The Basics of Drug Patents

The Patent System
Congress and the Administration can effect change through:

• Statutes Governing Patents
  – The Patent Act (1952)
  – Biologics Price Competition and Innovation Act (2009)
  – America Invents Act (2012)

• Regulatory Agencies Governing Patents
  – U.S. Patent and Trademark Office (PTO)
  – U.S. Food and Drug Administration (FDA)
The How

HOW ARE PATENTS GRANTED?
THE STANDARDS OF PATENTABILITY

PATENTABILITY TESTS: WHAT DOES IT TAKE TO GET A 20 YEAR MONOPOLY?

Section 101
“Is the subject matter patentable?”

Section 102
• “Is this new?”

Section 103
• “Is the invention obvious?”

Section 112
• “Is the invention fully disclosed (explained)?”
Types of Pharmaceutical Patents

**Types of Pharmaceutical**

- **Small Molecule**
  - Example: Sovaldi
  - Generic
- **Biologic**
  - Example: Humira
  - Biosimilar
TYPES OF PHARMACEUTICAL PATENTS

Pharmaceutical manufacturers pursue patents in three areas:

- **Base patents**: These patents cover the core active ingredient or protein sequence/DNA that make up a medicine and are the foundational patents for every pharmaceutical drug.

- **Secondary patents**: derivative compounds that are inherent within the base patent e.g. different crystalline and **substantially pure forms**, enantiomers, formulations, of the base compound, methods of use, new indications (new use), changes in strength or dosage; new dosing route; combinations with other drugs; segmented patient populations; different processes for manufacturing; packaging/patient instructions; pharmaco-kinetic/therapeutic parameters.

- **Tertiary patents**: Using medical devices paired with an active ingredient that may be off patent to prolong market exclusivity.

**Patent Games**
America’s 12 best-selling drugs in 2017

- Over half of the top 12 drugs have more than 100 attempted patent applications per drug.
- +68% Average price hike since 2012.
- 15 Years already on the U.S. market.
- 125 Average # of patent applications.
- 71 patents granted.
- 38 Average years blocking generic competition.

Humira’s 247 patent applications in the U.S. more than triple those in Europe, and almost quadruple those in Japan.

- TOTAL: 386
- USA: 247
- EUROPE: 76
- JAPAN: 63
LANTUS

74

total patent applications filed for Lantus

95%
of all applications filed after Lantus was on the market

<table>
<thead>
<tr>
<th>Year</th>
<th>Lantus approved by US FDA and on the market</th>
<th>Today</th>
<th>First Lantus biosimilar/generic product stated to launch</th>
</tr>
</thead>
<tbody>
<tr>
<td>'95</td>
<td></td>
<td>'05</td>
<td>Exp 2015</td>
</tr>
<tr>
<td>'05</td>
<td></td>
<td>'10</td>
<td>46 other granted and live patents</td>
</tr>
<tr>
<td>'15</td>
<td></td>
<td>'20</td>
<td>Exp 2031</td>
</tr>
<tr>
<td>'25</td>
<td></td>
<td>'30</td>
<td></td>
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</tbody>
</table>

Table 1: Top-selling biologics and possible term of patent exclusivity

<table>
<thead>
<tr>
<th>Branded Biologic Product</th>
<th>Total # patent applications filed</th>
<th>Potential years blocking biosimilar competition</th>
<th>% of patent applications filed after FDA approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humira</td>
<td>247</td>
<td>39</td>
<td>89%</td>
</tr>
<tr>
<td>Avastin</td>
<td>219</td>
<td>43</td>
<td>73%</td>
</tr>
<tr>
<td>Rituxan</td>
<td>204</td>
<td>47</td>
<td>90%</td>
</tr>
<tr>
<td>Herceptin</td>
<td>186</td>
<td>48</td>
<td>84%</td>
</tr>
<tr>
<td>Remicade</td>
<td>123</td>
<td>32</td>
<td>93%</td>
</tr>
<tr>
<td>Lantus</td>
<td>74</td>
<td>37</td>
<td>95%</td>
</tr>
<tr>
<td>Eylea*</td>
<td>67</td>
<td>31</td>
<td>37%</td>
</tr>
<tr>
<td>Enbrel</td>
<td>57</td>
<td>39</td>
<td>72%</td>
</tr>
<tr>
<td>average</td>
<td>151</td>
<td>40</td>
<td>80%</td>
</tr>
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</table>
PATENT GAMES ARE NOT LIMITED TO BIOLOGICS

<table>
<thead>
<tr>
<th>Brand</th>
<th>Company</th>
<th>FDA Approved</th>
<th>No. of Patent Applications</th>
<th>No. of Granted Patents</th>
<th>Years of potential protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copaxone</td>
<td>Teva</td>
<td>1997</td>
<td>137</td>
<td>67</td>
<td>40</td>
</tr>
<tr>
<td>Epclusa</td>
<td>Gilead</td>
<td>2016</td>
<td>80</td>
<td>43</td>
<td>32</td>
</tr>
<tr>
<td>Truvada</td>
<td>Gilead</td>
<td>2004</td>
<td>72</td>
<td>51</td>
<td>45</td>
</tr>
<tr>
<td>Imbruvica</td>
<td>AbbVie</td>
<td>2016</td>
<td>152</td>
<td>83</td>
<td>30</td>
</tr>
</tbody>
</table>

Is the patent system delivering progress?
11% of the pharmaceutical industry’s 2017 revenue is coming from new products.

“For all the talk of innovation in pharma, a term used with loose abandon, and even looser definition, the challenge of seeing ‘return on invention’ is a significant one.”

- Mark Rea, CEO, IDEA Pharma

Source: IDEA Pharma, Pharmaceutical Innovation Index 2018 - Freshness Index

The need for reform

Some Thoughts
• Modify the “inventiveness” standard for patents
• Severely restrict continuation applications at the USPTO

We can’t solve the drug pricing crisis until we solve the drug patent problem