IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT

STATE OF ALASKA, Plaintiff, v. ELI LILLY AND COMPANY, Defendant.	Case No. 3AN-06-5630 CIV

AFFIDAVIT OF TIMOTHY R. FRANSON IN SUPPORT OF DEFENDANT ELI LILLY AND COMPANY'S MOTION REQUESTING PROTECTION OF REGULATORY COMMUNICATIONS NOT SUBJECT TO PUBLIC DISCLOSURE

I, TIMOTHY R. FRANSON, being duly sworn, state as follows:

1. I am currently employed by Eli Lilly and Company ("Lilly") as Vice President, Global Regulatory Affairs.

2. Since 1996, I have had regulatory management responsibility in the United States for all products within the neuroscience therapeutic area. I have worked closely with the regulatory scientists who have primary responsibility for Zyprexa®.

3. During my tenure, I have participated in meetings and discussions with the Food and Drug Administration ("FDA") regarding changes to the United States label for Zyprexa in 2003 and 2007.

4. On January 12, 2007, the FDA sent Lilly a letter requesting certain information in response to articles published in *The New York Times*. On February 20, 2007, Lilly submitted to the FDA the solicited response, in three parts. Part one of this response, structured in direct reply to allegations in *The Times* articles, offers Lilly's views regarding the allegations. The second part contains literature requested by the FDA, and the third part contains data requested by the FDA.

5. In March 2007, in the context of an approvable letter for a new indication for Symbyax® (combination of olanzapine and fluoxetine), the FDA requested certain analyses of Zyprexa clinical trial data with the intent of updating the United States label. The FDA made a similar request in April 2007, in an approvable letter for a new indication for Zyprexa.

6. In August and September 2007, Lilly submitted the requested analyses to the FDA.

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7. During this time, Lilly and the FDA also exchanged communications regarding draft labeling. Lilly revised the Zyprexa label on October 5, 2007.

8. Pharmaceutical companies and regulatory bodies regularly exchange confidential information to facilitate the drug approval and compliance process in an efficient and fair manner. These protections encourage full and frank communications, and both parties maintain these communications in confidence.

9. Regulatory submissions and communications between Lilly and the FDA are private and confidential, not subject to public disclosure. They contain confidential proprietary information, confidential commercial information, confidential trade secret information, and other confidential information. These submissions and communications are exchanged between Lilly and the FDA with an expectation and understanding that they will not be disclosed or disseminated.

10. Such regulatory submissions and communications are not widely disseminated within Lilly, but instead are restricted to those employees with responsibility for regulatory affairs. Lilly employees, in general, do not have access to these documents.

11. Within Lilly, measures are taken to guard the secrecy of these documents. In addition to the measures Lilly takes to guard its computer systems from external disclosures and its physical plant facilities with security personnel, Lilly employees are bound by The Red Book – Code of Business Conduct, and by Global Lilly Policies, each of which delineates confidentiality measures for Lilly Information Assets.

12. Such regulatory submissions and communications are not publicly available, nor have they been disclosed to the public.

13. These types of documents would not be subject to disclosure under the Freedom of Information Act ("FOIA"), even if requested.

14. Documents such as the New Drug Applications for Zyprexa and for Symbyax, which typically contain such submissions and communications, also are not publicly available, nor have they been disclosed to the public. Such documents contain a cover sheet typically reflecting the following statement:

> THIS DOCUMENT CONTAINS TRADE SECRETS, OR COMMERCIAL OR FINANCIAL INFORMATION, PRIVILEGED OR CONFIDENTIAL, DELIVERED IN CONFIDENCE AND RELIANCE THAT SUCH INFORMATION WILL NOT BE MADE AVAILABLE TO THE PUBLIC WITHOUT EXPRESS WRITTEN CONSENT OF ELI LILLY AND COMPANY.

15. Clinical data discussed in such submissions and communications is owned by Lilly. Lilly dedicates a substantial amount of resources to clinical trials and data analysis. The data is proprietary because it has definable value to Lilly, and that value could be transferred to Lilly's competitors if disclosed. With access to such information, competitors could gain

considerable insight into Lilly's strategies, plans, processes, goals, and actions. This type of information is useful as a guide for competitors' own drug development and research efforts.

16. Dissemination of the data and of these strategies could cause commercial hardship to Lilly and would benefit its competitors in the marketplace.

17. In particular, the 2007 submissions and communications are so current that companies with products in competition with Zyprexa and Symbyax could use this information to gain unfair insight to their benefit, as well as to exploit this information to harm Lilly in the marketplace today.

Timothy R. Franson MD

Timothy R. Franson

SWORN TO AND SUBSCRIBED
BEFORE ME, NOTARY, this
27th day of February, 2008
Lana L Dishman
Notary Public

Lana Dishman
My Commission Expires:
February 8, 2015
Resident of Johnson County

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