IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, KBI-E, INC., KBI, INC. and ASTRAZENECA LP, Plaintiffs, v. DEXCEL LTD., DEXXON LTD., DEXCEL PHARMA TECHNOLOGIES LTD. and DEXCEL PHARMA TECHNOLOGIES, Defendants.	Civil Action No. 06-358 (SLR) **REDACTED PUBLIC VERSION**

DEFENDANTS' REPLY BRIEF IN SUPPORT OF ITS MOTION TO TRANSFER OR DISMISS

November 30, 2006

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I. SUMMARY OF THE ARGUMENT

Plaintiffs and their affiliates reportedly earn $800,000,000 per year on sales of Prilosec® OTC, which sales are currently protected by the asserted patents. Ex. 1.[1] Unless Dexcel Pharma Technologies Ltd. ("DPT Ltd.") completes its challenge to two of the asserted patents, which expire in April 2007, Plaintiffs will win *by default* an additional six month period of exclusivity worth approximately $400,000,000. *See* n. 2, *infra*. This is why Plaintiffs seek to delay resolution of this action, including by litigating in this Court. They have no need to prevail on the merits if they can continue to manipulate the courts into a delaying a trial for a few more months.

The ultimate venue for this action, whether Delaware or Virginia, has enormous implications for the parties. This Court has indicated that its docket will not permit a trial any earlier than November 2007. The Virginia court, on the other hand, previously indicated that it could try this action as early as January 2007. Ex. 2. The Virginia court thus offers the opportunity of a trial; this Court does not.

It would be an extreme miscarriage of justice if Plaintiffs reaped an unwarranted windfall simply because the courts were "too busy" to bring this action to trial. Plaintiffs filed this action in May 2006; they should be prepared to try this action prior to April 2007. DPT Ltd. is entitled to its day in court.

The American public also has an overriding interest in this action being tried before the expiration of these patents. It should be offered the opportunity to purchase DPT Ltd.'s lower cost generic products if they do not infringe the asserted patents. The Virginia court offers the best hope for definitive resolution of this matter prior to April .

[1] All Exhibits are included in the attached Declaration of Saumil S. Mehta.

2007, and this action should be transferred to that court without further delay.

In the alternative, this action should be dismissed for lack of personal jurisdiction. Plaintiffs' 40 page Opposition fails to identify even a single direct contact between DPT Ltd., the party that filed the NDA at issue, and Delaware. Not one. This is because none exist. Plaintiffs have likewise completely failed to establish this Court's personal jurisdiction over any other Defendant.

In evaluating the personal jurisdiction issue, the Court should reject Plaintiffs' attempt to lump together under the name "Dexcel" three separate legal entities: Dexxon Ltd., Dexcel Ltd. and Dexcel Pharma Technologies Ltd. Although Plaintiffs bear the burden of establishing personal jurisdiction over *each* of these entities, their Opposition erroneously attributes the activities of certain of these entities to others. Plaintiffs have utterly failed to establish which "Dexcel" entity, if any, conducted the activities alleged to support jurisdiction, and the Court cannot simply presume that each did.

Plaintiffs hint throughout their Opposition that the Court should perhaps disregard the corporate form of these entities due to common ownership or control. They acknowledge in a footnote, however, that they do not actually rely on any theory of "agency" or "alter ego" to pierce the corporate structure. *See* Plaintiffs' Brief in Opposition (hereinafter "Opp.") at 27, n.19. Plaintiffs cannot therefore treat Defendants as a single monolithic entity for the purpose of personal jurisdiction. The Court should treat Plaintiffs' failure to connect the source of alleged jurisdictional contacts with a particular Defendant as a failure of proof of *any* alleged jurisdictional contact.

Even if this Court does treat Defendants as one entity, which it should not, Plaintiffs' arguments still fail. Plaintiffs rely only on a theory of "general" jurisdiction,

see Opp. at 16 (*citing* 10 DEL. C. § 1034(c)(4)), which requires "a higher level of regular contacts in the State than [for]. . .'specific jurisdiction.'" *Saft Am., Inc. v. Ovonic Battery Co.*, No. CIV. A. 95-430-SLR, 1996 WL 190008, at *3 (D. Del. Mar. 25, 1996). Plaintiffs specifically advance three inapposite arguments in support of general jurisdiction: (1) "Dexcel" derives substantial revenue in Delaware from sales of dental products wholly unrelated to this action; (2) "Dexcel" maintains a Delaware corporation; and (3) "Dexcel" distributors advertise dental products in Delaware. Opp. at 19. These arguments are factually and legally baseless.

This Court has held "the general jurisdiction provision of the long-arm statute does not anticipate that placing a product into the stream of commerce would give rise to jurisdiction." *Merck & Co., Inc. v. Barr Labs., Inc.*, 179 F.Supp.2d 368, 373-74 (D. Del. 2002). This Court has further held that sales to national distribution chains that may do business in Delaware are too attenuated to warrant the exercise of general jurisdiction. *Id.* Third party sales of dental products in Delaware, which are both *de minimis* and unrelated to Plaintiffs' claims, cannot support general jurisdiction.

In addition, and contrary to Plaintiffs' argument, Dexcel Pharma Inc. ("DPI") is no longer a Delaware corporation and has not been one since at least March 2005. Indeed, Plaintiffs' own evidence establishes this fact. The report attached as Ex. 34 to Plaintiffs' Opposition state that DPI is a "VOID" entity that has not filed an annual report since 2002. By operation of law, this entity ceased to exist in 2005 after to a three year period of dormancy. 8 DEL. C. § 510. The former existence of DPI in Delaware cannot be a contact that establishes general jurisdiction over entirely different "Dexcel" parties in May 2006, the date of the lawsuit. Even if DPI still existed, and it does not, it could

not be considered a contact of Defendants, none of which own or control it. This is particularly true in view of Plaintiffs' express disavowal of any theory of agency or veil piercing in relation to Defendants. *See* Opp. at 27, n.19. DPI is completely irrelevant.

The absence of any meaningful contact (let alone *direct* contact) between the Defendants and Delaware necessarily means that this Court may not, under the due process clause of Fourteenth Amendment, exercise "general" personal jurisdiction over the Defendants. The Court, however, can and should avoid making a Constitutional pronouncement. It should simply transfer this action to Virginia.

II. STATEMENT OF ADDITIONAL FACTS

Plaintiffs have asserted U.S. Patent Nos. 4,786,505 ("the '505 patent") and 4,853,230 ("the '230 patent") against the Defendants. D.I. 1. These two patents expire in April, 2007. See Ex. 3. These patents purportedly protect the product sold as Prilosec® OTC, which is a drug used to treat stomach acid. Opp. at 4. Plaintiffs and their affiliates reportedly earn $800,000,000 per year on sales of Prilosec® OTC. Ex. 1. These patents thus allegedly protect approximately $2,000,000 per day in sales.

DPT Ltd., Dexcel Ltd. and Dexxon Ltd. are separate and distinct entities under Israeli law. Each Defendant, with the exception of the non-entity Dexcel Pharma Technologies, maintains separate financial documentation to respect the corporate form. Ex. 4, Oren Dep. 150:9-11. DPT Ltd. has independent manufacturing capabilities and is an independently capitalized entity in which Dexcel Ltd. and Dexxon Ltd. have no equity interest. *Id.* at 51:8-10; 155:14-156:6. DPT Ltd. maintains an office in Norfolk, Virginia and in no other forum in the U.S. *Id.* at 67:19-69:2. DPT Ltd. is the only Defendant that owns the subject NDA No. 22-032. *Id.* at 234:5-236:16.

All products manufactured by Dexcel Ltd. and DPT Ltd., which does not include products manufactured according to the NDA at issue in this lawsuit, are sold in the U.S. by third-party distributors with nationwide distribution. No Defendant or other "Dexcel" party sells directly to U.S. customers. Ex. 5, Jackson Dep. 25:19-26:8. DPT Ltd. has given Omnii Oral Pharmaceuticals ("Omnii") the U.S. distribution rights for two DPT Ltd. dental products, Periochip® and Xantia®. *Id.* at 22:12-17; 25:4-26:8. None of the Defendants ever instructed Omnii to makes sales in Delaware. *Id.* at 63:14-18. Omnii is solely in charge of its sales strategy for the Periochip® and Xantia® products. *Id.* at 65:3-10.

REDACTED

Ex. 6. Dexcel Ltd. has given Watson Pharmaceuticals, Inc. ("Watson") the U.S. distribution rights for its diclofenac sodium product. None of the Defendants ever instructed Watson to make sales in Delaware. Since 2003,

REDACTED is attributable to Delaware. Ex. 7.

III. ARGUMENT

In the interests of judicial economy, Defendants respectfully request that this Court transfer this action for consolidation with the duplicative action pending in Virginia. Alternatively, and pursuant to FED. R. CIV. P. 12(b)(2), Defendants respectfully move that this action be dismissed for lack of personal jurisdiction.

A. This Action Should Be Immediately Transferred to Virginia

Time is of the essence in this litigation. Because of the four-month delay caused by Plaintiffs, the window of opportunity to try this case is closing. Specifically, two of the patents asserted by the Plaintiffs, the '505 and '230 patents, expire in April 2007. If

these patents expire prior to a trial, the AstraZeneca parties will obtain, by default, an additional six-month period of exclusivity.[2] Unless a district court addresses the merits of this action before April 2007, jurisdiction over the patents will be lost and the public will have been denied by Plaintiffs' abusive procedural tactics an opportunity to purchase a lower cost, non-prescription version of omeprazole until, at least, October 2007.

The Court may transfer this action to Virginia pursuant to 28 U.S.C. § 1406 because Plaintiffs contend that this action could have been brought in the Eastern District of Virginia, which is not disputed by Defendants. Ex. 8, at p. 2. The Court may also transfer this action pursuant to 28 U.S.C. § 1404(a) for the convenience of the parties and witnesses and in the interests of justice. The analysis of § 1404(a) transfer is broad and encompasses numerous factors. *Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879 (3d Cir. 1995). In particular, courts should consider both private and public interests. *Id.*

1. The Private Interest Factors Favor Transfer

In its initial scheduling order, the Virginia court indicated it could preside over a trial before the April 2007 expiration of the '505 and '230 patents. See Ex. 2. This Court has contrariwise indicated that the earliest possible date for a trial is November 2007, a date long after the expiration of these patents.

Defendants obviously have a strong interest in transferring this action to Virginia because they will otherwise lose their ability to challenge two of the patents. Plaintiffs

[2]The reason for this relates to the AstraZeneca parties' claim of "pediatric exclusivity." During the terms of the '505 and '230 patents, and for a potential six-month period thereafter, the Food and Drug Administration ("FDA")will not approve a generic drug manufacturer's application to make and sell a drug prior to the expiration of an automatic 30-month period or a judgment in the generic manufacturer's favor, whichever occurs first. See 21 U.S.C. § 355; 35 U.S.C. § 271(e). In the event a patent expires during litigation without judgment, however, district courts (under current case law) lose subject matter jurisdiction over the dispute. The additional six-month

likewise have no legitimate reason to avoid a trial on the merits of their own claim. If this Court immediately transfers this case to Virginia, the parties will have a chance to address the merits before the expiration of two patents. The private interests thus favor the forum (Virginia) that can actually conduct a trial within the limited time available.

2. The Public Interest Factors Favor Transfer

The public interest factors in this case also clearly indicate that this action should be transferred to Virginia. The American public reportedly pays to Plaintiffs and their affiliates $800,000,000 per year on sales of Prilosec® OTC. Ex. 1. This amounts to approximately $2,000,000 per day in sales, or an astounding $400,000,000 over the six months of additional exclusivity that Plaintiffs will gain *by default* if they succeed in convincing this court to deny transfer. This payment might be warranted if the products at issue actually infringed the asserted patents. They do not. But, even to the extent that there is a legitimate dispute on this point, the public will pay for exclusivity by default and, in so doing, reward Plaintiffs for their abuse of process.

There is no legitimate public interest reason for Plaintiffs to win by default. Failure to transfer this action to Virginia would be manifestly against the interests of justice and the public's interest in a timely adjudication of this action.

3. Plaintiffs' Delay Tactics Further Favor Transfer

Plaintiffs have long possessed samples of the products at issue. Despite their enormous financial interest in the outcome of this action, they have yet to explain to Defendants exactly how these products infringe the patents in suit, including particularly the two patents expiring in 2006. Plaintiffs are clearly trying to run out the clock.

"pediatric exclusivity" period recognized by the FDA, therefore, effectively cannot be challenged. *Ranbaxy Labs. v. U.S. Food and Drug Administration*, 307 F.Supp.2d 15, 21 (D.D.C. 2004).

This Court's August 10, 2006 scheduling order required Plaintiffs to conduct jurisdictional discovery in an "expeditious manner." D.I. 31. Plaintiffs have been anything but expeditious. All told, Plaintiffs delayed briefing for 4 months. Defendants ultimately forced Plaintiffs' hand with an emergency request to have this motion heard on December 6, 2006. Absent this request, Plaintiffs likely still would not have filed a brief.

There is no reason to reward Plaintiffs' delay tactics. At the earliest stages of this action, Defendants informed the Court of the timing issues in this case. That is why the Court's Scheduling Order required Plaintiffs to proceed "in an expeditious manner." Plaintiffs nevertheless engaged in a series of procedural maneuvers designed to delay all proceedings, including a successful request to stay the Virginia action and a failed request to the Judicial Panel for Multidistrict Litigation to transfer this action to yet another court, the Southern District of New York. Ex. 9. Given these attempts to manipulate venue, Plaintiffs should not now be heard to complain that the Defendants have engaged in "forum shopping." Opp. at 2.

B. <u>This Action Should Be Dismissed For Lack of Personal Jurisdiction</u>

Plaintiffs, which have conducted extensive discovery of Defendants, bear the burden of establishing with "reasonable particularity" that sufficient minimum contacts have occurred between Defendants and Delaware to support jurisdiction. *Monsanto Co. v. Syngenta Seeds, Inc.*, 443 F.Supp.2d 636, 642 (D. Del. 2006). Plaintiffs must present facts sufficient to establish a statutory basis for jurisdiction under the Delaware long arm statute and that such exercise of jurisdiction comports with Defendants' right to due process. *Id.* at 642-43. In particular where the defendants are foreign parties, the Supreme Court has stated that "[g]reat care and reserve should be exercised when

extending our notions of personal jurisdiction into the international field." *Id.* at 643.

1. Plaintiffs Opposition Fails to Establish Jurisdiction Over Each of the Separate and Independent Defendants

Plaintiffs' attempt to establish jurisdiction over each of the Defendants fails because Plaintiffs do not identify with the required "reasonable particularity" specifically which Defendants engaged in the contacts alleged to support jurisdiction. DPT Ltd., Dexcel Ltd. and Dexxon Ltd. are recognized by the state of Israel as separate and distinct legal entities. Ex. 4, Oren Dep. 27:19-28, 14; 165:11-166:12. Each of these Defendants maintains separate board meetings and minutes, separate financial documentation, files separate tax returns, and is audited separately in respect of the corporate form. *Id.* at 87:17-21. DPT Ltd. has independent manufacturing capabilities, *Id.* 51:8-10, and is independently capitalized. Neither Dexcel Ltd. nor Dexxon Ltd. has equity interest in DPT Ltd. *Id.* at 155:14-156:6. Nor do Defendants own or control DPI, upon which defunct entity Plaintiffs heavily rely as a contact with Delaware.

Plaintiffs do not assert that Defendants failed to operate under corporate formalities such that their respective corporate structures may be disregarded. Indeed, Plaintiffs expressly acknowledge the opposite: "AstraZeneca's theory does not depend on any notions of agency or 'alter ego'/'piercing the corporate veil'." Opp. at 27, n.19.

Plaintiffs' forego these alternative theories of personal jurisdiction because there is absolutely no evidence to support them. The alter ego theory applies "only in the interest of justice, when such matters as fraud, contravention of law or contract, public wrong, or where equitable consideration among members of the corporation require it, are involved." *Bell Helicopter Textron, Inc. v. C&C Helicopter Sales, Inc.*, 295 F.Supp.2d 400, 407-08 (D. Del. 2002) (internal quotation omitted). In this case, there is

absolutely no evidence of fraud or illegality. An agency theory would likewise require evidence that does not exist. Among other things, Plaintiffs would have to establish the parent had actual, participatory and total control of the subsidiary. *Akzona Inc. v. Du Pont De Nemours & Co.*, 607 F.Supp. 227, 237 (D. Del. 1984). Absent such proof, which Plaintiffs do not attempt to produce, it is presumed that substantial control does not exist. *See Mellon Bank, N.A. v. Metro Comms., Inc.*, 945 F.2d 635, 643 (3d Cir. 1991).

Plaintiffs' attempt to treat all Defendants, as well as other "Dexcel" entities, as a single monolithic entity should be rejected. In addition, Plaintiffs failure to connect specific alleged contacts with specific Defendants should be treated as a complete failure of proof as to any alleged jurisdictional contact. In particular, Plaintiffs have failed to allege even a single specific contact between any specific Defendant and Delaware. None of these parties maintain an office or employees in Delaware, and none pay Delaware taxes. In addition, none sell directly in Delaware. Accordingly, absent any evidence connecting any specific Defendant with Delaware, there is no basis for general jurisdiction over them in Delaware.

2. **Defendants Are Not Subject To This Court's Jurisdiction**

DPT Ltd.'s filing of NDA 22-032 is a highly artificial act of infringement that does not provide a basis for ***specific*** jurisdiction. *Zeneca Ltd. v. Mylan Pharms., Inc.*, 173 F.3d 839 (Fed. Cir. 1999). Plaintiffs apparently agree that Defendants are not subject to specific jurisdiction under Delaware's long-arm statute §§ 3104(c)(1), (2), or (3) because they do not argue that any of these sections apply. As a result, Plaintiffs are forced to contend that Defendants are subject to ***general*** jurisdiction in Delaware under 10 Del. C. § 3104(c)(4). *See* Opp. at 1, 15-16.

Cases of general jurisdiction in Delaware are rare. *Commissariat a L'Energie Atomique v. Chi Mei Optoelecs Corp.*, 293 F.Supp.2d 423, 429 (D. Del. 2003). Plaintiffs must establish that Defendants' activity in Delaware is "continuous and substantial." *See Sears, Roebuck & Co. v. Sears plc.*, 744 F.Supp.1289, 1304 (D. Del. 1990). Plaintiffs must further show "significantly more than mere minimum contacts." *Foster Wheeler Energy Corp. v. Metallgesellschaft AG*, 1993 WL 669447, *3 (D.Del., Jan. 4, 1993).

Plaintiffs advance only three inapposite arguments in support of general jurisdiction: (1) "Dexcel" derives substantial revenue in Delaware from sales of products wholly unrelated to this action; (2) "Dexcel" maintains a Delaware corporation; and (3) "Dexcel" distributors advertise dental products in Delaware. *See* Opp. at 19. These arguments are factually and legally baseless. Indeed, Plaintiffs' argument completely ignores Delaware case law regarding "stream of commerce" jurisdiction under section 3104(c)(4) and instead attempts to lead this Court, in further abuse of process, along a circuitous route of case law from Illinois, New York, the District of Columbia, Louisiana, Texas, and the Virgin Islands, all of which is entirely distinguishable on the facts.

a) Revenue Derived From the Sale of Unrelated Products in Delaware is Insubstantial

Plaintiffs' contention that Defendants allegedly generated "substantial revenue" in Delaware is simply incorrect. The dental products identified by Plaintiffs as being sold in Delaware are entirely unrelated to the cause of action. Moreover, these products reached Delaware after being placed in the stream of commerce by independent third-party distributors. In any event, the revenue percentages for all of the unrelated products are so small as to be insignificant. There is no evidence any of Defendants had the intent and purpose of reaching Delaware customers in particular.

Plaintiffs' Opposition, in a glaring omission, presents percentage sales in Delaware for only Periochip®, which is sold by Omnii and Omnii's distributor Benco Dental. By omitting the sales revenue numbers for the remaining products, Plaintiffs misrepresented the facts in an apparent attempt to mislead this court. Plaintiffs' brief reports that of Omnii's and Benco Dental's total U.S. sales revenue for Periochip® product is attributable to Delaware, Opp. at 13, but omits any mention of the even lower Delaware sales percentages for the Xantia® and diclofenac sodium products.[3] Only of Omnii's U.S. sales for the Xantia® product, Ex. 6, and of Watson's U.S. sales for diclofenac sodium, Ex. 7, are attributable to Delaware. **REDACTED**

Delaware law makes it clear that 2-3% total revenue is sufficient to confer general jurisdiction, and that revenue less than 1% is insufficient to confer general jurisdiction, especially when derived from the sale of products unrelated to the cause of action. *See, e.g., M&M Techs., Inc. v. Gurtler Chem. Co., Inc.*, 2005 WL 293509, *5 (D. Del., Feb. 8, 2005) (0.007% and 0.14% insufficient); *Bell Helicopter Textron, Inc.* 295 F.Supp.2d at 405 (< 1% insufficient); *Merck*, 179 F.Supp.2d at 368 (0.13% insufficient); *Cont'l Trading Co. v. Naporano Iron & Metal Co.*, 1997 WL 297661 (D. Del. 1997) (0.0013% insufficient); *Foster Wheeler Energy Corp. v. Metallgesellschaft AG*, 1993 WL 669447, *6 (D. Del. 1993) (0.007% and 0.005% insufficient); *United States v. Consol'd Rail Corp.*, 674 F.Supp. 138, 144 (D. Del. 1987) (< 1% insufficient).

Regardless of whether this Court applies Delaware law rigidly or flexibly, the paltry stream of commerce sales of any of Defendants' unrelated products in Delaware sales, totaling a mere ~0.1-~0.3% of national revenue, are manifestly insufficient to

[3] A fourth product authorized for sale in the United States is extended release isosorbide mononitrate (ISMN ER), which has not yet been sold in the United States.

confer *general* jurisdiction. Plaintiffs' argument that ~0.3% total sales is "substantial" relies on only *specific* jurisdiction cases where the sales at issue were for products directly relating to the cause of action.[4] Plaintiffs either do not understand these distinct legal theories, or they do and improperly cited specific jurisdiction cases as support of their general jurisdiction theory. Regardless, the sales of a small amount of unrelated products by third parties is an insufficient basis upon which general jurisdiction may be predicated. Plaintiffs reliance on *Magid v. Marcal Paper Mills, Inc.*, 517 F.Supp. 1125 (D. Del. 1981), is misplaced. The defendant, Marcal, *directly* contacted Delaware, by regularly visiting to sell to retailers and to supervise a wholesale account. *Id.* at 1127-28.

In this case, Defendants' dental products are unrelated to this action and the indirect and limited sales in Delaware cannot establish personal jurisdiction in Delaware. Plaintiffs' cited law makes clear that when jurisdiction is based on the sale of products unrelated to the cause of action, a volume of sales less than 0.3% without more, even if in proportion to the state population, falls far short of being "substantial and continuous."

b) Defendants Do Not "Maintain" A Delaware Corporation

Plaintiffs' second argument fares no better than their first. The existence of Dexcel Pharma Inc. ("DPI"), an entity recognized by the Delaware Secretary of State as

[4] *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1566 (Fed. Cir. 1994) (jurisdiction based on "substantial" sales found where defendants sold allegedly infringing product to Delaware residents); *Stabilisierungsonds Fur Wein v. Kaiser Stuhl Wine Distrib.*, 647 F.2d 200, 206 (D.C. Cir. 1981) (jurisdiction based on "substantial" sales found where defendants sold allegedly infringing wine to a Delaware business); *Curtis Publ'g Co. v. Golino*, 383 F.2d 586, 591 (5th Cir. 1967) due process satisfied on basis of sales of newspapers and magazines containing the allegedly libelous, defamatory, or slanderous content; *Schwegmann Bros. Giant Super Markets, Inc. v. Pharmacy Reports, Inc.*, 486 F.Supp. 606, 611-12 (E.D. La. 1980) (same); *Samad v. High Soc'y Magazine*, 1983 WL 1752, *2 (D.V.I. 1984) (same); *Akbar v. NY Magazine Co.*, 490 F.Supp. 60, 65 (D.D.C. 1980) (same); *Stabler v. NY Times Co.*, 569 F.Supp. 1131, 1134 (S.D.Tex. 1983) (same); *Delahanty v. Hinckley*, 686 F.Supp. 920, 923 (D.D.C. 1986) (jurisdiction

having a "void" status since March 2005, *see* Opp. Fulton Decl. Ex. 33., is of absolutely no import to this analysis. Sufficient contacts must exist at the time the action arose. *Simplicity Inc. v. MTS Prods., Inc.*, 2006 WL 924993, *3 (E.D Pa. Apr. 6, 2006) (*citing Metro. Life Ins. Co. v. Robertson-Ceco Corp.*, 84 F.3d 560, 569 (2d Cir. 1995)).

Plaintiffs allege that because another "Dexcel" entity, which is not a Defendant, created and operated a Delaware corporation, which is also not a Defendant, each of the Defendants somehow availed themselves of Delaware law. Defendants neither own nor control DPI, and Plaintiffs agree DPI is not Defendants' alter ego or agent. Opp. at 27, n.19. Moreover, as discussed above, each of Defendants is a separate and independent entity. According to Plaintiffs' organizational chart, DPI is at least 4 or 5 steps removed from Dexxon, Ltd., Dexcel, Ltd. and DPT Ltd. Opp. at 5. In addition, DPI has been inactive and totally defunded since 2004. Indeed, DPI has not paid the statutorily required franchise fee since 2004, and accordingly has been dissolved by operation of law. *See* 8 DEL. C. § 510. Plaintiffs point to DPI's name appearing on some leftover marketing materials and an infrequently updated website. Opp. at 10. Such facts are irrelevant to whether DPI exists or not. Plaintiffs also point to Dan Oren's testimony in which he jokingly offers to sell DPI "on the cheap" in an effort to highlight what a business failure DPI had been. Ex. 4, Oren Dep. at 59:2-21. Mr. Oren's attempt at humor is hardly evidence of DPI's continued existence.

Even if actions taken by DPI during its existence can be attributed to some or all of the Defendants, DPI's Delaware contacts are still insufficient to establish jurisdiction over Defendants. DPI's incorporation in Delaware is only relevant insofar as it

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based on sales of handguns alleged to have caused injury); *Ajax Realty Corp. v. J.F. Zook, Inc.*, 493 F.2d 818, 821 (4th Cir. 1972) (jurisdiction based on sales of injury-causing windows).

constitutes a jurisdictional act that may be attributed to Defendants. Absent alter ego or agency theory, DPI's creation cannot be attributed to Defendants, which have no ownership interest in DPI. Even if DPI's incorporation was attributable to Defendants, Delaware courts hold mere creation of a Delaware entity insufficient to confer general jurisdiction. *Monsanto Co.*, 443 F.Supp.2d 636, 646 (D.Del. 2006); *Applied Biosys., Inc. v. Cruachem, Ltd.*, 772 F.Supp. 1458, 1469 (D.Del. 1991).

Plaintiffs can point to no other activity in Delaware related to the existence of DPI beyond its incorporation there and in particular have not shown DPI's contacts with Delaware were continuous and systematic. DPI never engaged in business activity of any type within Delaware. DPI's principal place of business was in Edison, New Jersey and while it was in existence, the volume of sales in Delaware fell far short of satisfying the requirement of "continuous and systematic" contacts with Delaware.

c) The Defendants Do Not Advertise in Delaware

Plaintiffs' final argument regarding Delaware is, once again, factually and legally incorrect. Defendants do not solicit business or directly advertise to Delaware residents and Plaintiffs' carefully worded argument to the contrary does not establish the opposite. The relevant third-party distributors act independently of any of Defendants and are the only entities making sales to Delaware customers. Plaintiffs cannot attribute the distributors' acts to Defendants. Defendants do not control the distributors at any level and thus are not responsible for any advertising or solicitations made in Delaware.

The Periochip® and Xantia® product websites are for informational purposes only. At most, web users can request information about the listed products via email. Operating such a website is not a sufficient to establish personal jurisdiction. *Miller*

Yacht Sales v. Smith, 384 F.3d 93, 106 (3d Cir. 2004). Even a commercially interactive website is not by itself a sufficient basis for personal jurisdiction. *Toys "R" Us v. Step Two*, 318 F.3d 446, 454 (3d Cir. 2003). Mere maintenance of an interactive website is insufficient to support personal jurisdiction in the absence of evidence indicating that the website operator intentionally aimed the website at a forum state or knowingly conducted business with forum residents via the website. *Sanitec Inds., Inc v. Sanitec Worldwide, Ltd.*, 376 F.Supp.2d 571 (D. Del. 2005). Here, Plaintiffs have failed to identify which Defendant they seek to "tag" with the relevant websites. In addition, none of the Defendants do anything more than maintain an informational website on which users have the ability to email questions. There is absolutely no evidence that any Delaware resident has ever seen, let alone used, the websites in question. Finally, Delaware residents cannot order Defendants' products from these websites. Plaintiffs' attempt to connect all Defendants to Delaware via the World Wide Web is insufficient.

3. **Plaintiffs' Reliance on *Abbott* and *Purdue* Is Misplaced**

Other than specific jurisdiction cases, Plaintiffs rely only on *Abbott Labs. v. Mylan Pharm., Inc.*, 2006 WL 850916 (N.D. Ill. 2006) and *Purdue Pharma L.P. v. Impax Labs., Inc.*, 2003 WL 22070549 (S.D.N.Y. 2003), both of which are distinguishable. The *Abbott* and *Purdue* courts found defendants subject to general jurisdiction only because they engaged in substantial sales or solicitation in the forum as well as several "plus factors" which, in aggregate, were "systematic and continuous contact."

In *Abbott*, the court held that defendant, Mylan, had availed itself of Illinois in at least five different ways, which, when viewed in aggregate, were sufficient to confer general jurisdiction. The court specifically noted that Mylan's sales were insufficient to

warrant exercise of jurisdiction even though such sales were in proportion to the relative customer population of the forum state at more than 3-5% of total sales. *Abbott Labs.*, 2006 WL 850916 at *4. Accordingly, the court further considered "plus factors": (1) the existence of Mylan licenses in Illinois, (2) Mylan's interactive website, (3) Mylan's many contracts with Illinois, and (4) Mylan's prior consent to litigation in Illinois. *Id.* at *5-*6.

Defendants, in contrast to Mylan's Illinois contacts, have no licenses in Delaware, no contracts in Delaware, and no prior litigation in Delaware. Thus under *Abbott*, even if this Court finds the revenues generated by third-party sales of Defendants' other products in Delaware "substantial," exercise of general jurisdiction is not warranted because, at most, only one "plus factor" (a national website operated by one Defendant) is present.

Plaintiffs' reliance on *Purdue Pharma* is equally misguided. In this case, the court held Impax's *direct* sales of unrelated products to New York customers constituted 3.61% ($590,477) of its total sales revenue and when combined with its distributors' sales in New York the percentage rose to ~8%. *Purdue*, 2003 WL 22070549 at *2. Although the dollar value ($1.1-$1.5 million) of Impax's New York revenue was substantial, the court still relied on "plus factors," as did the *Abbott* court, to establish general jurisdiction over Impax. *Id.* The court noted Impax additionally (1) *directly* solicited business in New York through advertising and mailing brochures to customers; (2) made *direct* sales calls to New York customers; (3) operated a website that solicited business nationally; (4) *directly* sought investment capital from New York investment banks, while its CEO solicited capital from hedge funds and private investors in New York; and, (5) developed plans with New York underwriters to issue stock. *Id.* at *1-2.

In contrast, Defendants never directly solicited business in Delaware, and what

advertising or sales calls made to sell Defendants' dental products in Delaware was undertaken not by Defendants but by third-party distributors on their own volition. Most significantly, none of Defendants ever solicited capital from any Delaware investment bank, hedge fund, private investor, or through the underwriting process.

Considered in aggregate, the small percentage of revenue generated by third-party sales of Defendants' unrelated products in Delaware and Defendants' lack of direct Delaware contacts relied upon as plus factors by the *Abbott* and *Purdue* courts are clearly insufficient to support general jurisdiction over Defendants in Delaware.

4. Exercise of Personal Jurisdiction Over Defendants Would Not Comport With the Due Process Clause of the U.S. Constitution

Dexxon Ltd., Dexcel Ltd. and DPT Ltd. have absolutely no physical presence in Delaware, and never made, used, or sold DPT Ltd.'s omeprazole tablets in Delaware. Even assuming *arguendo* that the Delaware long-arm statute is applicable to Dexcel Ltd. and DPT Ltd., Plaintiffs have failed to show that the maintenance of the suit does not "offend traditional notions of fair play and substantial justice." *Helicopteros Nacionales De Colombia S.A. v. Hall*, 466 U.S. 408, 414 (1984) (*citing Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). In particular, Plaintiffs have failed to demonstrate that any Defendant in particular should have reasonably anticipated being haled into Delaware.

DPT Ltd.'s NDA filing is a "highly artificial" act of infringement. *Zeneca*, 173 F.3d at 839. Accordingly, Plaintiffs' claim that all Defendants are imminently embarking on an infringing course of action is entirely premature. Indeed, the entire purpose of this litigation is to avoid infringement by having the patents at issue adjudicated invalid or not infringed before any product is sold. Similarly premature are Plaintiffs' assertions of future inducement of infringement by Dexcel Ltd. and Dexxon Ltd. Although

inducement is a recognized cause of action, Plaintiffs did not plead it and, in any event, Plaintiffs' cases cited are entirely distinguishable insofar as they establish only the existence of subject matter, not personal, jurisdiction.

Also, contrary to Plaintiffs' assertion that DPT Ltd.'s NDA filing constitutes a purposeful directed act towards Plaintiffs in Delaware; the Federal Circuit has considered and rejected that the situs of "injury" in patent infringement cases is the patentee's residence. *N. Am. Philips Corp. v. Am. Vending Sales, Inc.*, 35 F.3d 1576, 1579 (Fed.Cir. 1994); *Beverly Hills Fan Co.*, 21 F.3d 1558, 1571 (Fed. Cir. 1994). Therefore, Plaintiffs cannot claim that an injury will occur in Delaware upon approval of DPT Ltd.'s NDA.

Consideration of the relevant factors makes it clear jurisdiction over Defendants in Delaware is improper. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 474 (1985). First, Defendants would be burdened by having to litigate the claim in Delaware insofar as Defendants have no contacts with Delaware. Second, Delaware has no greater interest in adjudicating this dispute than Virginia, as all states have "an interest in discouraging patent infringement within [their] borders." *Amalia v. Conopco, Inc.*, 1995 WL 8055, *3 (E.D.Pa. 1995). Third, Plaintiffs cannot complain about Virginia: they admit jurisdiction over Defendants is proper there and that litigation in Virginia is no less convenient than in Delaware. Ex. 10, p.18. Fourth, the most efficient resolution of this action will occur in Virginia, not Delaware. These factors make clear this Court's exercise of jurisdiction over Defendants would offend traditional notions of fair play and substantial justice.

Finally, allowing the forum of a patent holder's residence to assert personal jurisdiction over an ANDA/NDA applicant merely because it filed a certificate asserting the invalidity or non-infringement of that patent holder's patent does not conform to

traditional notions of due process. If this was the case, a defendant in a patent case might find itself subject to personal jurisdiction in any forum in which the patent holder chooses to reside, regardless of any other contact with that forum. Such unilateral control of the personal jurisdiction analysis would essentially result in a type of nationwide service for patent cases. To apply such approach would substitute Plaintiffs' contacts with Delaware for the required minimum contacts of Defendants, a shift in focus that is forbidden by *International Shoe* and its progeny. Plaintiffs' contacts with Delaware cannot be decisive in determining whether Defendants' due process rights are violated.

C. Plaintiffs Fail to State a Claim Against Dexcel Ltd. and Dexxon Ltd.

DPT Ltd. is the only Defendant that filed NDA 22-032. Plaintiffs have not alleged any specific act taken by either Dexcel Ltd. or Dexxon Ltd. in the U.S. relating to DPT Ltd.'s NDA that would subject them to liability. Aiding and abetting another's filing of an ANDA does not constitute inducement of patent infringement in this jurisdiction. *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 321 F.Supp.2d 612 (D. Del. 2004). Plaintiffs' reliance on J. Farnan's order in *Forest Labs., Inc. v. Ivax Pharma., Inc.*, C.A. No. 03-891/04-1244 (D. Del. Mar. 23, 2005), is inapposite because Plaintiffs' complaint does not allege, as did the plaintiff in *Forest*, that if the NDA is approved, Dexcel Ltd. or Dexxon Ltd. will induce infringement by importing products into the U.S. *See* D.I. 1. Dexcel Ltd. and Dexxon Ltd. should be dismissed pursuant to FED. R. CIV. P. 12(b)(6).

IV. CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court either dismiss the present action, transfer this case for consolidation with Defendants' action in the Eastern District of Virginia, or stay this action until resolution of the Virginia case.

November 30, 2006

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CERTIFICATE OF SERVICE

The undersigned counsel certifies that, on December 15, 2006, he electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following:

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