containing chlortetracycline, penicillin and sulfamethazine, and that Cyanamid had become interested in Diamond Shamrock's product, which contained sulfathiazole instead of sulfamethazine, because "[s]ulfamethazine was coming under a great deal of scrutiny by FDA" and "sulfamethazine was retained in the tissues longer than sulfathiazole." App. 16-17. Thus, even if Cyanamid did not intend to market CSP 250 in the future, the information about sulfathiazole could be relevant with respect to future product development.

the proceeds of its sales. Diamond Shamrock was entitled to a minimum earned royalty of \$62,500, in addition to the full advance royalty (for a total of a minimum of \$212,500), within three years of the approval of the supplemental NADA; if it did not receive this sum, it could terminate the agreement under Article 8. Of course, given the potential volume of Cyanamid's sales, Diamond Shamrock could earn a much larger sum in royalties. Under Article 9.2, however, the costs to Cyanamid for a permanent license to use the TECHNICAL INFORMATION was only \$25,000.⁵ Based both on the parties' understanding of the time and expense of prosecuting a NADA application and on the amount of the royalties specified in the agreement for the rights Cyanamid was to possess over the limited period of the agreement, it seems highly unlikely that Diamond Shamrock would have been willing to convey for \$25,000 a perpetual license that would include both the right to use its proprietary information and the right to use the supplemental NADA. Stated conversely, the

⁵. The \$87,500 price paid by Cyanamid as consideration for the Amendment consisted of two components: (1) the \$25,000 provided for by Article 9.2 of the Agreement in exchange for a perpetual license to the TECHNICAL INFORMATION, and (2) \$62,500 for the royalties which Cyanamid would have owed under Article 8 of the Agreement on its minimum sales obligation of \$5 million. The \$62,500 was calculated as follows: Article 3 of the Agreement provided that earned royalties were to be calculated at the rate of 2.5 percent on the first \$10,000,000 of net sales, and at the rate of one percent thereafter. Therefore, on \$5,000,000, the royalty would be \$125,000 ($\$5,000,000 \times 2.5\%$). However, Article 3 also provided for an advance royalty of \$150,000 creditable against 50 percent of earned royalties. Accounting for that credit, the royalty remaining to be paid on \$5,000,000 minimum sales would be \$62,500.

economics of the matter at least suggest that the option to buy a perpetual license to use TECHNICAL INFORMATION for \$25,000 did not include the use of the supplemental NADA in perpetuity.

In these respects, the extrinsic evidence confirms that according the terms of the agreements their plain meaning makes commercial sense.

The extrinsic evidence stressed most heavily by Cyanamid as throwing light on the intention of the parties is the conduct of Fermenta's employees in the period following July of 1987. Shortly after the execution of the 1983 amendment, SDS Biotech acquired Diamond Shamrock's animal health business. SDS Biotech, in turn, was acquired by Fermenta in October of 1985, after the perpetual, paid-up license had been purchased with a lump sum payment, but still during the five year term of the original agreement. Thus, after Fermenta succeeded to Diamond Shamrock's rights, it was never entitled to receive royalties under the agreement and it received none. When June of 1987 came and the original five year term of the agreement expired, Cyanamid continued to sell CSP 250 under its own name and trademark. Over the six years from June of 1987 to October of 1993, Fermenta did not protest Cyanamid's continuing sales. The explanation for this failure to protest, which was uncontradicted in the record and accepted by the district court, was given by Fermenta's general counsel. He testified that over the years, he and others were aware of the existence of the contract and of Cyanamid's use of the supplemental NADA because of inquiries from the FDA about that use. However, no one at Fermenta read the

contract and focused on its terms until a more serious regulatory problem arose in the Fall of 1993, at which point Fermenta's general counsel reviewed the contract in its entirety.

The significance of Fermenta's failure to protest is diminished by the fact that Diamond Shamrock, rather than Fermenta, negotiated the original agreement and the 1983 amendment and oversaw its execution during the period when Cyanamid was paying royalties. Nevertheless, we acknowledge that the evidence does not rule out the possibility that the failure to protest may have been attributable in part to someone at Fermenta having read the agreements at some point after June of 1987 and having concluded that they conveyed to Cyanamid the right to continue to use the supplemental NADA. Even if this occurred, however, we would not regard it as a justification for us to read the agreements of the parties in a different way. Like the parties in Mellon Bank, the parties here used words quite common in agreements of this kind with generally accepted meanings. Like Aetna's pre-contract conduct in Mellon Bank, Fermenta's post-contract conduct does not suggest that the parties had an unusual "linguistic reference." As a result, we agree with the district court that a reasonable person reading the agreements against the background of the extrinsic evidence could not find them susceptible of a reading that would bestow upon Cyanamid a perpetual right to use the supplemental NADA.

On appeal, Cyanamid advances an additional argument that it insists provides an "independent reason" for us to reverse the declaratory judgment of the district court. According to Cyanamid, although the holder of a NADA has the sole right to apply for authority to permit others to manufacture its product at "alternate manufacturing sites," the issuance of the supplemental NADA, by operation of law, permanently deprives the holder of control over the continued manufacture of its product at those facilities. It is apparent from an examination of the transcript of the proceedings before the district court and the brief Cyanamid submitted to it that Cyanamid did not advance this legal argument before the district court. "It is well established that failure to raise an issue in the district court constitutes a waiver of the argument." Brenner v. Local 514, United Brotherhood of Carpenters and Joiners of America, 927 F.2d 1283, 1298 (3d Cir. 1991). We will not depart from this well established principle of appellate review to consider the merits of Cyanamid's regulatory argument, and we accordingly express no view with respect to it.

VI.

For these reasons, the judgment of the district court will be affirmed.