DANIEL E. YONAN
ATTORNEY
(202) 772-8899
DYONAN@SKGF.COM

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

February 2, 2011

The Honorable James R. Holbein
Acting Secretary
U.S. International Trade Commission
500 E Street S.W.
Washington, D.C. 20436

Via EDIS

Re: Certain Gemcitabine and Products Containing Same
Docket No. 2780

Our Ref: 2886.014ITC0

Dear Secretary Holbein:

On January 20, 2011, Complainant Eli Lilly and Company ("Lilly") filed a complaint with the Commission requesting institution of an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended. Docket No. 2780. Lilly alleges that proposed Respondents Jaingsu Hansoh Pharmaceutical Co. Ltd., in conjunction with its intermediary ChemWorth, Inc. ("ChemWorth"), manufacture the active pharmaceutical ingredient ("API") gemcitabine. *See, e.g.*, Compl. at ¶¶ 53 and 55. This API is allegedly transferred to our client and proposed Respondent Intas Pharmaceuticals Ltd. ("Intas") for finishing, and the final formulation is either imported into the United States directly by Intas and sold to proposed Respondent Hospira, Inc. ("Hospira"), or sold for importation by Intas to ChemWorth and/or Hospira. *See, e.g.*, Compl. at ¶¶ 53-54. Lilly's assertions against Intas are unsupported and ignore readily accessible public information, as well as Lilly's prior, gratuitous litigation brought against Intas' subsidiary Accord Healthcare, Inc. ("Accord") on related subject matter.[1]

As its jurisdictional base, Lilly alleges that Intas "sells for importation, imports, and/or sells after importation" the accused gemcitabine products that are manufactured using the processes claimed by the patent-in-suit. Compl. at ¶ 14; *see also* 19 U.S.C. § 1337(a)(1)(B)(ii). For support, Lilly relies on Exhs. 23-25 of the Complaint. These exhibits, however, are outdated (printed nearly 18 months ago), originate from a foreign government website (New Zealand), and provide *no current indication* that Intas is involved in any of the alleged unlawful activities.

[1] Although Intas is named as a proposed Respondent in the complaint, Accord is a wholly-owned subsidiary of Intas and is responsible for Intas' United States marketing efforts. The Accord matter is relevant because Accord was sued by Lilly for infringement of a patent involving methods of using gemcitabine. *See discussion infra*.

Lilly's complaint *completely lacks* any information that suggests Intas is committing any unfair acts in the United States import trade.

Lilly is well aware of the fact-pleading requirements outlined by 19 C.F.R. § 210.12. If Lilly had performed an adequate pre-filing investigation before it filed its complaint, it would have learned -- through relevant, current, publicly available information -- that another company (other than Intas) is involved in the importation of gemcitabine on behalf of Hospira. Ex. A; Hospira Safety Data Sheet for Gemcitabine. That is, Hospira's Safety Data Sheet identifies only three entities responsible for the manufacture and importation of gemcitabine on Hospira's behalf into the United States: Hospira itself, Hospira Australia Pty Ltd., and Zydus Hospira Oncology Pvt. Ltd. *Id.* This information is nowhere to be found in the Complaint.

Indeed, Intas is not involved in any importation into the United States, the sale for importation, or the sale within the United States after importation of gemcitabine. Ex. B; Declaration of S. Mehta at ¶ 5. Even if Intas wanted to market and supply gemcitabine in the United States (through its subsidiary Accord), it would not be able to do so because Intas does not have tentative approval from the United States Food and Drug Administration. *Id.* at ¶ 6. Lilly previously acknowledged these facts, and was aware of them in December 2010, over one month before Lilly filed its complaint. Ex. C; 12/8/10 ltr. from R. Bajefsky to D. Yonan.

Moreover, Lilly withheld from the Commission that gemcitabine was the subject of other related domestic litigations. *See* 19 C.F.R. § 210.12(a)(5). On October 19, 2010, Lilly sued Accord -- Intas' subsidiary -- in the Middle District of North Carolina based upon the submission of an Abbreviated New Drug Application that sought approval to market gemcitabine. Ex. D; 10/19/10 Complaint. Lilly filed that lawsuit after the patent in that action (directed to a method of using gemcitabine) had already been declared invalid by a district court and that decision was affirmed by the Federal Circuit. Ex. E; 10/29/10 ltr. from K. Sabharwal to S. Martin. Despite repeated requests by Accord, and only after Accord was forced to move the court for sanctions and attorneys' fees, did Lilly finally agree to dismiss the action. *Id.*; *see also* Ex. F; 11/1/10 ltr. from D. Yonan to S. Martin; Ex. G; 11/5/10 email from K. Sabharwal to Lilly's counsel; and Ex. H; 12/6/10 ltr. from D. Yonan to S. Martin. Similar lawsuits filed by Lilly against other defendants involving methods of using gemcitabine (as well as lawsuits over the molecule gemcitabine) have not been disclosed to the Commission. *See, e.g.*, Ex. I; 10/1/10 Complaint re Eli Lilly and Company v. Dr. Reddy's Laboratories, Ltd., *et al.* (1:10-cv-01251-SEB-DML, S.D. Ind.).

As counsel for Intas, we respectfully request that the Commission consider these factors when issuing and defining the scope of any notice of investigation. Intas should not be forced -- once again -- to expend needless attorneys' fees as its subsidiary Accord did in the North Carolina district court action. The relevant facts, which were ignored by Lilly, show that no jurisdiction exists over proposed Respondent Intas, and that the naming of Intas should have been avoided entirely had Lilly performed an adequate pre-filing investigation. If an

investigation is instituted with Intas named as a Respondent, Intas will aggressively move to have the portion relating to it terminated on the basis of a lack of jurisdiction.[2]

Very truly yours,

Daniel E. Yonan

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue NW
Washington, DC 20005

COUNSEL FOR PROPOSED RESPONDENT INTAS PHARMACEUTICALS INC.

cc: Counsel for Eli Lilly and Company

Enclosures

[2] This correspondence was submitted to the Commission within five (5) business days of publication of the Notice of Receipt of Complaint and Solicitation of Comments Relating to the Public Interest. *See* 76 Fed. Reg. 4722 (Jan. 26, 2011). Although the issues raised in this letter do not relate to public interest considerations directly, they do identify inherent problems with Lilly's complaint, and are intended to alert the Commission as to Lilly's pattern of conduct with respect to prior litigation involving gemcitabine.

Exhibit A

MATERIAL SAFETY DATA SHEET

Product Name: Gemcitabine Powder for Solution for Infusion

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Names And Addresses	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA	Hospira Australia Pty Ltd 1 Lexia Place Mulgrave VIC 3170 AUSTRALIA
	Zydus Hospira Oncology Pvt. Ltd. Plot No.3, 'Pharmez'-Special Economic Zone Sarkhej-Bavia Highway, N.H.No.8-A, Village: Matoda, Tal.Sanand, Dist. Ahmedabad-382 213, Gujarat, India	
Emergency Telephone #'s	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia (02) 8014 4880	
Hospira, Inc., Non-Emergency	224 212-2055	
Product Name	Gemcitabine Powder for Solution for Infusion	
Synonyms	2′-deoxy-2′,2′-difluorocytidine monohydrochloride (β–isomer); Cytidine, 2'-deoxy-2',2'-difluoro-, monohydrochloride.	

2. HAZARD INFORMATION

Emergency Overview	Gemcitabine Powder for Solution for Infusion is a powder that contains gemcitabine hydrochloride, an analog of cytarabine that inhibits DNA synthesis and induces apoptosis (cell death). Clinically, gemcitabine hydrochloride is used to treat certain types of cancers. In the workplace, this material should be considered irritating to the skin, eyes and respiratory tract, cytotoxic, neurotoxic, and a potential occupational reproductive hazard. Based on clinical use, possible target organs include the skin, eyes, nervous system, blood, liver, kidney, and fetus.
Occupational Exposure Potential	Information on the absorption of this product via inhalation or skin contact is not available. Avoid dust or liquid aerosol generation and skin contact. There are scientific studies that suggest that personnel (e.g. nurses, pharmacists, etc.) who prepare and administer parenteral antineoplastics (e.g. in hospitals) may be at some risk due to potential mutagenicity, teratogenicity, and/or carcinogenicity of these materials if workplace exposures are not properly controlled. The actual risk in the workplace is not known.
Signs and Symptoms	In clinical use, adverse effects have included bone marrow suppression (leukopenia, neutropenia, thrombocytopenia, and anemia), nausea, vomiting, diarrhea or constipation, pain, fever, rash, alopecia, stomatitis, dyspnea, hemorrhage, neurotoxicity (mild paresthesias), elevated liver enzymes, and adverse renal effects (proteinuria and hematuria).
Medical Conditions Aggravated by Exposure	Pre-existing hypersensitivity to gemcitabine hydrochloride; pre-existing skin, eye, bone marrow, blood, nervous system, liver, or kidney ailments; pregnancy.
Carcinogen Lists:	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Gemcitabine Hydrochloride
Chemical Formula $C_9H_{11}F_2N_3O_4 \bullet HCl$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Gemcitabine Hydrochloride	48.5	122111-03-9	HA3840000
Sodium Acetate Trihydrate	3	6131-90-4	AJ4580000

Non-hazardous ingredients include mannitol. Hazardous ingredients present at less than 1% include hydrochloric acid and/or sodium hydroxide which may be added to adjust the pH.

4. FIRST AID MEASURES

Eye Contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary

5. FIRE FIGHTING MEASURES

Flammability Non-flammable powder. However, powder may be ignitable under high temperature.

Fire & Explosion Hazard None anticipated. As with all powders, minimize the creation of dusty environments.

Extinguishing Media As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures Firefighters should wear self-contained breathing apparatus. Protective equipment and clothing should be worn to minimize contact with the respiratory tract, skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal For spilled powder, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect the spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Absorb any liquid with an inert absorbent material (e.g. absorbent pad). Dispose of materials according to the applicable federal, state, or local regulations.

If a spill occurs after reconstitution, absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling

Gemcitabine hydrochloride is a cytotoxic anti-neoplastic agent. Appropriate procedures should be implemented during the handling and disposal of cytotoxic anti-neoplastic agents to minimize potential exposures. Several guidelines on handling cytotoxic anti-neoplastic agents have been published. There is no general agreement that all of the procedures recommended in the guidelines are necessary or appropriate. Consult your hygienist or safety professional for your site requirements.

Avoid ingestion, inhalation, skin contact, and eye contact. If handling the powder, precautions may include the use of a containment cabinet during the weighing, reconstitution and/or solubilization of this antineoplastic agent. The use of disposable gloves and respiratory protection is recommended. Proper disposal of contaminated vials, syringes, or other materials may be required when working with this material.

Storage

No special storage is required for hazard control. However, employees should be trained on the proper storage procedures for anti-neoplastic agents. For product protection, follow controlled room temperature storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions

Persons with known hypersensitivities to gemcitabine hydrochloride, women who are pregnant, or women who want to become pregnant, should consult a health and/or safety professional prior to handling this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Gemcitabine Hydrochloride	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established
Sodium Acetate Trihydrate	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL : Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

Respiratory Protection

Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N99 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION: continued

Skin Protection	When handling this material, disposable gloves should be worn at all times. Further, the use of double gloves is recommended. Disposable gloves made from nitrile, neoprene, polyurethane or natural latex generally have low permeability to chemotherapy agents. Persons known to be allergic to latex rubber should select a non-latex glove. Gloves should be changed regularly, and removed immediately after known contamination. Care should be taken to minimize inadvertent contamination when removing and/or disposing of gloves.
Eye Protection	Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
Engineering Controls	When handling, local exhaust ventilation is recommended to minimize employee exposure. The use of an enclosure, such as an approved ventilated cabinet designed to minimize airborne exposures, is also recommended.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	White to off-white powder in a vial
Odor	Odorless
Odor Threshold:	NA
pH:	NA
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range	NA
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Evaporation Rate	NA
Specific Gravity	NA
Solubility	It is soluble in water, slightly soluble in methanol, and practically insoluble in ethanol and polar organic solvents.
Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature	NA
Decomposition temperature	NA

10. STABILITY AND REACTIVITY

Reactivity Not determined.

Chemical Stability Stable under standard use and storage conditions.

Hazardous Reactions Not determined

Conditions to avoid Not determined

Incompatibilities Not determined

Hazardous Decomposition Products Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), hydrogen chloride and hydrogen fluoride.

Hazardous Polymerization Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
*Gemcitabine Hydrochloride	100	LD50	Oral	>500	mg/kg	Rat
*Gemcitabine Hydrochloride	100	LDLo	Oral	333	mg/kg	Mouse
Gemcitabine Hydrochloride	100	LD50	Intravenous	236	mg/kg	Rat
Gemcitabine Hydrochloride	100	LD50	Intravenous	500	mg/kg	Mouse
*Gemcitabine Hydrochloride	51-53	LD50	Dermal	>1000	mg/kg	Rabbit
Sodium Acetate	100	LD50	Oral	3530 6891	mg/kg mg/kg	Rat Mouse
Sodium Acetate	100	LD50	Dermal	> 10,000	mg/kg	Rabbit

LD 50: Dosage that produces 50% mortality.
*Eli Lilly and Company MSDS

Aspiration Hazard None anticipated from normal handling of this product.

Dermal Irritation/Corrosion None anticipated from normal use of this product. However, inadvertent skin contact with this product may produce skin irritation with redness.

Ocular Irritation/ Corrosion None anticipated from normal use of this product. However, inadvertent eye contact with this produce may produce eye irritation with redness and discomfort.

Dermal or Respiratory Sensitization None anticipated from normal handling of this product. Gemcitabine hydrochloride was negative in a sensitization assay in guinea pigs. Hypersensitivity reactions have been reported infrequently during the clinical use of this product.

Reproductive Effects Intraperitoneal administration of gemcitabine to male mice at a dosage of 0.5 mg/kg/day produced moderate to severe hypospermatogenesis, decreased fertility, and decreased implantations. In female mice, fertility was not affected but maternal toxicities were noted at intravenous dosages of 1.5 mg/kg/day, and fetotoxicity or embryolethality was observed at an intravenous dosage of 0.25 mg/kg/day. Gemcitabine is embryotoxic, producing fetal malformations (cleft palate, incomplete ossification) at a dosage of 1.5 mg/kg/day in mice. Gemcitabine is fetotoxic causing fetal malformations (fused pulmonary artery, absence of gall bladder) at a dosage of 0.1 mg/kg/day in rabbits. Embryotoxicity is characterized by decreased fetal viability, reduced live litter sizes, and developmental delays.

11. TOXICOLOGICAL INFORMATION: continued

Mutagenicity Gemcitabine induced forward mutations *in vitro* in a mouse lymphoma (L5178Y) assay and was clastogenic in an *in vivo* mouse micronucleus assay. Gemcitabine was negative when tested using the Ames, *in vivo* sister chromatid exchange, and *in vitro* chromosomal aberration assays, and did not cause unscheduled DNA synthesis *in vitro*.

Carcinogenicity Long-term animal studies to evaluate the carcinogenic potential of gemcitabine have not been conducted.

Target Organ Effects Based on clinical use, possible target organs include the skin, eyes, nervous system, blood, liver, kidney, and fetus.

12. ECOLOGICAL INFORMATION

***Aquatic Toxicity** Not determined for product. Information for gemcitabine hydrochloride* is as follows:

Rainbow trout 96-hour median lethal concentration: > 1043 mg/L
Fathead minnow 96-hour median lethal concentration: > 1014 mg/L
Daphnia magna 48-hour median effective concentration: > 999 mg/L
Green algae (S. capricornutum) median effective concentration: 5.4 mg/L (average specific growth rate)
Microorganisms
- Fungus (Chaetomium globosum): MIC > 1000 mg/L
- Mold (Aspergillus flavus): MIC > 1000 mg/L
- Soil bacteria (Comamonas acidovorans): MIC > 1000 mg/L
- N-fixing bacteria (Azotobacter chroococcum): MIC > 1000 mg/L
- Blue-green algae (Nostoc sp.): MIC 800 mg/L

***Persistence/ Biodegradability** Not determined for product. Information for gemcitabine hydrochloride* is as follows:

Dissociation constant (pKa): 3.58
Kow: 0.053, 0.053, 0.052 (pH 5, 7, 9)
Solubility (g/L): 16.0, 15.3, 15.8 (pH 5, 7, 9)
Light absorption (nm): 268 - 269
Hydrolysis: no significant hydroylsis
Aerobic biodegradation half-life: 30% in 28 days

Bioaccumulation Not determined for product.

Mobility in Soil Not determined for product.

*Eli Lilly and Company MSDS
Notes:
1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EC50: Concentration in water that produces 50% inhibition of growth in algae.

13. DISPOSAL CONSIDERATIONS

Waste Disposal All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

DOT STATUS:	Not regulated
Proper Shipping Name:	NA
Hazard Class:	NA
UN Number:	NA
Packing Group:	NA
Reportable Quantity:	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name:	NA
Hazard Class:	NA
UN Number:	NA
Packing Group:	NA
Reportable Quantity:	NA
IMDG STATUS	Not regulated
Proper Shipping Name:	NA
Hazard Class:	NA
UN Number:	NA
Packing Group:	NA
Reportable Quantity:	NA

Notes: DOT - US Department of Transportation Regulations.

15. REGULATORY INFORMATION

U.S. TSCA Status	Exempt.
U.S. CERCLA Status	Not listed
U.S. SARA 302 Status	Not listed
U.S. SARA 313 Status	Not listed
U.S. RCRA Status	Not listed
U.S. PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

U.S. OSHA Classification	Irritant Reproductive Toxin Target Organ Toxin

15. REGULATORY INFORMATION: continued

GHS Classification* *In circumstances where medicinal products are not exempted, the recommended GHS classification for this product is as follows:

Hazard Class	Acute Oral Toxicity	Eye Irritation	Toxic to Reproduction	Mutagenicity	Target Organ Toxicity
Hazard Category	4	2B	2	2	2
Symbol		NA			
Signal Word	Warning	Warning	Warning	Warning	Warning
Hazard Statement	Harmful if swallowed	Causes eye irritation	Suspected of damaging fertility or the unborn child	Suspected of causing genetic defects	May cause damage to the skin, eyes, nervous system, blood, liver, or kidney through prolonged or repeated exposure

Prevention:
Obtain special instructions before use.
Do not eat, drink or smoke when using this product.
Do not handle until all safety precautions have been read and understood.
Use personal protective equipment as required.
Do not breathe dust//mist/vapors/spray.
Wash hands thoroughly after handling.

Response:
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
Rinse mouth.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.
Wash hands after handling.
IF exposed or concerned: Get medical attention/advice.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance gemcitabine hydrochloride.

Classification(s):	Harmful	Irritant	Toxic to Reproduction Category 2	Mutagen Category 2
Symbol:				
Indication of Danger	Xn	Xi	T	T

Risk Phrases:
R21 – Harmful in contact with skin
R22 – Harmful if swallowed
R36/37/38 - Irritating to eyes, respiratory system and skin
R46 – May cause heritable genetic damage
R62 – Possible risk of impaired fertility
R63 – Possible risk of harm to the unborn child

Safety Phrases:
S22: Do not breathe dust
S24: Avoid contact with the skin
S25: Avoid contact with eyes
S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD_{50}	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator:	Hospira GEHS
Date Prepared:	April 22, 2009
Revision Date:	February 23, 2010

Disclaimer:
The information and recommendations contained herein are based upon tests believed to be reliable. However, Hospira does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Hospira assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

Exhibit B

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of **GEMCITABINE AND PRODUCTS CONTAINING SAME**	**Investigation Docket No. 2780**

DECLARATION OF DR. SAMIR MEHTA

I, Dr. Samir Mehta, state the following, based upon personal knowledge:

1. I am over the age of 18 years and am otherwise competent to make the statements contained herein.

2. I am currently the Executive Vice President at Intas Pharmaceuticals, Ltd., USA in Durham, North Carolina ("Intas USA"), which is an affiliated entity of Intas Pharmaceuticals Ltd. of Gujarat, India ("Intas").

3. I understand that Intas was recently identified as a proposed Respondent in a complaint filed at the Commission under Section 337 of the Tariff Act of 1930, as amended, having the above-referenced caption.

4. The complaint was filed by Complainant, Eli Lilly and Company ("Lilly"), and identifies additional proposed Respondents Jiangsu Hansoh Pharmaceutical Co., Ltd. ("Jiangsu"), ChemWorth, Inc. ("ChemWorth"), and Hospira, Inc. ("Hospira"). *See, e.g.*, Compl. at ¶ 1.

5. On best information and belief, Intas has never imported into the United States, sold for importation into the United States, or sold within the United States after importation any

gemcitabine supplied by Jiangsu, either by itself, on behalf of Intas' subsidiaries, affiliated entities, or on behalf of Jiangsu, ChemWorth and/or Hospira.

6. In addition, neither Intas, nor its subsidiaries or affiliated entities, have approval from the United States Food and Drug Administration to market or sell gemcitabine, in any form, within the United States.

* * *

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge.

Executed on February 2, 2011 in North Carolina.

Dr. Samir Mehta

Exhibit C

ROBERT D. BAJEFSKY
202.408.4095
robert.bajefsky@finnegan.com

December 8, 2010

Daniel E. Yonan, Esq.
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1100 New York Avenue, NW
Washington, DC 20005

Via Electronic Mail

Re: *Eli Lilly and Company v. Accord Healthcare, Inc.*
Case No. 1:10-cv-0781 M.D.N.C.

Dear Mr. Yonan:

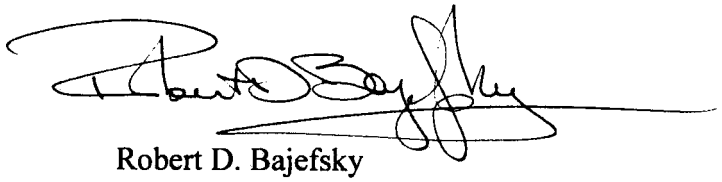
I write in response to your December 6, 2010, letter to Mr. Martin, requesting that Lilly reimburse the fees you apparently plan to charge your client for your services in the referenced civil action. Lilly will not agree to pay those fees.

Your assertion that the action was objectively baseless and not filed in good faith is incorrect. Lilly instituted this action on October 19, 2010, to preserve its rights during the pendency of the Federal Circuit appeal in *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly and Company*, Appeal No. 2010-1105. One cannot seriously claim that Lilly's filing of the referenced civil action and its position on the appeal was baseless in view of the dissent from the court's denial of Lilly's petition for rehearing, authored by Judge Newman and joined by three additional Federal Circuit judges, strongly criticizing the underlying panel decision.

As I explained in my earlier correspondence, the filing of the complaint in this action did not cause any meaningful damage to your client, which cannot market a generic gemcitabine product before May 2011, at the earliest. In fact, Accord does not even have tentative approval as of this date. And you have not identified any such damage in your letters or in the motion to dismiss. Moreover, we proposed two alternatives that would have allowed Accord to avoid any meaningful litigation expenses. You refused both proposals, choosing instead to file an "expedited" motion to dismiss. Had you accepted either one of Lilly's proposals, and allowed Lilly time to reevaluate its position once the Federal Circuit issued the mandate in the *Sun* appeal, this case would have ended without your client incurring the cost of a needless motion to dismiss.

If you are interested in discussing this matter, please call me.

Sincerely,



Robert D. Bajefsky

cc: Joseph W. Eason, Esq.
Stephen D. Martin, Esq.

Exhibit D

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
CIVIL ACTION NO.: 1:10-CV-781

ELI LILLY AND COMPANY,

Plaintiff,

vs.

ACCORD HEALTHCARE, INC.,

Defendant.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") brings this action for patent infringement against Accord Healthcare, Inc. ("Accord") under 35 U.S.C. § 271(e)(2). This action involves a patent for the use of the pharmaceutical drug product GEMZAR® as a treatment for susceptible neoplasms.

JURISDICTION AND PARTIES

1. Lilly is an Indiana corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. Upon information and belief, Defendant Accord Healthcare, Inc. is a corporation organized and existing under the laws of the State of North Carolina, having its principal place of business at 1009 Slater Road, Suite 210B, Durham, North

Carolina 27703. Upon information and belief, Accord is a generic pharmaceutical company that produces and markets generic pharmaceutical products for sale in the Middle District of North Carolina and throughout the United States.

3. This Court has personal jurisdiction over Accord because, on information and belief, Accord is a North Carolina corporation and has principal place of business in the Middle District of North Carolina.

4. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT

5. United States Patent No. 5,464,826 ("the '826 patent"), entitled "Method of Treating Tumors in Mammals with 2',2'-Difluoronucleosides," was duly and legally issued to Lilly by the United States Patent and Trademark Office on November 7, 1995. The '826 patent expires on November 7, 2012, followed by a six-month period of market exclusivity granted by the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355a, ending on May 7, 2013. A true and correct copy of the '826 patent is attached as Exhibit A. Lilly has been the owner of the '826 patent since it issued.

6. Claims 2 and 6-7 of the '826 patent were found invalid for obviousness-type double patenting in an order issued on August 17, 2009, in *Sun Pharmaceutical Industries Ltd. v. Eli Lilly and Company*, No. 2:07-cv-15087-GCS-RSW (E.D. Mich.) ("Michigan decision"). Lilly appealed the decision to the United States Court of Appeals for the Federal Circuit ("Federal Circuit"), and a three-judge panel affirmed the Michigan decision on July 28, 2010. Lilly has petitioned for rehearing and rehearing en banc, and a mandate has not yet issued from the Federal Circuit. Lilly's petition is supported by three amici curiae. Further, at the Federal Circuit's request, Sun has submitted a response to Lilly's petition for rehearing. The parties await the court's decision on Lilly's petition.

7. Lilly is the holder of approved New Drug Application No. 20-509 for the use of Gemzar® as a treatment for non-small cell lung cancer, pancreatic cancer, breast cancer, and ovarian cancer.

8. Upon information and belief, Accord filed with the FDA in Rockville, Maryland, an Abbreviated New Drug Application ("ANDA") No. 91-594 under 21 U.S.C. § 355(j), to obtain approval for the commercial manufacture, use, sale, and/or importation of Gemcitabine Hydrochloride 200 mg base/vial, 1 g base/vial, and 2 g base/vial. Upon information and belief, Accord filed ANDA No. 91-594 to obtain approval to market these generic versions of Gemzar® before the expiration date of the '826 patent. Upon information and belief, ANDA No. 91-594 contains a certification

pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the '826 patent are invalid or would not be infringed.

9. Accord sent Lilly a letter ("Notice Letter") dated September 1, 2010, notifying Lilly that Accord filed ANDA No. 91-594 for Gemcitabine Hydrochloride 200 mg base/vial, 1 g base/vial, and 2 g base/vial and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Lilly received the Notice Letter, sent by certified mail, on or about September 4, 2010. The Notice Letter alleges that claims 1, 2, 6, and 7 of the '826 patent are invalid under the doctrine of obviousness-type double patenting. The Notice Letter further states that claims 3, 4, and 5 of the '826 patent are not infringed.

10. Under 35 U.S.C. § 271(e)(2)(A), Accord's filing of its ANDA seeking approval for the commercial manufacture, use, sale, and/or importation of its Gemcitabine Hydrochloride drug products before the expiration of the '826 patent constitutes an act of infringement. If ANDA No. 91-594 is approved by the FDA, the sale of Accord's Gemcitabine Hydrochloride drug products will infringe one or more claims of the '826 patent under 35 U.S.C. § 271(a)-(c).

11. Upon information and belief, Accord knows that physicians prescribing or using its Gemcitabine Hydrochloride drug products according to the indications sought by Accord will be using them in a manner that will infringe one or more claims of the '826 patent.

12. Lilly will be substantially and irreparably harmed by Accord's infringing activities unless those activities are enjoined by this Court. Lilly has no adequate remedy at law.

COUNT II FOR DECLARATORY JUDGMENT

13. Lilly realleges and incorporates by reference paragraphs 1-12.

14. Upon information and belief, Accord has filed ANDA No. 91-594 with the FDA, seeking authorization to commercially manufacture, use, sell, and/or import Gemcitabine Hydrochloride drug products. Upon information and belief, Accord knows that doctors prescribing or using its Gemcitabine Hydrochloride drug products according to the indications sought by Accord will be using them in a manner that will infringe one or more claims of the '826 patent.

15. Upon information and belief, Accord seeks approval of at least one indication for its Gemcitabine Hydrochloride drug products.

16. Upon information and belief, Accord plans to selling its Gemcitabine Hydrochloride drug products soon after the FDA approves ANDA No. 91-594.

17. Such conduct will constitute inducement of infringement of the '826 patent under 35 U.S.C. § 271(b) and contributory infringement under 35 U.S.C. § 271(c).

18. Accord's infringing activity complained of herein is imminent and will begin following FDA approval of ANDA No. 91-594.

19. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and Accord concerning liability for

infringement of the '826 patent. Accord's actions create a reasonable apprehension of irreparable harm and loss resulting from its threatened imminent actions.

WHEREFORE, Lilly demands judgment against Accord as follows:

(a) declaring United States Patent No. 5,464,826 not invalid and not unenforceable;

(b) declaring that Accord would infringe one or more claims of United States Patent No. 5,464,826 by the threatened act of sale of its Gemcitabine Hydrochloride drug products prior to the expiration of said patent;

(c) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Accord's ANDA No. 91-594 relating to Gemcitabine Hydrochloride before the expiration of the six-month period of market exclusivity for the '826 patent granted under 21 U.S.C. § 355a, which follows the expiration of the patent;

(d) enjoining Accord from the sale of its Gemcitabine Hydrochloride drug products, in accordance with 35 U.S.C. § 271(e)(4)(B); and

(e) awarding Lilly any further and additional relief as this Court deems just and proper.

Respectfully submitted, this the 19th day of October, 2010.

NELSON MULLINS RILEY & SCARBOROUGH LLP

By: */s/ Stephen D. Martin*

Joseph W. Eason
N.C. Bar No. 7699
Stephen D. Martin
N.C. Bar No. 28658
4140 Parklake Avenue
GlenLake One / Second Floor
Raleigh, North Carolina 27612
Telephone: (919) 877-3800
Facsimile: (919) 877-3799

E-mail: joe.eason@nelsonmullins.com
E-mail: steve.martin@nelsonmullins.com

Attorneys for Plaintiff
ELI LILLY AND COMPANY

Confidential Exhibit E

Confidential Exhibit F

Exhibit G

From: Ke eto Sabharwal
Sent: Friday, November 05, 2010 1:10 PM
To: Cudnik, Ryan; Daniel E. Yonan
Cc: Steve Martin (steve.martin@nelsonmullins.com); Bajefsky, Robert; Kozikowski, John; Suresh B. Pillai; Jorge Goldstein; David Cornwell
Subject: RE: Lilly v. Accord

Counsel:

I have just reviewed the letter from Mr. Bajefsky in which you have inexplicably refused to dismiss the Complaint filed against Accord, despite the Federal Circuit's recent denial of Lilly's Petition for Rehearing. I note that you do not -- and cannot -- rebut the undisputed fact that you have knowingly and intentionally filed, and maintained, a lawsuit against Accord based on a patent that has been deemed to be invalid, both by a District Court as well as the Federal Circuit.

We do **not** accept your absurd proposal that we stay this frivolous action pending any writ of cert to the United States Supreme Court.

You have only one option at this point: dismiss this case **immediately**, or we will seek immediate dismissal from the Court. Please be advised that, if you force us to incur the expense of filing any such dismissal motions with the Court, we will also seek sanctions against both law firms for violating your Rule 11 obligations under FRCP, as as other potential relief.

You have until noon on Monday, November 8 to advise us that you will be dismissing this case with prejudice.

Regards,

Keeto Sabharwal

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Keeto Sabharwal
Director
Sterne, Kessler, Goldstein & Fox PLLC.
1100 New York Avenue, NW
Washington, DC 20005
Direct: 202.772.8511
Fax: 202.371.2540
Main: 202.371.2600
Email: keetos@skgf.com
www.skgf.com

Administrative Assistant: Cecilia Zhang
Direct: (202) 772-8682

From: Cudnik, Ryan [mailto:Ryan.Cudnik@finnegan.com]
Sent: Friday, November 05, 2010 12:35 PM
To: Keeto Sabharwal; Daniel E. Yonan
Cc: Steve Martin (steve.martin@nelsonmullins.com); Bajefsky, Robert; Kozikowski, John
Subject: Lilly v. Accord

Counsel:

Please see the attached correspondence.

Best,

Ryan J. Cudnik
Attorney at Law
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
901 New York Avenue, NW, Washington, DC 20001-4413
202.408.4180 | fax: 202.408.4400 | ryan.cudnik@finnegan.com | www.finnegan.com

Exhibit H

DANIEL E. YONAN, ESQ.
OF COUNSEL
(202) 772-8899
DYONAN@SKGF.COM

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

December 6, 2010

Stephen D. Martin, Esq.
Nelson Mullins Riley & Scarborough LLP
4140 Parklake Avenue
GlenLake One / Second Floor
Raleigh, NC 27612

Via Email

Re: *Eli Lilly and Company v. Accord Healthcare, Inc.*
Case No. 1:10-CV-0781 [unassigned]-LPA (M.D.N.C.)

Dear Mr. Martin:

We repeatedly instructed you and your client Eli Lilly and Company ("Lilly") that no good-faith basis existed in law or fact to file the above-referenced lawsuit. Only after we prepared and filed a Motion to Dismiss ("Motion"), and incurred needless attorney and client costs in doing so, did you finally agree the action was without any merit. Dkt. 15, Notice of Voluntary Dismissal.

Although the dismissal terminated any 30-month stay put into place against Accord Healthcare, Inc. ("Accord"), this matter is not closed. Accord's Motion contained a request that the case be declared exceptional and that Accord be awarded all attorneys' fees and other appropriate sanctions from the Court. Our total fees through the date of this letter are $25,600. If Lilly agrees to reimburse us for our fees, we will drop our pending request and not pursue any additional sanctions.

Please let us know your position by **December 8, 2010**. If you do not agree, or we do not hear from you by this time, we will renew our request before the Court.

Very truly yours,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Daniel E. Yonan

cc: All counsel of record

Exhibit I

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,
Plaintiff,

v.

DR. REDDY'S LABORATORIES, LTD.
and DR. REDDY'S LABORATORIES, INC.,
Defendants.

Civil Action No.:

1:10-cv-1251 TWP -TAB

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") brings this action for patent infringement against Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (collectively "Dr. Reddy") under 35 U.S.C. § 271(e)(2). This action involves a patent for the use of the pharmaceutical drug product GEMZAR® as a treatment for susceptible neoplasms.

JURISDICTION AND PARTIES

1. Lilly is an Indiana corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. Upon information and belief, Defendant DRL Ltd. is a public limited liability corporation organized and existing under the laws of India, having its principal place of business at 7-1-27, Ameerpet, Hyderabad, 500 016, India. Upon information and belief, DRL Ltd. is a generic pharmaceutical company that develops, manufactures, and markets generic pharmaceutical products, as well as bulk active pharmaceutical ingredients ("API"). Upon

information and belief, DRL Ltd. imports and ships those products and API into the United States for distribution and sale in the Southern District of Indiana and throughout the United States.

3. Upon information and belief, Defendant DRL Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 200 Somerset Corporate Boulevard, Building II, 7th Floor, Bridgewater, New Jersey 08807-2862. Upon information and belief, DRL Inc. is a wholly owned and directly controlled subsidiary of DRL Ltd. Upon information and belief, DRL Inc. is the exclusive agent in North America for DRL Ltd. and distributes and markets DRL Ltd.'s generic pharmaceutical products and API for sale in the Southern District of Indiana and throughout the United States.

4. Upon information and belief, DRL Ltd. uses and works with DRL Inc. to carry out its business of importing, manufacturing, selling, formulating, filling, labeling, and packaging finished dosage forms of generic pharmaceutical products for distribution in the Southern District of Indiana and throughout the United States.

5. This Court has personal jurisdiction over DRL Ltd. and DRL Inc. because, on information and belief, they have maintained continuous and systematic contacts with the State of Indiana and have purposefully availed themselves of the benefits and protections of the laws of the State of Indiana.

6. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT

7. United States Patent No. 5,464,826 ("the '826 patent"), entitled "Method of Treating Tumors in Mammals with 2',2'-Difluoronucleosides," was duly and legally issued to Lilly by the United States Patent and Trademark Office on November 7, 1995. The '826 patent expires on November 7, 2012, followed by a six-month period of market exclusivity granted by the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355a, ending on May 7, 2013. A true and correct copy of the '826 patent is attached as Exhibit A. Lilly has been the owner of the '826 patent since it issued.

8. Claims 2 and 6-7 of the '826 patent were found invalid for obviousness-type double patenting in an order issued on August 17, 2009, in *Sun Pharmaceutical Industries Ltd. v. Eli Lilly and Co.*, No 2:07-cv-15087-GCS-RSW (E.D. Mich.) ("Michigan decision"). Lilly appealed the decision to the United States Court of Appeals for the Federal Circuit ("Federal Circuit"), and a three-judge panel affirmed the Michigan decision on July 28, 2010. Lilly has petitioned for rehearing and rehearing en banc, and a mandate has not yet issued from the Federal Circuit. Lilly's petition is supported by three amici curiae. Further, at the Federal Circuit's request, Sun has submitted a response to Lilly's petition for rehearing. The parties await the court's decision on Lilly's petition.

9. Lilly is the holder of approved New Drug Application No. 20-509 for the use of Gemzar® as a treatment for non-small cell lung cancer, pancreatic cancer, breast cancer, and ovarian cancer.

10. Upon information and belief, Dr. Reddy filed with the FDA in Rockville, Maryland, an Abbreviated New Drug Application ("ANDA") No. 91-365 under 21 U.S.C. § 355(j), to obtain approval for the commercial manufacture, use, sale, and/or importation of

Gemcitabine Hydrochloride for Injection, 200 mg base/vial and 1 gm base/vial. Upon information and belief, Dr. Reddy filed ANDA No. 91-365 to obtain approval to market these generic versions of Gemzar® before the expiration date of the '826 patent. Upon information and belief, ANDA No. 91-365 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the '826 patent are invalid or would not be infringed.

11. Upon information and belief, DRL Ltd. participated in the submission of ANDA No. 91-365 or otherwise acted in concert with DRL Inc. in the submission of ANDA No. 91-365.

12. Upon information and belief, if ANDA No. 91-365 is approved, it is the intention of DRL Ltd. and DRL Inc. that the products will be distributed in the United States by or through DRL Inc.

13. DRL Inc. sent Lilly a letter ("Notice Letter") dated August 13, 2010, notifying Lilly that Dr. Reddy filed ANDA No. 91-365 for Gemcitabine Hydrochloride for Injection, 200 mg base/vial and 1 gm base/vial, and providing information pursuant to 21 U.S.C. § 355(b)(3). Lilly received the Notice Letter, sent by certified mail, on or about August 20, 2010. The Notice Letter alleges that claims 1, 2, 6, and 7 of the '826 patent are invalid under the doctrine of obviousness-type double patenting. The Notice Letter further states that claims 3-5 of the '826 patent are not infringed.

14. Under 35 U.S.C. § 271(e)(2)(A), Dr. Reddy's filing of their ANDA seeking approval for the commercial manufacture, use, sale, and/or importation of Dr. Reddy's Gemcitabine Hydrochloride for Injection products before the expiration of the '826 patent constitutes an act of infringement. If ANDA No. 91-365 is approved by the FDA, Dr. Reddy's

commercial manufacture, use, offer to sell, sale, or importation of Gemcitabine Hydrochloride for Injection products will infringe one or more claims of the '826 patent under 35 U.S.C. § 271(a)-(c).

15. Upon information and belief, Dr. Reddy knows that physicians prescribing or using their Gemcitabine Hydrochloride for Injection drug products according to the indications sought by Dr. Reddy will be using them in a manner that will infringe one or more claims of the '826 patent.

16. Lilly will be substantially and irreparably harmed by Dr. Reddy's infringing activities unless those activities are enjoined by this Court. Lilly has no adequate remedy at law.

COUNT II FOR DECLARATORY JUDGMENT

17. Lilly realleges and incorporates by reference paragraphs 1-16.

18. Upon information and belief, Dr. Reddy has filed ANDA No. 91-365 with the FDA, seeking authorization to commercially manufacture, use, sell, and/or import Gemcitabine Hydrochloride for Injection drug products. Upon information and belief, Dr. Reddy knows that doctors prescribing or using their Gemcitabine Hydrochloride for Injection drug products according to the indications sought by Dr. Reddy will be using them in a manner that will infringe one or more claims of the '826 patent, either literally or under the doctrine of equivalents.

19. Upon information and belief, DRL Ltd. participated in the submission of ANDA No. 91-365 or otherwise acted in concert with DRL Inc. in the submission of ANDA No. 91-365.

20. Upon information and belief, Dr. Reddy seeks approval of at least one indication for their Gemcitabine Hydrochloride for Injection drug products.

21. Upon information and belief, Dr. Reddy plans to begin manufacturing, marketing, offering to sell, selling, and/or importing their Gemcitabine Hydrochloride for Injection drug products soon after the FDA approves such indications.

22. Such conduct will constitute inducement of infringement of the '826 patent under 35 U.S.C. § 271(b) and contributory infringement under 35 U.S.C. § 271(c).

23. Dr. Reddy's infringing activity complained of herein is imminent and will begin following FDA approval of ANDA No. 91-365.

24. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and Dr. Reddy concerning liability for infringement of the '826 patent. Dr. Reddy's actions create a reasonable apprehension of irreparable harm and loss resulting from their threatened imminent actions.

WHEREFORE, Lilly demands judgment against Dr. Reddy as follows:

(a) declaring United States Patent No. 5,464,826 not invalid and not unenforceable;

(b) declaring that Dr. Reddy would infringe one or more claims of United States Patent No. 5,464,826 by the threatened acts of manufacture, use, offer to sell, sale, and importation of their Gemcitabine Hydrochloride for Injection drug products prior to the expiration of said patent;

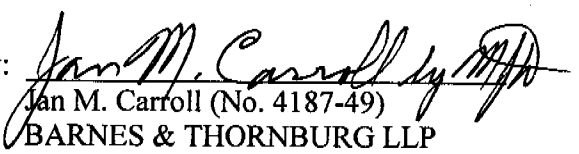
(c) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Dr. Reddy's ANDA No. 91-365 relating to Gemcitabine Hydrochloride for Injection before the expiration of the six-month period of market exclusivity for the '826 patent granted under 21 U.S.C. § 355a, which follows the expiration of the patent;

(d) enjoining Dr. Reddy from the commercial manufacture, use, offer to sell, sale, or importation of their Gemcitabine Hydrochloride for Injection drug products, in accordance with 35 U.S.C. § 271(e)(4)(B); and

(e) awarding Lilly any further and additional relief as this Court deems just and proper.

Respectfully submitted,

Dated: October 1, 2010

By: 

Jan M. Carroll (No. 4187-49)
BARNES & THORNBURG LLP
11 South Meridian Street
Indianapolis, IN 46204-3535
(317) 236-1313

Attorney for Plaintiff
ELI LILLY AND COMPANY