

IP Strategy: How To Make The Most Of Patents, Copyrights, Trademarks, and Trade Secrets

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Agenda

- **What are the tradeoffs between investing in IP, product development, and getting to market?**
- **What are the technology and market differences in the timing of investing in IP?**
- **When do investors care about IP?**
- **Costs for US Patent Applications**
- **Foreign Filing Costs and Strategies**

What are the tradeoffs between investing in IP, product development, and getting to market?

- **For most technologies, you need to invest in:**
 - Developing an IP portfolio
 - Developing your product
 - Defining a market and placing your product into that market
- **For therapeutic products, focus on:**
 - Building a strong IP portfolio
 - Developing your product at least to proof of principle
 - Providing investors some evidence that your product works
 - You will not likely run clinical trials and get your product to market

What are the tradeoffs between investing in IP, product development, and getting to market?

- **For software apps or consumer products that may have a short period of relevance**
 - The race to be first to market is often key
 - Developing your product to the point of commercial utility is paramount
 - IP protection may, in some circumstances, take a second seat, but some investors may want to see at least some patent application filing

What are the technology and market differences in the timing of investing in IP?

- **File on your key inventions as soon as you have reduced the invention to practice**
 - And as soon as you have adequate funding
- **File before any public disclosures if you want to protect foreign patent rights**
 - This is true for all areas of technology

What are the technology and market differences in the timing of investing in IP?

- **Only for products that may become obsolete before a patent issues, might you consider forgoing patent protection**
 - For only some software
 - Certain consumer goods
- **Do you want to grow and enter the market yourself, or be acquired?**
 - First case, focus on keeping our competitors for your key products
 - Second case, focus on building as large a portfolio as you can afford, as that may be the most valuable asset you have after your team

What are the technology and market differences in the timing of investing in IP?

- **File 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
- **Get all of your IP “ducks in a row” before a major new investment or before an acquisition**
- **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
 - be thinking 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 might arise: patent litigation, which requires a huge investment of time and money**

When do investors care about IP?

- **Investment in building 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
 - Legitimacy / Marketing Benefits
- **Investors know this is generally true, but does this vary depending on the underlying technology?**

When do investors care about IP?

- **Always protect your inventions in healthcare**
 - 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 protection long term for major drug**
- **Typically in mechanical inventions**
 - Unless the first to market advantage is sufficient for a quick return

When do investors care about IP?

- **In software, it depends on the particular application, market and expected lifetime of the software**
 - The software may become obsolete before a patent issues
 - Trade secret protection may work if the software is kept in-house and used to provide a service and cannot be easily reverse engineered or recreated, but some inventors 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

Costs for US Patent Application

- **Legal costs for drafting US quality application can range from \$5,000-\$20,000**
- **Initial Official Fees**
 - US non-provisional \$830 (small entity, no excess claim or page fees) - \$1820 (large entity)
 - PCT ~ \$3,000 (small entity, 50 pages, US search authority)
- **During prosecution of US application**
 - Responding to each Office Action ~\$2,000-\$12,000
 - Fees associated with Request for Continued Examination (*if needed*) (~\$680 for first, ~\$1,000 subsequent)
 - Issue Fee \$600 (small entity) - \$1200 (large 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)

Foreign Filing Costs and Strategies

- **Costs – PCT National Stage**
- **Assume you have a patent application – 50 pages, no drawings, 25/3 claims, large entity – the filing fee for this in the US would be about \$3,220 and maintenance fees would run about \$3900**
- **What would filing in 15 typical countries cost?**
 - Translation costs – almost \$35,000
 - Annuities – although spread out over many years, you will still be spending almost \$175,000 to maintain all patents for total of 20 years
 - This is just for one patent family
 - 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**

Foreign Filing Costs and Strategies

Costs – PCT National Stage - Details

Country	Official Fees	Translation	Misc.	Associate	In-house Fees	Annuities	Total
AR	\$416	\$3,219	\$76	\$7,748	\$600	\$10,661	\$22,449
AU	\$1,084	N/A	\$76	\$4,678	\$600	\$15,171	\$21,609
BR	\$607	\$2,925	\$76	\$4,595	\$600	\$14,433	\$23,236
CA	\$1,076	N/A	\$76	\$3,704	\$600	\$10,969	\$16,425
CN	\$1,152	\$4,405	\$76	\$3,135	\$600	\$16,966	\$26,335
EP	\$8,295	N/A	\$0	\$7,464	\$500	\$1,986	\$18,245
IL	\$1,022	N/A	\$76	\$5,663	\$600	\$7,325	\$14,686
IN	\$901	N/A	\$76	\$4,153	\$600	\$10,868	\$16,598
JP	\$2,563	\$7,316	\$76	\$5,281	\$600	\$17,813	\$33,649
KR	\$1,893	\$5,280	\$76	\$3,275	\$600	\$20,507	\$31,631
MX	\$667	\$2,842	\$76	\$5,493	\$600	\$2,567	\$12,295
NZ	\$767	N/A	\$76	\$3,724	\$600	\$11,976	\$17,143
RU	\$332	\$4,680	\$76	\$3,746	\$600	\$8,944	\$18,378
SG	\$1,494	N/A	\$76	\$3,785	\$600	\$13,386	\$19,341
TW	\$850	\$3,418	\$76	\$3,080	\$600	\$11,413	\$19,437
TOTALS	\$23,119	\$34,085	\$1,064	\$69,524	\$8,900	\$174,985	\$311,457

Using Global IP Estimate; assuming 50 pages, no drawings, 25 total claims (with 3 independent claims), large entity

Costs – EP regional stage

- **Regional examination can be cost effective – different regions include EP, Eurasian, ARIPO and OAPI**
 - Regionalization 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 Costs and Strategies

Costs – EP regional stage - details

Country	Official Fees	Translation	Misc.	Associate	In-house Fees	Annuities	Total
BE	\$0	0	\$0	\$705	\$0	\$10,852	\$11,557
CH	\$0	\$0	\$0	\$724	\$0	\$13,961	\$14,685
DE	\$65	\$0	\$0	\$710	\$0	\$20,921	\$21,696
ES	\$629	\$3,147	\$0	\$887	\$0	\$11,816	\$16,479
FI	\$434	\$0	\$0	\$1,361	\$0	\$14,922	\$16,717
FR	\$0	\$0	\$0	\$629	\$0	\$12,596	\$13,225
GB	\$0	\$0	\$0	\$558	\$0	\$11,434	\$11,992
IT	\$0	\$3,581	\$0	\$705	\$0	\$13,096	\$17,382
NE	\$27	\$0	\$0	\$699	\$0	\$16,254	\$16,980
SE	\$0	\$0	\$0	\$892	\$0	\$12,498	\$13,390
TOTALS	\$1,155	\$6,728	\$0	\$7,870	\$0	\$138,350	\$154,103

Using Global IP Estimate; assuming 50 pages, no drawings, 25 total claims (with 3 independent claims), large entity

Foreign Filing Costs and Strategies

- **How do you try to 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?

- **You need to ask / answer several questions:**
 - Look at your foreign filings like an investor. Consider filing in markets the investors are likely to value (China).
 - What 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?
 - Consider major markets or strategic venues for enforcement, like shipping hubs or countries like Germany where you can get quick relief.

- **Additional questions:**

- Look at your foreign filings like an investor. Consider filing in markets the investors are likely to value (China).
- What 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?
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- **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)**
 - **“Proximity to the US” markets (Canada and Mexico)**

Foreign Filing Costs and 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/photronics** – 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 Costs and 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.tradecompliance.pitt.edu/embargoed-and-sanctioned-countries>

Thank you!

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

With well over 30 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, RNAi and CRISPR therapeutics, 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 of therapeutic agents, automated blood analysis systems, nucleic acid probes, tissue engineering, infusion pumps, biochips, laser systems, cellulose processing for ethanol production, implantable drug delivery devices and microcapsules, ultrasound probes, wind and solar power, and diagnostic and therapeutic methods for, e.g., AIDS, cancer, autism, diabetes, psoriasis, and arthritis.