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The Patent Winter Is Here: Do You Have a Winning IP Strategy or Will You Be Left in the Cold?

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The Big Pharma superpowers are on the edge of a patent cliff. The combination of patent expirations, uncertain product and patent pipelines, and expiring regulatory exclusivities will negatively impact a host of Big Pharma blockbuster products. Due to these factors, pharma firms are set to lose approximately $200 billion in revenue between now and 2030 to generic and biosimilar competitors. And with a shortage of new products coming down research and development (R&D) pipelines, Big Pharma is in an IP and regulatory race to replace lost profits and maintain market exclusivity.

To blunt the impact of this patent cliff, Big Pharma has turned its crosshairs to biotech and biopharma companies to replenish flagging IP portfolios. With the explosion of development of protein therapeutics, therapeutic antibodies, and cellular and gene therapies, biotech and biopharma companies have a stockpile of innovative assets ripe for acquisition. However, these IP-rich companies have the upper hand and are assessing whether to sell their valuable IP or launch their own products into the market.

Whether you're a pharma firm looking to weather the patent winter, or a life sciences company ready to capitalize on the impending patent gap, you need a strong IP strategy to ensure your patent portfolio will lead you to victory.

Audit Your IP Arsenal

The first step to a winning IP strategy is to understand the strengths and weaknesses of your patent portfolio. This is typically accomplished with a regular audit performed by experienced patent counsel. An audit will preemptively identify your strongest assets and where IP gaps may exist. We recommend performing this type of analysis regularly to ensure your company is prepared for commercialization, partnering, or financing opportunities.

A company should always perform its audit proactively. Overlooking an IP issue can be costly and can derail a product launch or tank a potential transaction. With a proactive audit, a company will be ready for any diligence process and be on offense rather than defense.

An audit will also provide a full inventory of a company's current IP portfolio. An experienced IP attorney can provide an assessment of the strength of each patent and whether your portfolio protects your key products, particularly in light of the ever-changing life sciences case law. Understanding how full patent coverage can be achieved will enhance the value of your company and provide an edge over any competition. An audit will also identify IP that no longer fits your company's current business objectives and, therefore, can be sold off or licensed — providing funds for R&D or other strategic initiatives.

Know Your Enemy

Knowing your IP inventory is only half the battle. Understanding your competitors' IP portfolios is also essential to a company's IP strategy, and it will help identify any defensive tactics a company may need to undertake.

A competitor analysis should include a freedom-to-operate (FTO) assessment, which identifies any third-party patent rights that may interfere with a company's ability to market its own product(s). Ideally a FTO analysis should be obtained early in any product R&D process. If any risks are detected, there are multiple options available. This might include monitoring the identified third-party's patent activity or redesigning the company's product to avoid potential infringement. A company can also choose to go on the offensive and challenge the validity of third-party patents. A competitor analysis also allows companies to plan for the best venues and mechanisms to enforce their IP rights.

Similarly, companies should be prepared for generics and biosimilars inching into the market. By identifying competitors and analyzing their potential market entry points, a company can craft strategies in product development, during patent prosecution, and in connection with regulatory filings to maximize protection of key IP and commercial assets.

Make Strategic Moves

If a company can't prevent a generic or biosimilar's entry into the market, it may be able to soften the blow. Understanding the likelihood of generic or biosimilar entry and the timing will allow a company to use mechanisms like authorized generic launches and over-the-counter approval options to protect commercial value.

Recognizing risks of generic or biosimilar entry can also increase your leverage in the context of settling abbreviated new drug application or biosimilar litigations in a manner that best protects your IP and commercial assets. This includes the opportunity to pursue licensing arrangements or strategic IP collaborations.

Be Prepared

The impeding patent cliff is creating market uncertainty as 2023 begins, but R&D marches on, and new technologies and therapeutics are advancing at a pace never seen before. Proactive planning and analysis to ensure IP portfolios are enhanced and properly positioned will allow companies to take advantage of the opportunities that are sure to arise this year, as well as protect their valuable IP assets.

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