STN IP PROTECTION SUITE™

SYNERGIZING INNOVATION AND PROTECTION

Strategies for effective collaboration between R&D and IP in pharma

CAS

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American Chemical Society

Introduction

Collaboration between the IP and R&D teams spans the entire drug development process, from initial research and investment planning to commercialization. Their collaboration minimizes the risk of infringement, ensures that future investments can be protected by intellectual property rights, and maximizes the potential for successful commercialization in the market.

Phases of drug development	Core activities and areas of collaboration
Program/investment selection — pre-specific target identification	– The team identifies unmet medical needs and market opportunities. A broad IP assessment is required at this stage to look for opportunities and guide investment strategy at a higher level. – Answer questions such as: Who is active in this space? Is this particular research space crowded (even before we get to infringement)?
Program/investment selection — diving deeper into opportunities	– The IP team collaborates with R&D scientists to review existing patents and publications related to the target area, ensuring that the proposed drug candidate is novel and non-obvious. – Answer questions such as: What are the most recent patent applications and clinical trials in a specific area of interest? Are there opportunities to buy, license, or partner with players in this space to accelerate our own efforts?
Target identification	– R&D scientists conduct extensive research to identify potential drug candidates based on their knowledge and expertise in a specific therapeutic area. – The IP team conducts patent landscape analysis and searches to identify existing patents and ensure the proposed drug candidate does not infringe on any prior IP rights.
Pre-clinical studies	– R&D scientists synthesize/generate and test the drug candidate in preclinical models to assess its efficacy and safety. – The IP team conducts a patentability assessment to determine if the drug candidate meets the criteria for patent protection. They collaborate with R&D to identify and document unique features or potential patentable aspects of the compound. – The IP team helps R&D scientists draft detailed invention disclosures, capturing the novelty and inventiveness of the drug candidate and providing the necessary technical information for the patent application.

Phases of drug development	Core activities and areas of collaboration
Clinical development	– R&D scientists design and conduct clinical trials to evaluate the safety and efficacy of the drug candidate in humans. – The IP team collaborates closely with R&D scientists to monitor the evolving patent landscape in the therapeutic area and assess potential infringement risks. – The IP team works with legal counsel to review and analyze any relevant patents owned by competitors to identify potential freedom-to-operate (FTO) issues or licensing opportunities. – The IP team, in collaboration with R&D scientists, prepares and files patent applications to protect the novel aspects of the drug candidate, including the composition of matter, methods of synthesis, or therapeutic uses. – The IP team assists in responding to patent office actions, working closely with R&D scientists to provide the necessary technical and scientific support to strengthen the patent application.
Pre-clinical studies	– R&D and IP teams collaborate to ensure the appropriate IP protection is in place for the successful commercialization of the drug candidate. – The IP team works with legal counsel to conduct due diligence on third-party patents to avoid potential infringement risks during the commercialization phase. – The IP team and R&D scientists collaborate on IP strategy, considering factors such as potential licensing opportunities, defensive patenting, and monitoring competitor patents

The collaboration between IP and R&D teams can differ in the context of discovering new therapeutics versus developing generics versus drug repurposing. Let's explore the key differences.

Discovering new therapeutics

Research focus
When discovering new therapeutics, the R&D team's primary objective is to identify and develop novel compounds or biological entities with potential therapeutic applications. The focus is on innovation and creating new intellectual property.

IP strategy
The IP team collaborates closely with R&D scientists to identify patentable aspects of the new therapeutic, such as the composition of matter, methods of synthesis, or novel therapeutic uses. The IP strategy involves drafting and filing patent applications to protect these novel aspects, with the goal of securing market exclusivity for the new drug.

Regulatory considerations
Discovering new therapeutics involves navigating regulatory pathways for drug approval, including conducting preclinical and clinical trials to demonstrate safety and efficacy. The IP team collaborates with R&D scientists to ensure that the IP strategy aligns with regulatory requirements and supports commercialization efforts.

Market dynamics
The market for new therapeutics is driven by innovation, and there may be more opportunities for securing strong IP protection and exclusivity, leading to potential market advantage and commercial success.

Developing generics

Research focus
Generics development focuses on developing equivalent versions of existing approved drugs that have lost patent protection. The goal is to offer more affordable alternatives to the original branded drugs, leveraging existing scientific knowledge.

IP strategy
In the case of generics, the IP team collaborates with R&D scientists to conduct freedom-to-operate analyses, ensuring that the development and commercialization of the generic drug do not infringe upon existing patents. The focus is on avoiding potential patent infringement and navigating patent landscapes to identify opportunities for market entry.

Regulatory considerations
Developing generics requires demonstrating bioequivalence to the original drug through comparative studies. The IP team collaborates with R&D scientists to understand the regulatory requirements and ensure that the generic product meets the necessary criteria for approval.

Market dynamics
The generics market is characterized by competition and price sensitivity. While IP protection for generics may not be as robust, collaboration between the IP and R&D teams becomes crucial in navigating patent landscapes, ensuring FTO, and optimizing the development and commercialization process.

Drug repurposing

Research focus
Instead of discovering new therapeutics from scratch, drug repurposing involves identifying existing drugs or compounds that have demonstrated potential for use in different indications or disease areas. The R&D team focuses on exploring the therapeutic potential of these repurposed drugs.

IP strategy
The IP team collaborates with R&D scientists to conduct prior art searches and analyze existing patents and scientific literature related to the repurposed drug's new use. They aim to identify any potential IP barriers or FTO challenges associated with repurposing the drug. Additionally, the IP team may explore opportunities to secure IP rights for the new use or formulation of the repurposed drug, if applicable.

Additional IP considerations for drug repurposing:

- **Novel use patents:** Repurposing a drug for a new indication may involve identifying and pursuing patent protection for novel therapeutic use. The IP team collaborates with R&D scientists to identify the unique aspects or mechanisms of action that support the repurposed use and formulate a patent strategy accordingly.

- **Licensing and collaboration:** In drug repurposing, collaboration and licensing agreements play a significant role. The IP team collaborates with R&D scientists to identify potential partners who may hold IP rights for the drug in question or have expertise in the targeted indication. Negotiating licensing agreements or forming collaborative partnerships becomes crucial for leveraging existing IP and sharing resources to advance the repurposed drug.

Regulatory considerations
Drug repurposing involves providing evidence of safety and efficacy for the repurposed use. The IP and R&D teams collaborate to design and conduct preclinical and clinical studies to generate the necessary data required for regulatory approval. Depending on the regulatory framework in a particular jurisdiction, repurposing a drug for a new indication may offer opportunities for regulatory exclusivity or other incentives. The IP team works with R&D scientists to understand and navigate these regulatory considerations to maximize market exclusivity for the repurposed drug.

Market dynamics
Drug repurposing often involves competition from existing drugs in the market that may already have regulatory approval for the targeted indication. Collaboration between the IP and R&D teams is essential for assessing the competitive landscape, identifying differentiating factors, and developing strategies to position the repurposed drug effectively. Collaboration between the IP and R&D teams is crucial to evaluate reimbursement strategies, pricing considerations, and market access opportunities for the repurposed drug. Existing treatment options and the competitive pricing landscape must also be taken into account.

In all cases, collaboration between the IP and R&D teams remains essential for successful outcomes. However, the specific focus areas and strategies may vary depending on the nature of the therapeutic development, the intellectual property landscape, and the regulatory considerations associated with discovering new therapeutics versus developing generics.

Seven strategies for balancing conflicts between scientific innovation and patentability

Managing conflicts between scientific innovation and patentability requires a careful balance between pushing the boundaries of scientific discovery and meeting the legal criteria for obtaining a patent. Here are some strategies for effectively navigating this challenge:

1.

Collaborate and communicate early

Foster open and frequent communication between R&D scientists and IP professionals from the early stages of research. This collaboration allows for a better understanding of scientific innovations and potential patentable aspects. By involving IP experts in the process, conflicts can be identified and addressed proactively. Consider including IP counsel at R&D department or group meetings to streamline information sharing and to remain aligned on patent programs and pursuable R&D initiatives.

2.

Prioritize patentability assessments

Conduct thorough patentability assessments early to evaluate the potential patentability of scientific innovations. This involves analyzing the existing prior art, assessing novelty, and considering the patentability criteria specific to the jurisdiction of interest. By conducting these assessments upfront, you can identify potential conflicts and develop strategies to enhance patentability earlier.

3.

Explore multiple patent filing strategies

Depending on the nature of the scientific innovation, consider different patent filing strategies. This may involve filing broader patent claims to protect the core invention while also considering narrower claims to cover specific embodiments or applications. By strategically tailoring the patent claims, you can mitigate conflicts between innovation and patentability requirements.

4.

Collaborate with experienced IP counsel

Engage experienced IP professionals who specialize in the relevant technology area. They can provide guidance on the patentability landscape, legal requirements, and strategies for effectively protecting your specific scientific innovations. IP counsel can offer insights on improved search strategies, patent prosecution strategies, potential workarounds, and ways to position the invention to overcome patentability challenges.

5.

Explore defensive publishing

In cases where patentability requirements pose significant challenges, consider the option of defensive publishing. This involves disclosing the scientific innovation through publications or open-access platforms, ensuring that the information becomes prior art for others. While this approach may forego patent protection, it can still establish ownership, facilitate collaborations, and deter competitors from obtaining exclusive rights over similar innovations.

6.

Collaborate on IP strategy

Establish a collaborative IP strategy that aligns with the overall research and business goals of the organization. This includes regularly reviewing and updating the IP strategy based on the evolving scientific landscape and patentability considerations. By involving the R&D and IP teams in shaping the strategy, conflicts can be addressed proactively and innovative solutions can be developed.

7.

Use IP search and monitoring tools built for precision

Patent landscapes shift every day as the volume and complexity of patent and non-patent literature grow. Searchers within R&D and IP teams need tools that help them identify reliable and relevant IP insights. Several IP databases and search platforms exist, but vary in content comprehensiveness, indexed properties, and searchability. Look for tools that deliver efficient and reliable results for those with varying degrees of patent search sophistication. This allows stakeholders throughout the drug development process to confidently perform their search tasks and improve collaboration between R&D and IP teams.

Ultimately, managing conflicts between scientific innovation and patentability requirements needs a multi-pronged approach, effective communication, and a clear understanding of both scientific and legal considerations. By fostering collaboration and implementing these strategies, organizations can navigate this delicate balance and optimize their patenting efforts while fostering scientific advancement.

The STN IP Protection Suite™ synergizes IP and R&D

For effective collaboration between R&D and IP teams, your team needs to access, search, and analyze patent and non-patent literature with precision and efficiency. The STN IP Protection Suite augments IP search strategies by offering unmatched content and technologies for diverse searchers like scientists, R&D leaders, patent analysts, patent attorneys, and business stakeholders.

The STN IP Protection Suite includes three core tools: CAS STNext®, CAS Scientific Patent Explorer™, and FIZ PatMon, and is complemented with access to CAS experts for IP search support and consultation. While organizations can use each tool independently, they can take full advantage of the suite by incorporating all of them.

IP professionals and experts get search precision and comprehensiveness
CAS STNext is the premier IP information platform and the preferred choice for patent experts.

Scientists and analysts can understand and communicate the IP landscape
CAS Scientific Patent Explorer offers a unique combination of patent analytics, IP content, and visualization tools to accelerate IP search and analysis.

R&D leaders, IP professionals, and business stakeholders can monitor competitors and collaborations to maximize IP value
FIZ PatMon provides global surveillance of patents and applications.

Innovative scientific organizations gain access to outside expertise to boost search strategy
CAS provides expanded capacity and trusted expertise when you need it most.

"CAS solutions have evolved to open up IP analytics to innovators across R&D sectors. We take pride in partnering with organizations around the globe to protect inventions, monitor competitor IP, support legal status and due diligence study, and assist in the integration of IP workflows to maximize the return from R&D efforts."

Anne Jones,
Senior Customer Success Specialist, CAS

Improve collaboration between your R&D and IP teams. Explore the STN IP Protection Suite from CAS at **cas.org/stn-ip-protection-suite**

CAS is a leader in scientific information solutions, partnering with innovators around the world to accelerate scientific breakthroughs. CAS employs over 1,400 experts who curate, connect, and analyze scientific knowledge to reveal unseen connections. For over 100 years, scientists, patent professionals, and business leaders have relied on CAS solutions and expertise to provide the hindsight, insight, and foresight they need so they can build upon the learnings of the past to discover a better future. CAS is a division of the American Chemical Society.

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