UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL No. 2804

Master Docket No. 1:17-MD-02804-DAP

This document relates to:

Hon. Judge Dan A. Polster

AMANDA HANLON, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED;

AMY GARDNER, INDIVIDUALLY AND ON BEHALF OF HER MINOR DAUGHTER A.L.D. AND ALL OTHERS SIMILARLY SITUATED,

Plaintiffs,

v.

PURDUE PHARMA L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY, INC.;
TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
ALLERGAN PLC f/k/a ACTAVIS PLC;
WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.;
WATSON LABORATORIES, INC.; ACTAVIS LLC; and
ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.;

Defendants.

Case No. 1:19-op-45206

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I. PRELIMINARY INJUNCTION DURING PENDENCY OF OPIOID LITIGATION IS NECESSARY TO ABATE NAS AND OUD BIRTHS

The incidence of opioid use and addiction was stable in this country until 1995 when a synthetic time-released opioid called Oxycontin was FDA approved.[1] This approval coupled with the advent of drugs similar to Oxycontin and aggressive marketing campaigns by the defendants led to sky-rocketing opioid use, addiction, misuse, and explosions of the diversionary and the illicit drug markets to the point where a national-opioid epidemic now exists.[2] This country's need for pain medications by chronic pain sufferers or those with acute pain needs did not, however, increase during this same time.[3]

The primary purpose of this suit, the others in this MDL, and those pending in state courts, is to permanently abate the opioid epidemic.[4] This motion seeks a preliminary injunction to assist abatement during the pendency of these actions by reducing the number of NAS[5] and OUD[6] births by requiring a negative pregnancy test before an opioid can be dispensed to a woman capable of becoming pregnant, dispensing only a seven-day supply, and if additional opioids are prescribed after seven days, that there be another negative pregnancy test before dispensing the prescription. This request is not unlike other programs established by drug manufacturers, distributors, pharmacies, and the FDA for drugs with teratogenic properties which successfully protect fetal development.[7]

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[1] See attached Undisputed Material Facts Supporting Motion for Preliminary Injunction (UMF): 6, 8
[2] UMF: 11, 14
[3] UMF: 10
[4] Rec. Doc 71 January 9, 2018 Telephone Conference; see also docket of these proceedings. Courts may take judicial notice of court dockets. Fed. R. Evid. 201.
[5] UMF: 34
[6] UMF: 34
[7] UMF: 59, 60; Isotretinoin (Accutane) is known to cause birth defects when taken during pregnancy. These birth defects can be severe and include deformities of the heart, face, and brain. These birth defects are like those caused by opioids.

Abatement of the opioid epidemic has always been this court's goal; this proposed preliminary injunction serves this goal:

> So, my objective is to do something meaningful to abate this crisis and to do it in 2018. And we have here -- we've got all the lawyers. I can get the parties, and I can involve the states. So, we'll have everyone who is in a position to do it. And with all of these smart people here and their clients, I'm confident we can do something to dramatically reduce the number of opioids that are being disseminated, manufactured, and distributed. Just dramatically reduce the quantity, and make sure that the pills that are manufactured and distributed go to the right people and no one else, and that there be an effective system in place to monitor the delivery and distribution, and if there's a problem, to immediately address it and to make sure that those pills are prescribed only when there's an appropriate diagnosis, and that we get some amount of money to the government agencies for treatment. Because sadly, every day more and more people are being addicted, and they need treatment. So that's what I am interested in doing.[8]

Anything a pregnant woman ingests or breathes is transmitted to her baby by the placenta.[9] Some things cross the placenta with ease; included among them, are opioids.[10] Opioids are lipid (fat) based and easily cross the placenta; they have an affinity for the developing brain structures which are also lipid based.[11] Science has not (yet) determined what dose of opioid or what length of time opioids are taken that will result in NAS or OUD.[12] Babies with in-utero opioid exposure are subject to addiction and brain and other organ insult.[13]

The CDC has concluded there are hundreds of thousands of children in this country with a NAS or OUD diagnosis.[14] The costs associated with these children in first weaning them from their addiction and then evaluation and services related to their injuries are astronomical.[15] These costs

[8] Rec. Doc. 71, pp 4-5 January 9, 2018 Telephone Conference
[9] UMF: 25
[10] UMF: 25
[11] UMF: 25
[12] UMF: 25
[13] UMF: 25, 34, 36, 37-44
[14] UMF: 51; Only 28 states reported these conditions.
[15] UMF: 99

threaten the budgets of every family with such a child and every political subdivision in the country. The only realistic means of reducing the NAS and OUD births is prevention.

What is proposed here is an economically and medically sound means of eliminating in-utero prescription-opioid exposure. This proposal serves the public by reducing the likelihood of addiction in women, reducing the incidence of medical treatments related to opioid misuse, and facilitating education of opioid dangers to healthcare professionals and the public, and reduces injury to babies not yet conceived.

Women are more likely to be prescribed opioids than men.[16] Women have a higher opioid plasma concentration (up to 25%) more than men on a body weight adjusted basis.[17] This means that the drugs' effects, including the likelihood of addiction, are higher in women than men.[18] The government reports that one third of all pregnant women in this country are prescribed opioids.[19] A natural consequence of opioid use in pregnant women is the tragic increase in the number of children exposed in-utero to opioids.[20] The incidence of children born in this country with a NAS or OUD diagnosis has surged to the point where we are at risk of a lost generation.[21] The problems from in-utero exposure may not end with the baby. A study suggests that opioids modify genes that make addiction more likely in the baby and this modification may carry on generations forward.[22]

The dangers from exposure occurs at any point during pregnancy, save the first 10 to 14 days.[23] In-utero opioid exposure leaves most children with physical, social, educational disabilities that require

[16] UMF: 20
[17] UMF: 21
[18] UMF: 22
[19] UMF: 22, 23
[20] UMF: 33
[21] UMF: 35
[22] UMF: 50
[23] UMF: 31

constant and regular interventions.[24] Most of these disabilities are considered permanent.[25] Medical understanding of NAS, OUD, and addiction remain poorly understood.[26] There is no cure. For those pregnant women who are opioid addicted, the only treatment protocol involves other opioids which also can cause NAS and OUD.[27]

Beyond the epidemic, another result of the defendants' aggressive marketing campaigns to healthcare professionals was to change the medical understanding of opioids from strong respect of their addictive nature and judicious use to more liberal and expansive use based on what we now know was false information that these engineered drugs would not result in addiction.[28] As a result, standards of care and practice concerning opioids changed and are continuing to change. Leading associations of healthcare professionals devoted to the care of women and children have announced practice guidelines covering opioids and pregnancy; caution is the guide.[29] Medical standards of care concerning opioids are evolving and are not consistent nationwide.[30] And, it is no understatement to say that the standards of care regarding opioid administration remain muddled as a result of defendants' conduct.

Sharp rises in addiction and crime resulting from opioid use were first identified in 2000.[31] At that time, the opioid problem was not an epidemic and was limited to a small handful of states.[32] Congress and the Executive Branch, through a number of agencies (FDA, DEA, NIH, SAMSHA and others), joined by states, medical organizations, and others (including some of the defendants)

[24] UMF: 35
[25] UMF: 36-43, 50
[26] UMF: 48
[27] UMF: 45-46
[28] UMF: 56-58
[29] UMF: 58
[30] UMF: 56-58
[31] UMF: 16
[32] UMF: 16

immediately implemented a series of policies and actions to curb the crisis.[33] Notwithstanding these substantial, expensive, and broad-based efforts, the crisis bloomed into our current nationwide disaster.[34] The proposal here- a negative pregnancy test and a seven day limit- was not a part of any of those efforts. It is not unreasonable to say that the first abatement efforts were geared to addiction and crime. No particular efforts were focused on the babies.

The negative pregnancy tests and seven-day limit requirements will protect future babies and their families. It will serve the public interest by assisting healthcare professionals in understanding and abating the opioid epidemic. The costs of reliable pregnancy tests are such that the burden they create is far outweighed by the benefits gained. What is proposed here is entirely consistent with what the FDA requires for Accutane, a non-opioid prescription medication with teratogenic properties.[35] That FDA program is a success and its tenants are followed here to the extent the law governing preliminary injunction allow.

II. PRELIMINARY INJUNCTION SEEKING TO ALTER STATUS QUO IS PERMISSIBLE IF PREVENTING IRREPARABLE INJURY

The purpose of a preliminary injunction is to maintain the status quo until the merits of the case are concluded.[36] Here, admittedly, Petitioners seek something different than maintaining the status quo.[37] But that is no impediment as courts have found that a preliminary injunction is not vulnerable to attack even if it changes the status quo.[38] However, "[i]f the currently existing status quo itself is causing one of the parties' irreparable injury, it is necessary to alter the situation so as to prevent the injury, either by returning to the last uncontested status quo between the parties, by the issuance

[33] UMF: 16
[34] UMF: 6, 14, 15, 16
[35] UMF: 40; https://www.birthinjuryguide.org/birth-injury/causes/medication/accutane/
[36] *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395, 101 S. Ct. 1830, 68 L. Ed. 2d 175 (1981)
[37] *Dominion Video Satellite, Inc. v. EchoStar Satellite Corp.*, 269 F.3d 1149, 1154–55 (10th Cir. 2001); *Aoude v. Mobil Oil Corp.*, 862 F.2d 890, 893 (1st Cir. 1988)
[38] Plaintiffs seek a 'status quo' before the 1995 introduction of Oxycontin and its debilitating effects.

of a mandatory injunction, or by allowing the parties to take proposed action that the court finds will minimize the irreparable injury."[39] "Temporary restraining orders and preliminary injunctions are extraordinary remedies which should be granted only if the movant carries his burden of proving that the circumstances clearly demand it."[40] Where "a preliminary injunction is mandatory—that is, where its terms would alter, rather than preserve, the status quo by commanding some positive action...the requested relief should be denied unless the facts and law clearly favor the moving party."[41] The opioid epidemic is an extraordinary national crisis that requires the exercise of this extraordinary remedy. It is impossible to mandate a return to the pre-Oxycontin status quo. But this injunction realistically seeks to put plaintiffs' in a position where irreparable harm will be avoided during the pendency of this litigation.

III. LEGAL STANDARDS FOR PRELIMINARY INJUNCTION

A preliminary injunction is an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.[42] Plaintiff must prove "(1) whether the movant has a strong likelihood of success on the merits; (2) whether the movant would suffer irreparable injury absent the injunction; (3) whether the injunction would cause substantial harm to others; and (4) whether the public interest would be served by the issuance of an injunction."[43] These factors "simply guide the discretion of the court; they are not meant to be rigid and unbending requirements."[44]

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[39] *Stenberg v. Cheker Oil Co.*, 573 F.2d 921, 925 (6th Cir. 1978)

[40] *Ciavone v. McKee*, No. 1:08CV771, 2009 WL 2096281, at *1 (W.D. Mich. July 10, 2009) (citing *Overstreet v. Lexington-Fayette Urban Cty. Gov't*, 305 F.3d 566, 573 (6th Cir. 2002)

[41] *Glauser-Nagy v. Med. Mut. of Ohio*, 987 F. Supp. 1002, 1011 (N.D. Ohio 1997)

[42] *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 129 S. Ct. 365, 172 L. Ed. 2d 249 (2008). 20 (2008) citing *Munaf v. Geren*, 553 U.S. 674, 689–90, 128 S. Ct. 2207, 171 L. Ed. 2d 1 (2008); *Amoco Prod. Co. v. Vill. of Gambell, AK*, 480 U.S. 531, 542, 107 S. Ct. 1396, 94 L. Ed. 2d 542 (1987); *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311–12, 102 S. Ct. 1798, 72 L. Ed. 2d 91 (1982)

[43] *Hall v. Edgewood Partners Ins. Ctr., Inc.*, 878 F.3d 524, 526–27 (6th Cir. 2017)

[44] *McPherson v. Michigan High Sch. Athletic Ass'n, Inc.*, 119 F.3d 453, 459 (6th Cir. 1997) (*en banc*)

Plaintiff bears the burden of production and persuasion when moving for preliminary injunction.[45] The Supreme Court in *Winter*[46] concluded that courts should weigh the preliminary injunction factors on a sliding scale, allowing a weak showing on one factor to be overcome by a strong showing on another factor. A failure to show a likelihood of irreparable harm remains, standing alone, is sufficient to defeat the motion.[47] The evidence supporting this motion is admissible and cannot be controverted.

IV. PLAINTIFFS VERY LIKELY TO SUCCEED ON MERITS

Plaintiff is Amanda Hanlon, she has sued individually and in a representative capacity for a NAS baby in her care and custody and she also sues here for preliminary and permanent injunction.[48] Amanda came to know the birth mother who was addicted from prescription opioids while pregnant. Amanda understood the baby was at risk and that the birth mother was unable to care for the child. Amanda worked with CPS authorities before birth. She has had sole custody of the baby since discharge from the NICU; she cares for the child along with her own children. She is capable of becoming pregnant and fears that what happened to the birth mother could happen to her. Amy Garner appears on her own behalf and that of her teen-age daughter A.L.D.; she is fearful of the risks like Amanda.

Amanda and Amy have standing to bring this motion.[49] And, they will likely prevail on the merits in their quest for abatement. The defendants' contribution to the opioid epidemic is a fact

[45] *Mazurek v. Armstrong*, 520 U.S. 968, 972, 117 S. Ct. 1865, 138 L. Ed. 2d 162 (1997); *Qualls v. Rumsfeld*, 357 F. Supp. 2d 274, 281 (D.D.C. 2005); *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004)
[46] *Winter*, 555 U.S. 7. 20 (2008); *Six Clinics Holding Corp., II v. Cafcomp Sys., Inc.*, 119 F.3d 393, 399 (6th Cir. 1997)
[47] *Id.*
[48] *See* Exhibit 57: Hanlon Declaration.
[49] *Warth v. Seldin*, 422 U.S. 490, 498, 95 S. Ct. 2197, 45 L. Ed. 2d 343 (1975) The essence of standing is whether the litigant is entitled to have the court decide the merits of the dispute. Since these plaintiffs could be prescribed opioids and are capable of becoming pregnant, they are entitled to have this court decide the merits of the dispute.

recognized by the FDA, the CDC, and the DEA.[50] Their regulatory and criminal settlements along with their many label changes is excellent evidence of their culpability.

V. IRREPARABLE INJURY WILL OCCUR IF A PRELIMINARY INJUNCTION DOES NOT ISSUE

A plaintiff's harm from the denial of a preliminary injunction is irreparable if it is not fully compensable by monetary damages.[51] Such harm must be likely, not just possible.[52] If the nature of plaintiffs' injuries or loss is such that they are difficult to calculate they are irreparable. "The concept of irreparable harm does not readily lend itself to definition,"[53] The harm claimed must be "beyond remediation."[54] 'The key word in this consideration is irreparable. Mere injuries, however substantial, in terms of money, time, and energy necessarily expended in the absence of an injunction are not enough.[55] Case law reveals that when a business seeks a preliminary injunction when the loss threatens the very existence of the movant's business or its reputation, irreparable injury exists."[56]

The risk of in utero exposure to opioids is that once born he or she will suffer a life fraught with physical, social, educational, and other permanent disability. The potential for opioid induced genetic modification may endanger and diminish the quality of life for that family in generations to come. There is no cure for the opioid caused injuries. And, the risk of developing future addiction in these children is real as they were once addicted, and their mother was as well.

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[50] UMF 15

[51] *Winter*, 555 U.S. 7. 20 (2008); *Overstreet*, 305 F.3d at 578; *Basicomputer Corp. v. Scott*, 973 F.2d 507, 511 (6th Cir. 1992); Loss of business goodwill may constitute irreparable harm because of the difficulty of calculating damages." *Langley v. Prudential Mortg. Capital Co., LLC*, 554 F.3d 647, 649 (6th Cir. 2009); *Certified Restoration Dry Cleaning Network, L.L.C. v. Tenke Corp.*, 511 F.3d 535, 550 (6th Cir. 2007); Loss of goodwill is not calculable *Collins Inkjet Corp. v. Eastman Kodak Co.*, 781 F.3d 264, 279 (6th Cir. 2015)

[52] *Id.*

[53] *Judicial Watch, Inc. v. U.S. Dep't of Homeland Sec.*, 514 F. Supp. 2d 7, 10 (D.D.C. 2007),

[54] *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006).

[55] *Morgan v. Fletcher*, 518 F.2d 236, 240 (5th Cir. 1975) (quoting *Virginia Petroleum Jobbers Ass'n v. Fed. Power Comm'n*, 259 F.2d 921, 925 (D.C. Cir. 1958)).

[56] Loss of business goodwill may constitute irreparable harm because of the difficulty of calculating damages." *Langley*, 554 F.3d at 649; *Virginia Petroleum Jobbers Ass'n*, 259 F.2d at 925

The only remedy the law allows for physical and mental injuries is monetary compensation to those already injured. Women often times do not appreciate that they are pregnant for weeks, by then, an unwitting mother has exposed her child to a strong potential of permanent harm.[57] And she is also exposed to the risk of losing her addicted child to child protection services, her liberty, and anguish in the years ahead. This injunction will lessen, if not eliminate, this pathway of irreparable harm.

Irreparable injury is said to be flexible to the point of being elusive.[58] There is nothing elusive about the ability of opioids to adversely affect fetal development. It can occur at any time during the gestation period, save the first 10 to 14 days. Even the treatment protocol for pregnant women abusing, misusing, or taking opioids, involves medications themselves capable of causing NAS and OUD in the infant. Injury to an exposed fetus will occur; the only question is the extent of fetal injury.

The court may take judicial notice that a mother will suffer personal anguish by later learning her actions in taking opioids while pregnant contributed to her child's injury.[59] The costs associated with moderate to severe NAS are high and could easily bankrupt a family or social services. Injury to their offspring may also exist. This potential for permanent injury in children yet to be conceived is real, it is serious, and it is avoidable. The nature of the harm is a certainty.

If irreparable harm includes a loss that threatens the very existence of a business, it must surely include a threat to the quality of a human's very life and that potentially of their children and grandchildren.[60]

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[57] UMF: 24
[58] *Parks v. Dunlop*, 517 F.2d 785 (5th Cir. 1975)
[59] Fed. R. Evid. 201
[60] *Herrera v. Santa Fe Pub. Sch.*, 792 F. Supp. 2d 1174, 1198 (D.N.M. 2011)

VI. BALANCING OF INTERESTS

Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents.[61] The purpose of such interim equitable relief is not to conclusively determine the rights of the parties, but to balance the equities as the litigation moves forward. In awarding a preliminary injunction a court must also "conside[r] ... the overall public interest." [62] In the course of doing so, a court "need not grant the total relief sought by the applicant but may mold its decree to meet the exigencies of the particular case."[63]

In balancing these equities, the relative position of the parties is a worthy consideration. The babies have, of course, 'clean hands.' Those giving birth to them do as well as they began their addiction odyssey with a lawfully issued prescription opioid. The defendants' hands are, however, not clean. And this is so, even if we put aside the charge that defendants knew that their marketing campaigns and statements about addiction, pseudo-addiction, and the like, were knowingly falsely made. It is sufficient that the defendants were in a superior position to these plaintiffs and the information they provided was wrong and subject to much subsequent correction.

The doctrine of unclean hands is an equitable concept that allows a court to deny injunctive relief when the party applying for such relief is guilty of conduct involving fraud, deceit, unconscionability, or bad faith related to the matter at issue to the detriment of the other party. It works against defendants too who oppose the injunctive request.[64]

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[61] *Winter*, 555 U.S. at 20, 24; § 2948Grounds for Granting or Denying a Preliminary Injunction, 11A Fed. Prac. & Proc. Civ. § 2948 (3d ed.)

[62] *Winter*, 555 U.S. 7

[63] Wright, supra, § 2947, at 115

[64] Although the unclean hands doctrine is typically employed by a defendant against a plaintiff who seeks equitable relief, it applies equally to a defendant who seeks equitable relief; while it is not normally employed against a defendant merely brought to court by the suit of another, insofar as a defendant seeks to invoke the powers of the court to bar a plaintiff's claim due to laches, the unclean hands doctrine can foreclose a defendant's laches argument. *Osborn v. Griffin*, 865 F.3d 417 (6th Cir. 2017)

VII. PUBLIC INTERESTS SERVED BY NEGATIVE PREGNANCY TEST REQUIREMENT

Public interests are served by healthy babies and healthy adults. Government and professional efforts undertaken since the opioid problem was first identified have met with only a modicum of success.[65] The court may take judicial notice of the MDL pleadings and similar lawsuits around the country.[66] Most, if not all, seek reimbursement for the increased costs associated with foster care and NAS and OUD births. The negative costs associated with NAS and OUD births burden more than the public coffers, they destroy society and families, today, tomorrow, and for generations to come. These costs far exceed the cost and burden of pregnancy tests and a second office visit.[67]

VIII. GRANTING THE INJUNCTION WILL NOT CAUSE SUBSTANTIAL HARM TO OTHERS

The I-Pledge (Accutane) program is evidence that institutional requirements, like those sought here, do protect babies from teratogenic injuries.[68] The costs associated with the proposal here are urine pregnancy tests and communications between the physician and the dispensing agent.[69] The manufacturers can require this communication of their distributors and dispensers. Communications between physicians and pharmacies can, in most cases, be accomplished electronically. Another opportunity for the patient to confer with a physician about pain and treatment options benefits both. Anyone recently filling a prescription will have encountered delays associated with insurance companies and the like, the proposal adds a slight burden to an already busy transaction.

[65] Ohio, for example passed several laws and its health department issued opioid guidelines. Though some progress was noted, Ohio health officials remain unsatisfied. UMB: 15
[66] FRE Rule 201
[67] UMF: 53, 55
[68] UMF: 60
[69] UMF: 53, 55

There will, of course, be exceptions to the preliminary injunction such as surgical patients or those with chronic diseases like sickle cell or lupus.[70] Working through these details will take some effort but nothing that outweighs the gains to be achieved by the preliminary injunction. Pain will and can be treated, and future babies will not be injured.[71] There are non-opioid pain medications available to potential patients like the plaintiffs.[72]

IX. RELIEF REQUESTED

Women, children, and families will be strengthened by this preliminary injunction as the incidence of in-utero opioid exposure will be substantially reduced. A natural consequence of strong and healthy families is a strong and healthy country. Medical, social, education, and countless other public expenses will be preserved for other uses including helping the NAS/OUD population that already exists. The costs associated with the injunction are negligible when compared to the costs associated with NAS and OUD.

The preliminary injunction should be granted.

Respectfully submitted,

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[70] Exhibit 29: Anand Declaration
[71] UMF: 62
[72] UMF: 62

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on 28TH of March 2019, the foregoing document was served on all counsel of record by the CM/ECF system.

/s/ Celeste Brustowicz
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