Reducing the Cost of Biologics with Innovation Intelligence

A PatSnap Report

patsnap

Reducing development costs and increasing ROI of Biologics through Innovation Intelligence

1. Reduce legal expenditure by improving communication between teams

Invention, despite the romantic image of the lone genius, is usually a team endeavor. When a task requires creativity and novelty, as in the case of explorative research and development (R&D), the formation of problem-focused creative teams involving individuals with varied backgrounds has become a staple across organizations.

In the Life Science industry, due to the high capital costs required to research and commercialize an effective drug, this is particularly true. Take Humira, one of the world's bestselling drugs and the first fully human monoclonal antibody approved by the Food and Drug Administration (FDA). The successful development of this drug is a direct result of the effective collaboration between multiple heterogeneous teams spanning various disciplines and organizations (BASF Bioresearch Corporation and Cambridge Antibody Technology). The importance that the role of effective communication had in moving the R&D process forward between these teams can't be overstated.

Of course, discovery and development are not all that's required to develop a successfully commercial product. An effective intellectual property (IP) strategy is also paramount should we want any hope of making a profit on R&D investment. This requires the involvement of the legal team in the R&D process. Affording the legal team as much visibility as possible allows them to effectively offer counsel on avoiding already-protected solutions that are present in the market, reducing the risk of exposure and ultimately allowing them to develop an effective IP strategy for the products that the R&D teams are developing.

IP lawyers are not research scientists, and research scientists are not IP lawyers. However, both groups possess valuable expertise and it's of the utmost importance that these groups do not operate within a vacuum of each other for your business' R&D strategy to be successful.

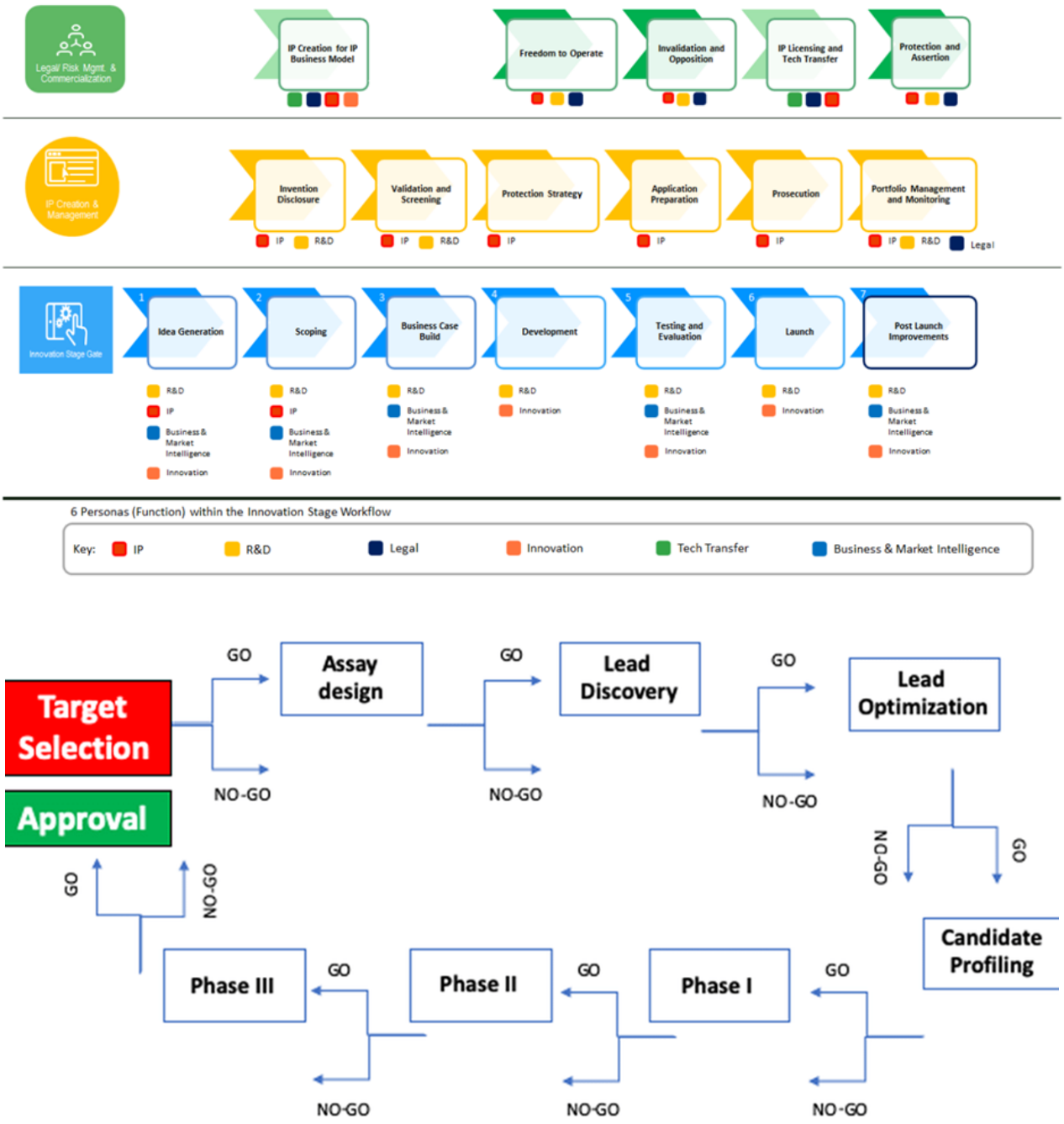
That said, challenges remain around effective communication and information sharing within and across teams. In fact, the higher coordination costs of a creative team that spans multiple disciplinary and/or organizational areas lowers the probability of commercialization success.

Here's the problem: the modern solutions require multiple interdisciplinary teams to collaborate effectively. This collaboration results in higher coordination costs which lowers the probability of commercial success relative to that of smaller R&D teams.

Logically, this follows, as processes involving more people tend to increase the risk of inefficiency. And what do you hear when you hear the word "inefficiency"? You hear the crackle of the flames igniting a pile of money.

This begs the question: how do we go about addressing this problem?

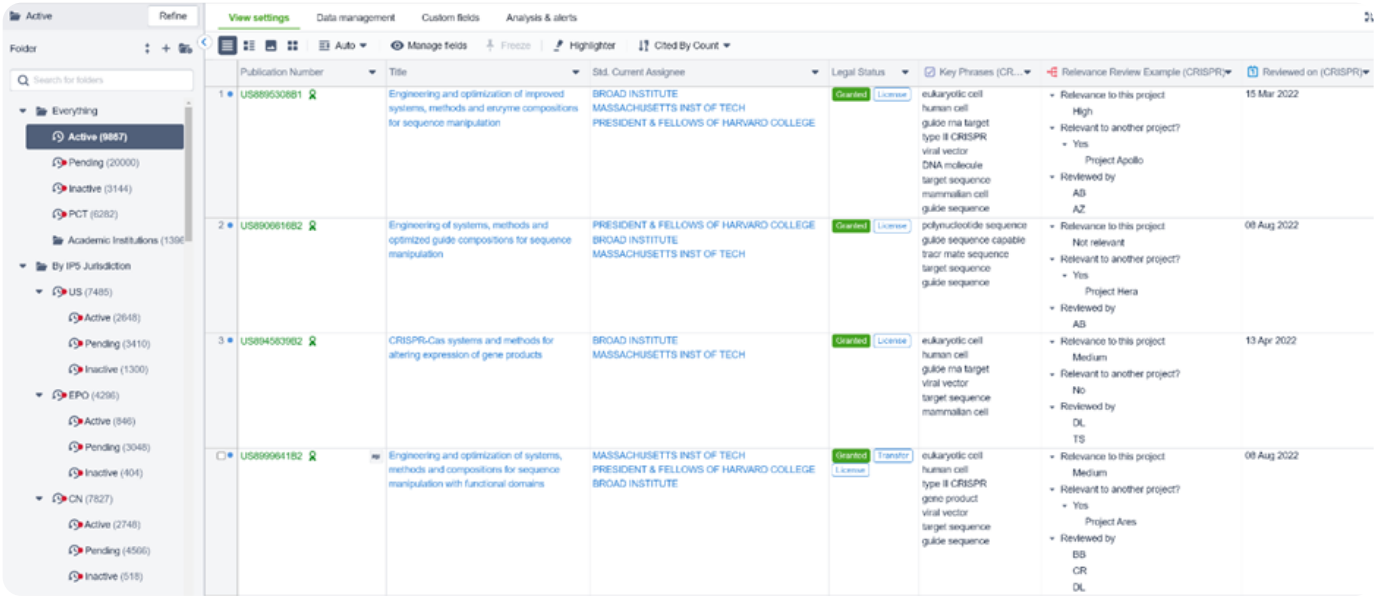
The key to avoiding these issues is to adopt an effective innovation stage-gate. A set of processes that set out the response is to an action and who's responsible. These processes are different for every company, for the development of biologics, a variation on a combination of the two generic workflows shown below are likely to be what you would see, as illustrated on the next page.



Innovation stage gate process, biologic stage gate

To facilitate the success of these processes and reduce R&D overhead in the digital age, fit-for-purpose tools designed for the modern-day R&D infrastructure are a necessity. At PatSnap, we work closely with the world's best, from leading pharmaceutical companies to the next generation of biotech startups. Our goal is to help implement and optimize an effective innovation intelligence strategy involving all teams from R&D to legal.

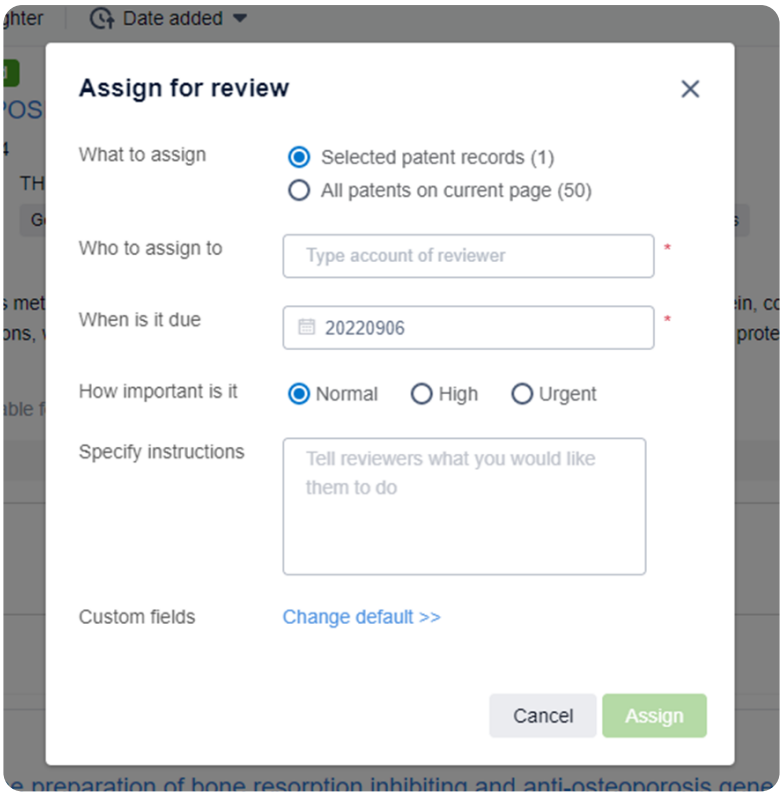
Operationally, the multifaceted nature of today's novel innovation means that inventions often contain compounding features that need to be checked against the broader market for novelty and legal clearance. This means that the greater the scope of the invention, the more complex the validation process becomes. The more checking that is required, the greater the importance of effective communication between teams. The back-and-forth communication between the R&D teams and the legal department must be optimized in order to avoid bottlenecks and delays. To this end, PatSnap's Workspaces offer an effective environment to distribute and manage innovation knowledge across all teams through automatic updating, task assignment, notifications, custom fields, and permission setting across all relevant teams and individuals involved in the process.



Workspaces, PatSnap Analytics

This way, expertise can be easily shared across teams. Allowing R&D to easily share domain knowledge that might be required for a legal decision, and legal teams to effectively share counsel that might affect R&D pathways, without delay.

Workspaces offer distributed insight into the relevant patent and market intelligence data at each stage of the innovation process and are completely customizable to suit your needs. Notifications are sent to the relevant people when certain actions, like reviewing a patent, are completed. Additionally, specific tasks can be assigned to individuals on an ad-hoc basis, allowing you to control the flow of information and prioritize particular documents over others.



Patent assignment, Workspaces, PatSnap Analytics

2. Fail quickly with unpromising or legally problematic candidates

Failing quickly with candidates that are not commercially viable is an important attribute to consider during the R&D process in order to avoid wasting time and money. One of the biggest challenges in the R&D process is determining freedom to operate (FTO) and balancing that versus commercial viability. In an ideal world, this process would be as quick as possible while maintaining decision-making confidence. This way, the expected value of R&D projects can be estimated swiftly, and projects can be moved forward or scuttled in an effective manner.

In order to determine FTO, a comprehensive dataset coupled with an efficient workflow is key. Many tools exist for sequence searching, but they often lack in data comprehensiveness. For instance, a sequence searching tool may allow you to effectively search your reference sequence across a broad database to look for published matches, but the source of that match, let's say a patent publication, will then require you to go to an additional database (this time, the relevant country's patent office website) to understand the context of that subject sequence. This creates a cumbersome experience that only serves to inflate the time required to complete these essential tasks.

Using PatSnap Bio, you can quickly and efficiently run your candidate sequences, prioritize by existing prior art, and collaborate between teams on opinion and pipeline management, all in the most comprehensive sequence searching platform available.

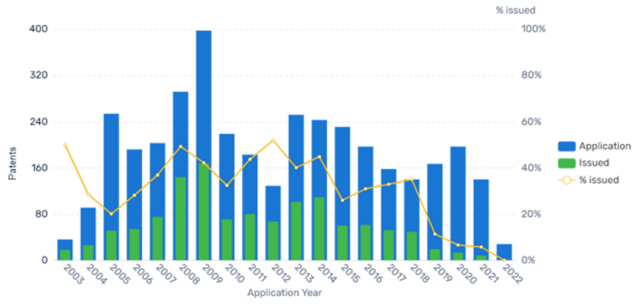
3. Iterate on original to generate new IP opportunities and outcompete biosimilars

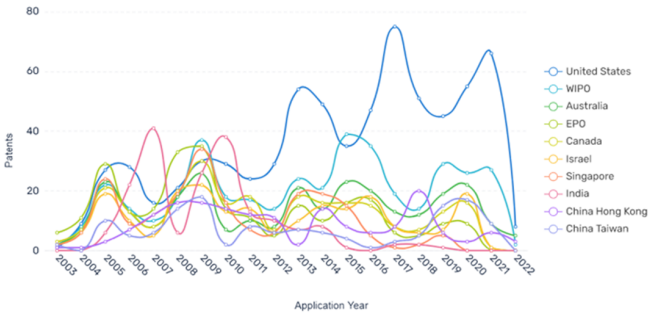
A key strategy for improving the return on investment afforded to a biologic is to mitigate the risk of interchangeable status being afforded to a biosimilar. To tackle this, originators should continue to iterate on their biologic by reducing the frequency of dosing schedules or providing more convenient administration techniques that may extent patent protection or achieve new exclusivity. Other strategies worth mentioning include price decreases, patent defences (and extensions), as well as the use of trade secrets. These strategies will help to foster an overall perception of superiority of branded innovator drugs over their biosimilar counterparts, leading to increased return on investment.

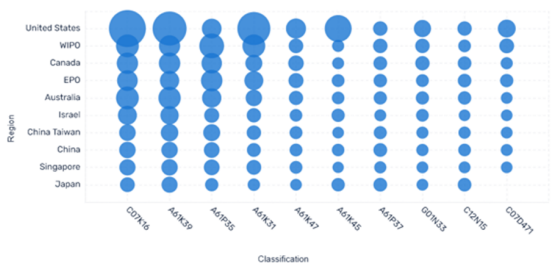
Examples of this include the work of Roche, who, beginning in 2013, developed a new subcutaneous formulation for MabThera that cut treatment time from 2.5 hours to five minutes. Another example is Amgen's first-generation drug Epogen, which required multiple weekly doses. In contrast, the second-generation version of this drug, Aranesp, requires only a weekly injection. These developments improve the perception of superiority by improving healthcare outcomes through increased patient adherence with once-weekly dosing.

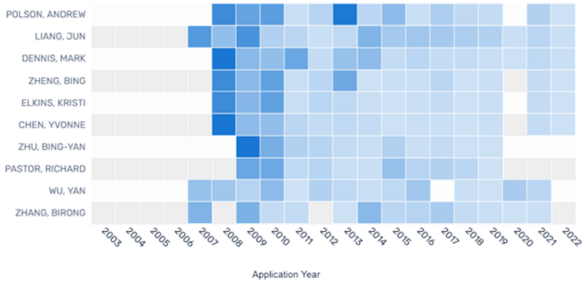
The key to maintaining leadership as an originator is to outmaneuver your biosimilar competitors. To achieve this, a sophisticated competitive intelligence strategy is key. Through a tool such as PatSnap, effective competitor monitoring combined with laser-focused alerts will allow you to keep a pulse on competitor activity. This way, you can be the first to know when information of your competitors activities become publicly available. Of course, publication can sometimes be too late. That's why PatSnap also offers you the ability to infer your competitor's strategy through the creation of bespoke dashboards and innovation tracking, like we've created for Genentech's activity around Rituximab, below.

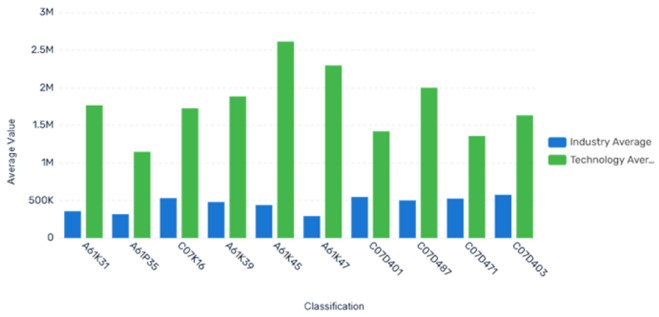
Genentech and Rituximab









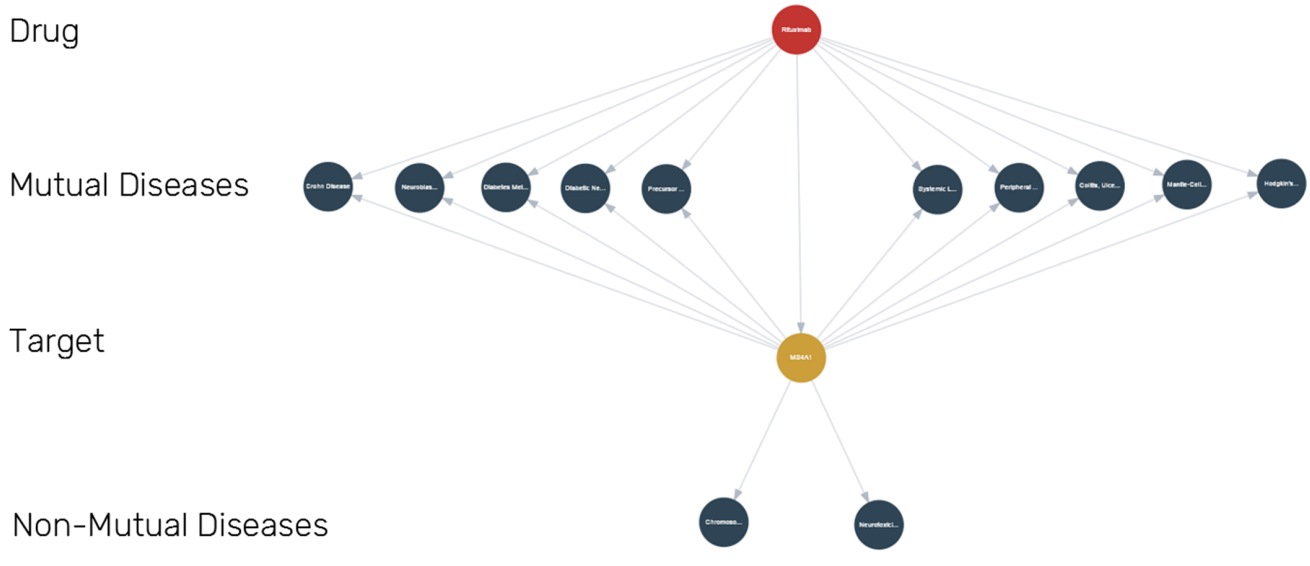


Outmaneuvering your competitors will ultimately lead to increased availability of a superior second-generation biosimilar. It's worth mentioning that the availability of a superior second-generation biosimilar could significantly decrease the demand for an inferior first-generation biosimilar, however, the pricing of a second-generation biosimilar near that of a first-generation biosimilar could help the branded drug to control the market. An example of this is Amgen's Neulasta, a second-generation of Neupogen (filgrastim), which has a single treatment cycle cost of $3,400 compared with Neupogen's cost of $6,000. This is almost a 40% cost reduction. Biosimilars priced at the average reduction of 30% cheaper would not be able to compete with such a second-generation biologic, maintaining Amgen's market share, without cannibalising their ROI opportunity.

4. Increase commercialization opportunity through repurposing

Most of the successful and best-known drug repurposing stories (e.g. sildenafil, minoxidil, aspirin, valproic acid) have emerged, if not from serendipitous observations, from unorganized discovery processes, often relying on the already known pharmacology of a drug (such as an off-target adverse effect) to solve a clinical problem from another domain. Recently though, the drug discovery community has committed to the implementation of organized, systematic, data-driven drug repurposing approaches. Drug repurposing has been advocated as an interesting strategy to explore new pharmaceutical solutions for rare and neglected conditions (in fact, many of the available medications for such conditions can be regarded as repurposed drugs). The pursuit of pharmaceutical solutions for rare and neglected disorders, whereas maybe not particularly profitable in purely economic terms, does imply other forms of value, such as corporate social responsibility and the consequent increased social awareness/perception of pharmaceutical companies. This, in turn, can indirectly increase ROI by improving the selection for treatment of one company's drug over another when an equivalent generic or biosimilar may exist.

PatSnap Synapse offers companies a way to investigate potential repurposing avenues through simple data-driven workflows that equip you with a starting point alongside supporting data that will assist you in validating a particular avenue, such as patents, clinical trial data, academic publications, and approval data. The image below demonstrates the outcome of a simple drug/target comparison using Rituximab. The two non-mutual diseases highlighted are chromosomal disorders and neurotoxicity syndromes.



Knowledge graph, PatSnap Synapse

Founded in 2007, PatSnap is the company behind the world's leading Connected Innovation Intelligence platform. PatSnap is used by more than 10,000 customers in over 50 countries around the world to access market, technology, and competitive intelligence as well as patent insights needed to take products from ideation to commercialization. Customers are innovators across multiple industry sectors, including agriculture and chemicals, consumer goods, food and beverage, life sciences, automotive, oil and gas, professional services, aviation and aerospace, and education.

PatSnap's team of 1000+ employees work from its global headquarters in Singapore, London, and Toronto. To learn more about how PatSnap is improving the way companies innovate, visit www.patsnap.com.

Visit patsnap.com/demo to speak with an innovation specialist or to book a demo.