LIFE SCIENCES INTELLECTUAL PROPERTY REVIEW
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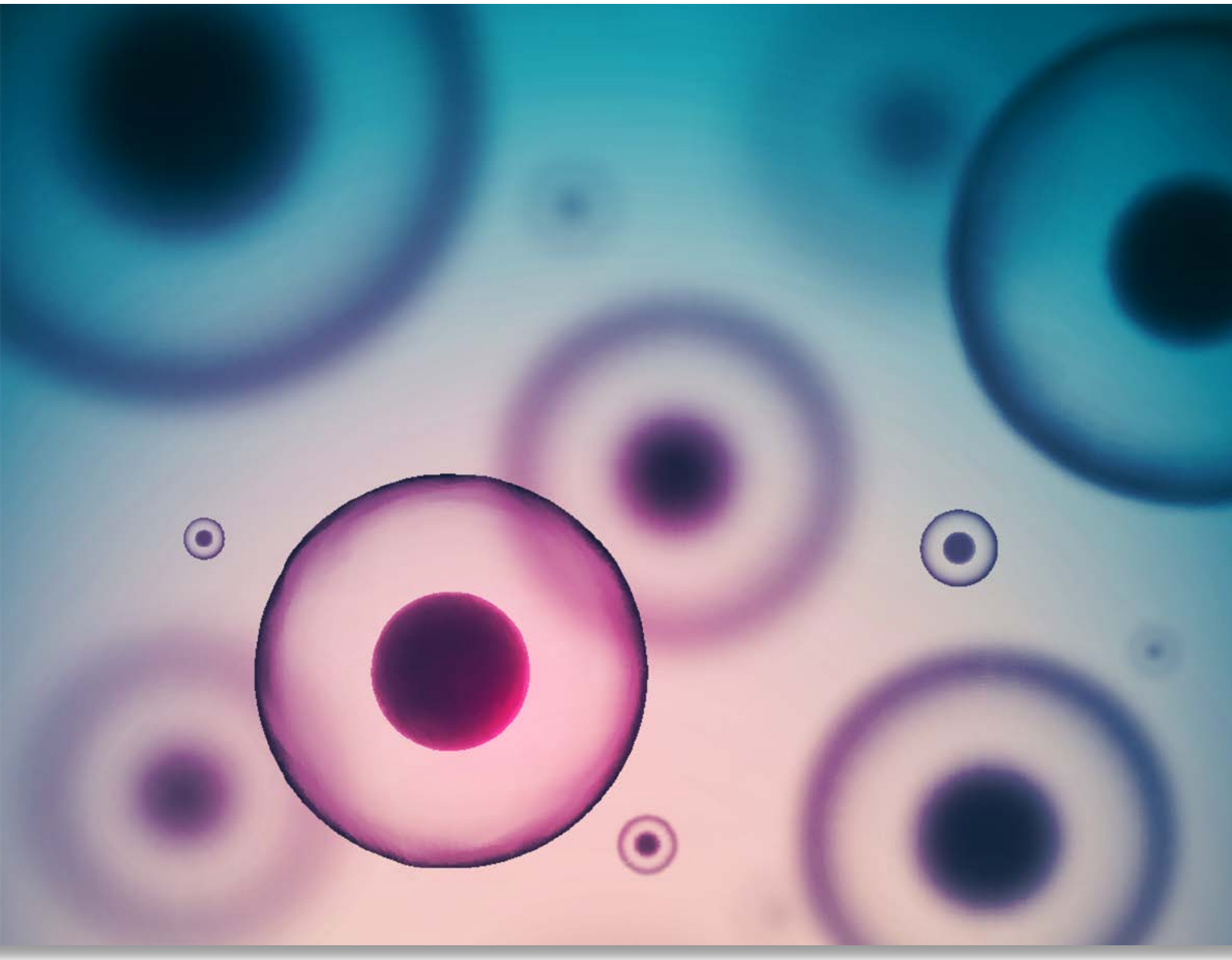
SPECIAL REPORT

Patent litigation trends: the future of biologics and next generation therapies



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INTRODUCTION

BY PETER SCOTT
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BIOLOGICS AND BIOSIMILARS are an emerging patent battleground across the globe, with significant litigation, particularly in the US, making regular headlines. *Life Sciences IP Review* has partnered with international law firm Gowling WLG to survey those at the sharp edge of this industry, in an attempt to understand what's happening, and to help you gain a sense of how it is likely to develop in the future.

"It provides an intriguing snapshot of current sentiment."

With responses from across private practice and in-house counsel active in biosimilar litigation, it provides an intriguing snapshot of current sentiment, and food for thought as to how strategies may need to adapt in the future.

The report also includes a coda on the broader picture for next generation therapies—those technologies that will likely dictate what happens in the longer term—to help you identify where your next patent challenges will occur.

We hope you find it informative and welcome your feedback.

FOREWORD


BY PATRICK DUXBURY (HEAD OF LIFE SCIENCES IN UK) AND JOHN NORMAN (HEAD OF LIFE SCIENCES IN CANADA), GOWLING WLG

GOWLING WLG

Patent litigation trends: the future of biologics and next generation therapies

THE RISE IN BIOSIMILARS is gaining some momentum and, with increased innovation, we are seeing more products come to market and an equally high rise in litigation. But as regulation in this complex area continues to evolve, it feels a timely point to take a look at companies' own experiences with these complex molecules and the issues they present.

In working together with *Life Sciences IP Review* for this study, we are keen to compare our own perceptions of what's happening in the industry to the first-hand experiences of those trying to forge ahead with new biologics and biosimilars.

The findings not only shine a light on some of the challenges innovators are facing in different jurisdictions, but highlight alternative litigation strategies, the factors influencing those strategies and the likely trends expected in the future.

As a sector-focused, international law firm Gowling WLG pairs specialist industry knowledge with renowned service area expertise to help clients succeed in an ever-changing world. With more than 150 professionals in the global Gowling WLG Life Sciences group around the world, we have the technical understanding required to advise on the unique challenges you face throughout your life cycle.

Patent, brand protection and litigation are specialisms within a full suite of legal services provided to clients worldwide. Our IP litigators have decades of experience of highly technical disputes in the life sciences sector and an impressive record of achieving success.

"Regulation in this complex area continues to evolve."

And as many of the team hold life sciences-related degrees and have spent time in their careers as scientists, they bring genuine sector insight and understanding. Learn more at: **gowlingwlg.com/lifesciences**.

We hope you find the survey results insightful and helpful in planning your future approaches in this exciting and dynamic market.

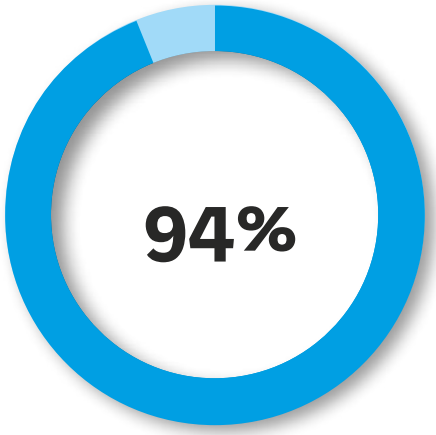
Biologics vs biosimilars: headline trends

Litigation volume

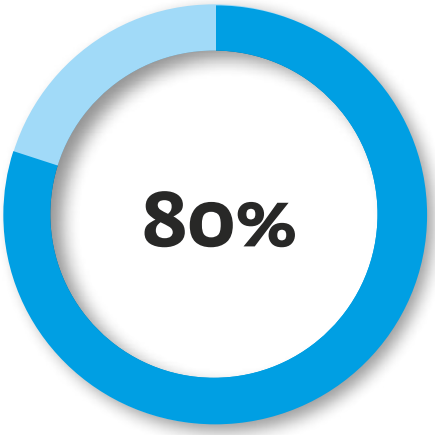
The picture is mixed in many areas in terms of how companies and their advisors are approaching biosimilar litigation, but everyone agrees that we're unlikely to see any drop in the volume of litigation any time soon.

Ninety-four percent of our respondents expect biosimilar litigation to increase over the next five years, while 6% think it will remain the same. Indeed, as the biologics market grows, it seems likely that litigation will keep pace with that growth.

This also holds true for so-called innovator vs innovator litigation, where 80% of respondents expect an increase, and again, no-one expects a decrease.



Expect biosimilar litigation to increase over the next five years



Expect an increase in "innovator vs innovator" litigation

This type of litigation is becoming more common in the biologics market when compared to small molecules, partly because of the time and resources required to develop a new large molecule invention.

Where competing innovator companies are working on the same target, it may make more sense to litigate than to spend lots of time and money trying to work around it.

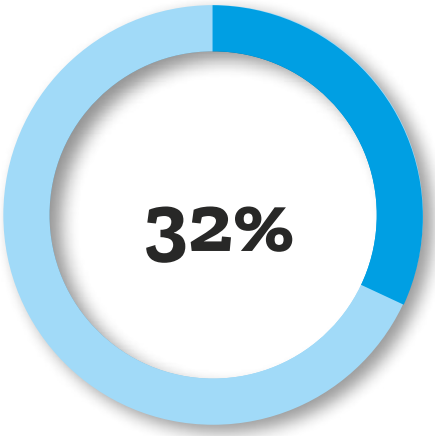
Paul Inman, partner at Gowling WLG, says: "Once you've got a biologic out there, competitors may be able to come up with a molecule with a different sequence, and if there is additional blocking IP then the commercial opportunity may make a fight worthwhile."

Patrick Duxbury, partner at Gowling WLG, agrees, noting that "the commercial opportunities in the biological field are significant, so the innovator companies are fighting over the same territory."

"This type of litigation is becoming more common in the biologics market."

How will it play out?

We asked our survey respondents whether they felt there were differences between biosimilar litigation and other types of life sciences litigation in terms of the likely course they would take.



Expect biosimilar litigation to go to trial more often

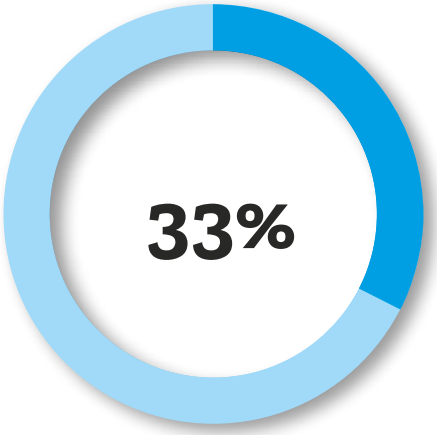
Overall, 32% of respondents expect this litigation to go to trial more often, while 40% expect it to settle more often than other types of litigation.

Research published in *Nature* ("**An administrative fix for manufacturing process patent thickets**", by Arti K. Rai and W. Nicholson Price II) has suggested that, in the US, most patent assertions against follow-on biosimilars concern patents that were filed post-approval of the originator biologic by the US Food and Drug Administration (FDA). Further, the research found that the largest group of asserted patents was for manufacturing process patents.

The prevalence of these post-approval patent assertions, first, indicates the sheer value to originator companies of biologics, and second, may suggest that originator companies have a certain advantage when it comes to litigation in the market; being able to build up strong and diverse patent portfolios that relate to the biologics.

We asked whether the current environment favours one type of company over another—people's responses to that were, as you might expect, largely dictated by the kind of work they're doing in the space, with innovator responses suggesting that the environment favoured biosimilars, and *vice versa*.

"The largest group of asserted patents was for manufacturing process patents."



Think the current environment favours innovator companies

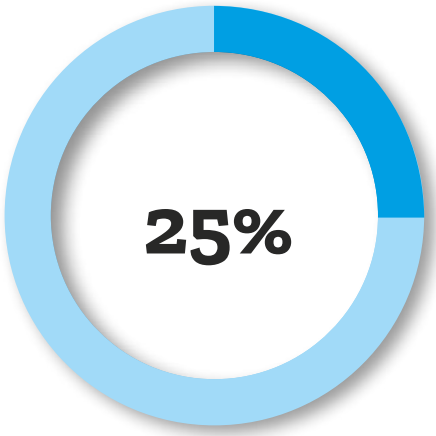
Overall, 33% of respondents think the environment favours innovator companies, while 20% think biosimilars have the advantage; the balance of respondents think there's no advantage to either.

Strategic considerations

We asked all survey respondents what their strategy is when considering litigation, to try to understand their appetite and attitudes surrounding it. For 25% of our respondents, litigation is a first option, and a further 19% look to litigate in a single jurisdiction first and try to leverage the result elsewhere. In contrast, 37% of respondents explore other avenues initially, and 19% would always try to come to an agreement and avoid litigation.

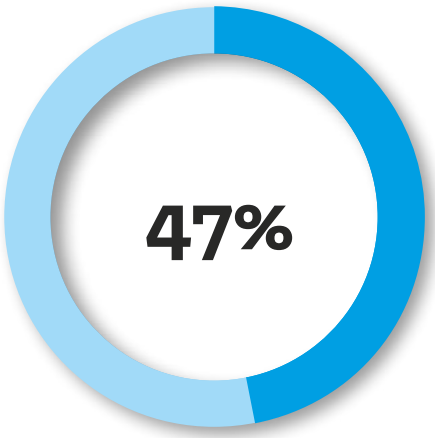
When it comes down to agreements, 47% look to do so on a global basis, with 53% preferring to handle things jurisdiction by jurisdiction.

For companies who are litigation-shy, there was bad news from some respondents. One said: "It is unavoidable looking at current trends—the best strategy is a strong and diverse patent portfolio, covering the innovator drug with a duration exceeding regulatory exclusivity."



Consider litigation as a first option in their strategy

More flippantly, some respondents suggested that "developing innovative products" was the key to avoiding litigation. Another suggested that even that wouldn't work without a "strategic patenting strategy" combining "internal inventing and external patent acquisition". Considering reasonable licensing terms for secondary patents early on was also advised.



Look to make agreements on a global basis

"'Skinny labelling' was also suggested as a productive strategy."

Other advice to help avoid litigation down the line, for biosimilars in particular, was to engage in it up front, using "clear the path" strategies and proactive litigation, aiming for a declaration of non-infringement if possible. "Skinny labelling" was also suggested as a productive strategy to carve out particular patented indications for the biosimilar.

Indeed, in the US in particular, there has been significant recent litigation around skinny labelling, albeit primarily in the small molecule field thus far.

"We are seeing biosimilars adopt a variety of regulatory filing strategies in Canada."

One Federal Circuit case found that Teva had infringed GSK's patented method of use for its Coreg (carvedilol) drug, despite Teva's product having a skinny label that carved out the patented indication. While that case was arguably fact-specific, it is a contentious area.

Nevertheless, skinny label issues are being raised in biologic cases currently before the courts. John Norman, partner at Gowling WLG in Canada, notes that "this is not surprising given biologics tend to be approved for multiple indications and biosimilars may not carry out clinical trials on all of the approved indications."

Alex Gloor, partner at Gowling WLG in Canada, adds "we are seeing biosimilars adopt a variety of regulatory filing strategies in Canada that appear to be designed for patent litigation purposes."

A problem that needs solving?

One question was whether there is anything that needs "fixing" with the patent system or the laws that govern it in order to encourage or facilitate biologics and biosimilar development.

Respondents were split almost equally between those who thought something should be done and those who thought existing systems are adequate for the industry, but there were some interesting comments as to what could be usefully changed. Most of these were directed at the US landscape, perhaps because it is the current most prominent locus of biosimilars patent litigation.

A few comments were directed at US Patent and Trademark Office practice: "There is a need to balance the race to file first and the need for sufficient data to support the invention," said one respondent.

In terms of legislation and regulation, the key areas highlighted were around the interchangeability of biosimilars, and the perceived need for an easier regulatory regime for products that are well understood.

"Respondents were split almost equally."

One commentator said that new legislation was required in the US to govern the listing of patents by an innovator company in the US FDA's *Purple Book*.

The *Purple Book* came in under the US Biologics and Price Competition Act and was refined following the 2020 Biological Product Patent Transparency Act, which requires publication of certain patents associated with biological drug products. In practice, that has meant a lot of listed patents, leading to some commentators to describe the *Purple Book* as "unwieldy".

"The US will continue to be the key jurisdiction to watch."

Jurisdictions to watch

Our respondents were overwhelmingly of the view that the US will continue to be the key jurisdiction to watch for biosimilars litigation over the next five years.

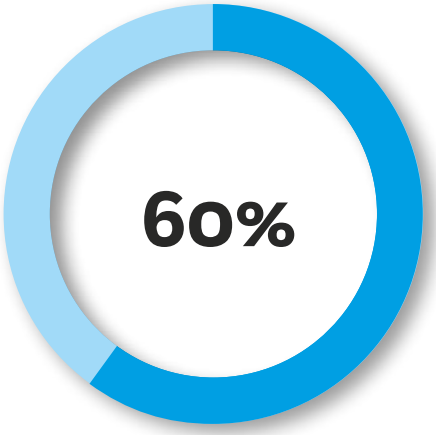
China and Germany were also highlighted as key potential battlegrounds—China because of its market size and global importance, and Germany because of the bifurcation between invalidity and infringement proceedings, which makes it an attractive jurisdiction in which to launch infringement proceedings.

The UK and the Netherlands were highlighted as good jurisdictions for biosimilar litigation, due to their speed and the quality of their judgments in invalidity proceedings.

The other major recent development that could have an impact on biosimilar litigation is the expected launch of the Unified Patent Court in Europe.

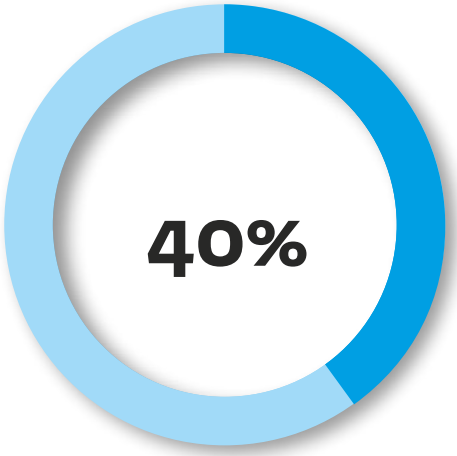
Although there's widespread expectation that large innovator companies will avail themselves of the seven-year opt-out period from the new system, eventually biologics patents will be litigated on a cross-European basis, raising the stakes significantly.

Sixty percent of respondents expect to see more innovation from biosimilars companies in the next five years, with 47% expecting the same from innovators.



Expect to see more innovation in the next five years

Next-generation therapies



Work in so-called next-generation therapies

Prediction of **moderate volumes of litigation** over the **next five years,** apart from in **very specialised fields** with **fewer operators.**

KEY AREAS RESPONDENTS WORK IN

- **CAR-T and immunotherapies**
- **Cannabinoids**
- **Gene therapies**
- **Vaccines**
- **Monoclonal antibodies**
- **Antibody / drug conjugates**

KEY CHALLENGES

Ensuring the description sufficiently supports the claims

Some countries don't grant claims on combination therapies—patentability is becoming more challenging

The disfavor of genus claims in the US

To prove workability in the entire scope of possibilities from claim one

Identifying the infringer where the patent covers a process incorporating the novel treatment, including steps performed in healthcare settings

Evidence gathering

Market size is often unclear and so affects the likelihood and utility of litigation

Increasing personalisation of therapies may make it difficult to obtain protection across a broad patient population

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