



December 22, 2008

Federal Trade Commission  
Office of the Secretary  
Room H-135 (Annex F)  
600 Pennsylvania Avenue NW  
Washington, DC 20580

RE: Emerging Health Care Competition and Consumer Issues – Comment,  
Project No. P083901

Dear Commissioners:

Hospira, Inc. was grateful for the opportunity to participate in the Federal Trade Commission's (FTC) workshops on emerging health care competition and consumer issues. We thought they were productive workshops and look forward to reading the report of your findings early next year.

Additionally, we appreciate the chance to provide additional comments and information on the topic. Developing an abbreviated pathway for the approval of safe, effective biogenerics is a top priority for Hospira and we are pleased that the FTC is interested in the issue.

If Hospira can provide additional information or answer additional questions, please let us know. We look forward to working with the Commission and Congress on this critical issue.

Sincerely,

John Lane  
Vice President, Biologics

Lori Bowman  
Director, Federal Government Affairs

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**Federal Trade Commission  
Supplemental Request for Comments: Submission by Hospira, Inc.  
Emerging Health Care Competition and Consumer Issues Comment, Project No. P083901  
December 22, 2008**

**I. Potential Clinical Savings with Biosimilar/Biogeneric Pathway**

Hospira expects that a biosimilar/biogenic product, as with a small molecule generic drug, will have reduced requirements as compared to an innovator application under the BLA process. Generally, we anticipate that the biosimilar/biogenic model would require (a) fewer preclinical studies, (b) no Phase II study and (c) a reduction in or no clinical studies based on the FDA's requirements. The scientists at the FDA should determine the specific requirements for a biosimilar/biogenic on a case by case basis. For example, certain simple proteins with demonstrated biochemical and biophysical sameness and good safety histories should require less clinical work than more complex proteins. Clinical requirements would likely be influenced by (a) complexity of the protein, (b) number and type of indications of the reference product, (c) safety history of the reference product and (d) the evolution and experience the market and FDA has with other biosimilar/biogenics, among other things.

The reduction in the clinical development program produces the greatest savings to the manufacturer and ultimately to the consumer. For example, when Phase III clinical studies are required by the FDA, manufacturers should be able to conduct a single Phase III study in one indication and the results of the study should be extrapolated across other indications, presuming the product has the same mechanism of action in each indication. Therefore, if the reference product had several indications all based on the same mechanism of action, then one could expect a significant reduction in clinical work for the biosimilar/biogenic. The reduction in clinical development cost also creates an opportunity for more manufacturers to develop biosimilar/biogenics. With more biosimilar/biogenics on the market, competition will drive down the costs to consumers and the federal government.

The estimated savings for a biosimilar/biogenic manufacturer with a reduced clinical development program requirement could range from 40-50% of the work done by the innovator. The greatest savings will come depending on FDA's view of how much of the innovators work will have to be duplicated to demonstrate clinical activity.

A biosimilar/biogenic pathway would undoubtedly result in savings to manufacturers that could reach hundreds of millions of dollars per product but it is dependent on a number of factors including, but not limited to, the final bill passed by Congress and the FDA regulatory requirements.

**II. Impact of Interchangeability on Clinical Investment**

In medicine today, biologics are used interchangeably in current practice without any additional clinical trials to show safety of interchangeability, e.g., the erythropoietin products Epogen®, Procrit®, Aranesp® can be used interchangeably in the U.S. and Eprex®, Neorecormon®, and Aranesp® in Europe.

The same practice should apply to a biogenic pathway. A product demonstrated to be biogenic should not need additional clinical evidence to demonstrate interchangeability. If the FDA did impose additional requirements on a biosimilar/biogenic manufacturer in order to achieve an interchangeability rating, it is conceivable that those additional requirements could result in more clinical assessments performed for the biosimilar/biogenic product than initially performed by the innovator. For example, where the reference product had only one approved indication, there is discussion that the biogenic equivalent may not only have to conduct an initial Phase III trial but also an additional Phase III trial to support interchangeability, a study that the innovator did not have to perform when first approved over 20 years ago.

The scientists at the FDA should determine the requirements to support an interchangeability rating on a case-by-case basis. If the Congress or FDA requires onerous, repetitive clinical work for biogenerics applicants, the result will be fewer savings to consumers and federal government.

### **III. Access to Innovator's Clinical Data and Impact on Biosimilar/Biogenic Manufacturer**

If a company pursuing the development of a biosimilar/biogenic cannot reference any of the innovators' preclinical or clinical data, there would be no incentive to embark on an abbreviated approval pathway. If that is the case, manufacturers would be better off pursuing a full approval pathway. The purpose in establishing an abbreviated pathway is to create a shortened process that would enable companies to develop, based on biochemical and biophysical sameness, a "generic" version of an innovator product without being required to repeat scientifically unnecessary work, which would drive up development costs. This would then allow a biosimilar/biogenic company to provide consumers with an alternative choice that is deemed to be safe and effective and at a more affordable price.

### **IV. Biosimilar/Biogenic Patent Landscape**

#### **A. Biopharma patents are neither narrow nor easily circumventable**

The suggestion was made by a number of panellists in panel three at the FTC workshop that biopharmaceutical patents are narrow and easily circumventable. This is simply incorrect. Hospira made detailed submissions on point in its September 30, 2008 response to the FTC questions, and will not repeat those comments here.

We simply wish to reinforce the following:

- Biotech process patents in practice may be much more difficult to circumvent than small molecule process patents due to the relative immaturity of the biopharmaceutical industries compared to small molecule industries – there may be only one known way to make a biopharmaceutical product.
- Platform patents are in fact very broad, and are often overlapping. For example, there are three families of patents, controlled by Genentech, Inc., Protein Design labs, Inc., and the Medical Research Counsel, respectively, all directed to methods of producing humanized antibodies and antibodies created using those methods. In another example, The Trustees of Columbia University control a single patent directed to processes for inserting into eucaryotic cells a multiplicity of DNA molecules, including genes coding for desired proteinaceous materials. Again due to the immaturity of the U.S. biopharma industries, those broad platform technology patents currently apply routinely to multiple biopharma products. This is evidenced by the fact that many of these platform patents have been licensed by innovators (as acknowledged by many of the branded company participants in panel three).
- Whilst smaller biopharma products (such as peptides, fragments and small proteins) may have granted patents covering the full sequence of the product, Amgen's recent success on EPO full sequence claims against Roche and TKT (different products and technologies) shows the power in such claims.<sup>1</sup>
- For "larger biopharma" product (such as monoclonal antibodies), sequence claims do not cover the whole molecule but instead cover all or part of the variable domain of the antibody. Generally such patents will only claim the CDRs (complementarity determining regions, i.e., very short sequence located in the variable domain of the antibody that specify antigen binding or "complements" the target antigen). CDRs make up approximately 12% of the sequence of the

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<sup>1</sup> See *Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 2008 U.S. Dist. LEXIS 77343 (D. Mass. Oct. 2, 2008) and *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293 (Fed. Cir. 2006).

antibody light chain and 7 – 9% of the sequence of the heavy chain of a monoclonal antibody. Sequence claims to CDRs are very broad! Note:

- As long as the claimed CDR sequences are copied by the biosimilar/biogenic/generic company (i.e. the biosimilar/biogenic/generic company copies the claimed 7 – 12% of the monoclonal antibody sequence), it is immaterial for infringement purposes what the rest of the molecule looks like. It is also often irrelevant whether the rest of the molecule even exists!
- Sequence changes outside the CDR are immaterial to infringement – all variants to sequences outside the CDRs will still infringe such a patent.
- Minor and immaterial sequence changes within the CDR may potentially expose the biogenic company to an infringement risk under the doctrine of equivalents.

## **B. Biopharma patents protect the innovator’s monopoly (on average) for between 15.26 and 18.57 years after launch**

Hospira also wishes to address the suggestion made by branded company representatives in panel three that by the time a product is launched, the initial primary patent term has, or will shortly, expire. For example:

Doug Norman, General Patent Counsel at Eli Lilly and Co.: *“Many times by the time you’re on the market with your molecule, your initial primary patent has expired because it often takes that long.”*<sup>2</sup> ..... [In the context of patent term extensions] *“if you only have one or two or three years left on your key patent, whatever key patents that is covering your product, then you are only allowed to add to that a maximum of three years or five years beyond that giving you a total of maybe a whopping eight years of patent protection, if you get that far.”*<sup>3</sup>

This is simply incorrect. In every instance that Hospira examined (see *Table 1* below), the identified biopharmaceutical had greater patent protection than indicated by Mr. Norman. In fact, the average minimum remaining patent protection for the biopharmaceuticals in *Table 1* (as identified in the innovator’s Form 10-Ks) was nearly double the eight years identified by Mr. Norman. To assist in explaining how this is incorrect, Hospira has:

- Identified the top 10 biopharmaceutical products identified in the LaMerie Business Intelligence report *Top 20 Biologics 2006* (Feb 2007).
- For each of those products, identified patent information provided by the branded sponsor of those biopharmaceutical products in its 10K statements<sup>4</sup>; and
- Calculated the **post launch average effective patent term** according to the information provided by that branded sponsor to the market.

This simple analysis shows us that on the innovator’s own calculations, for the top 10 biopharma products of 2006, patents protect the innovator’s monopoly (on average) for between 15.26 and 18.57 years after launch. It is at that point when the innovator expects competition in the marketplace on these biopharmaceuticals, and not the 3 years or even 8 years identified by Mr. Norman above.

The full analysis is included in *Attachment 1*. However, a summary of that information is set out in *Table 1* below.

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<sup>2</sup> Comments of Doug Norman, General Patent Counsel at Eli Lilly and Co., at page 17 of the transcript of Session 3 of the FTC Nov. 21, 2008 Roundtable.

<sup>3</sup> Comments of Doug Norman, General Patent Counsel at Eli Lilly and Co., at page 33 of the transcript of Session 3 of the FTC Nov. 21, 2008 Roundtable.

<sup>4</sup> Form 10-K is an annual report filed by a company pursuant to section 13 and 15(d) of the Securities Exchange Act of 1932

**Table 1: Time between approval and Innovator’s 10-K patent expiry date for top 10 biopharma molecules of 2006**

<b>Product/2006 Sales (MM)</b>	<b>FDA Approval</b>	<b>Patents from Innovator 10-K</b>	<b>Time btw FDA Approval and Innovator 10-K Patent Expiry</b>
1. Enbrel/ Embrel (etanercept) US \$4,474	2Nov1998	5 Sept 2009 5 Sept 2009 23 Oct 2012	Min. Period <sup>5</sup> : <b>10 years, 10 months, 3 days</b> Max. Period <sup>6</sup> : <b>13 years, 11 months, 21 days</b>
2. Aranesp (darbepoetin alfa) US \$4,121	17Sep2001	15 May 2024 12 Oct 2010 16 Aug 2014	Min. Period: <b>9 years, 25 days</b> Max. Period: <b>22 years, 7 months, 28 days</b>
3. Rituxan/ MabThera (rituximab) US \$3,912	26Nov1997	14 Oct 2014 7 Apr 2015	Min. Period: <b>16 years, 10 months, 18 days</b> Max. Period: <b>17 years, 4 months, 12 days</b> (may be extended by additional patents)
4. Remicade (infliximab) US \$3,764	24Aug1998	N/A.	N/A
5. Procrit/ Eprex (epoetin alfa) US \$3,180	1Jun1989	N/A	N/A
6. Herceptin (trastuzumab) US \$3,175	25Sep1998	3 May 2019 18 Jun. 2019 3 May 2019	Min. Period: <b>20 years, 7 months, 8 days</b> Max. Period: <b>20 years, 8 months, 24 days</b> (may be extended by additional patents)
7. Epogen (epoetin alfa) US \$2,844	1Jun1989	15 Aug 2012 20 Aug 2013 20 Aug 2013 26 May 2015	Min. Period: <b>23 years, 2 months, 14 days</b> Max. Period: <b>25 years, 11 months, 25 days</b>
8. Neulasta (pegfilgrastim) US \$2,710	31Jan2002	20 Oct 2015 8 Feb 2015	Min. Period: <b>13 years, 8 days</b> Max. Period: <b>13 years, 8 months, 20 days</b>
9. Actrapid/Novolin US \$2,653	25Jun1991	N/A	N/A
10. Avastin (bevacizumab) US \$2,395	26Feb2004	7 Apr 2017 23 Mar 2019	Min. Period: <b>&lt; 13 years, 1 month, 12 days</b> Max. Period: <b>&lt; 15 years, 25 days</b> (may be extended by additional patents)
			<b>Average Min. Period: 5569 days (~15.26 years)</b> <b>Average Max. Period: 6779 days (~18.57 years)</b>

With regard to Epogen above, by the time the last of Amgen’s patents covering that product expire (on 26 May 2015), Amgen will have enjoyed a 31.5 year monopoly on its epoetin alfa product.

**C. Data exclusivity (encourages data collation for U.S. market) and patents (encourages innovation) are separate and distinct and should not be confused**

Data exclusivities should not be confused with patent monopolies.

Patent monopolies are an important but limited exception to (otherwise) anti-competitive conduct. Patents are excepted in this manner in order to reward and incentivize innovation. For the potential

<sup>5</sup> The term “Min. Period” refers to the period of time from FDA Approval to the earliest expiring innovator patent identified in its Form 10-K.

<sup>6</sup> The term “Max. Period” refers to the period of time from FDA Approval to the latest expiring innovator patent identified in its Form 10-K.

prize of a 20-25 year (with extensions) (post GATT) U.S. patent monopoly (plus any additional PTA), a person is motivated to innovate.

However, data exclusivity does not incentivize innovation. Rather, data exclusivity motivates a person to introduce a drug into the U.S. market. For the potential prize of five years small molecule New Chemical Entity (NCE) data exclusivity a person is motivated to collate the clinical data necessary to support a new drug application in the U.S., and to file an application for regulatory approval of that drug in the U.S.

Further periods of data exclusivity such as pediatric exclusivity, new indication exclusivity and exclusivity for new formulation/dosage regimes similarly incentivize a person to develop further clinical data to support further use of their pharma product in the U.S.

Hospira is not anti-patent. On the contrary, Hospira supports the grant and enforcement of the current extended and adjusted 20 year U.S. patent monopolies for inventions which meet all of the relevant statutory requirements.

Hospira is also not anti-data exclusivity. Hospira supports the grant of limited term data exclusivity for clinical information collected for the purpose of ensuring a product is safe and effective to sell in the U.S. Hospira believes Hatch Waxman provides a workable data exclusivity model for all drugs, including small molecule and biopharmaceutical drugs.

It is incorrect and confusing to speak about data exclusivity as providing an incentive to innovate: that is the role of patent monopolies, not data exclusivity. When we confuse the issues, we end up speaking about data exclusivity as though it is a “quasi patent”, which it is not. Patent protection is enough to motivate.

#### **D. Legislation must deal with the present biopharma product world and the future biopharma product world.**

As discussed by various panel three and five members at the FTC workshop, the current U.S. biopharmaceutical technologies and industries are immature, and biopharmaceutical companies currently operate in a “hybrid” pre-GATT and post-GATT patent landscape.<sup>7</sup>

In the future, U.S. biopharmaceutical technologies and industries will mature, and the biopharmaceutical companies will be operating in a post-GATT patent landscape

Hospira supports the introduction of a biogeneric pathway that is suitable for today, and for the future.

#### **E. Greater uncertainty and greater potential damages means “launch at risk” unlikely for biopharma products**

Hospira strongly disagrees with the suggestion made by Novartis that launching at risk was not a real risk in the U.S. Ken Goldman, MS, Vice President of Intellectual Property Strategy, Novartis International AG, stated that “*The need for an early resolution of early litigation because of the fear of launching at risk is not a serious one we contend.*”<sup>8</sup>

Again this is simply incorrect. Launching without patent certainty into the U.S. involves significant risk for a biopharmaceutical drug product than a small molecule drug product for the following reasons:

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<sup>7</sup> For those patent applications filed or patents granted before 8. Jun. 1995, patent protection extends for 20 years from the date of the earliest filed application or 17 years from the date the patent issues, whichever is longer. For those patent applications filed on/after 8 Jun. 1995, any resulting patent protection extends for 20 years from the date of the earliest filed application. Many biopharmaceutical technologies are old enough to be protected by patent applications filed (and thus patents granted) on both sides of the 8 Jun. 1995 date.

<sup>8</sup> Comments of Ken Goldman, MS, Vice President of Intellectual Property Strategy, Novartis International AG, at page 13 of the transcript of Session 5 (Patent Dispute Resolution Processes) of the FTC Nov. 21, 2008 Roundtable.

- The R&D investment for a biogeneric is significantly greater and could approach \$100 million.
- The patent landscape is significantly more complex & uncertain.
- The body jurisprudence is extremely immature for biotech related patents.
- Due to the greater market value of the product, the potential damages payable for infringing a biotech patent are significantly greater than the potential damages payable for infringing a small molecule patent. The risk of treble damages multiplies this difference exponentially.

Absent a workable model which enables a biogeneric company to obtain patent certainty prior to launch (including litigation certainty on infringement and invalidity risks), there is a very real likelihood that competition in the biogeneric marketplace could be limited to only the largest, most aggressive, and resourced biogeneric companies that could consider a “launch at risk” into the U.S. Hospira believes the cumulative effect of these conditions may delay biogeneric market entry, and therefore biopharmaceutical competition, for many years, perhaps longer than a decade.

**F. We need a workable model to enable biogenerics competition in the U.S.**

Hospira supports a workable model that would improve the current small molecule Hatch-Waxman pathway by addressing the patent resolution process, process and submarine patents and keeps data exclusivity to 5 years. This type of model will enable robust biogenerics competition in the U.S.

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The biologic drugs included below were identified in a February 2007 report by LaMerie Business Intelligence as, in order from 1 to 10, the top 10 selling biologics worldwide for calendar year 2006.<sup>9</sup>

<b>Product Name/2006 Sales (min)</b>	<b>FDA Approval</b>	<b>Latest-to-Expire Patents from Innovator 10-K</b>	<b>Comments</b>	<b>Difference Between FDA Approval and Innovator 10-K Patent Expiry</b>								
1. Enbrel/ Embrel (etanercept)  US \$4,474	2 November 1998	From the <a href="#">Amgen 2007 Form 10-K (dated 28 Feb. 2008)</a> <sup>10</sup> :  <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;"><b>Subject Matter</b></th> <th style="text-align: left;"><b>Expiry</b></th> </tr> </thead> <tbody> <tr> <td>Methods of treating TNF — dependent inflammatory response</td> <td>5 Sept 2009</td> </tr> <tr> <td>TNFR proteins and pharmaceutical compositions</td> <td>5 Sept 2009</td> </tr> <tr> <td>TNFR DNA vectors, cells and processes for making proteins</td> <td>23 Oct 2012</td> </tr> </tbody> </table>	<b>Subject Matter</b>	<b>Expiry</b>	Methods of treating TNF — dependent inflammatory response	5 Sept 2009	TNFR proteins and pharmaceutical compositions	5 Sept 2009	TNFR DNA vectors, cells and processes for making proteins	23 Oct 2012	From the Amgen 2007 Form 10-K (dated 28 Feb. 2008):  “We have filed applications for a number of patents, have been granted patents or have obtained rights relating to our products and various potential products. Our material patents are set forth in the table below.” [part of table replicated in chart]  “There can be no assurance that our patents or licensed patents will afford legal protection against competitors or provide significant proprietary protection or competitive advantage. In addition, our patents or licensed patents	Min. Period <sup>11</sup> : <b>10 years, 10 months, 3 days</b>  Max. Period <sup>12</sup> : <b>13 years, 11 months, 21 days</b>
<b>Subject Matter</b>	<b>Expiry</b>											
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<sup>9</sup> From “Top 20 Biologics 2006,” LaMerie Business Intelligence, dated February 2007.

<sup>10</sup> According to the Securities and Exchange Commission ([www.sec.gov](http://www.sec.gov)), Form 10-K is an annual report filed by a company pursuant to section 13 and 15(d) of The Securities Exchange Act of 1934.

<sup>11</sup> The term “Min. Period” refers to the period of time from FDA Approval to the earliest expiring innovator patent identified in its Form 10-K.

<sup>12</sup> The term “Max. Period” refers to the period of time from FDA Approval to the latest expiring innovator patent identified in its Form 10-K.

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			<p>could be held invalid or unenforceable by a court, or infringed or circumvented by others, or others could obtain patents that we would need to license or circumvent. Competitors or potential competitors may have filed patent applications or received patents, and may obtain additional patents and proprietary rights relating to proteins, small molecules, compounds or processes competitive with ours. Additionally, for certain of our product candidates, competitors, or potential competitors may claim that their existing or pending patents prevent us from commercializing such product candidates in certain territories. Further, when our patents expire, other companies could develop new competitive products to our products.”</p>	

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Subject Matter	Expiry											
Glycosylation analogs of erythropoietin proteins	15 May 2024											
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3. Rituxan/ MabThera (rituximab)  US \$3,912	26 November 1997	From the <a href="#">Genentech 2007 Form 10-K (dated 26 Feb. 2008)</a> :  <table border="0"> <thead> <tr> <th data-bbox="787 1211 1018 1263">Identified U.S. Patent(s)</th> <th data-bbox="1060 1211 1165 1239">Expiry</th> </tr> </thead> <tbody> <tr> <td data-bbox="787 1295 1018 1323">5,677,180</td> <td data-bbox="1060 1295 1165 1323">14 Oct 2014</td> </tr> <tr> <td data-bbox="787 1356 1018 1383">5,736,137</td> <td data-bbox="1060 1356 1165 1383">7 Apr 2015</td> </tr> </tbody> </table>	Identified U.S. Patent(s)	Expiry	5,677,180	14 Oct 2014	5,736,137	7 Apr 2015	From the Genentech 2007 Form 10-K (dated 26 Feb. 2008):  “[W]e have identified in the following table the latest-to-expire U.S. patents that are owned or controlled by or exclusively licensed to Genentech having claims	Min. Period: <b>16 years, 10 months, 18 days</b>  Max. Period: <b>17 years, 4 months, 12 days</b> (period may be extended by additional patents – see Comments)		
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			<p>directed to product-specific compositions of matter (e.g., nucleic acids, proteins, protein-producing host cells). This table does not identify all patents that may relate to these products. For example, in addition to the listed patents, we have patents on platform technologies (that relate to certain general classes of products or methods), as well patents on methods of using or administering many of our products, that may confer additional patent protection. We also have pending patent applications that may give rise to new patents relating to one or more of these products. The information in this table is based on our current assessment of patents that we own or control or have exclusively licensed and is subject to revision, for example, in the event of changes in the law or legal rulings affecting our patents or if we become aware of</p>	

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			new information. Significant legal issues remain to be resolved as to the extent and scope of available patent protection for biotechnology products and processes in the U.S. and other important markets outside of the U.S. We expect that litigation will likely be necessary to determine the validity, enforceability, and scope of certain of our patents and other proprietary rights.”	
4. Remicade (infliximab)  US \$3,764	24 August 1998	From the <a href="#">J&amp;J 2007 Form 10-K (dated 26 Feb. 2008)</a> :  No specific patent information provided.	From the J&J 2007 Form 10-K (dated 26 Feb. 2008):  “Johnson & Johnson and its operating companies have made a practice of obtaining patent protection on their products and processes where possible. They own or are licensed under a number of patents relating to its products and manufacturing processes, which in the aggregate are believed to be of material importance to Johnson & Johnson in the	N/A

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			operation of its businesses. Sales of the Company's two largest products, RISPERSDAL ® and REMICADE ®, accounted for approximately 6% and 5% of Johnson & Johnson's total revenues, respectively, for fiscal 2007. Accordingly, the patents related to these products are believed to be material to Johnson & Johnson as a whole."									
5. Procrit/ Eprex (epoetin alfa)  US \$3,180	1 June 1989	From the <a href="#">J&amp;J 2007 Form 10-K (dated 26 Feb. 2008)</a> :  No specific patent information provided.	See generally comments above from J&J 2007 Form 10-K for 4. Remicade.									
6. Herceptin (trastuzumab)  US \$3,175	25 September 1998	From the <a href="#">Genentech 2007 Form 10-K (dated 26 Feb. 2008)</a> :  <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Identified U.S. Patent(s)</th> <th style="text-align: left;">Expiry</th> </tr> </thead> <tbody> <tr> <td>6,339,142</td> <td>3 May 2019</td> </tr> <tr> <td>6,407,213</td> <td>18 Jun. 2019</td> </tr> <tr> <td>7,074,404</td> <td>3 May 2019</td> </tr> </tbody> </table>	Identified U.S. Patent(s)	Expiry	6,339,142	3 May 2019	6,407,213	18 Jun. 2019	7,074,404	3 May 2019	See generally comments above from Genentech 2007 Form 10-K for 3. Rituxan/MabThera.	Min. Period: <b>20 years, 7 months, 8 days</b>  Max. Period: <b>20 years, 8 months, 24 days</b> (period may be extended by additional patents – see Comments)
Identified U.S. Patent(s)	Expiry											
6,339,142	3 May 2019											
6,407,213	18 Jun. 2019											
7,074,404	3 May 2019											

**Federal Trade Commission  
Supplemental Request for Comments: Submission by Hospira, Inc.  
Emerging Health Care Competition and Consumer Issues  
December 22, 2008  
Attachment #1**

Product Name/2006 Sales (mln)	FDA Approval	Latest-to-Expire Patents from Innovator 10-K	Comments	Difference Between FDA Approval and Innovator 10-K Patent Expiry										
7. Epogen (epoetin alfa)  US \$2,844	1 June 1989	From the <a href="#">Amgen 2007 Form 10-K (dated 28 Feb. 2008)</a> :  <table border="0"> <tr> <td style="text-align: right;"><b>Subject Matter</b></td> <td style="text-align: left;"><b>Expiry</b></td> </tr> <tr> <td>Process of making erythropoietin</td> <td>15 Aug 2012</td> </tr> <tr> <td>Product claims to erythropoietin</td> <td>20 Aug 2013</td> </tr> <tr> <td>Pharmaceutical compositions of erythropoietin</td> <td>20 Aug 2013</td> </tr> <tr> <td>Cells that make certain levels of erythropoietin</td> <td>26 May 2015</td> </tr> </table>	<b>Subject Matter</b>	<b>Expiry</b>	Process of making erythropoietin	15 Aug 2012	Product claims to erythropoietin	20 Aug 2013	Pharmaceutical compositions of erythropoietin	20 Aug 2013	Cells that make certain levels of erythropoietin	26 May 2015	See generally comments above from Amgen 2007 Form 10-K for 1. Enbrel/Embrel.	Min. Period: <b>23 years, 2 months, 14 days</b>  Max. Period: <b>25 years, 11 months, 25 days</b>
<b>Subject Matter</b>	<b>Expiry</b>													
Process of making erythropoietin	15 Aug 2012													
Product claims to erythropoietin	20 Aug 2013													
Pharmaceutical compositions of erythropoietin	20 Aug 2013													
Cells that make certain levels of erythropoietin	26 May 2015													
8. Neulasta (pegfilgrastim)  US \$2,710	31 January 2002	From the <a href="#">Amgen 2007 Form 10-K (dated 28 Feb. 2008)</a> :  <table border="0"> <tr> <td style="text-align: right;"><b>Subject Matter</b></td> <td style="text-align: left;"><b>Expiry</b></td> </tr> <tr> <td>Pegylated G-CSF</td> <td>20 Oct 2015</td> </tr> <tr> <td>Pegylated G-CSF</td> <td>8 Feb 2015</td> </tr> </table>	<b>Subject Matter</b>	<b>Expiry</b>	Pegylated G-CSF	20 Oct 2015	Pegylated G-CSF	8 Feb 2015	See generally comments above from Amgen 2007 Form 10-K for 1. Enbrel/Embrel.	Min. Period: <b>13 years, 8 days</b>  Max. Period: <b>13 years, 8 months, 20 days</b>				
<b>Subject Matter</b>	<b>Expiry</b>													
Pegylated G-CSF	20 Oct 2015													
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<b>Product Name/2006 Sales (mln)</b>	<b>FDA Approval</b>	<b>Latest-to-Expire Patents from Innovator 10-K</b>	<b>Comments</b>	<b>Difference Between FDA Approval and Innovator 10-K Patent Expiry</b>						
9. Actrapid/Novolin  US \$2,653	25 June 1991	No information available in annual report and no regulatory filing identified.								
10. Avastin (bevacizumab)  US \$2,395	26 February 2004	From the <a href="#">Genentech 2007 Form 10-K (dated 26 Feb. 2008)</a> :  <table style="width: 100%; border: none;"> <tr> <td style="text-align: center;"><b>Identified U.S. Patent(s)</b></td> <td style="text-align: center;"><b>Expiry</b></td> </tr> <tr> <td style="text-align: center;">6,884,879</td> <td style="text-align: center;">7 Apr 2017</td> </tr> <tr> <td style="text-align: center;">7,169,901</td> <td style="text-align: center;">23 Mar 2019</td> </tr> </table>	<b>Identified U.S. Patent(s)</b>	<b>Expiry</b>	6,884,879	7 Apr 2017	7,169,901	23 Mar 2019	See generally comments above from Genentech 2007 Form 10-K for 3. Rituxan/MabThera.	Min. Period: < <b>13 years, 1 month, 12 days</b>  Max. Period: < <b>15 years, 25 days</b> (period may be extended by additional patents – see Comments)
<b>Identified U.S. Patent(s)</b>	<b>Expiry</b>									
6,884,879	7 Apr 2017									
7,169,901	23 Mar 2019									
<b>Average Min. Period: 5569 days (~15.26 years)</b> <b>Average Max. Period: 6779 days (~18.57 years)</b>										