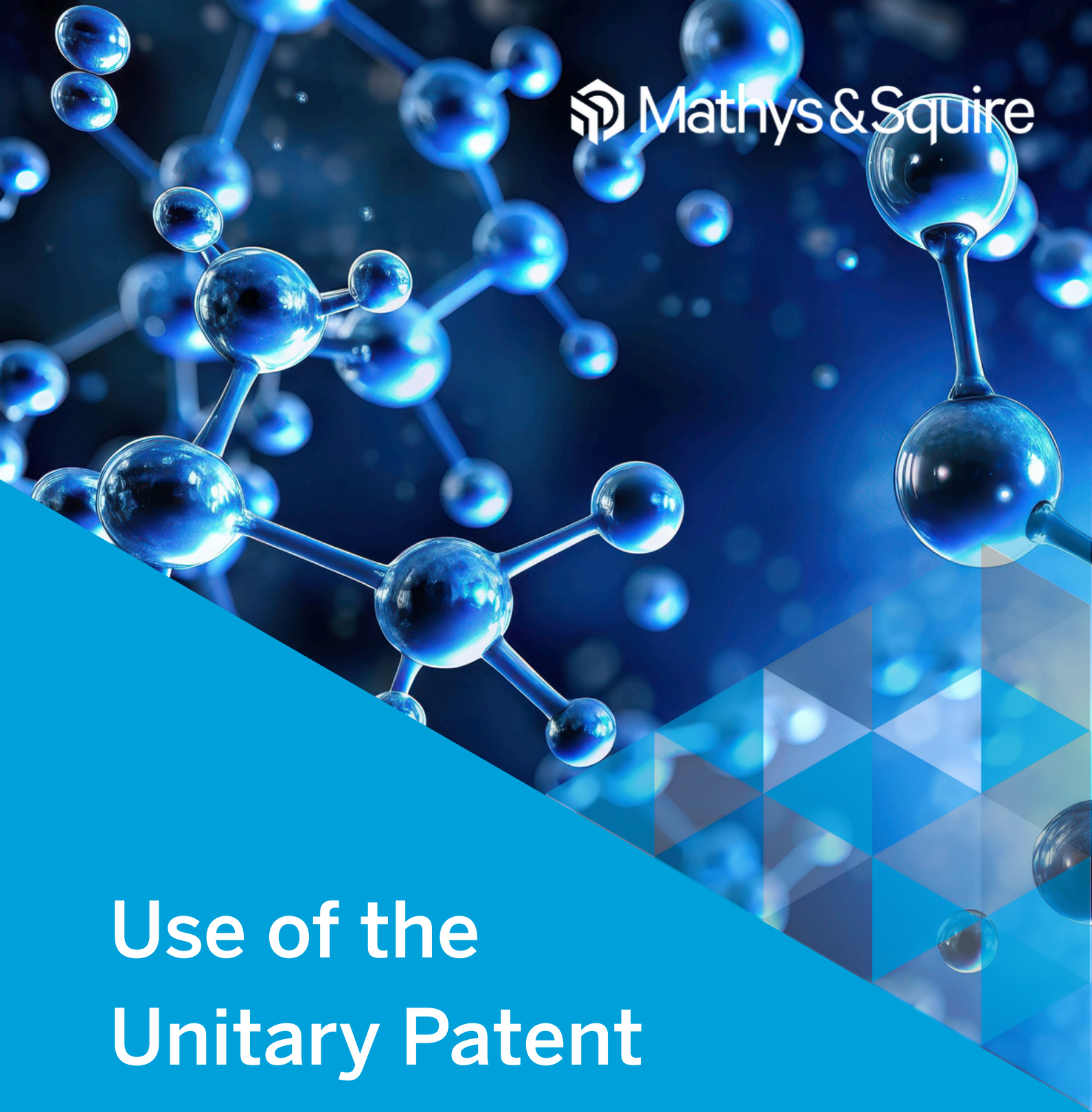


Mathys & Squire

Use of the Unitary Patent System

Healthcare & Life Sciences

January 2025

January 2025

About Mathys & Squire

Dedicated to protecting and defending your future.

Mathys & Squire is an intellectual property (IP) powerhouse that puts its specialist knowledge to work for clients, to strengthen and secure what most modern businesses today treat as one of their most valuable strategic assets - intellectual property.

The firm's agile teams of attorneys, scientists and strategists are steeped in experience, working with IP-rich and high-growth industries to leverage complex technologies and sophisticated commercial models across a broad range of industry sectors.

A full-service IP firm, Mathys & Squire has unrivalled expertise in patents, trade marks, design protection and litigation. Highly ranked in leading legal and IP directories, and leading the field with insight, innovation and quality, Mathys & Squire will be celebrating its 115th Anniversary this year, testament to its proven track record in the protection and commercialisation of IP rights.

The firm has a broad spread of clients, ranging from start-ups to major UK and global corporations, many of which are household names. Clients of the firm value its commitment to professional excellence and technical expertise.

Mathys & Squire has over 100 attorneys (both training and qualified) and a dedicated IP consulting team across offices in London, Birmingham, Cambridge, Manchester, Newcastle, Oxford, Luxembourg, Munich and Paris, as well as teams based in China and Japan. The firm's attorneys and trainees have a mix of scientific degrees extending from chemistry, biochemistry, pharmacology, genetics, microbiology, plant sciences and zoology through to physics, electronics, telecommunications and engineering.

We are passionate about creating and delivering innovative, high-quality, client-focused services and building close and longstanding relationships with clients in order to establish defensive and offensive IP portfolios that generate commercial value. We are proactive when working with clients and valued for our integrity, honesty and collegiate approach.

We protect, so that you can invent the future.

Contents

Introduction

Upon your patent application being granted by the EPO, you can choose whether to allow the granted patent to be granted as a Unitary Patent or as a bundle of national patents, which potentially involves filing opt-outs to prevent the national patents undergoing central revocation in the Unified Patent Court (UPC).

You can learn more about the advantages and disadvantages of the UPC here.

The pharmaceutical industry has been expected to adopt a cautious approach towards the UPC due to the value of individual patents and the potentially significant economic impact of a patent being revoked in multiple jurisdictions in a single court action.

This report will be looking at whether healthcare applicants are indeed opting their healthcare patents out of the UPC. The number of Unitary Patents granted in 2023 and 2024 was surveyed across four technical areas: organic chemistry, organic pharmaceuticals, biologics and medical devices. A range of applicants in each area was also sampled to assess the activity of specific applicants.

Authors

Nicholas Fox
Partner
NRFox@mathys-squire.com

Nicholas is a solicitor specialising in intellectual property law. In addition to being qualified as a solicitor, he also qualified as a European and Chartered British patent attorney with full rights of audience to appear in intellectual property proceedings at all levels in the English High Court, and is also qualified and admitted as an Attorney-at-Law in the State of New York.

Nicholas specialises in contentious and non-contentious intellectual property matters with a focus on patent litigation in the English courts and acting before the European Patent Office. He has experience litigating cases involving a wide range of technologies ranging from biotechnology through to electronics, software and communications.

Nicholas is the author of the practitioner's work, 'A Guide to the EPC 2000' and is the consulting editor and author of the UK intellectual property, European patents, European enforcement and Unified Patent Court chapters of the book 'Intellectual Property in Electronics and Software' published by Globe Law and Business.

Maxwell Haughey
Associate
MBHaughey@mathys-squire.com

Maxwell is a qualified European Patent Attorney. He joined Mathys & Squire in 2023 as part of the Life Sciences & Chemistry team.

Maxwell has experience in the prosecution and opposition of European patent applications. He has been involved in drafting new patent applications for clients ranging from multinational companies to universities, and he particularly enjoys speaking to inventors about their new products.

Maxwell has also helped to secure patent term extension, patent listing, and regulatory data protection for marketed pharmaceutical products.

Maxwell has a first class master's degree in chemistry from the University of Oxford. He also holds a DPhil in organic chemistry from the University of Oxford.

The Unitary Patent System - Background

The Unitary Patent System

The Unitary Patent system came into effect on 1 June 2023. Prior to that date, whenever a European Patent was granted, the European patent automatically became a bundle of national rights for each of the countries designated in the patent. Such national rights need to be maintained separately. In contrast, a Unitary Patent is a unitary right which provides patent protection across all the member states participating in the Unitary Patent system.

Maintaining a European Patent as a Unitary Patent is potentially a cost-effective way for patent proprietors to obtain wide geographical protection in Europe. The maintenance fees for a Unitary Patent are roughly equivalent to the cost of maintaining national patent protection in four European countries and can be obtained by filing a single translation of the granted patent with the European Patent Office – into English if a patent is prosecuted in French or German or into any EU language if a patent is prosecuted in English. This contrasts to national rights where in many cases the filing of a translation of the patent or the claims of the patent into a national language is required to maintain rights in force in a particular jurisdiction.

Actions to enforce a Unitary Patent can only be brought in the Unitary Patent Court. The Unitary Patent Court also has exclusive jurisdiction to invalidate Unitary Patents. If revoked, a Unitary Patent is invalidated in all the jurisdictions where it has effect. This is unlike an equivalent bundle of national rights where each national patent has effect only in a single jurisdiction and invalidating an individual national patent has no effect on equivalent national patents arising from the grant of the same European patent.

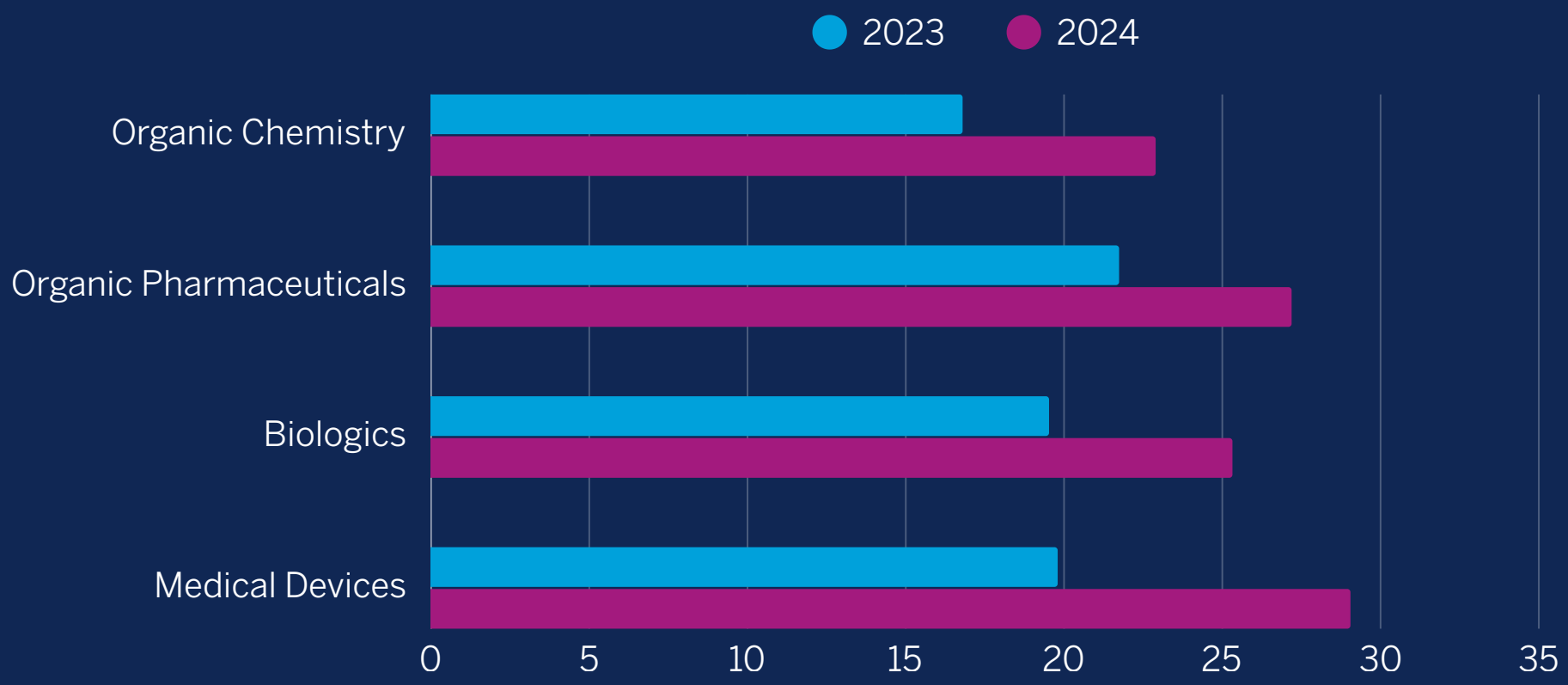
Healthcare and Life Sciences Unitary Patents - Survey

The UPC entered into force on 1 June 2023, but it was possible to delay the grant of a European Patent from the beginning of the year until Unitary Patents might be granted. In practice this means that 2024 was the first full year when patent proprietors had the choice of obtaining Unitary Patents, even though, at least theoretically, any European Patent application found in order for grant since 1 January 2023 could have been converted into a Unitary Patent if a patent proprietor chose to do so.

It is unsurprising, therefore, that the percentage of European patents in healthcare fields which ended up being maintained as Unitary Patents increased from 2023 to 2024. This was true across all healthcare fields sampled, as seen in FIG.1.

Use of the Unitary Patent was particularly high in the case of medical devices where approximately 30% of all patents granted in Europe in 2024 were maintained as Unitary Patents up from around 20% in 2023. FIG.1 illustrates that significant proportions of granted European Patents end up as Unitary Patents subject to the jurisdiction of the UPC across all healthcare fields. Any suggestion that healthcare companies are opting all their patents out from the jurisdiction of the UPC is clearly wrong.

FIG. 1: Percentage UPs by Technical Field



Organic Chemistry

FIG. 2 shows the results of our survey for major patentees for patent applications relating to organic chemistry. The graph shows the numbers of European Patents (EPs) each applicant has chosen to maintain as national patents and the numbers of patents where the applicant has opted to have the patents maintained as Unitary Patents (UPs). The figure breaks these numbers down across patents granted in 2023 and 2024 to see if any change in behaviour of an individual applicant can be identified.

A number of the significant filers in organic chemistry have engaged very little with the Unitary Patent system, having either zero or low single digit numbers of Unitary Patents granted in 2023/24.

For example, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, LG Group, , Merck Sharp & Dohme (Merck & Co Inc.), Novartis and Samsung all had no Unitary Patents granted in 2023, and most had a single Unitary Patent granted in 2024. This group includes Bristol-Myers Squibb, LG Group and Merck Sharp & Dohme who were among the largest filers for patents in this area of technology.

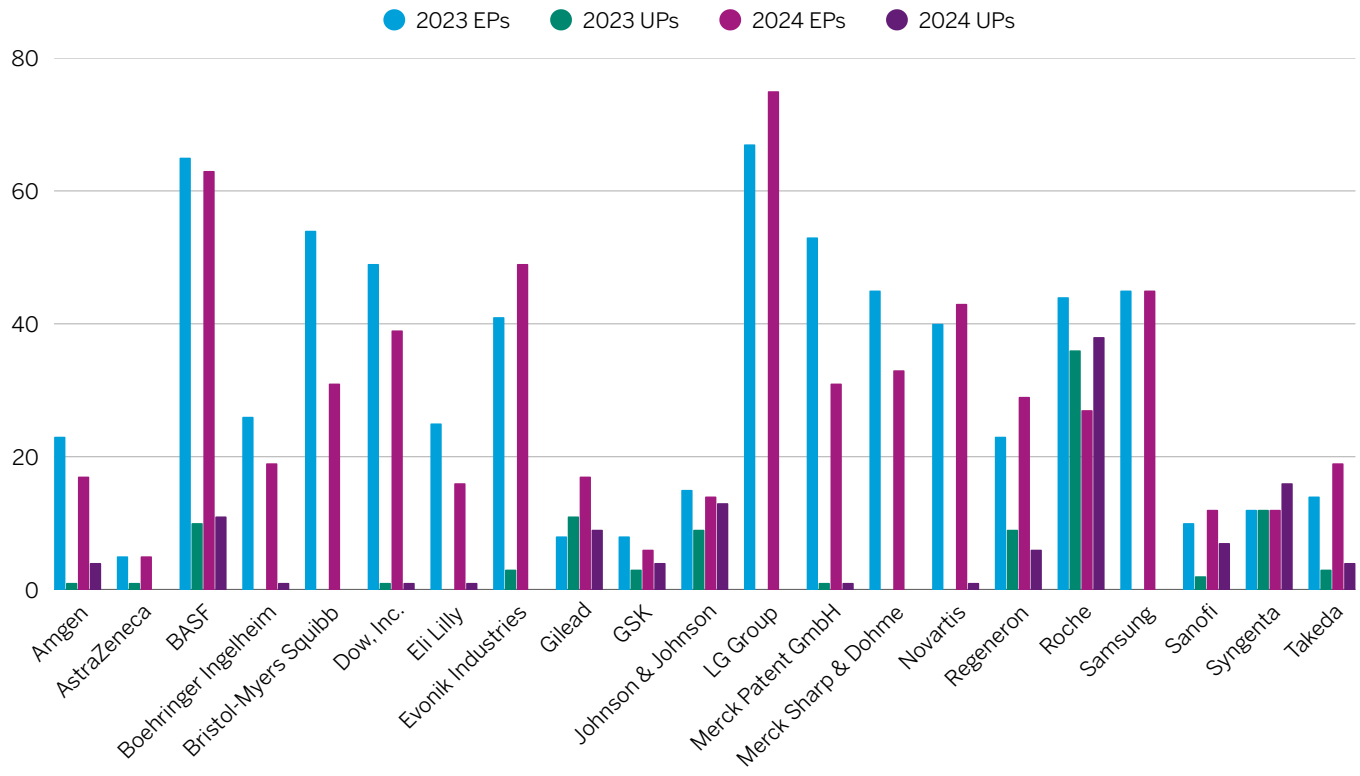


FIG. 2: Granted EPs and UPs - Organic Chemistry

Where an applicant has been very selective about engagement with the Unitary Patent system, it may be the case that a or particular patent/s relate to technology for which a Unitary Patent is particularly suitable. Potentially, this may explain the single Merck Patent GmbH (Merck KGaA) Unitary Patent granted in 2024. That patent concerned a chemical process which involved multiple individual process steps which potentially could be conducted in different European countries. This means protection via a Unitary Patent would be particularly suitable.

Boehringer Ingelheim, Eli Lilly and Novartis all had no Unitary Patents granted in the field of organic chemistry in 2023/24, and each had a single organic chemistry Unitary Patent granted in 2024. Potentially, these might also have been chosen as "test cases" for using the Unitary Patent system or for specific reasons relating to the individual inventions that the patents cover.

Other applicants have used the Unitary Patent system more widely, for example BASF, Gilead, GSK, Johnson & Johnson, Regeneron, Roche, Sanofi, Syngenta and Takeda.

Collectively, the figures indicate that different companies are taking very different approaches to the UPC and the Unitary Patent System. There is no uniformity of approach.

By way of example, Roche and Novartis are both multinational Swiss pharmaceutical corporations ranking in the top five global pharmaceutical companies by revenue. In the field of organic chemistry, Novartis converted none of their European Patents into Unitary Patents in 2023 and obtained only a single Unitary Patent in 2024. This compares with 40 and 43 organic chemistry patents in 2023 and 2024 respectively, where Novartis maintained their patents as a bundle of national rights.

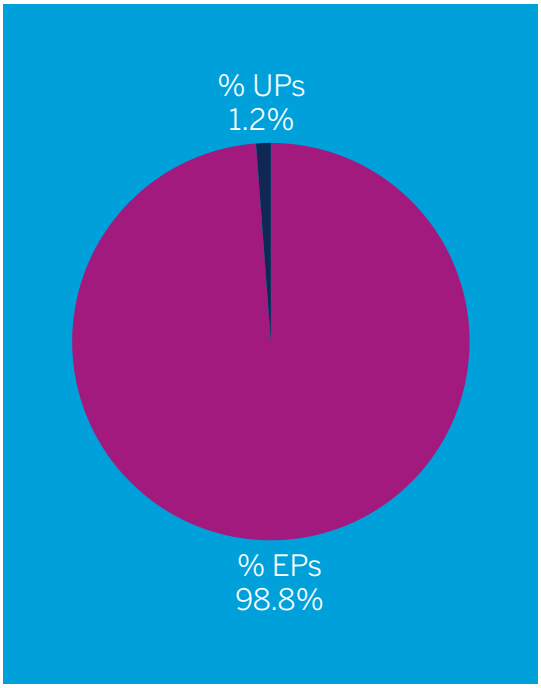


FIG. 3: Patents Maintained by Novartis 2023-2024

In contrast, Roche had 36 organic chemistry Unitary Patents granted in 2023 (compared to 44 European Patents maintained as a bundle of national rights), and this increased to 38 Unitary Patents granted in 2024 (compared to 27 European Patents maintained as a bundle of national rights). Hence, in contrast to Novartis who is yet to really engage with the Unitary Patent system, the majority of Roche's organic chemistry applications are now being maintained as Unitary Patents.

The upward trend in the proportion of patents maintained as Unitary Patents which is apparent from Roche can also be seen in the figures for other applicants.

For example, Syngenta also had a greater proportion of patents maintained as Unitary Patents in 2024 compared with 2023. In 2024 a majority of Syngenta's patents in the field of organic chemistry were maintained as Unitary Patents rather than a bundle of national rights (16 Unitary Patents compared with 12 patents maintained as national rights).

Tentatively, this may suggest that some applicants are overcoming their initial caution about the use of the Unitary Patent system. However, as we only have two year's data, and the data from 2023 is necessarily impacted by the introduction of the Unitary Patent half-way through that year (albeit with the option of selectively delaying patent grant where a proprietor really wished to obtain a Unitary Patent), it is probably too early to tell.

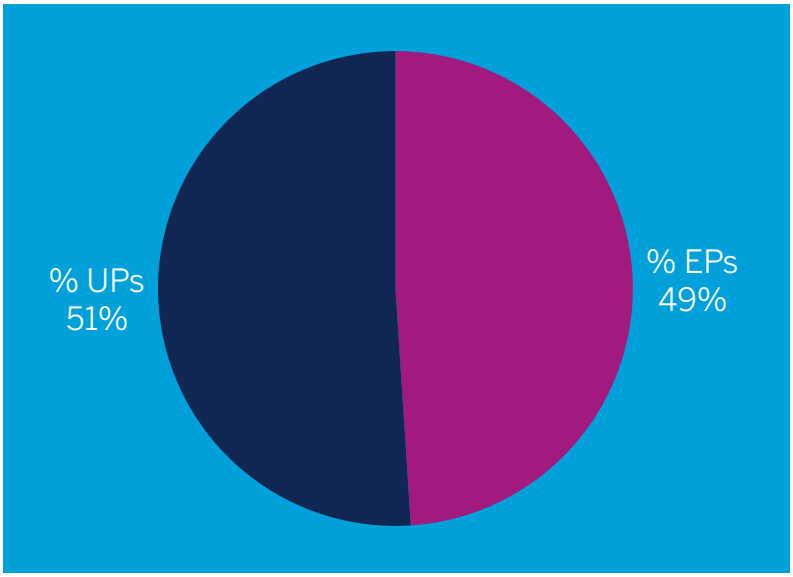


FIG. 4: Patents Maintained by Roche 2023-2024

Organic Pharmaceuticals

FIG. 5 shows the numbers of patents converted into Unitary Patents by major filers in the field of organic pharmaceuticals, displaying similarly mixed signals as organic chemistry.

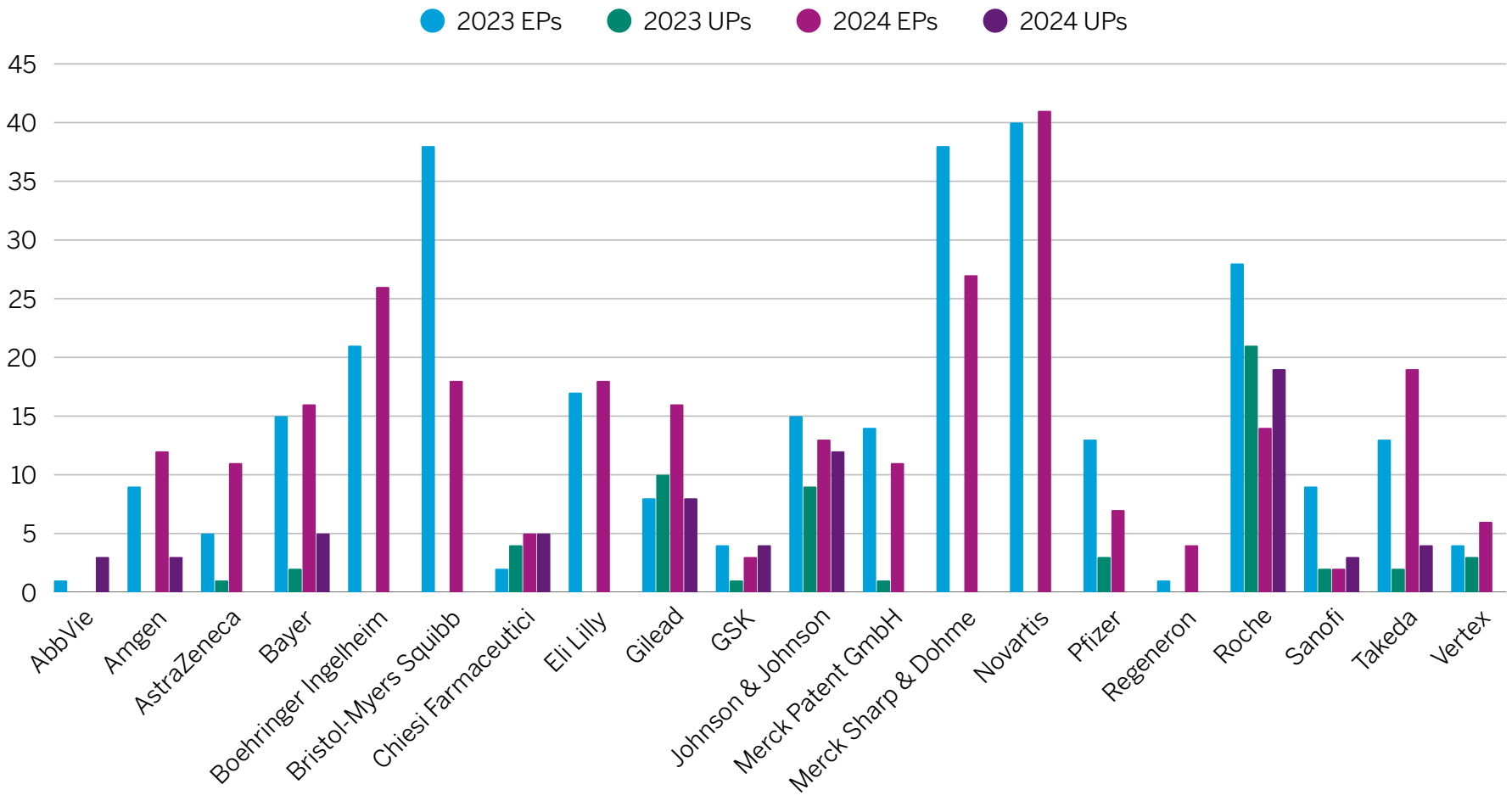


FIG. 5: Granted EPs and UPs - Organic Pharmaceuticals

AbbVie, Bayer, Chiesi Farmaceutici, Gilead, GSK, Johnson & Johnson, Roche, Sanofi and Takeda all show relatively widespread uptake of Unitary Patents in the field of organic pharmaceuticals.

Chiesi Farmaceutici has chosen to convert the majority of their granted patents into Unitary Patents. This was the case in both 2023 and 2024 when 4 and then 5 of Chiesi Farmaceutici patents were converted into Unitary Patents compared to 2 and then 5 patents which were maintained as national rights.

Although the sample size is small, AbbVie had no organic pharmaceutical Unitary Patents granted in 2023 (and a single patent maintained as a bundle of national rights), but 3 Unitary Patents granted in 2024 with no rights not being maintained as Unitary Patents.

Some applicants – Amgen, Bayer, Chiesi Farmaceutici, GSK, Johnson & Johnson, Sanofi and Takeda – increased their use of the Unitary Patent system in 2024.

In comparison, others – AstraZeneca, Merck Patent GmbH, Pfizer and Vertex – obtained Unitary Patents in 2023 but obtained no Unitary Patents in 2024.

Other major players in the field – Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, Merck Sharp & Dohme, Novartis and Regeneron – have entirely avoided the Unitary Patent system for organic pharmaceutical inventions and have chosen instead to maintain all their European patents as bundles of national rights.

Biologics

FIG. 6 shows a similar analysis, this time in the field of biologics.

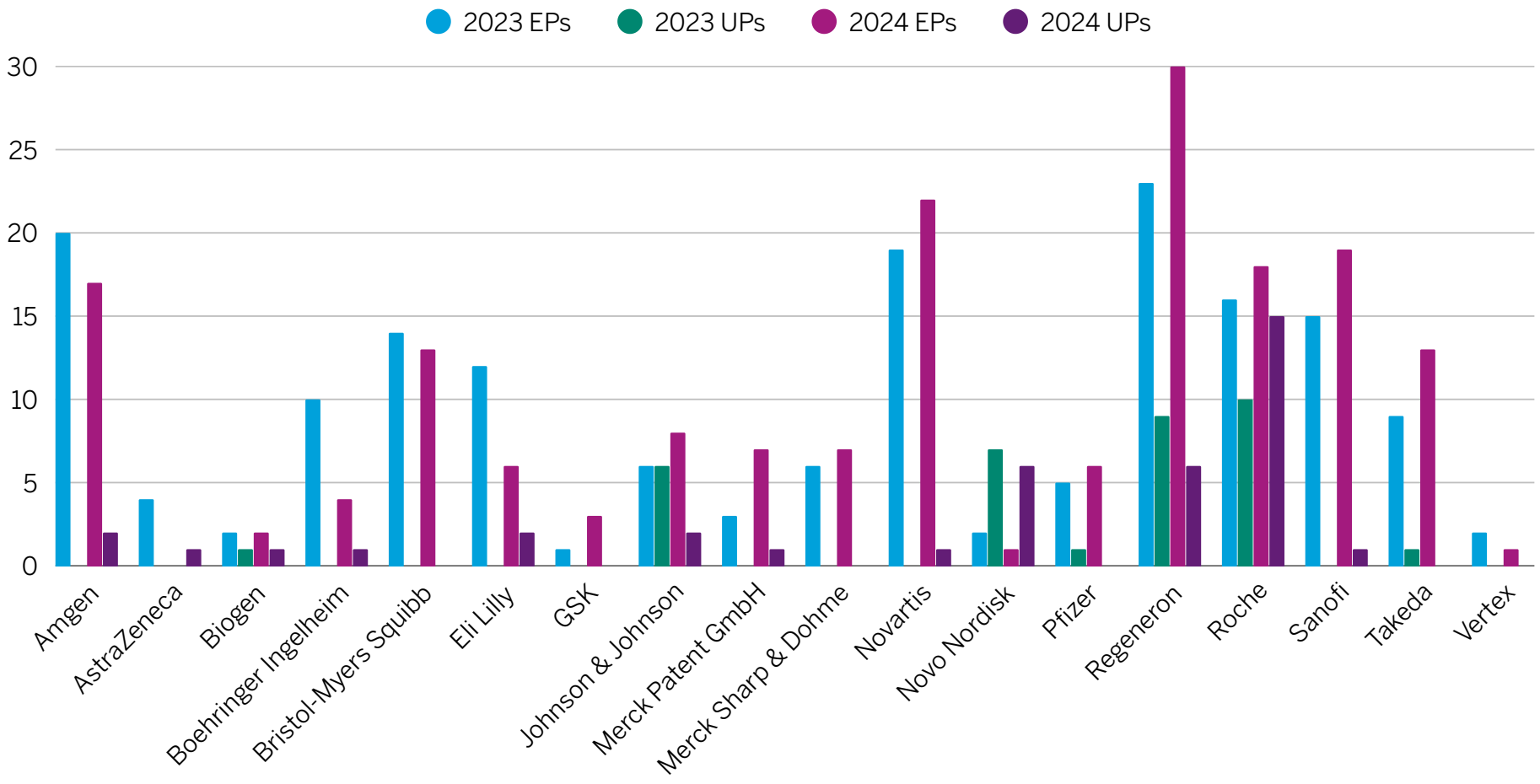


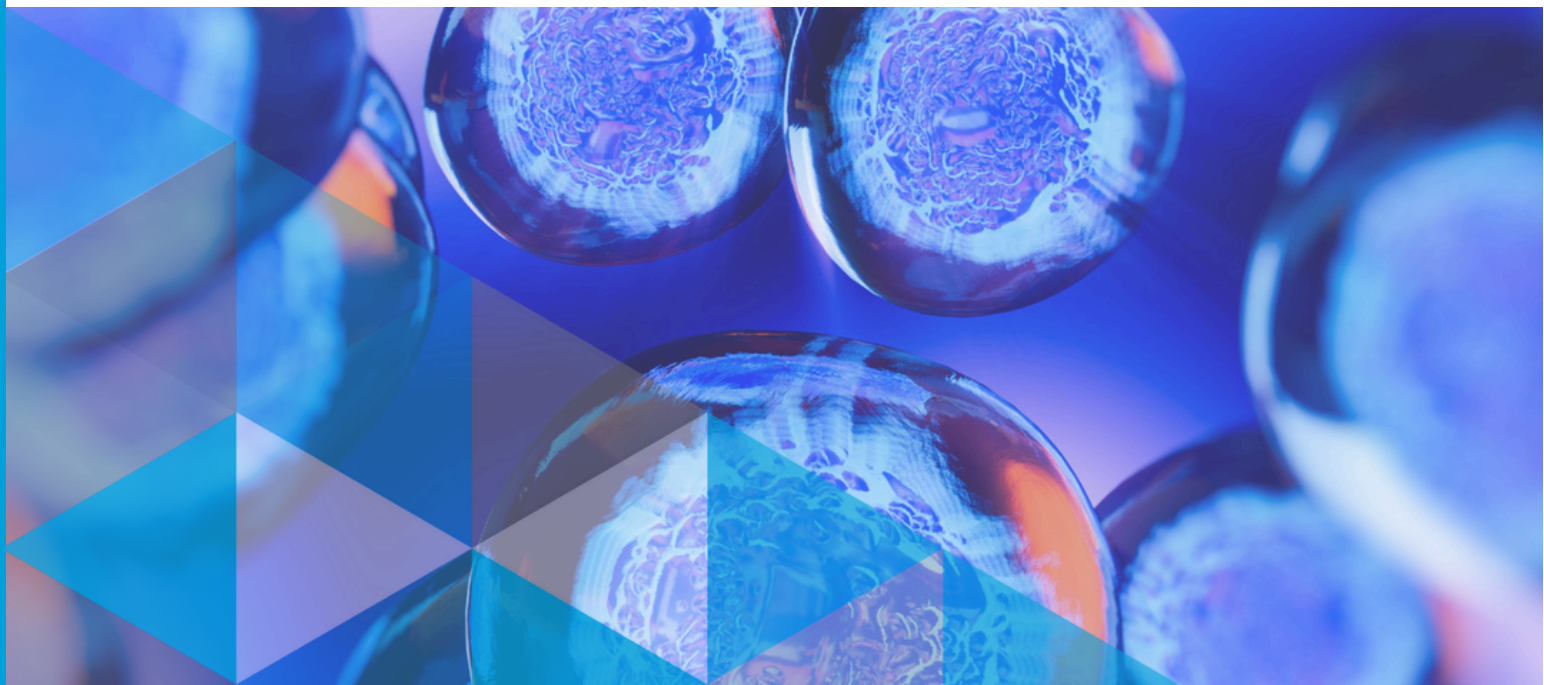
FIG. 6: Granted EPs and UPs - Biologics

Apart from Biogen, Johnson & Johnson, Novo Nordisk, Regeneron and Roche, applicants generally seem to be more reluctant to use the Unitary Patent system for biologics. Of the applicants sampled, only Novo Nordisk obtained Unitary Patents for a majority of their granted patent applications (7 and 6 Unitary Patents in 2023 and 2024, respectively compared to 2 and then 1 patent/s which was maintained as a bundle of national rights).

The greatest number of biologics Unitary Patents in our sample were granted to Roche. However, that was due to the higher number of patents that Roche obtained compared to the companies in the survey and still represented a minority of Roche's biologics patents overall (10 and then 15 Unitary Patents in 2023 and 2024, compared with 16 and then 18 patents maintained as national rights in 2023 and 2024 respectively).

Bristol-Myers Squibb and Merck Sharp & Dohme converted none of their European Patents into Unitary Patents in 2023/24, despite these applicants being among the largest filers in this field. Similarly, Novartis chose to maintain only a single European patent as a Unitary Patent in 2024, opting for national rights for 19 and then 22 biologics patents in 2023 and 2024 respectively.

Applicants generally seem to be more reluctant to use the Unitary Patent system for biologics.



Medical Devices

The results of our survey for the field of medical devices are shown in FIG. 7.

Medical device applicants appear to be most divided in their adoption of the UPC.

A significant number of applicants sampled have chosen not to obtain Unitary Patents – see Intuitive Surgical, Novartis, ResMed, Smith and Nephew, Solventum (3M Health Care) and Stryker. This is particularly significant because some of the largest filers in the field of medical devices have chosen to take this approach.

Other applicants such as Abbott Laboratories, Braun, Dexcom, Fujifilm, GE Healthcare and Medtronic, had either a single or low single digit number of Unitary Patents granted in 2023/2024, compared with significantly higher number of patents which were maintained as national rights. Of these applicants, all but Abbott Laboratories and Dexcom deferred their adoption of the Unitary Patent system for medical devices until 2024.

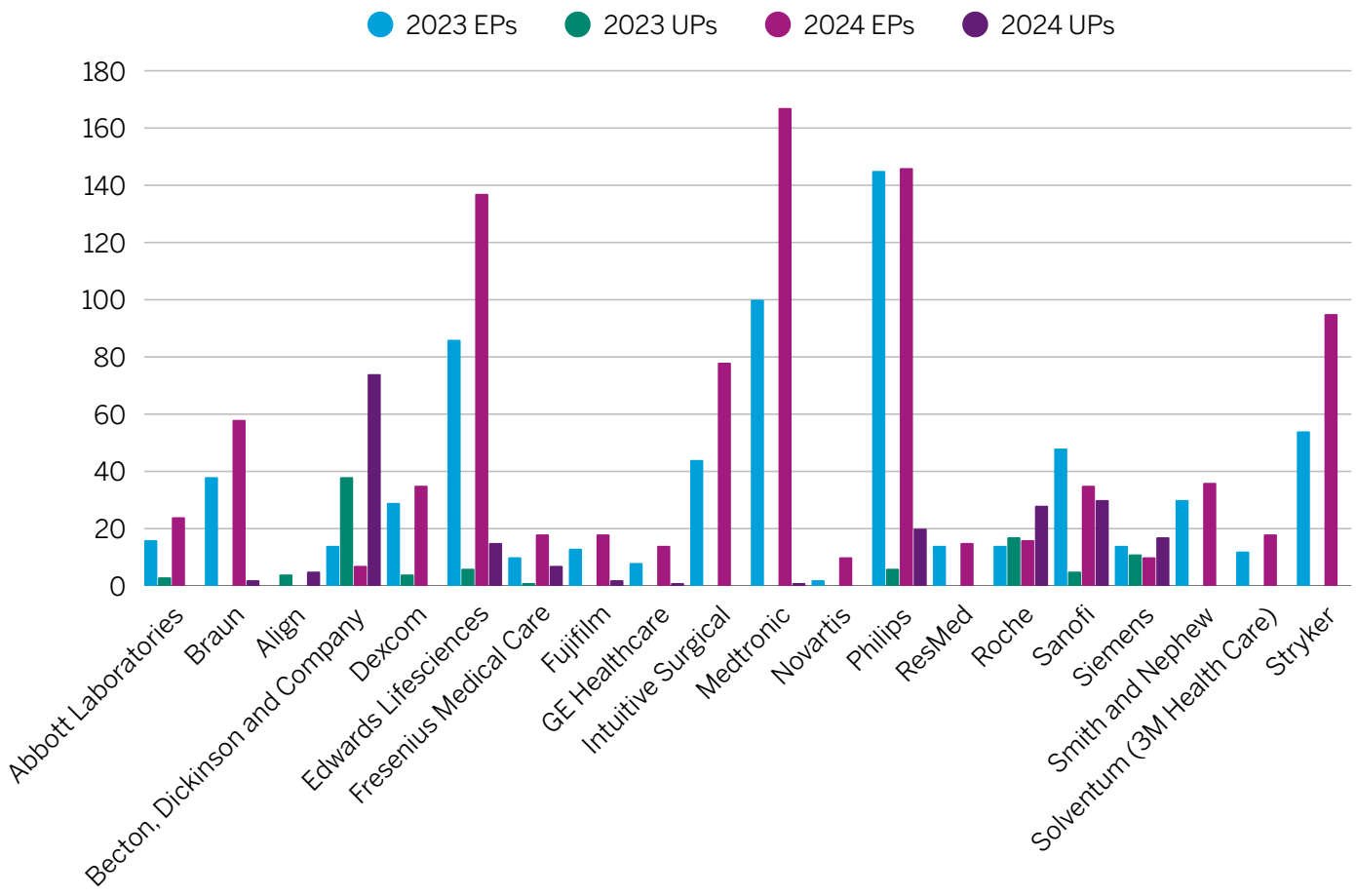


FIG. 7: Granted EPs and UPs - Medical Devices

On the other hand, Becton, Dickinson and Company is notable for obtaining 38 medical device Unitary Patents in 2023 (compared to 14 patents maintained as national rights). Then in 2024, Becton Dickinson's number of Unitary Patents was significantly greater than the number maintained as a bundle of national rights – 74 Unitary Patents compared to 7 maintained as national rights.

All of the medical device patents granted in Europe to Align were maintained as Unitary Patents in both 2023 and 2024. In fact, out of 49 patents granted to Align in Europe in 2023 (in all areas of technology), only a single patent (relating to a computer program) was not maintained as a Unitary Patent.

Other large filers, including Edwards Lifesciences and Philips, are choosing to obtain a mix of Unitary Patents and bundles of national rights. Although both companies are opting for the Unitary Patent route for only a minority of their patents, in both cases the numbers of Unitary Patents granted doubled in 2023 compared with 2024. Potentially, this suggests that these companies chose not to delay grant of patents prior to 1 June 2023 for the opportunity to obtain Unitary Patents which would cause the 2023 numbers to represent grants for only around half a year, but since then they have been converting a consistent proportion of their medical device patents into Unitary Patents.

Roche, Sanofi and Siemens had a large proportion of their medical device patents granted as Unitary Patents in both 2023 and 2024 with between 45% and 65% of medical device patents for these three companies being maintained as Unitary Patents in 2024.

Sanofi and Roche provide an interesting example of how take up of the Unitary Patent is impacted by technical field.

Looking at the figures for 2024, Sanofi converted a greater proportion of their medical device patents to Unitary Patents (46%) than was the case for organic chemistry patents (37%) or biologics (5%). Similarly, Roche's figures vary significantly across different fields and in many cases are quite different from those for Sanofi. Roche obtained Unitary Patents for 64% of their medical device patents, 37% of their organic chemistry patents, 58% of their organic pharmaceutical patents and 45% of their biologics patents.

Concluding Remarks

As shown above, it is clear that, at present, different companies are adopting very different approaches to the use of the Unitary Patent system and that the approaches are nuanced depending upon the area of technology a patent involves.

Widespread adoption of the Unitary Patent has not been limited to European-domiciled companies, with several US applicants now maintaining a significant proportion of patents in Europe as Unitary Patents.

It is clearly not the case that large companies choose to maintain all their patents as national rights, opting the patents out from the jurisdiction of the UPC to protect such rights from central revocation.

How those approaches develop further, only time will tell.

Methodology

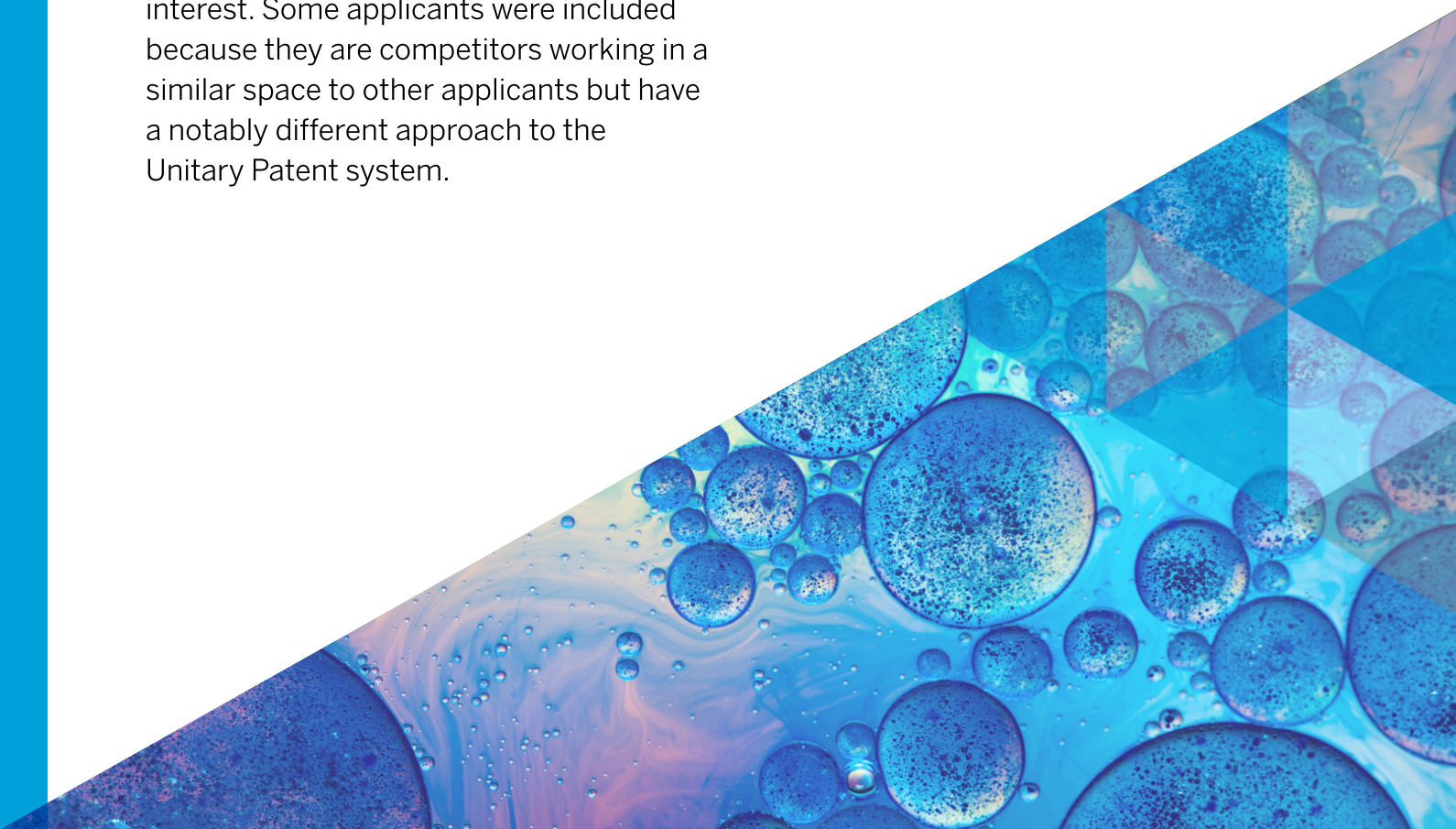
A comprehensive list of applicants in the healthcare & life sciences sector was compiled with respect to four different industry areas. The sample from which the applicants were selected was not limited to any specific country or continent. The sectors' lists are not mutually exclusive and applicants which file patent applications in multiple areas of technology have been included in whichever categories apply.

To narrow down the number of applicants surveyed, two factors were taken into consideration: the number of patents the applicants filed at the EPO in 2023 and 2024, and how well known they are in their field. The priority was to include the top filers, but also select applicants of interest. Some applicants were included because they are competitors working in a similar space to other applicants but have a notably different approach to the Unitary Patent system.

In total the patent activity of 45 applicants was analysed. The technical areas chosen were:

- Organic chemistry
- Organic pharmaceuticals
- Biologics
- Medical devices

The data was obtained from the EPO Register. The data extracted included the number of European Patents granted to each applicant in 2023 and 2024, and the number of patents maintained as Unitary Patents by each applicant in 2023 and 2024.



Mathys & Squire

T +44 (0)20 7830 0000 // E info@mathys-squire.com // @Mathys_Squire // www.mathys-squire.com