IPWatchdog Life Sciences Masters 2023 Takeaways

Choate recently attended the IPWatchdog Life Sciences Masters, which provided insights on the latest updates and trends in intellectual property law and the biopharmaceutical industry. The conference featured several Choate panelists, who spoke about multi-forum challenges, best practices and tips for winning at the PTAB, the future of claim drafting after Amgen v. Sanofi, and current trends in ANDA and competitor v. competitor biopharma patent litigation. Below are some of the key takeaways from the conference.

Recent Trends

The pendulum may be swinging back toward more patent-friendly approaches in the context of 35 U.S.C. § 101, but patentees face mounting challenges under 35 U.S.C. § 112. In the wake of Amgen v. Sanofi, Juno v. Kite, and other developments from the courts, patent owners must be vigilant, careful, and creative in drafting claims and crafting related litigation strategies. If patent owners choose to pursue broad genus claims, they should have robust specifications as well as a diverse array of claims, including narrower claims tailored to their most important and valuable inventions. Patent owners should also anticipate and prepare for continued focus on these issues in ANDA and other competitor patent litigation.

There has been much innovation in immunotherapy, cell therapy, gene therapy, and precision medicine treatment for patients, but recent changes in policy, such as the Inflation Reduction Act (IRA), may impair future innovation if companies de-prioritize certain specialized research and clinical trials in order to target larger populations of patients. The IRA places government-set prices for certain selected medications. This may discourage investment in products that, as a result of price caps, are less likely to be economically advantageous for companies. Additionally, the IRA provides for a four-year difference in exclusivity periods for biologics vs. small molecules, which may lead companies to invest more in biologics and less in small molecules. Differences in exclusivity periods will need to be incorporated into patent strategy.

There is an emerging complex patent landscape related to CRISPR/Cas9 technology. Since CRISPR's discovery in 2012, there are now 15,000 patent families related to CRISPR/Cas9. Vertex recently announced that FDA has granted priority review status and set an approval decision date of December 8, 2023, for exagamglogene autotemcel (exa-cel), the potential treatment of sickle cell disease (SCD) and transfusion-dependent beta thalassemia (TDT). However, it is unclear how the CRISPR/Cas9 patent landscape will take shape, since several foundational cases are currently in legal proceedings. Patent exhaustion issues may come to play in downstream manufacturing processes, which gives rise to further uncertainty, as the courts have provided little guidance on self-replicating technologies like those implicated by CRISPR.

The Federal Circuit's recent decision in *In re Cellect* expands the bounds of the judicially-created doctrine of nonstatutory obviousness-type double patenting (ODP). The doctrine of ODP was intended to prevent improper patent term extensions where a patentee owns multiple patents (with multiple expiration dates) covering substantially similar subject matter. In its *Cellect* decision the Federal Circuit held that

ODP can operate to invalidate a patent even where term is extended based not on any actions by the patentee, but on delays at the USPTO. If this decision stands, it will require patent owners to re-evaluate their patent portfolios. In some instances, they may consider preemptively filing terminal disclaimers to cut short the term of patents with later expiration dates – in order to avoid their being invalidated altogether by operation of ODP. Where patent owners anticipate future litigation, they can expect that defendants will look for opportunities to raise an ODP invalidity defense.

Incorporating Recent Decisions into Your Own Practice

The speakers at the conference noted several best practices.

1. Invest in your patent disclosures and be careful to list and explain everything you intend your patent to cover. This will help to guard against written description and enablement challenges. If you draft a robust patent application, and diversify your patent portfolio, you will have a better chance to survive recent and future court trends.
2. Work closely and collaboratively with scientists as well as lawyers and focus your energy on what is most valuable.
3. Consider the advantages and disadvantages of a joint defense group, particularly when it comes to expert discovery. From the plaintiff's perspective, consider whether you can (or want) to sue all defendants in one forum and whether you may be able to get leverage over multiple defendants with respect to settlement.
4. When it comes to CRISPR technology, safe harbor protections may be helpful if clients develop an antibody using CRISPR as a research tool. Remember, however, that you may be subject to royalties.
5. Plan and coordinate patent prosecution, litigation, and regulatory efforts -- early, often, and worldwide. It is critical to follow a consistent strategy, particularly in view of recent case law trends. Having litigation counsel assess the merits early on -- and advise on strengthening claims while they are going through the patent office -- can prevent a lot of headache, cost, and litigation risk in the future.

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