UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: Elysium Health-ChromaDex Litigation	Case No. 1:17-cv-07394 (CM)

MEMORANDUM OF LAW OF PLAINTIFF ELYSIUM HEALTH, INC. IN SUPPORT OF ITS MOTION FOR RECONSIDERATION UNDER LOCAL CIVIL RULE 6.3 AND FEDERAL RULE OF CIVIL PROCEDURE 59(e)

Joseph N. Sacca
Esterina Giuliani
Benjamin D. Pergament
BAKER & HOSTETLER LLP
45 Rockefeller Plaza
New York, New York 10111
Tel.: (212) 589-4200
Fax: (212) 589-4201
jsacca@bakerlaw.com
egiuliani@bakerlaw.com
bpergament@bakerlaw.com

Attorneys for Plaintiff Elysium Health, Inc.

TABLE OF CONTENTS

PRELIMINARY STATEMENT 1

PROCEDURAL HISTORY AND STATEMENT OF FACTS.....4

ARGUMENT 7

I. THE COURT'S DECISION IS CONTRARY TO CONTROLLING SECOND CIRCUIT PRECEDENT BECAUSE IT HELD THAT A PARTY'S CESSATION OF ANY PORTION OF THE PETITIONED-AGAINST ACTIVITY IS CONCLUSIVE ON THE ISSUE OF OBJECTIVE BASELESSNESS. 7

A. The Court's Ruling Contravenes Controlling Second Circuit Precedent. 8

B. The Case Law Relied On By the Court Shows that the Totality of the Circumstances Must Be Considered. 10

C. The Court's Rule of Law Invites Adverse Effects. 12

II. THE COURT IMPROPERLY RESOLVED DISPUTED ISSUES OF MATERIAL FACT AND DREW INFERENCES AGAINST THE NON-MOVING PARTY IN GRANTING CHROMADEX'S CONVERTED, PRE-DISCOVERY MOTION FOR SUMMARY JUDGMENT. 12

A. The Court Improperly Resolved a Disputed Issue of Material Fact when It Found, Contrary to Record Evidence, that Elysium's Removal of Toluene Came In Response to the Sham Petition. 13

B. The Court Improperly Resolved a Disputed Issue of Material Fact when It Found, Contrary to Record Evidence, that Removal of Toluene from Basis Was the Outcome ChromaDex Petitioned For. 15

III. THE COURT COMMITTED A CLEAR ERROR OF LAW WHEN IT CONVERTED CHROMADEX'S MOTION AND THEN DENIED ELYSIUM THE OPPORTUNITY TO CONDUCT DISCOVERY BEFORE GRANTING SUMMARY JUDGMENT. 17

CONCLUSION 21

TABLE OF AUTHORITIES

Page(s)

Cases

Agosto v. INS,
436 U.S. 748 (1978) 13

Apotex, Inc. v. Acorda Therapeutics, Inc.,
823 F.3d 51 (2d Cir. 2016) 20

Casey v. Odwalla, Inc.,
338 F. Supp. 3d 284 (S.D.N.Y. 2018) 20

Chambers v. TRM Copy Ctrs. Corp.,
43 F.3d 29 (2d Cir. 1994) 18

City of Columbia v. Omni Outdoor Advert., Inc.,
499 U.S. 365 (1991) 11

EDF Renewable Dev., Inc. v. Tritec Real Estate Co., Inc.,
147 F. Supp. 3d 63 (E.D.N.Y. 2015) 11

FLLI Moretti Cereali v. Cont'l Grain Co.,
563 F.2d 563 (2d Cir. 1977) 15

Gov't Emps. Ins. Co. v. Hazel, No. 11-CV-00410 CBA VMS,
2014 WL 4628655, (E.D.N.Y. Aug. 11, 2014) 10

Hellstrom v. U.S. Dep't of Veterans Affairs,
201 F.3d 94 (2d Cir. 2000) 3, 18

In re Dana Corp.,
574 F.3d 129 (2d Cir. 2009) 14

In re Fresh Del Monte Pineapple, No. 04MD1628 (RMB) (MHD),
2007 WL 64189, (S.D.N.Y. Jan. 4, 2007) 10

In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.,
64 F. Supp. 3d 665 (E.D. Pa. 2014) 7, 8, 17

In re Terazosin Hydrochloride Antitrust Litig.,
335 F. Supp. 2d 1336 (S.D. Fla. 2004) 11

Int'l Audiotext Network, Inc. v. Am. Tel. & Tel. Co.,
62 F.3d 69 (2d Cir. 1995) 20

TABLE OF AUTHORITIES

Page(s)

Landmarks Holding Corp. v. Bermant,
664 F.2d 891 (2d Cir. 1981) ..... passim

Magan v. Lufthansa German Airlines,
339 F.3d 158 (2d Cir. 2003) 14

Miller v. Wolpoff & Abramson, L.L.P.,
321 F.3d 292 (2d Cir. 2003) 18

Mover's & Warehousemen's Ass'n of Greater New York, Inc. v. Long Island Moving & Storage Ass'n, Inc., No. 98 Civ. 5373 (SJ), 1999 WL 1243054,
(E.D.N.Y. Dec. 16, 1999) 10

Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus.,
508 U.S. 49 (1993) 8

Schoenbaum v. Firstbrook,
405 F.2d 215 (2d Cir. 1968) 18

Smithfield Foods, Inc. v. United Food & Commercial Workers Int'l Union,
593 F. Supp. 2d 840 (E.D. Va. 2008) 10

STMicroelectronics, Inc. v. Avago Techs. U.S., Inc., No. 5:10-cv-5023(JF)(PSG),
2011 WL 1362163, (N.D. Cal. Apr. 11, 2011) 10

T.F.T.F. Capital Corp. v. Marcus Dairy, Inc.,
312 F.3d 90 (2d Cir. 2002) 9

Theme Promotions, Inc. v. News Am. Mktg. FSI,
546 F.3d 991 (9th Cir. 2008) 10

Statutes

21 U.S.C. § 301 *et seq.* 4

Other Authorities

Fed. R. Civ. P. 12(d) 20

Fed. R. Civ. P. 59(e) 7, 21

S.D.N.Y. Local Civil Rule 6.3 ..... 7, 21

PRELIMINARY STATEMENT

The Court's grant of summary judgment against Elysium Health, Inc. ("Elysium"), ECF No. 63, was based entirely on the premise that a party's cessation of any portion of the petitioned-against activity conclusively establishes that the petition was not objectively baseless for purposes of *Noerr-Pennington* immunity, *without regard to any other evidence of objective baselessness before the Court*. That rule contravenes the Second Circuit's controlling decision in *Landmarks Holding Corp. v. Bermant*, 664 F.2d 891 (2d Cir. 1981), and thus constitutes a clear error of law requiring reconsideration.

Application of this rule, which focuses narrowly on whether the petitioner achieved *any* of the outcomes it sought and by *whatever* means, resulted in the Court disregarding record evidence that ChromaDex, Inc's ("ChromaDex") citizen petition submitted to the United States Food and Drug Administration ("FDA") in August 2017 (the "Sham Petition") was objectively baseless, including the fact that ChromaDex itself sold toluene-containing products direct to consumers—which the Court previously stated was "[m]ost damning on the issue of objective baselessness." ECF No. 44 at 13.

Such a narrow rule of law would incentivize the very abuses that the "sham exception" to *Noerr-Pennington* immunity is intended to curb, because it tells abusive litigants that their tactics will actually pay off if they are so effective that they force their opponent into submission. As illustrated in the Second Circuit's controlling *Landmarks* decision, the Court should have considered the totality of the circumstances bearing on the Sham Petition's objective baselessness rather than simply focusing on whether ChromaDex's abusive tactics could be said to have paid off. Because the Court's test contravenes controlling appellate authority and undermines the very purposes of the "sham exception" to *Noerr-Penington* immunity, the Court committed a clear error of law in granting ChromaDex's converted, pre-discovery motion for summary judgment.

Even if the rule applied by the Court properly reflected controlling law, granting summary judgment prior to discovery was improper because, in doing so, the Court made determinations about issues of material fact that are squarely in dispute while drawing inferences against Elysium, the non-moving party. Specifically, the Court found that Elysium removed toluene from its product Basis in response to ChromaDex's Sham Petition, that Elysium admitted that it did so to eliminate a potential harm to consumers, that securing the removal of toluene from Basis was ChromaDex's purpose in filing the Sham Petition, and that ChromaDex believed toluene to be unsafe at the levels found in Basis. ECF No. 63 at 10. To make these findings and draw these inferences, the Court explicitly rejected evidence that Elysium removed toluene from Basis not in response to the Sham Petition but instead "as part of its continuing efforts to ensure superior product quality," as Elysium explained in its comment to the FDA. ECF No. 51-18 at 1. Elysium's uncontradicted comment to the FDA—the only record evidence on the issue—establishes a genuine issue of material fact on the point.

Similarly, in finding Elysium's statement that it removed toluene from Basis as part of its continued efforts to ensure "superior product quality" to be "a euphemism for a potentially safer product" and thus an admission that the toluene in Basis posed a potential harm to consumers, the Court disregarded record evidence to the contrary, including Elysium's direct statement to the FDA that it did not believe the minimal levels of toluene ChromaDex claimed to have found in Basis pose any potential safety issue at all.

What is more, the Court overlooked evidence that the "outcome" ChromaDex sought was not the removal of toluene from Basis (a remedy ChromaDex *didn't even ask for* from the FDA) but rather the removal of a competitor from the market. And the Court likewise erred when it credited ChromaDex's supposed "belief" that toluene is unsafe in the levels purportedly found in

Basis, even in the face of evidence that ChromaDex demonstrated no such belief when it sold its own products containing toluene at similar levels. The Court's resolution of these disputed factual issues on a motion for summary judgment was a clear error of law and the Court should exercise its discretion in granting reconsideration.

The Court also erred when it denied Elysium the opportunity for discovery prior to granting summary judgment, in contravention of settled Second Circuit precedent that pre-discovery summary judgment should be granted "only in the rarest of cases," and which cautions against denying a party the opportunity to obtain discovery going to knowledge and intent – issues that were core to the Court's finding of facts and its grant of summary judgment based thereon. *Hellstrom v. U.S. Dep't of Veterans Affairs*, 201 F.3d 94, 97 (2d Cir. 2000). Elysium therefore should have been allowed to conduct discovery on the "single, discrete issue" of "objective baselessness under *Noerr-Pennington*'s sham exception." ECF No. 44 at 14.

At the outset of this case, a stay of discovery was granted, over Elysium's objection, and thus no discovery has yet occurred. Because *Landmarks* shows that the Court should consider the totality of the circumstances when analyzing objective baselessness, and because further documents showing ChromaDex's goals in filing the Sham Petition and the insincerity of its purported belief that the levels of toluene in Basis (and, necessarily, in its own products) posed a threat of potential harm to consumers are exclusively in ChromaDex's control, the Court clearly erred in denying discovery, and the Court should exercise its discretion to authorize discovery on the issue of objective baselessness under *Noerr-Pennington*'s sham exception. Such discovery would include, at a minimum, discovery into ChromaDex's intent in filing the Sham Petition, its true position regarding the safety of toluene at the levels found in Basis as well as in its own products, and its awareness of the FDA's inability to grant the relief requested.

PROCEDURAL HISTORY AND STATEMENT OF FACTS

Elysium initiated this action by filing its complaint against ChromaDex in September of 2017. ChromaDex moved to dismiss the complaint one month later while simultaneously filing its own complaint against Elysium by opening a separate action in the Southern District of New York. The Honorable Valerie Caproni consolidated both actions and stayed discovery at ChromaDex's request and over Elysium's objection by Order dated November 3, 2017, ECF No. 27, and Elysium then moved to dismiss ChromaDex's complaint. ECF No. 31. The case was thereafter reassigned to this Court while the motions to dismiss were pending. ECF No. 39.

Elysium's complaint asserted three causes of action, all predicated on the damages it suffered as a result of the Sham Petition ChromaDex filed with the FDA. In its Sham Petition, ChromaDex asserted that Elysium's product Basis was purportedly "adulterated" within the meaning of the Food, Drug, & Cosmetic Act, 21 U.S.C. § 301 *et seq.*, because miniscule amounts of toluene it allegedly contained supposedly rendered it "injurious to health" and because it was purportedly not covered by a New Dietary Ingredient Notification ("NDIN"). Based on these allegations, ChromaDex purported to demand that the FDA initiate specific "enforcement action" that included seizure of Elysium's inventory of Basis and an injunction against any further manufacture or distribution of it. In its complaint, Elysium claimed that ChromaDex publicly submitted its Sham Petition to the FDA solely to injure Elysium's reputation because, *inter alia*, the relief requested in the Sham Petition is unavailable through that process and, further, ChromaDex itself sold products that are not covered by an NDIN and that contained toluene at levels that it claimed rendered Elysium's product "injurious to human health."

The Court ruled on the motions to dismiss by Order dated September 27, 2018. ECF No. 44. In its Order, the Court stated that "[m]ost damning on the issue of objective baselessness is Elysium's contention that [ChromaDex's pterostilbene] product, pTeroPure®, also contains

toluene in levels comparable to the toluene in Basis," and observed that, "[a]ssuming *arguendo* that [ChromaDex] does not intend to market an adulterated product, it would be objectively baseless for it to argue to the FDA that a competitor's product is adulterated because it contains an ingredient that is found in [ChromaDex's] own competing product." ECF No. 44 at 13. The Court denied ChromaDex's motion to dismiss Elysium's complaint, reserving judgment on the "single, discrete issue [of] objective baselessness under *Noerr-Pennington*'s sham exception" and converting the motion on that point to a motion for summary judgment. *Id.* at 14 ("The conversion is limited to this one issue. The motion is otherwise denied.") The Court also explained that, "[a]ssuming that ChromaDex is not immunized under *Noerr*, the Complaint easily passes the test of whether it pleads claims on which relief could be granted, pursuant to Fed. R. Civ. P. 12(b)(6)." *Id.*

The Court gave the parties "thirty days to submit any and all evidence that may bear on the objective baselessness of ChromaDex's Sham Petition - which would include, but is not limited to the evidence referred to in Paragraph 65 of Elysium's Complaint - at which time the court will take up the *Noerr-Pennington* challenge again." *Id.* at 27. Paragraph 65 of Elysium's complaint described documents showing that ChromaDex's own products contained toluene, the substance that it claimed rendered Elysium's product "injurious to human health." ECF No. 1 at 16-17. The parties thereafter simultaneously submitted affidavits, accompanying exhibits, and short briefs on the issue of objective baselessness, ECF Nos. 49 through 53-21, though Elysium in its papers sought relief under Federal Rule of Civil Procedure 56(d), arguing that it was entitled to discovery on the issue prior to a ruling on summary judgment. ECF No. 52 at 8-10. ChromaDex thereafter sought and obtained leave to file a supplemental declaration attaching hundreds of pages of exhibits, which were filed at ECF Nos. 59 and 62. In response, Elysium submitted a letter to the

Court, ECF No. 60, noting, among other things, that ChromaDex admitted that it sold pTeroPure to Elysium that contained toluene in levels comparable to those it claimed to have found in Elysium's Basis, ECF No. 51 ¶¶ 51-52, and that the documents attached to the supplemental declaration showed that ChromaDex also sold toluene-containing products directly to consumers. ECF No. 60 at 2; ECF No. 62-02 at 8. ChromaDex has not responded to any discovery requests from Elysium and has not produced a single document in this action.

The Court granted ChromaDex's converted, pre-discovery motion for summary judgment by order dated January 3, 2019. ECF No. 63. Without addressing Elysium's Rule 56(d) request, the Court held that objective baselessness turned on the single issue of whether ChromaDex had achieved any of its objectives in filing the Sham Petition. The Court made factual findings that ChromaDex sought to cause the removal of toluene from Basis and that Elysium, which had removed toluene from its product, did so in response to the Sham Petition. The only record evidence on the point is to the contrary. Elysium stated to the FDA that it had removed toluene from Basis "as part of its continuing efforts to ensure superior product quality," and also stated to the FDA that ICH guidelines establish the safety of toluene at the levels previously found in Basis. ECF No. 51-18 at 1. Notwithstanding this evidence, and while acknowledging that Elysium never attributed the removal of toluene from Basis to the Sham Petition, the Court inferred that it would be "unreasonable" to deny that Elysium acted in response to the Sham Petition. ECF No. 63 at 10. The Court further found that Elysium's reference to "superior product quality appears to be a euphemism for a potentially safer product" notwithstanding Elysium's clear statement to the contrary in its comment to the FDA and notwithstanding evidence submitted by both sides showing that product "quality" and "safety" are distinct terms that are not used interchangeably. *Id.* at 8.

The Court granted summary judgment based on these findings. *Id.* The next day, the Court entered judgment on Elysium's complaint. ECF No. 64. ChromaDex's complaint and Elysium's counterclaims remain pending, and Elysium now moves under Local Civil Rule 6.3 and Federal Rule of Civil Procedure 59(e) for an order granting reconsideration of the Court's January 3, 2019 Decision and Order Granting Defendant's Motion for Summary Judgment, ECF No. 63.

ARGUMENT

I. THE COURT'S DECISION IS CONTRARY TO CONTROLLING SECOND CIRCUIT PRECEDENT BECAUSE IT HELD THAT A PARTY'S CESSATION OF ANY PORTION OF THE PETITIONED-AGAINST ACTIVITY IS CONCLUSIVE ON THE ISSUE OF OBJECTIVE BASELESSNESS.

The record shows, and ChromaDex has admitted, that ChromaDex sold products containing toluene, including direct to consumers. ECF No. 20 at 5 (admitting that toluene has been found in pTeroPure); ECF No. 53, Sacca Dec. ¶¶ 6-8 & Exs. 2, 3 (Certificates of Analysis showing presence of toluene in ChromaDex product); ECF No. 62-19 at 4 (Certificate of Analysis showing presence of toluene in the pterostilbene ChromaDex sold direct to consumers through BluScience). As the Court rightly recognized in its ruling on ChromaDex's motion to dismiss, this fact renders ChromaDex's Sham Petition hypocritical and objectively baseless: "Most damning on the issue of objective baselessness is Elysium's contention that ChromaDex's PT product, pTeroPure®, also contains toluene in levels comparable to toluene in Basis." ECF No. 44 at 13 (citing *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 690 (E.D. Pa. 2014), *on reconsideration in part sub nom. In re Suboxone (Buprenorphine Hydrochloride & Nalaxone) Antitrust Litig.*, No. 13-MD-2445, 2015 WL 12910728 (E.D. Pa. Apr. 14, 2015) (finding citizen petition a sham where petitioner requested the FDA investigate why a pharmaceutical had not been pulled from the market, yet continued to sell the same drug)). ChromaDex likewise in its Sham Petition purported to fault Elysium for selling a product to

consumers that was not covered by an NDIN, despite itself having engaged in the exact same conduct. ECF No. 52 at 6.

Notwithstanding the manifest baselessness of a citizen petition against conduct in which the petitioner itself is engaged, and notwithstanding persuasive authority (*In re Suboxone*) concluding that such conduct is evidence of objective baselessness, the Court nevertheless concluded that objective baselessness turns on one fact and one fact alone: Elysium's removal of toluene from Basis in supposed response to the Sham Petition. Sweeping aside the facts showing, at a minimum, a genuine factual dispute as to the Sham Petition's objective baselessness, the Court held that *nothing else matters as long as Elysium removed toluene from Basis in response to the Sham Petition*, writing: "Having achieved a favorable outcome, the Citizen Petition cannot be said to be objectively baseless." ECF No. 63 at 8 (citing *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 60 (1993)). The Court's failure to consider the totality of the facts bearing on ChromaDex's conduct and intent is contrary to controlling Second Circuit precedent and defeats to the very purpose of the "sham exception" to *Noerr-Pennington* immunity.

A. The Court's Ruling Contravenes Controlling Second Circuit Precedent.

The Court's reasoning that any success of the petitioner means that a citizen petition is not objectively baseless conflicts with the Second Circuit's decision in *Landmarks.* There, the defendants, local business owners and shopping centers in New Haven, Connecticut, engaged in litigation, lobbying, and other activity in an attempt to block the plaintiff's application for a zoning change needed for a new development. *Landmarks*, 664 F.2d 891 at 896-97. The defendants initially succeeded in getting the local zoning commission to deny the plaintiff's zoning application. *Id.* at 893. After the zoning commission eventually did approve the zoning change, the defendants saw further success in the courts, securing a ruling on appeal that the zoning commission's approval of the zoning change had not been passed by the requisite two-thirds

majority. *Id.* at 894. And the defendants ultimately succeeded in their campaign to thwart the development when the plaintiff was forced to abandon the venture. Yet despite this very favorable (from defendants' perspective) outcome, and despite defendants' intermediate success before the zoning commission and in court, the Second Circuit nevertheless rejected their arguments for *Noerr-Pennington* immunity, writing:

> In sum, by the bringing of numerous meritless appeals, by deliberate delay in the prosecution of those appeals, by the solicitation and subsidization of meritless litigation by the landowners, and by their attorney's failure to convey a settlement offer to the Neals, the Plaza defendants successfully stalled plaintiffs' applications for zoning changes on the Evergreen Avenue property for five years. This delay ultimately forced the plaintiffs to abandon their venture. We hold that these allegations state a cause of action under the antitrust laws.

Id. at 896-97. The defendants in *Landmarks* surely got what they wanted, but that fact did not end the inquiry in *Landmarks*, nor should it have done so here. Instead, additional evidence of objective baselessness, separate and apart from action taken by the victim in supposed response to the petition, can preclude *Noerr-Pennington* immunity, notwithstanding the petitioner's apparent success in obtaining a certain outcome. *Id.* Indeed, Second Circuit precedent from both before and after *Prof'l Real Estate Inv'rs., Inc.*, establishes that a party's apparent success before the adjudicative body does not end the *Noerr-Pennington* inquiry and that the totality of the circumstance should instead be considered. *See T.F.T.F. Capital Corp. v. Marcus Dairy, Inc.*, 312 F.3d 90, 94 (2d Cir. 2002) ("although it is a winning lawsuit, a default judgment does not *ipso facto* constitute a determination of the 'objective reasonableness' of the lawsuit, especially in a case where the plaintiff claims that the judgment in the prior action was obtained through deceit."). The Court therefore committed a clear error of law when it failed to consider the totality of the circumstances and instead focused on the perceived success of the petition. *See also Gov't Emps. Ins. Co. v. Hazel*, No. 11-CV-00410 CBA VMS, 2014 WL 4628655, at *17 (E.D.N.Y. Aug. 11,

2014), *report and recommendation adopted*, No. 11-CV-0410 CBA VMS, 2014 WL 4628661 (E.D.N.Y. Sept. 15, 2014) (rejecting argument that settlement of litigation determined objective reasonableness based on allegation that settlement was obtained through collusive back-room dealings); *Smithfield Foods, Inc. v. United Food & Commercial Workers Int'l Union*, 593 F. Supp. 2d 840, 844 (E.D. Va. 2008) ("In assessing whether the Defendants fall under the sham exception to the Noerr–Pennington doctrine, the Court must consider the totality of the [disputed] harassing conduct.").

B. The Case Law Relied On By the Court Shows that the Totality of the Circumstances Must Be Considered.

Cases cited by the Court in its summary judgment decision further illustrate that the *Noerr-Pennington* inquiry is not restricted to such a bright-line rule that any success is sufficient to show that a petition is not objectively baseless; instead it requires the Court to consider the totality of the circumstances when analyzing the objective baselessness prong. *See In re Fresh Del Monte Pineapple*, No. 04MD1628 (RMB) (MHD), 2007 WL 64189, at *19 (S.D.N.Y. Jan. 4, 2007), *subsequently aff'd sub nom. Am. Banana Co. v. J. Bonafede Co., Inc.*, 407 F. App'x 520 (2d Cir. 2010) (identifying settlement as one of five factors indicating lack of objective baselessness); *Mover's & Warehousemen's Ass'n of Greater New York, Inc. v. Long Island Moving & Storage Ass'n, Inc.*, No. 98 Civ. 5373 (SJ), 1999 WL 1243054, at *6 (E.D.N.Y. Dec. 16, 1999) (examining entire course of conduct when analyzing objective baselessness prong, rather than simply focusing on the parties' settlement of the supposed sham litigation); *Theme Promotions, Inc. v. News Am. Mktg. FSI*, 546 F.3d 991, 1008 (9th Cir. 2008) (relying on party's right to enforce contractual rights to find that threatened litigation was not objectively baseless); *STMicroelectronics, Inc. v. Avago Techs. U.S., Inc.*, No. 10-CV-05023-JF(PSG), 2011 WL 1362163, at *2 (N.D. Cal. Apr. 11, 2011)

(characterizing settlement not as conclusive but rather simply as "evidence of the merits of the case.").

As for *EDF Renewable Dev., Inc. v. Tritec Real Estate Co., Inc.,* 147 F. Supp. 3d 63 (E.D.N.Y. 2015), that case neither supports such a bright-line rule nor applies to the facts of this case. There, the petitioning party got what it wanted *from the petitioned entity*, whereas here the supposed "relief" came not from the FDA, which ChromaDex petitioned, but from Elysium's volitional and independent choice to remove toluene. *Id.* at 70. What is more, because the FDA is unable to grant the relief requested in the Sham Petition, ChromaDex lacked a reasonable basis to believe that it could achieve the "'governmental result'" sought therein, and the Sham Petition was therefore "'not genuinely aimed at procuring favorable government action at all.'" ECF No. 63 at 12 (quoting *City of Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365, 380 (1991)). In contrast, the defendant's actions in *EDF Renewable* were "genuinely aimed at procuring favorable government action" because the defendant actually sought and actually obtained the County's refusal of a competitor's building permit. *EDF Renewable Dev., Inc.*, 147 F. Supp. 3d at 70. Likewise distinguishable is *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336 (S.D. Fla. 2004). In that case, the relief came in the context of the lawsuits (including settlement and information disclosure), whereas here there is evidence in the record disputing that the supposed "outcome" was a result of the Citizen Petition. *Id.* at 1358. And the allegedly baseless lawsuits in that case were withdrawn after the filer got what he wanted, whereas here the Citizen Petition has not been withdrawn, itself powerful evidence that ChromaDex *has not* achieved the outcome it sought in filing the Citizen Petition. *Id.*

C. The Court's Rule of Law Invites Adverse Effects.

The practical effects of the Court's rule likewise should be considered. If the Court is correct that cessation in response to petitioning activity conclusively establishes lack of objective baselessness, then it doesn't matter how deceptive, manipulative, fraudulent, or coercive the activity is, so long as it eventually forces the petitioned party to cry uncle. Under the Court's newly announced rule, the petitioning party can do literally *anything* and still enjoy *Noerr-Pennington* protection so long as the petitioner's cynical harassment was too much for the opposing party to bear. In fact, the more abusive the conduct, the better: such a bright-line rule *rewards* abusive activity, providing a perverse incentive for a petitioner to ramp up its harassment until the victim concludes that the game isn't worth the candle, at which point the petitioner's abuses are by definition not objectively baseless—"the proof is in the pudding." ECF No. 63 at 10.

Because the Court's rule overlooks controlling Second Circuit precedent, is contrary to extensive case law which considers the totality of the circumstances, and incentivizes the very conduct that the sham exception to *Noerr-Pennington* immunity is meant to deter, the Court committed a clear error of law in holding Elysium's removal of toluene in supposed response to the Sham Petition to be conclusive on the issue of objective baselessness, and the Court's grant of summary judgment (and the resultant entry of judgment) was in error.

II. THE COURT IMPROPERLY RESOLVED DISPUTED ISSUES OF MATERIAL FACT AND DREW INFERENCES AGAINST THE NON-MOVING PARTY IN GRANTING CHROMADEX'S CONVERTED, PRE-DISCOVERY MOTION FOR SUMMARY JUDGMENT.

The Court's outcome-based rule led it to improperly resolve three disputed factual issues when it found: that the Sham Petition caused Elysium to remove toluene from Basis, that removal of toluene was an outcome ChromaDex sought, and that ChromaDex believed toluene to be unsafe

at the levels it claimed to have found in Basis. The record evidence on each point is to the contrary—Elysium's removal of toluene was not in response to the Sham Petition, ChromaDex neither sought from the FDA, nor had a genuine interest in, the removal of toluene from Basis, and ChromaDex lacked a genuine belief that the levels of toluene in Basis were unsafe because, among other reasons, its own products contained similar levels of toluene. Yet the Court disregarded that evidence and made factual findings that Elysium acted in response to the Sham Petition such that "CMDX achieved the very outcome it petitioned for - the removal of toluene from a dietary supplement sold directly to consumers that it believed rendered that product potentially 'injurious' to public safety." ECF No. 63 at 8. In doing so, the Court impermissibly made credibility determinations and drew inferences against the non-moving party. Because "a district court generally cannot grant summary judgment based on its assessment of the credibility of the evidence presented" nor draw inferences against the non-moving party, the Court's improper finding of facts and resultant grant of summary judgment were clear errors of law requiring reconsideration. *Agosto v. INS*, 436 U.S. 748, 756 (1978).

A. The Court Improperly Resolved a Disputed Issue of Material Fact when It Found, Contrary to Record Evidence, that Elysium's Removal of Toluene Came In Response to the Sham Petition.

The only record evidence regarding Elysium's reason for removing toluene from Basis is Elysium's comment letter to the FDA. In that comment, Elysium stated: "Although Elysium believes that the ICH Guidelines establish the safety of toluene at the minimal levels previously found in Basis, Elysium elected to eliminate the presence of toluene from Basis *as part of its continuing efforts to ensure superior product quality*." ECF No. 51-18, at 1 (emphasis added). The Court disregarded that uncontradicted evidence and inferred that there must have been a connection between the Sham Petition and Elysium's removal of toluene, writing: "While Elysium does not expressly attribute to the filing of the Citizen Petition its decision to remove toluene from

Basis, denying the connection between the two events would be unreasonable." ECF No. 63 at 10.

"*[C]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge.*" *In re Dana Corp.*, 574 F.3d 129, 152 (2d Cir. 2009) (emphasis in original). The Court contravened this fundamental restraint on a motion for summary judgment when, based on an inference as to what evidence not in the record might show, it concluded that "denying the connection between the two would be unreasonable." ECF No. 63 at 10. In fact, Elysium *had* denied a connection between the two when it explained to the FDA that "its continuing efforts to ensure superior product quality" prompted it to remove toluene. ECF No. 51-18 at 1. In branding that explanation "unreasonable" – in effect concluding without evidence that Elysium misrepresented its reasons for acting to the FDA – "the court failed to construe the record in the light most favorable to [the non-movant], as the summary judgment standard requires." *Magan v. Lufthansa German Airlines*, 339 F.3d 158, 166 (2d Cir. 2003).

The Court's inference that Elysium effectively conceded the danger of the minimal levels of toluene in Basis was likewise improper. The Court inferred that Elysium's comment to the FDA was "an admission that the presence of toluene in Basis posed potential harm to consumers" and that Elysium's reference to "[s]uperior product quality appears to be a euphemism for a potentially safer product." ECF No. 63 at 8. Those inferences are refuted not just by Elysium's comment to the FDA that "the ICH Guidelines establish the safety of toluene at the minimal levels previously found in Basis," but also ChromaDex and Elysium's disjunctive use of the terms "safety" and "quality" in material entirely unrelated to this litigation. *See* ECF No. 33-2 at 69-72 (Elysium marketing material using quality and safety in the disjunctive); ECF No. 53-11

(ChromaDex marketing material using quality and safety in the disjunctive). To draw these inferences against Elysium, the non-moving party, the Court therefore either had to overlook or conclude to be false Elysium's comment to the FDA, and to infer that Elysium had conflated the terms "quality" and "safety" when evidence in the record showed it had not done so before. ECF No. 51-18 at 1 (emphasis added). The Court's conclusion that Elysium removed toluene from Basis in response to the Sham Petition was therefore in error based on the extensive precedent cautioning district courts to abjure fact finding on a motion for summary judgment. *See, e.g.*, *FLLI Moretti Cereali v. Cont'l Grain Co.*, 563 F.2d 563, 565 (2d Cir. 1977) ("In this case, the court ran afoul of these principles by failing to view the evidence submitted in the light most favorable to" the non-moving party.).

B. The Court Improperly Resolved a Disputed Issue of Material Fact when It Found, Contrary to Record Evidence, that Removal of Toluene from Basis Was the Outcome ChromaDex Petitioned For.

The Court erred in resolving another disputed issue of material fact when it stated that ChromaDex "achieved the very outcome it petitioned for - the removal of toluene from a dietary supplement sold directly to consumers that it believed rendered that product potentially 'injurious' to public safety." ECF No. 63 at 8. ChromaDex's failure to withdraw the Sham Petition following Elysium's removal of toluene from Basis is powerful evidence that the removal of toluene from Basis was *not* the "outcome" ChromaDex petitioned for. In fact, the Sham Petition *does not request the removal of toluene from Basis* at all. Instead, ChromaDex makes crystal clear in its Sham Petition that its desired outcome is the wholesale removal of Basis from the marketplace and the seizure of Elysium's remaining supply of Basis, in addition to determinations from the FDA that Basis was adulterated because it contained toluene and because it was not covered by an NDIN. *See* ECF No. 63 at 2 ("CMDX also asked the FDA to 'take all appropriate remedial action, including [ordering] that Elysium cease distribution of its Basis product and take other appropriate

enforcement action, including seizure of violating products and an injunction against the manufacturers and distributors under 21 U.S.C. §§ 332 and 334.'"). The Court thus overlooked the clear text of the Sham Petition itself and improperly resolved a disputed issue of material fact when it concluded that ChromaDex had petitioned for the removal of toluene from Basis.

The Court also overlooked substantial record evidence refuting its finding that "the outcome [ChromaDex] petitioned for" was "the removal of toluene from a dietary supplement sold directly to consumers that it believed rendered that product potentially 'injurious' to public safety." ECF No. 63 at 8. Record evidence shows that ChromaDex explicitly asked the FDA to remove Basis from the market, and further that ChromaDex lacked a genuine belief that Basis was adulterated and unsafe. The Sham Petition claimed that Basis was adulterated for two reasons: 1) it purportedly contained trace amounts of toluene and 2) it was purportedly sold to consumers despite not being covered by an NDIN, *but the same was true of products sold by ChromaDex*: some of its products, including some sold directly to consumers, 1) contained toluene, and 2) some of its products were sold to consumers without being covered by an NDIN. ECF No. 51 ¶¶ 51-52; ECF No. 52 at 6; ECF No. 60 at 2; ECF No. 62-02 at 8. Indeed, Elysium's product is still sold without an NDIN (and thus according to ChromaDex is still "adulterated"), which further refutes the Court's finding that ChromaDex has secured the "outcome" it sought. And as for the alleged danger posed by the trace amounts of toluene in Basis, Elysium introduced record evidence that levels of toluene posed no such danger because they were below those set by ICH Guidelines – Guidelines which ChromaDex itself relies on to establish the safety of its own products. ECF No. 53 ¶¶ 16-17 & Exs. 9, 10.

The Court erred in holding that "[s]ince Elysium has not identified a genuine [] issue of material fact to suggest that CMDX acted solely to damage Elysium and without a genuine interest

in the removal of toluene from Basis, the sham exception is inapplicable." ECF No. 63 at 13. In so holding, the Court overlooked facts which show that "the outcome [ChromaDex] petitioned for" was neither the removal of toluene nor FDA action at all, but instead the anticompetitive removal of a competitor from the market. And record evidence shows that it was objectively baseless for ChromaDex to argue that Basis was adulterated and unsafe based on facts that applied equally to ChromaDex's own product. *See In re Suboxone*, 64 F. Supp. 3d at 690 (holding unavailability of requested relief from FDA and petitioner's concurrent sale of the same tablets petitioned against established objective baselessness); ECF No. 44 at 13 ("[a]ssuming *arguendo* that [ChromaDex] does not intend to market an adulterated product, it would be objectively baseless for it to argue to the FDA that a competitor's product is adulterated because it contains an ingredient that is found in [ChromaDex's] own competing product."). Based on the extensive record evidence of the Sham Petition's objective baselessness, the Court erred in granting summary judgment against Elysium, and the Court should therefore grant Elysium's motion for reconsideration.

III. THE COURT COMMITTED A CLEAR ERROR OF LAW WHEN IT CONVERTED CHROMADEX'S MOTION AND THEN DENIED ELYSIUM THE OPPORTUNITY TO CONDUCT DISCOVERY BEFORE GRANTING SUMMARY JUDGMENT.

The Court clearly erred when it denied Elysium the opportunity to obtain discovery into the factual issues it resolved in its grant of summary judgment. The Court's core and dispositive finding was that ChromaDex "achieved the very outcome it petitioned for – the removal of toluene from a dietary supplement sold directly to consumers that it believed rendered that product potentially 'injurious' to public safety." ECF No. 63 at 8. To so find, the Court necessarily found that "removal of toluene" was the "outcome" ChromaDex petitioned for and, relatedly, that ChromaDex "believed" that toluene rendered Basis "injurious to public safety." *Id.*

As discussed above, Elysium submitted evidence (which it obtained through its now-terminated commercial relationship with ChromaDex as well as from publicly available sources) refuting *both* of these points and thus, at a minimum, established a factual dispute precluding summary judgment. But even setting that evidence aside, the Court's grant of summary judgment was improper because it was entered before Elysium could take discovery on these issues – something that should occur "only in the rarest of cases." *Hellstrom*, 201 F.3d at 97. And the Second Circuit has directed that where, as here, the movant's intent is in issue, "caution must be exercised in granting summary judgment." *Chambers v. TRM Copy Ctrs. Corp.*, 43 F.3d 29, 40 (2d Cir. 1994). Such caution is doubly appropriate here because crucial evidence of knowledge and intent is in the movant's exclusive possession. *Schoenbaum v. Firstbrook*, 405 F.2d 215, 218 (2d Cir. 1968) ("Since the facts [concerning defendant's motives] are exclusively in the possession of the defendants, summary judgment should not ordinarily be granted where the facts alleged by the plaintiff provide a ground for recovery, at least not without allowing discovery in order to provide plaintiff the possibility of counteracting the effect of defendants' affidavits.").

Elysium established its right to discovery under Rule 56(d) by showing by affidavit and in its opposition papers:

1. that Elysium sought discovery from ChromaDex bearing, *inter alia*, on its motivations in filing the Sham Petition as well as its knowledge of the presence of toluene in products it sold to consumers, the lack of an NDIN covering its own product, and its belief (or lack thereof) in the safety of toluene, ECF No. 53, Sacca Dec. at ¶ 32;

2. that the requested documents would likely reveal that ChromaDex's sole intent was to harm a competitor and that it was aware its petition was objectively baseless due to its own sale of toluene-containing product as well as its sale of a product not covered by an NDIN, ECF No. 52 at 6;

3. that Elysium had already propounded the relevant discovery requests on ChromaDex, ECF No. 53 ¶¶ 32-36; but that

4. ChromaDex had not responded due to Judge Caproni's stay of discovery. *Id.*

See Miller v. Wolpoff & Abramson, L.L.P., 321 F.3d 292, 303 (2d Cir. 2003) (articulating four-part test for discovery under Rule 56(d)). The Second Circuit's *Landmarks* decision shows why Elysium was entitled to the discovery it sought prior to summary adjudication. There, the Second Circuit relied on the defendant's unguarded statements to prove that the defendants knew their litigation to be "'purely bull'" and thus objectively baseless. 664 F.2d at 896-97. Because those sorts of documents are unavailable to Elysium, Elysium was entitled to discovery into whether ChromaDex was aware that its Sham Petition dripped with hypocrisy and was "purely bull." At a minimum, discovery would likely have revealed whether ChromaDex filed the Sham Petition merely to eliminate toluene from Basis or instead, as Elysium alleged, to eliminate a competitor from the marketplace. It likewise could have informed the Court's factual finding regarding ChromaDex's "belief" in the supposed danger posed by the presence of toluene. The Court committed clear error when it denied Elysium discovery on these questions of fact – questions it then resolved adversely to Elysium despite evidence pointing the other way. Given the clear indicia of objective baselessness already in the record, the Court's denial of discovery going to the core of the objective baselessness inquiry was a clear error of law requiring reconsideration.

The Court likewise erred when it converted the motion to dismiss into a motion for summary judgment on the basis of documents concerning whether ChromaDex had an objective belief in the merits of the Sham Petition, but then decided the converted motion based on its narrow outcome-based rule while crediting ChromaDex's demonstrably false statement that the Sham Petition sought removal of toluene from Basis. If ChromaDex's achieving of its objective is the sole factor determining objective baselessness (which it is not), then the documents the Court cited in support of its decision to convert the motion are irrelevant to the objective baselessness inquiry and do not justify conversion. Indeed, even on their own terms and regardless of the *Noerr-*

Pennington test applied by the court, those documents do not require conversion under Rule 12(d), and the conversion order is thus an independent clear error of law requiring reconsideration.

The Court appeared to cite three sets of documents to justify its decision converting ChromaDex's motion to dismiss into a pre-discovery motion for summary judgment: 1) Certificates of Analysis ("COAs") that were described in but not appended to Elysium's complaint; 2) the Sham Petition that was the entire basis for Elysium's complaint and thus integral to it; and 3) the publicly available November 29, 2016 FDA letter, which ChromaDex submitted to the Court in support of its motion to dismiss. ECF No. 44 at 10. Under settled law in this Circuit, none of those documents support conversion. *See, e.g.*, *Int'l Audiotext Network, Inc. v. Am. Tel. & Tel. Co.*, 62 F.3d 69, 72 (2d Cir. 1995) (observing that documents integral to the complaint do not support conversion); *Apotex, Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 60 (2d Cir. 2016) (observing that documents subject to judicial notice do not support conversion); *Casey v. Odwalla, Inc.*, 338 F. Supp. 3d 284, 294 (S.D.N.Y. 2018) (observing that publicly posted FDA letters are subject to judicial notice); ECF No. 44 at 10 (noting that the FDA letter is "a matter of public record"); Fed. R. Civ. P. 12(d) (stating that conversion is appropriate "[i]f, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings *are* presented to and not excluded by the court" (emphasis added)). The Court therefore committed clear error in converting ChromaDex's motion to dismiss into a pre-discovery motion for summary judgment. The Court should exercise its discretion to revisit its conversion order and vacate the resultant grant of summary judgment.

CONCLUSION

Because the Court's grant of summary judgment (and the resultant entry of judgment) was based on a rule of law that overlooks contrary Second Circuit precedent, was based on the Court's drawing of inferences against the non-moving party and its resolution of disputed issues of material fact, was entered without affording Elysium a reasonable opportunity to conduct crucial discovery, and was decided after the Court improperly converted ChromaDex's motion to dismiss, the Court should grant Elysium's motion under Local Civil Rule 6.3 and Federal Rule of Civil Procedure 59(e) for an order granting reconsideration of its January 3, 2019 Decision and Order Granting Defendant's Motion for Summary Judgment, ECF No. 63.

Dated: New York, New York
January 17, 2019

Respectfully submitted,

BAKER & HOSTETLER LLP

By: */s/ Joseph N. Sacca*

Joseph N. Sacca
Esterina Giuliani
Benjamin D. Pergament
BAKER & HOSTETLER LLP
45 Rockefeller Plaza
New York, New York 10111
Tel.: (212) 589-4200
Fax: (212) 589-4201
jsacca@bakerlaw.com
egiuliani@bakerlaw.com
bpergament@bakerlaw.com

Attorneys for Plaintiff Elysium Health, Inc.