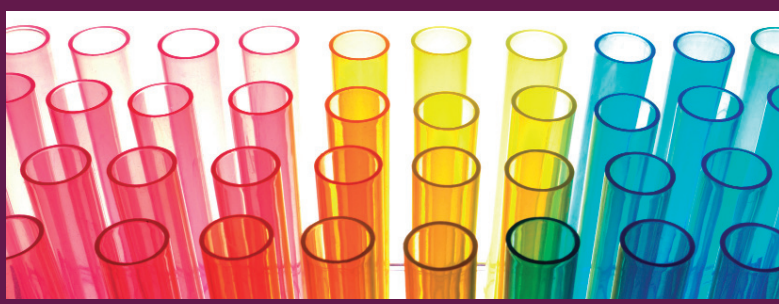
Managing Intellectual Property™

IPFocus



LIFE SCIENCES

8TH EDITION

WHAT THE EPO'S RULE CHANGES MEAN FOR LIFE SCIENCE APPLICANTS

VALEA

2010

What the EPO's rule changes mean for life science applicants

The European Patent Office has introduced rule changes to speed up patent examination. **Camilla Lidén**, **Ellen Setréus** and **Ylva Skoglösa** of **Valea** explain the possible implications for biotechnology and pharmaceutical companies

As part of the EPO's Raising the Bar initiative for applications filed at the Office, the EPO implemented a series of rule changes on April 1 2010. These new rules will affect the drafting and filing strategies for many applicants within the life science area.

The exact impact that these changes will have on applicants' filing and prosecution strategies is not yet clear, but they will certainly force all applicants within the biotechnology and pharmaceutical field to take actions and decisions earlier in the patenting process than before. In combination with the concurrent raising of the bar for inventive step and sufficiency of disclosure within the same field of technology, this will pose a high hurdle to overcome for the vast majority of applicants.

Three sample applicants

To illustrate better the possible impact of these changes on the IP strategy of different applicants within the life science field, we have constructed three examples based on typical clients from the pharmaceutical and biotechnology sector.

The large pharmaceutical company

Company A is a large pharmaceutical company with an active patenting strategy and a large patent portfolio. Company A usually files patent applications very early in the development process, covering a broad scope of, for example, small chemical compounds for pharmaceutical use. The applications often contain a large number of claims including several independent claims in each category. Following a lengthy and costly research and development process towards a potential new blockbuster, some of the covered compounds will successively emerge to be more important than others and, once a marketing authorisation is obtained, those will, if possible, be further protected by extensions.

The mid-size biotech business

Company B is a mid-size biotechnology or medical technology company having a moderate patent portfolio, very often based on early-filed and as broad as possible applications, protecting its core technology. Company B prefers to postpone major costs as long as possible, as it is dependent on external funding for financing of its patent portfolio. On the other hand, it is highly dependent on its IP for attracting the same funding. Company B often files follow-up patent applications urgently, due to upcoming scientific publications or presentations at conferences.

The individual inventor

Inventor C is based at a university, for example in Sweden, where the teacher's exemption gives the researchers a right to their own inventions. Inventor C has limited funds for intellectual property and is also highly dependent on publishing his/her results early to obtain funds for research. He/she often files very early due to upcoming scientific publications or presentations at conferences.

Limits on claims

The EPO has now effectively limited the number of independent claims that are allowed in one application (Rule 62a EPC). Accordingly, if the EPO considers that the application contains too many independent claims of the same category, the applicant will receive a communication under Rule 62a inviting him/her to choose which of the claims (that is, which parts of the invention) he/she wants to continue with. In their response, applicants are strongly advised to clearly indicate and explain the subject matter they want to have searched, as it is not possible to amend the claims to relate to unsearched subject matter later in the process (Rule 137(5) EPC). The only option to prosecute the non-selected subject matter would then be to file a divisional application, for which a time limit will be triggered from the first communication issued in the first application by the Examining Division (Rule 36(1)(a) EPC).

In the life science field, it is common practice to have

The EPO's rule changes at a glance

- Rule 62a EPC – The EPO has limited the number of independent claims allowed in one application, i.e. an application cannot contain multiple independent claims in the same category, with some exceptions (Rule 43(2) EPC). The applicant will be invited to limit the number of claims to be included in the search.
- Rule 63 EPC – The EPO will, when it is deemed to be impossible to carry out a meaningful search, invite the applicant to file a statement indicating the subject matter to be searched.
- Rule 70a EPC – It is now mandatory to respond to the search opinion, if negative, within the period for requesting examination. Otherwise the application will be deemed to be withdrawn (Rule 70a(3) EPC).
- Rule 161 EPC – When EPO acts as International Searching Authority (ISA) and/or International Preliminary Examining Authority (IPEA), it will be mandatory for the applicant to file a response to the written opinion issued during the international phase, if the opinion was negative, shortly after entry into the regional phase.
- Rule 36 EPC – The EPO has introduced strict time limits for filing divisional applications, i.e. a divisional application now has to be filed within 24 months from receiving the first communication from the Examining Division. This time limit has also been introduced for an application not fulfilling the requirements of unity, i.e. the filing of the divisional application must be performed before the end of 24 months from receiving the communication from the Examining Division pointing out the non-unity objection (Article 82 EPC; Rule 64 EPC).
- Rule 137(2) EPC – The applicant's right to make amendments of his own volition has been restricted to replies to the search opinion, if an invitation to file amendments has been issued therewith. Any further amendments can only be made with the consent of the Examining Division.

several independent claims in the same category to cover all medical aspects of an invention. For company A, the filing of divisional applications will have to occur earlier in the process than before. Still, company A, which has sufficient funds for filing a plethora of divisional applications, will probably file the same number of divisional applications as previously. In contrast, company B, as well as inventor C, will most likely lack the financial stability needed for filing one or more divisionals at this stage. Therefore, company B and inventor C in particular will now need to – at a much earlier stage – be able to define the subject matter for which protection is sought thoroughly. This is a far-from-optimal strategy considering the fact that, at such an early stage of the prosecution, there is a considerable risk that competitors might have still-unpublished IP in the pipeline.

Responses to search opinions

Furthermore, the EPO has also changed the procedure regarding responses to search opinions. Once a search has been finalised, a search report, as well as a search opinion, will be issued, the difference now being that the search opinion, if negative, needs to be responded to at once (Rule 70a EPC). Interestingly, the applicant is now required to file a substantive response before the application has even entered into the examination stage. Additionally, this might also be the only opportunity for the applicant to amend the description and claims of his/her own volition. Later amendments can only be made with the consent of the Examining Division (Rule 137(3) EPC), and how accommodating the examiners will be in allowing such amendments remains to be seen. It stands to reason, though, that the EPO will be more restrictive, as the intention of the rule changes is to speed up the examination procedure. Hence, it is necessary for the applicant to be well prepared already when entering the search stage.

For our applicants, company A, B and inventor C, this latter rule change means that full argumentation,

Camilla Lidén

Camilla is a European patent attorney. She has an MSc in Molecular Biology and specialises in patenting within the fields of medicine, biochemistry, molecular biology, genetics, immunology and gene technology.

Camilla handles all types of patent issues including pre-patenting investigations, patent drafting and prosecution. Camilla also works with business-related IP issues such as strategic IP consultation and questions regarding validity, infringement, due diligence and freedom to operate.

Before joining Valea in 2003, Camilla worked for three years at Karolinska Institutet Innovations AB on the commercialisation of university-based inventions. Camilla has been working in the life science field since 2000 and with IP since 2003.

including all relevant experimental data for supporting inventive step and/or sufficiency of disclosure, needs to be available already at the filing/search stage. As a result, more resources will probably have to be set aside for pre-filing activities.

As mentioned above, this will likely collide with the fundamental need within this field to file a patent application early for attracting financial partners, as many applicants are dependent on scientific publications as well as on presenting their scientific progress at conferences. Also, many applicants within the field, especially inventor C, would prefer to postpone the costs associated with prosecuting their patent portfolio for as long as possible. The speeding up of the examination process will instead trigger more substantial costs earlier than before.

The EPO has now effectively limited the number of independent claims that are allowed in one application

Will applicants still prosecute?

It remains to be seen if this aspect of speeding up the procedure will actually force some applicants, such as inventor C, to discontinue the prosecution of their applications if no funding can be found in time. For company A and B, the earlier arisen costs will also impact the managing of their IP portfolio, especially company B, which might have limited funds. Of course, there is also the potential scenario that the filing of the patent application was based on pilot studies and that the applicants are still awaiting substantial experimental data, rendering it difficult to meet any potential objections from the EPO already at the search stage. It stands to reason that very few applicants will be able to provide clinical data at such an early point in time. Thus, maybe we could hope that the EPO in the future will be more inclined to consider lowering the bar on the experimental standards to facilitate a quicker examination procedure.

PCT applications

The same procedure as described above will of course apply if the application was processed via the PCT regulatory network and the EPO was selected as the ISA (International Searching Authority) and/or IPEA (International Preliminary Examining Authority). The Rule 161 EPC communication issued by the EPO, shortly after entering the EP regional phase, will simply be a copy of the written opinion issued during the international phase. However, the difference is now that this communication, if negative, needs to be responded to more or less immediately.

Hence, the applicant is now forced to respond very quickly to any objections raised during the international phase. Again it is also important to remember that responding to the Rule 161 EPC communication could be the only opportunity for the applicant to amend the application and the claims of his/her own volition. Furthermore, it is not possible to change the scope of the claims to unsearched subject matter upon entry into the EP regional phase when a non-unity objection is raised during the international phase and no additional search fees have been paid (Rule 64 EPC, Rule 164 EPC). Consequently, the only option for the applicant is to continue with the invention that was prosecuted during the international phase. Any non-searched inventions now need to be protected in separate divisional applications.

If, on the contrary, the EPO was not chosen as ISA, again a Rule 161 EPC communication will be issued when the application enters the regional phase, the difference being that a response thereto is not mandatory even if the opinion is negative. What is more, the claims can in this case still be amended to exclude the invention prosecuted during the international phase and to include non-searched subject matter.

Consequently, when not selecting the EPO as ISA and/or IPEA, there will always be an additional opportu-

Ellen Setréus

Ellen is a European patent attorney. She has an MSc in chemical engineering and expertise within the areas of chemistry, pharmaceuticals and polymer technology. Ellen handles all types of patent issues, including patent drafting, prosecution, pre-patenting investigations, freedom-to-operate work, validity and infringement analyses and due diligence.

Before joining Valea in 2010, Ellen worked for six years in the IP department of AstraZeneca AB. She also had a position in the IP department of Pharmacia AB for three years. Ellen has been working within the IP field since 1998.

nity for the applicant to meet the objections raised during the international phase, as the EPO will not require any response until a supplementary search has been performed. This means that, in such a scenario, the applicant will have more time to prepare his/her case. This process will most likely appeal to companies preferring to postpone major costs, such as company B and inventor C.

Divisional applications

The introduction of strict time limits for filing divisional applications at the EPO has been widely discussed in the IP field. In combination with the more limited possibilities for prosecuting several parallel patentable inventive aspects in the parent application outlined above, these strict time limits will surely have a negative impact on the filing strategy of many companies within the life science field in a manner unforeseen by the legislators. For example, company A will most likely modify its filing strategy so as to file several co-pending or sequential divisional applications, optionally withdrawing them before receiving a first communication, to maintain the option of prosecuting most aspects of its applications even after the parent application has been granted. Alternatively, inventor C might try to provoke non-unity objections from the examining division to further extend the period for filing divisionals. Another option would be to simply start out with filing a series of parallel national applications.

The rule changes might also have an impact on company B. Prior to the rule changes, company B tended to file divisional applications at as late a stage of the examining process as possible. Such divisionals were directed to commercially attractive aspects of the original invention which potentially could be licensed-out to thereby provide a further source of income to fund future development. Since the new rule changes will require company B not only to identify, but also to file divisionals for, such aspects at a much earlier stage, there is a significant risk that company B will not have had time to recognise the potential of such aspects and thereby forfeit the possibility to increase its revenue.

Finally, inventor C will probably be the most affected as he/she lacks the early means to file divisional or co-pending applications in the first place, and will therefore have to rely on postponing the initial filing of the parent application, while relying on keeping his/her know-how secret.

Changes in strategy

We predict that these rule changes will lead to many applicants within the life science field reviewing their patent strategies. Typically, applicants may consider setting aside more resources in the pre-filing stage to be able to prepare a set case earlier in the process. Depending on the competition within the technical field and the financial situation, this will probably lead to patent applications being filed later in the developmental stage when the applicant is in possession of more thorough experimental data to use as a basis for the patent application.

Alternatively, we will see an increase in the number of filed patent applications with narrow claim scopes relating to more or less overlapping inventions by the same applicants.

In addition, if the grant proceedings have not come to an end before the end of the 24-month time limit after the first communication of the Examining Division, and there is an uncertainty about the granted scope, applicants will need to start considering filing divisional applications to keep their options open for subject matter not prosecuted in the parent application. The possibility to perform such a measure will of course be dependent on the financial resources that are available to the applicant, as already discussed.

In our view, the new and faster route through examination proceedings at the EPO, in combination with the limits on filing divisional applications will, at least within the life science field, lead to a great deal of legal uncertainty for applicants, while insignificantly contributing to the legal certainty of third parties. In particular, the changes will be most detrimental for applicants on a tight budget, such as SMEs. This is ironically the same group to whom the EPO has previously promoted patent awareness.

Ylva Skoglösa

Ylva is a European patent attorney. She has a PhD in medical research and expertise within the areas of medical biotechnology, genetics, microbiological processes, protein pharmaceuticals and substances and devices for medical or dental treatment. Ylva works with all types of patent issues including strategic IP consultation, prosecution and litigation. Ylva regularly assists potential investors and founding partners in evaluating third parties' IP positions, and conducting freedom-to-operate and due diligence analyses. Before entering the IP profession, she did research work at the San Diego State University in California, the Max Planck Institute in Munich and the BMC in Uppsala. Before joining Valea in 2002 she worked for three years as a patent attorney at Plougmann & Vingtoft in Denmark. Ylva has been working in the IP field since 1999.

Your Preferred Partner in Sweden and Europe

Intellectual property rights – A business opportunity

Patents • Trademarks • Design • Domain Names
Legal Services • Post-grant / Enforcement
Strategic Counselling • Annuities & Renewals
Since 1894

YLVA SKOGLÖSA
Ph.D. Medical Research, European Patent Attorney.

Ylva Skoglösa specializes in patent issues within medical biotechnology, molecular biology, immunology, biochemistry, microbiology and genetics, proteins, biotechnological methods, and substances and devices for medical and dental treatment. Ylva has worked in the field of IP since 1999.

www.valea.se

valea
TECHNOLOGY & LAW