Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.

VIA EDGAR

August 10, 2011

Mr. Jim B. Rosenberg
Senior Assistant Chief Accountant
Division of Corporate Finance
U.S. Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549

Re: Eli Lilly and Company
Form 10-K for the Fiscal Year Ended December 31, 2010
Filed February 22, 2011
File Number 001-06351

Dear Mr. Rosenberg:

Eli Lilly and Company (Lilly) submits this response to your letter dated July 13, 2011 commenting on our Form 10-K for the year ended December 31, 2010. For ease of reference, we have repeated your comments prior to our responses.

Comment:

Item 7. Management's Discussion and Analysis
Results of Operations
Executive Overview
Late-Stage Pipeline, page 17

1. Refer to your response to prior comment one. We acknowledge the additional proposed disclosure you provided regarding the general nature of patent terms, patent term adjustments, and patent term restoration. There appear to be known events, such as the date you initially file for a patent, as well as known uncertainties, such as the date of drug approval, that affect the patent term of your late stage projects. Please provide us additional proposed disclosure regarding patents for each of your late stage projects, including the dates on which you filed the relevant patents, and the current status of the patents' terms regarding timing, including whether your initial 20-year term has expired. For example, for your small molecule new chemical entities in the U.S., state whether you plan to rely on the data exclusivity period of five years, the remaining period in the initial 20-year term, or some other term. You may supplement this disclosure about the current status of your patents in order to put the information into proper context.

Response:

As noted during our telephonic discussion on July 28, 2011, one of the requirements of a New Drug Approval (NDA) submission is to list the relevant patents that the sponsor intends to rely on to provide exclusivity for that specific drug. Upon FDA approval, that list becomes public in the FDA's "Orange Book." Decisions about which patents to list are based on a number of factors and premature disclosure of an innovator's strategy could cause competitive harm. In addition, as we discussed, frequently there is significant uncertainty around the issuance, term and scope of a patent during Phase III clinical trials, and uncertainty about the effective patent term exists even up until FDA approval. Uncertainty can sometimes exist as to which patents need to be listed until the final approved indication is known. In response to your request, in future 10-K filings we will enhance our "Patents, Trademarks, and Other Intellectual Property Rights" disclosure. First, as discussed in previous correspondence, we will include expanded disclosures to describe the uncertainties affecting the ultimate effective exclusivity for pharmaceutical products, such as patent term adjustment and restoration. Second, for our new molecular entities (NMEs) that have been submitted to the FDA for regulatory review, we will disclose the patent expiration dates that are known at that time, with appropriate cautions regarding future adjustments or extensions. Revisions to our current 10-K, including those included in our response to your previous comments are highlighted:

Overview

Intellectual property protection is critical to our ability to successfully commercialize our life sciences innovations and invest in the search for new medicines. We own, have applied for, or are licensed under, a large number of patents in the U.S. and many other countries relating to products, product uses, formulations, and manufacturing processes.

The patent protection that is anticipated to be of most relevance to human pharmaceuticals is provided by national patents claiming the active ingredient (the compound patent), particularly those in major markets such as the U.S., various European countries and Japan. These patents may be issued based upon the filing of international patent applications, usually filed under the Patent Cooperation Treaty (PCT). Patent applications covering the compounds are generally filed during the Discovery Research Phase of the drug discovery process, which is described in the "Research and Development" section of "Item 1. Business". In general, national patents in each relevant country are available for a period of 20 years from the filing date of the PCT application, which is often years prior to the potential launch of a commercial product. Further patent term adjustments and restorations may extend the original patent term:

- **Patent term adjustment is a statutory right available to all U.S. patent applicants to provide relief in the event that a patent is delayed during examination by the United States Patent and Trademark Office.**
- **Patent term restoration is a statutory right provided to U.S. patents that claim inventions subject to review by the FDA. A single patent for a pharmaceutical product may be eligible for patent term restoration, to make up for a portion of the time invested in clinical trials and the FDA review process. Patent term restoration is limited by a formula and cannot be calculated until product approval due to uncertainty about the duration of clinical trials and the time it takes the FDA to review an application. There is a five year cap on any restoration, and no patent may be extended for more than fourteen years beyond FDA approval.**

Loss of patent protection often result in the loss of effective market exclusivity for the product, which can result in severe and rapid decline in sales of the product. However, in some cases the innovator company may achieve exclusivity beyond the expiry of the product patent through manufacturing trade secrets, later-expiring patents on methods of use or formulations, or data protection that may be available under pharmaceutical regulatory laws. The primary forms of data protection are as follows:

- **Regulatory authorities in major markets generally grant data protection for a period of years following new drug approvals in recognition of the substantial investment required to complete clinical trials. Data protection prohibits other manufacturers from submitting regulatory applications based on the innovator company's regulatory submission data for the drug. For small molecule new molecular entities this form of data protection is five years in the U.S., ten years in the European Union and eight years in Japan. This period of data protection begins on the date of product approval and runs concurrently with the patent term for any relevant patent.**
- Some of our current products, including Erbitux, Forteo, ReoPro, and Xigris, and many of the new molecular entities in our research pipeline are biological products ("biologics"). Based on the Biologics Price Competition and Innovation Act (enacted in the U.S. in 2010), the FDA now has the authority to approve similar versions ("biosimilars") of innovative biologic products. A competitor seeking approval of a biosimilar must file an application to show its molecule is highly similar to an approved innovator biologic, address the challenges of biologics manufacturing, and include a certain amount of safety and efficacy data which FDA will determine on a case-by-case basis. Under the data protection provisions of this law, FDA cannot approve a biosimilar application until 12 years after initial marketing approval of the innovator biologic. Regulators in the EU and other countries also have been given the authority to approve biosimilars. The extent to which a biosimilar, once approved, will be substituted for the innovator biologic in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.
- **In the U.S., the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations. If granted, this "pediatric exclusivity" provides an additional six months which are added to the term of data protection as well as to the term of any relevant patents, to the extent these protections have not already expired.**

Outside the major markets, the adequacy and effectiveness of intellectual property protection for pharmaceuticals varies widely. Under the Trade-Related Aspects of Intellectual Property Agreement (TRIPs) administered by the World Trade Organization (WTO), over 140 countries have now agreed to provide non-discriminatory protection for most pharmaceutical inventions and to assure that adequate and effective rights are available to all patent owners. Because of TRIPs transition provisions, dispute resolution mechanisms, and substantive limitations, it is difficult to assess when and how much, if at all, we will benefit commercially from this protection.

There is no assurance that the patents we are seeking will be granted or that the patents we hold would be found valid and enforceable if challenged. Moreover, patents relating to particular products, uses, formulations, or processes do not preclude other manufacturers from employing alternative processes or marketing alternative products or formulations that compete with our patented products. In addition, competitors or other third parties sometimes may assert claims that our activities infringe patents or other intellectual property rights held by them, or allege a third-party right of ownership in our existing intellectual property.

Our Intellectual Property Portfolio

We consider intellectual property protection for certain products, processes, and uses—particularly those products discussed below—to be important to our operations. For many of our products, in addition to the compound patent we hold other patents on manufacturing processes, formulations, or uses that may extend exclusivity beyond the expiration of the compound patent.

The most relevant U.S. patent protection or data-based protection for our major marketed products is as follows:

- *Alimta* is protected by a compound patent (2016), data protection for pediatric studies which extends this exclusivity to 2017, and a concomitant nutritional supplement use patent (2022).
- *Byetta* is protected by a patent covering its use in treating type 2 diabetes (2017).
- *Cialis* is protected by compound and use patents (2017).
- *Cymbalta* is protected by a compound patent (2013).
- *Effient* is protected by a compound patent (2017).

- *Evista* is protected by patents on the treatment and prevention of osteoporosis (2012 and 2014). Evista for use in breast cancer risk reduction is protected by orphan drug exclusivity (2014).
- *Humalog* is protected by a compound patent (2013).
- *Strattera* is protected by a patent covering its use in treating attention deficit-hyperactivity disorder (2016).
- ***Tradjenta* is protected by a compound patent (2023), and Boehringer Ingelheim has applied for a patent extension under the patent restoration laws to 2025.**

U.S. patent protection or data-based protection for new molecular entities which have been submitted for regulatory review is as follows. Additional information about these compounds is provided in the Management's Discussion and Analysis section under "Late Stage Pipeline". The dates below do not include any potential patent extensions or adjustments described above:

[Listing of submitted NMEs and protection period will be included here]

Worldwide, we sell all of our major products under trademarks that we consider in the aggregate to be important to our operations. Trademark protection varies throughout the world, with protection continuing in some countries as long as the mark is used, and in other countries as long as it is registered. Registrations are normally for fixed but renewable terms.

In addition to this enhanced disclosure about patent protection, we will also note in future filings which of our Phase III new molecular entities listed in the Management's Discussion and Analysis section under "Late Stage Pipeline" are biologics.

To summarize, in future filings we will enhance our disclosure to include:

- A discussion of the relevant protection periods provided in major jurisdictions, which ranges from:
  - A maximum of 20 years from the PCT filing, subject to extensions from patent term extension and/or restoration
  - A minimum term of data protection, depending on the applicable jurisdiction
- The point in the drug discovery process the PCT filing occurs, which will enable the reader to estimate the potential patent protection remaining at approval (if received)
- Current U.S. patent information for our NMEs in our late stage pipeline that have been submitted for regulatory review
- More clearly identifying which Phase III NMEs are biologics.

Comment:

Notes to Consolidated Financial Statements
Note 15, Contingencies, page 69
Zyprexa Litigation, page 70
Other Product Liability Litigation, page 71

2. Refer to your response to prior comment two where you state that you do consider on a quarterly basis whether you can reasonably estimate the range of potential losses on your material loss contingencies and that you would disclose this range as required by ASC 450 if you could reasonably estimate the range of potential losses. Please tell us how you identify your material loss contingencies to consider on a quarterly basis whether you can reasonably estimate the range of potential losses, as opposed to your immaterial loss contingencies. It appears that if you are able to distinguish between material and immaterial loss contingencies, you are able to make an estimate regarding the reasonably possible losses related to your litigation contingencies. Please clarify this matter. Additionally, tell us whether and, if so, to what extent you attempt to quantify the amount of reasonably possible losses for each litigation contingency on a quarterly basis, and if not, please explain your basis for not attempting to quantify those matters. If you maintain that you are not able to estimate a range of reasonably possible losses for each of your litigation contingencies individually or in the aggregate, please tell us the specific reason(s), in addition to the general factors you have already stated in your response, you are not able to estimate such a range.

Response:

In addition to the above, we understand from our telephonic conversation on July 28, 2011, that you would like us to explain why it is difficult to reasonably estimate a range of possible loss for our existing litigation contingencies.

As we discussed on that call, senior financial reporting management meets on a quarterly basis with internal legal counsel regarding litigation, as well as with our external SEC legal or litigation counsel as necessary. For litigation contingencies, the bottom of the range of possible loss is zero. With regard to each litigation matter, as well as for investigations and other similar matters, once we are able to reasonably estimate the bottom of the range or a best estimate for losses that are probable, we accrue the liability in accordance with ASC 450. Whether or not we have a probable loss, we typically conclude that the upper end of the range of possible loss cannot be reasonably estimated. Below we discuss examples of the factors that may prevent us from reasonably estimating the upper end of the range of possible loss for product liability litigation and we provide more information regarding patent litigation, the two types of outstanding litigation included in our contingencies disclosure.

Patent Litigation

Matters brought pursuant to procedures set out in the Hatch-Waxman Act are challenges to the enforceability of our U.S. patent exclusivity. While we believe our patents are enforceable, the

unsuccessful defense of patent exclusivity enables the other party to introduce generic compounds into the market. Strictly speaking, this does not result in a liability, but rather the loss of a specific product's future revenue. Consequently, disclosure of a range of possible losses is generally not applicable to this type of litigation. We discuss the potential for the loss of significant product revenue as a result of patent litigation in both our contingencies note and our MD&A. Additionally, in our second quarter 2011 Form 10-Q, we supplemented our patent litigation disclosure in both contingencies and MD&A with the following language, which we believe clarifies the potential impact of a negative patent litigation outcome:

> We believe the Hatch-Waxman challenges to Alimta and Strattera are without merit and expect to prevail in this litigation. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome in either of these cases could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position. **We expect a loss of exclusivity in the cases described above to result in a rapid and severe decline in future revenues in the relevant market. We are already experiencing this with Gemzar.**

Therefore, we believe we appropriately disclose the risk of potential future revenue loss related to this litigation.

Product Liability Litigation

With product liability litigation there may be hundreds or thousands of claims, all of which could ultimately be individually tried. Generally, individual claims are not material to the company; however, claims related to a certain product may be material in the aggregate. When evaluating whether a group of claims potentially may be material, we primarily consider qualitative factors (due to the difficulty in quantifying the potential loss contingency as discussed later in this section). These factors include the type of product, the nature of the claims asserted, the number of actual and potential claimants, historical judgments and settlements for similar claims, and the likelihood of receiving similar claims in the future. This qualitative assessment allows us to determine whether the potential loss contingency may be material (we typically disclose product liability litigation when we have a substantial number of claims even though it may be uncertain that the exposures will ultimately be material); however, this limited information does not provide enough detail to reasonably estimate a range of loss.

Assuming no credible scientific evidence to the contrary, we believe the likelihood that we will ultimately lose such cases is remote. In cases where there is arguably evidence to support liability on the part of the company, it is still often very difficult to estimate the range of possible loss. A financial claim made by a plaintiff is insufficient alone to establish a range of possible loss. In addition, it is impossible to reasonably estimate a range of possible loss until we have a good understanding of the facts of an individual case – which normally does not happen until we are well into the discovery phase of litigation.

Further, even if we understand the facts of an individual case there are a number of other factors, some of which are very subjective, that create significant uncertainty in predicting the outcome of litigation and may preclude us from being able to reasonably estimate the upper

end of the range of possible loss. These include, for example: the law and procedure of the jurisdiction; the judge(s) hearing the case; the potential jury pool; historical verdicts in the relevant court(s); the skills and strategy of our counsel and of opposing counsel, the specific facts of the case, and legal uncertainty or facts in dispute. The potential for punitive damages makes estimating the top end of the range especially difficult. Punitive damage awards in product liability cases are highly unpredictable. The law of punitive damages is uncertain in many jurisdictions, and the size of possible awards can vary widely based on subjective factors such as the judge and jury, the nature of the injury, the type of evidence that is deemed admissible, and other factors that may be unrelated to the specific claim.

Sometimes after product liability cases have progressed, we may decide to pursue a settlement strategy in order to mitigate disruption and risk to the business, even where we believe we have strong defenses to liability. If and when we reach a point in discussions where we believe it is probable that the other side will accept a settlement that is also acceptable to us, we accrue the liability in accordance with ASC 450. However, while negotiating the settlement we always preserve the option of continued litigation in the event we are unable to reach agreement on both the amount and the terms of a settlement. In this situation, we are still unable to reasonably estimate the upper end of the range of possible loss for the reasons cited above. Further, we do not believe that an offer of settlement from the other side is sufficient alone to establish a reasonable estimate of the upper end of a range of possible loss. Often the amounts of such offers are unreasonable or are offered on terms which are unacceptable to the company. Also, when there are many claimants and plaintiffs' attorneys, it is likely that not all claims will be covered in a single settlement. As a result, even when we have reached a point in settlement talks where a probable loss has occurred under ASC 450, we cannot reasonably estimate the range of possible loss without also considering the risks and uncertainty of litigation.

If you have any questions about these responses or require additional information, please contact me at 317-276-2024.

Sincerely,

ELI LILLY AND COMPANY

/s/ Arnold C. Hanish
Vice President, Finance and
Chief Accounting Officer