

Friends and Family and Other Seed Funding: IP Aspects

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by
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Meet The Speaker



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Peter Fasse is a Principal in the Boston office of Fish & Richardson.

With over 35 years of experience, Peter's practice emphasizes client counseling and patent prosecution in a wide variety of technologies, with an emphasis on healthcare, medical devices, and other biological and medical fields as well as various "green" technologies.

Peter helps clients from start-ups to multinationals to develop competitive worldwide patent strategies and to establish solid and defensible patent portfolios. He performs competitive patent analyses, identifies third-party patent risks, and provides patentability and freedom-to-operate opinions. Peter also has experience in opposing and defending patents before the European Patent Office and in U.S. litigation and post-grant proceedings.

Peter has experience in medical therapeutics, diagnostics, devices, and imaging, microfluidic systems, liquid biopsy, nucleic acid sequence analysis systems and software, cell culturing and bioprocessing, molecular biology, complex biomedical systems, optics, machine tools, and lasers.

Specific applications include, e.g., cancer antibodies, engineered AAV systems, microfluidic analysis of circulating tumor and fetal cells, cell-free DNA analysis, next generation sequence analysis, dendritic cell- and DNA- based vaccines, nanoparticle and vector-based delivery, blood analysis systems, nucleic acid probes, tissue engineering, infusion pumps, biochips, laser systems, green energy systems, and diagnostic and therapeutic methods for, e.g., AIDS, cancer, autism, diabetes, psoriasis, and arthritis.

Overview of Fish & Richardson

Established in 1878, Fish has represented many of history's leading innovators, a trend that started early in our history with representing Alexander Graham Bell and the Wright Brothers.

#1 US Firm for IP Litigation

From 2017 to 2021, Fish handled **more patent matters in U.S. District Courts** than any other national firm.

During the same period, Fish was Lead Counsel in **1 of every 6** newly filed ITC Section 337 investigation.

#1 US Firm for Post-Grant Proceedings

Fish was the #1 law firm at the PTAB in 2021

Fish represented petitioners and patent owners in 138 proceedings — handling **59 more PTAB cases overall than its closest competitor.**

Global Patent Prosecution Firm

Fish filed 17,400+ U.S. and foreign patent applications in 2021.

Fish obtained more U.S. utility patents in 2021 than any other firm, securing 5,088 patents — **nearly 500 more than its nearest competitor.**

Fish is a potent force in litigation, a leader in post-grant proceedings and a global prosecution powerhouse.

The firm doesn't just have handfuls of people dotted around the country, but teams stacked with accomplished trial lawyers and high-level strategists in innovation hubs from coast to coast.

-IAM Patent 1000, 2021

Agenda

- **Do investors care about IP?**
- **When to involve IP counsel?**
- **How to develop an IP strategy?**
- **What to budget for US and foreign patents?**
- **Foreign Filing Strategies**
- **Timing of IP Investments?**

Do investors care about IP?

- **Friends and Family?**
 - Often not too savvy about IP
- **Angel Investors?**
 - Often much more interested in your IP
- **VCs?**
 - Generally expect to see a solid IP portfolio
- **Investment in a strong patent portfolio can yield several advantages:**
 - Exclude Competitors
 - Increase Revenue – Licensing
 - Defensive Advantage – Cross Licensing
 - Build Tangible Assets Reflecting Value of R&D

Do investors care about IP?

- **More savvy investors generally know that IP is important, but this can vary depending on the underlying technology**
- **Always use patents to protect **healthcare** inventions**
 - Medical devices need patent protection
 - Medical therapies absolutely need patent protection because of the long time horizon before getting to market
 - Patents on improvements and new methods of administration can be critical to maintain long term protection for a major drug
- **Typically use patents to protect **mechanical** inventions**
 - Unless the first to market advantage is sufficient for a quick return

Do investors care about IP?

- **What about software inventions?**
 - The answer depends on the particular application, market, and expected lifetime of the software
 - If the software will likely become obsolete before a patent issues, then consider alternative forms of protection
 - Trade secret protection may work if the software is kept in-house and used to provide a service that cannot be easily reverse engineered or recreated, **but many investors may want to see at least some patent application filing**
 - Patent offices and courts around the globe are making it more difficult to obtain patent protection for software; however, patents are still being granted on software-based inventions

When to involve IP counsel?

- Try to find IP counsel as soon as you can to avoid costly errors
- Work with IP counsel rather than a friend or relative who is a general practice attorney
- Hire an IP attorney prior to launching your product and prior to any public disclosure of your technology
- If you wait until after disclosures have occurred and/or barring deadlines have passed you may have irreparably lost valuable IP rights
- US law provides a one-year “grace” period to file your application after your first sale or a public disclosure
- **However, many foreign countries have NO grace period**
- The bottom line - protect your IP rights early

How to develop an IP strategy?

- Work with your IP counsel to develop an overall IP strategy
- Identify the goals of your IP portfolio and develop a global strategy
- Develop a budget and filing schedule and identify the technologies to be protected
- The IP strategy should identify the types of IP (e.g., patents, trademarks, copyrights, or trade secrets) that will best protect your products
- Have a comprehensive IP strategy
 - Companies can waste time and money by randomly trying to protect IP that does not align with a clear strategy

What to budget for US and foreign patents?

- **Costs for US filing**
 - Initial US filing - \$5,000-\$20,000 or more
 - Prosecution of US patent application to patent issuance
 - \$5000 - if you happen to get a notice of allowance without any prosecution)
 - \$100,000 – if you get multiple office actions and need to appeal
 - Maintenance Fees after Issuance (small entity) – about \$7000 for life of patent
- **Costs for Foreign Filing**
 - Patent Cooperation Treaty (PCT) ~ \$4000/\$2000 (large/small entity, 50 pages, US search authority)
 - PCT National Stage - \$2000-\$20,000 per country to file, and then \$10,000-\$50,000 to prosecute, per country

Foreign Filing Strategies

- **How do you balance a desire to protect as broadly as possible with the required expense?**
- **You need to ask / answer several questions**
 - Company's goals and profile?
 - **What kind of company are you (size / technology / global presence – footprint / activities?)**
 - Company's resources to be devoted to patent protection?
 - **What will your IP budget support?**
 - **A strategy that lets you file broadly, but does not give you adequate funding to do additional patenting / FTOs / enforcement is far from ideal**
 - Where and how big are my present markets for the invention? Who is the customer? Who is my competition? Where are my business partners located?
 - Where will the product be manufactured? Where will product be used? Where would my competition manufacture its product?

Foreign Filing Strategies

- **You need to ask / answer several questions:**
 - Where would your investors file? Consider filing in markets the investors are likely to value (e.g., China).
 - Where are your emerging markets where future protection may become important?
 - Where does your IP reside (literally) - where could an employee or partner walk out the door with your know-how and start competing with you?
 - Where is your competition located – manufacturing and/or nerve centers?
 - Where are strategic venues for enforcement?
 - Consider shipping hubs or countries like Germany where you can get quick relief

Timing of IP Investments?

- **Consider filing on your key inventions before seeking investment**
 - Your idea and IP may be your only asset when you start seeking angel investor and friends and family funding
- **For many types of products, you may have an early IP investment phase and then an IP maintenance phase**
 - in therapeutics, keep in mind how long it takes to get to market vs. 20 year lifetime of a patent
 - think of new formulations, new modes of delivery, or new dosage regimens, to protect your market once initial patents on drug expire
- **Once you have commercialized your product, another phase of IP protection may arise**
 - Patent litigation, which requires huge investments of time and money (\$2-\$10 million+)
 - Post grant proceedings, such as Inter Partes Review (IPR)(\$200,000-\$500,000+)



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Thank You!



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Supplemental Materials

What other tasks to include in your IP budget?

- **IP acquisition/licensing**
 - Costs can vary dramatically, but should be part of your budget if part of your IP strategy
- **Freedom-to-Operate Analysis (Landscape Review)**
 - Don't assume that you can market and sell your product just because you own a patent or maintain a trade secret
 - Patents provide the right to exclude, NOT to practice the invention
 - Consider your freedom to operate (FTO) before you design your commercial products
 - Budget both time and money to identify competitor patents that may prevent you from making or selling your product
 - A detailed analysis can costs \$25,000-\$100,000 or more
- **Preparing for diligence by potential investor or acquiring company**

How much should you budget for US and foreign patent prosecution?

- **Costs for US filing**
- **Attorney fees for drafting one US quality application can range from \$5,000-\$20,000 or more**
- **Initial USPTO Official Filing Fees**
 - US provisional \$300/\$150 (large/small entity)
 - US utility \$1820/\$890 (large/small entity, no extras)
- **During prosecution of US application and Patent**
 - Responding to each Office Action ~\$2,000-\$15,000 (typically get 2-3 actions)
 - Issue Fee \$1200/\$600 (large/small entity)
 - Maintenance Fees after Issuance (small entity) – 3.5 years (\$1,000); 7.5 years (\$1,880); 11.5 years (\$3,850)(double for large entity)

How much should you budget for US and foreign patent prosecution?

- **Costs for Foreign Filing**
- **Patent Cooperation Treaty (PCT) ~ \$4000/\$2000 (large/small entity, 50 pages, US search authority)**
- **PCT National Stage**
- **What would filing **one patent** in 15 countries cost?**
 - Translation costs – \$35,000 or more, depending on countries
 - Annuities – although spread out over 20 years, you will still be spending almost \$175,000 to maintain all patents for 20 years
 - Prosecution can cost \$5,000 to \$20,000 per country, or more, e.g., if appeals are required
- **Total is \$300K-400K over the life of the patent to file, prosecute, and maintain one family outside the US in 15 top countries**

How much should you budget for US and foreign patent prosecution?

- **Cost for EP National Stage Filings**
- **Regional examination can be cost effective – different regions include EP, Eurasian, ARIPO, and OAPI**
 - Nationalization costs for the same application in 10 of the top EP countries can cost over \$150,000 over the life of the patents
- **Added to the foreign filings from the previous slide, this takes us to over \$450,000-\$550,000**

Foreign Filing Strategies

- **Where to file?**
 - Technology neutral strategy:
 - EPO (almost always)
 - Huge markets and economies (China, Japan, South Korea, and India)
 - Large markets and economies (Brazil, Russia, Taiwan, and Mexico)
 - “No translation required” markets (Canada, Australia, New Zealand, and South Africa – but these markets are quite small)
 - “Proximity to the US” markets (Canada and Mexico)

Foreign Filing Strategies

- **Where to file?**
 - Technology specific strategy:
 - **Software** – EP, AU, CA, CN, IN, JP, KR
 - **Energy** – EP, CA, CN, GCC/SA, MY, MX, NO, RU, UK
 - **Semiconductors/photonics** – EP, AU, CA, CN, IL, JP, KR, TW
 - **Life sciences** – EP, AU, BR, CA, CN, IN, JP, KR, MX, SG, TW
 - **Industrial chemicals** – EP, AU, CA, CN, JP, KR
 - **Medical devices** – EP, CN, CA, JP, AU, IL

Foreign Filing Strategies

- **Where to file?**
 - Filing in non-PCT countries:
 - **Taiwan – expensive translations, but patents typically enforceable**
 - **Argentina – examination very slow, no real procedures for accelerating exam; enforcement questionable**
 - **Venezuela - examination very slow; enforcement questionable especially for US held patents**

Foreign Filing Costs and Strategies

- **Where NOT to file?**
 - Avoid countries with export regulations
 - Export Administration Regulations (EAR)
 - International Traffic in Arms Regulations (ITAR)
 - Avoid: Crimea, Cuba, Iran, North Korea, Sudan, Syria
 - See, for example, <https://www.trade.compliance.pitt.edu/embargoed-and-sanctioned-countries>