Cancer Moonshot Challenge

Key Findings:

- **Evidence of immense value of NIH funding:** Analysis of the provided data[1] shows an irrefutable link between patent filings of NIH grant recipients and drug development:
  - 7,051 patent filings from NIH grant recipients
  - Staggering ~100,000 forward citations of the 7,051 patent filings of NIH grant recipients suggesting significant technology impact in anti-cancer drug development efforts
  - Broad based technology Impact indicated by the forward citations with thousands of forward citations per year. 43% of patent filings from NIH grant recipients are cited more than 10 times. Forward citing companies includes both academia and industry leaders
  - 175 back citations from the patents listed in the FDA orange book link to the patent filings of NIH grant recipients.
  - 25 patents are found in the direct co-occurrence matrix between patent filings of NIH grant recipients and FDA orange book applicants

- **FDA Approval Lag Time**: Analysis shows considerable lag time between patent filings and FDA approvals. There is less than 0.5% probability of a new patent application filing being listed in the FDA orange book. Only about 60-70 patent filings per year are listed in the FDA orange book. Similar low levels of approvals are expected for biologics.

- **Top FDA applicants and NIH Grant Recipients Trends**: Novartis has the highest number of patents among FDA orange book applicants. Stanford, Scripps, and UCSD are the top three patent filing NIH grant recipients with average of 230 patent filings.

- **Top Technology Trends (Peaks and Valleys):**
  - **Peaks:** In addition to chemical drugs, there is strong interest in biotech (nucleoside and protein sequences, antibodies), diagnostics, and devices.
  - **Valleys:** Food and Nutrition appears to be a big opportunity area, especially with a goal of prevention and making cancer a livable disease.
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- **Clinical Trials Analysis:**
  - 21% of the anti-cancer clinical trials identify NIH or U.S Federal Agency grants as the source of funding
  - Only Non-industry sponsored clinical trials appear to list NIH or U.S federal agency as the major source of funding. More investigation is needed to better understand listed funding sources.
  - 96% of the clinical trials are directed to all age groups and an overwhelming majority of the clinical trials are interventional

Technology Trends and Policy Implications:

Patent landscape and the accompanying IP competitive intelligence involves understanding and anticipating the competitive environment within which an entity (company or government) operates[2]. Analysis is based on the provided data (~270K records) coupled with additional citation data[3] and clinical trial data.[4]

Analysis of the ~100K forward citations of the 7,051 patent filings of NIH grant recipients shows broad-based significant technology impact. Technology areas of high interest (peaks) include chemical drugs, biotech, diagnostics, devices, and special dosage physical forms.

A key opportunity area (valley) includes food and nutrition. To quote Benjamin Franklin: "*An ounce of prevention is worth a pound of cure*." Thus, it would be beneficial to allocate a portion of anti-cancer NIH grants to focus on food and nutrition studies for cancer prevention. For example, this portion may include funding epidemiological studies to better understand cancer risk factors and to ascertain the links between diet, sugar consumption, fat consumption, grain consumption, exercise, lifestyle, nutritional supplements, exposure to carcinogens etc. with cancer risk.

Another opportunity area is the considerable lag time of (5+ year on average) between patent filings and FDA approvals. It would be beneficial to expedite FDA approval of promising "safe and effective" cancer drugs approved elsewhere. Analysis supports implementation of the policies advocated by Sen. Lamar Alexander (R-Tenn.) and Sen. Richard Burr (R-N.C.) in their recent senate report[5] "Innovation for Healthier Americans":

- *"Effective public policies to facilitate the translation of basic research into the successful development of innovative products, including enhanced collaboration between public sector, academic, and industry efforts;*
- *Modernized clinical trials and a more efficient and effective regulatory framework for medical product"*

In view of the analysis, the following top three policy directives are recommended:

[1] Allocate a larger portion of NIH grants to fund anti-cancer basic research (as applicable) knowing that the resulting publications will continue to advance drug development efforts. NIH grant recipients may be encouraged to find additional industry collaborations.

[2] Allocate a portion of NIH grants for prevention and making cancer a livable disease, including sponsoring more epidemiological studies to understand cancer risk factors and to ascertain the links between diet, sugar consumption, fat consumption, grain consumption, exercise, lifestyle, nutritional supplements, etc. with cancer risk.

[3] Expedite FDA approval of promising cancer drugs, especially those cancer drugs that have been approved elsewhere. This suggestion is in line with the recent Senate report "Innovation for Healthier Americans" from Senators Alexander and Burr.

References:

1. Patent data provided for the Cancer Moonshot challenge
2. Leveraging patent landscape analysis and IP competitive intelligence for competitive advantage, Yateen Pargaonkar, World Patent Information Volume 45, June 2016, Pages 10–20
3. Patent Citation Data: Thomson Innovation
4. Clinical Data: www.Clinicaltrials.gov
5. Innovation for Healthier Americans: Identifying Opportunities for Meaningful Reform to Our Nation's Medical Product Discovery and Development, Senators Alexander and Burr, January 2015
6. Vantage Point Tool available from Search Technology, January 2015

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Biography: Yateen Pargaonkar is the Managing Partner of Riser IP, LLC. Till recently, Yateen was the IP Competitive Trends Manager at Chevron Energy Technology Company. His patent analytics and competitive intelligence experience includes leadership roles of increasing responsibility in the energy sector, consumer goods, biotech, and pharmaceuticals. Previously, Yateen was a Competitive Intelligence Manager and a Senior Information Scientist at Procter & Gamble. He has also worked at different IP law firms and taught a course at UCSD on Patent Searching & Internet Research. Yateen has degrees in chemistry, biochemistry, and molecular biology, as well as three years of research experience at Columbia University. He is a registered U.S. Patent Agent and an active member of PIUG.

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