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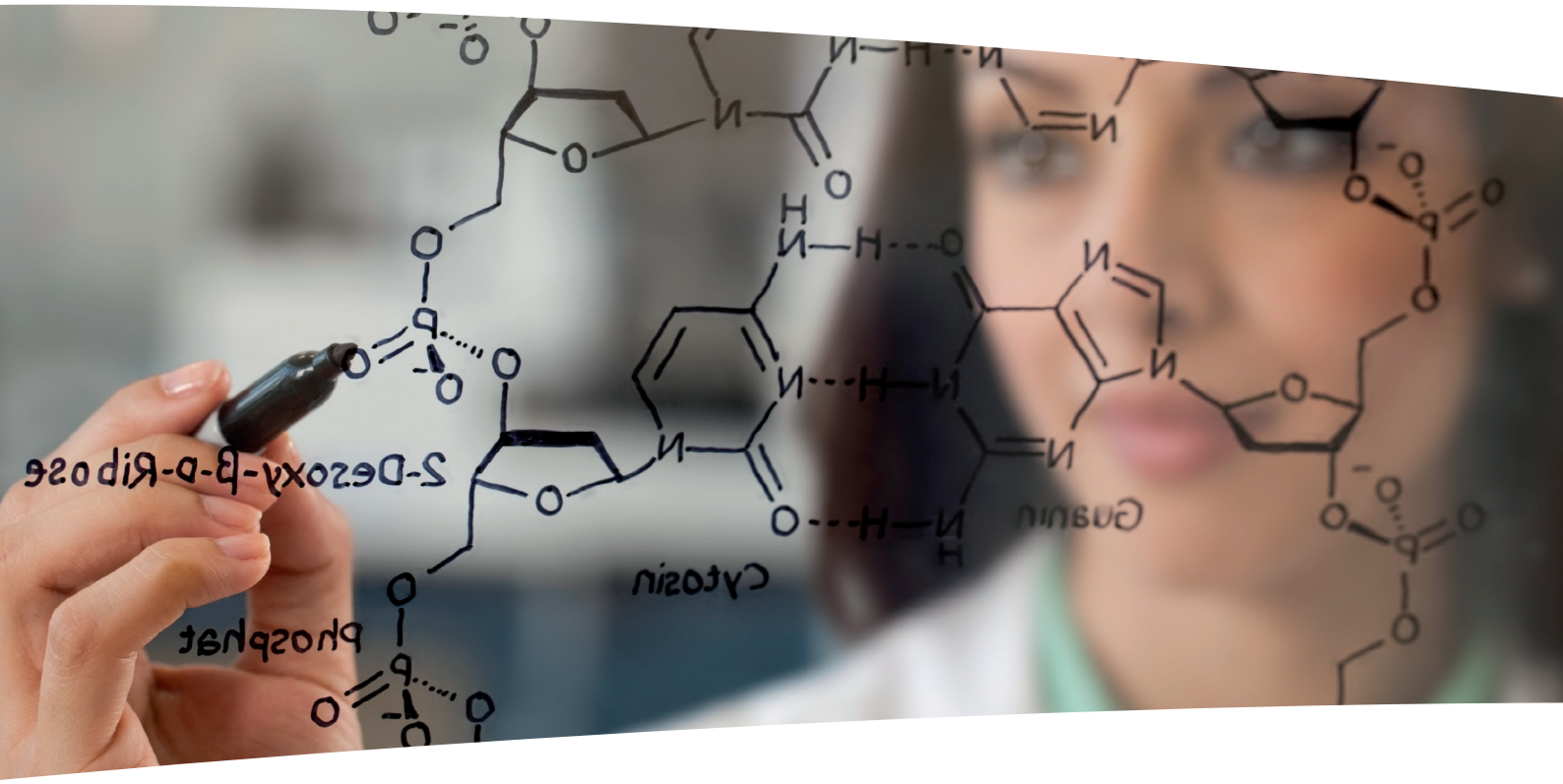
FORMAL OBLIGATIONS: BURDENS ON BIOTECH PATENTS

by Caroline Pallard and Peter ten Haaft



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Formal obligations:
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Although the patentability of biotechnological inventions as described in a European patent application should meet substantive requirements such as novelty, inventive step and industrial applicability, latest developments at the European Patent Office suggest that formalities have become more and more important, say Caroline Pallard and Peter ten Haaft.

DIVISIONAL APPLICATIONS

The rules for filing European divisional applications have been drastically limited for applicants for two years.

Since April 1, 2010, the rules for filing a European divisional patent application have been restricted—rules 36(1)(a) and 36(1) (b). Under rule 36(1)(a), an applicant has 24 months to file a European divisional calculated from the first European office action of the earliest application, the so-called 'voluntary divisional'. A second scenario is possible under rule 36(1)(b): if a lack of unity has been formulated by the examination division in an earlier application in any communication and if this 'specific objection (ie, lack of unity) was raised for the first time', then the applicant is given 24 months from said communication to file a divisional application ('mandatory divisional').

In practice, this means that applicants should anticipate upon filing of an application whether they would like to keep the possibility open to have more than 24 months after the first communication from the examining division for filing a divisional application. For several reasons, especially for biotechnological inventions, an applicant needs to postpone as much as possible the deadline for filing a divisional. The majority of biotechnological inventions (ie, antibodies, peptides, oligonucleotides, proteins, and uses thereof) encompass a plurality of inventions and potentially do not meet the requirements of Article 82 of the European Patent Convention (EPC). Biotechnological start-ups cannot afford to file one single application per invention in view of the costs involved especially since at the time of filing, they do not yet know which invention is the most promising and will be developed.

Therefore, in view of these new rules, applicants are forced to make use of the second scenario mentioned above: file a parental application with unified claims and a description comprising a reservoir of potential additional inventions. A voluntary divisional is filed following rule 36(1)(a) with claims that are non-unified. A lack of unity is then raised for the first time in an office action from the examining division triggering a new 24-month period for filing a second divisional application. The situation depicted here seems quite clear.

In practice, it means that it is crucial that the claims of the parental application should be considered as unified. An intensive written and oral discussion with one examiner in a specific case we handled taught that examiners at the European Patent Office (EPO) do not always seem aware of the impact of these new rules for biotechnological start-ups. It was crucial for the client to be sure that pending claims of a pending European patent (EP) application were unified to be entitled to get a 'first lack of unity' in a hypothetical future application. In this specific case, fortunately, the examiner admitted at the end of the interview that the set of claims was unified. It was even confirmed in a written communication.

Another hurdle is the meaning of the expression 'lack of unity raised for the first time' in rule 36(1)(b), which is still quite unclear. Imagine a parental application discloses peptides A, B, C and D. In the parental application, peptides A and B are claimed, while peptides C and D are present only in the description. A lack of unity is issued in this parental application.

Subsequently a divisional application is filed claiming peptides C and D. One would expect and assume that the lack of unity which will be raised in this divisional application should be considered as a 'first lack of unity' since peptides C and D have never been claimed before. The examiner indicated that this situation was quite uncertain. He seemed to be of the opinion that since peptides A, B, C, and D relate to 'similar types of inventions', it could be expected that this second lack of unity would not be considered as a 'lack of unity raised for the first time'. In this specific case, during an interview, the examiner advised us to file a divisional application and see how the EPO would react. This is of course an unacceptable, expensive and extreme solution, especially for

small start-ups. There is an urgent need for clarification of the meaning of 'raised for the first time' in rule 36(1)(b). However we fear that the applicant will have to wait for a few years and learn to live in the uncertainty until this specific point of law is clarified.

BASIS FOR AMENDMENTS DURING EXAMINATION AND OPPOSITION

Over the years, EPO examiners have become more strict in assessing whether an amendment has basis in the application as filed.

During examination and opposition proceedings, the applicant has the right to amend an application in view of prior art that manifested after the filing date of the application. In general this concerns limitation of the claims to overcome objections in view of the prior art cited. Since the applicant should not be placed in a position where he can improve his position in view of insight in the field of the invention that has been acquired since the date of filing, the amendments may not relate to subject matter that extends beyond the content of the application as filed. This is governed by Article 123(2) EPC, which thus protects the legal certainty of the public; the public can rely on the contents of the application as filed in the register of the EPO for assessing the aspired scope of protection.

When an amendment is made, the EPO applies the novelty test for assessing whether the amendment has been disclosed in the application as filed. Simply put, when the amendment is novel in view of the application as filed, the amendment extends beyond the application as filed.

Over the years, the novelty test has been applied increasingly strictly by EPO examiners. As a consequence, it appears that an amendment must be literally disclosed in the application as filed within a single embodiment to fulfil the requirements of Article 123(2) EPC.

This increasing stringency has, over the years, driven the EPO away from more liberal jurisdictions such as the requirements from the US Patent and Trademark Office. This has vast consequences for, eg, a Patent Cooperation Treaty (PCT) application written in US style without multiple dependencies that enters the EP regional phase. Suppose that claim 2 depends only from claim 1, and claim 3 also depends only from claim 1. Such application may have no problem in the US when limiting the claims to a preferred embodiment of the combined subject matter of claims 1 to 3 that has no verbatim basis in the application as filed.

However in EP, when limiting the claims, an embodiment of the combined subject matter of claims 1 to 3 would not be possible if there were no verbatim basis in the

description. Suppose that claim 2 comprises 10 embodiments and claim 3 comprises 12 embodiments, a two-list situation occurs and the description should already depict 120 permutations to cover all combinations of single embodiments of each list. These exemplified lists are still relatively short, it is not uncommon in biotechnology applications to have more than 100 embodiments per type of claim (eg, antibodies, peptides, oligonucleotides, proteins, disease conditions).

So in practice, the applicant is obligated to list all permutations of embodiments and their respective fallback options. Consequently, the description of the application in a field where inventions often comprise numerous embodiments, such as in biotechnology, grows to huge dimensions. The applicant is required to pay page fees not for providing extensive information on the invention, but merely to fulfil strict formal requirements.

It is therefore highly desirable that EPO examiners adopt a more liberal assessment of Article 123(2) EPC. In this respect, the recent decision G2/10 is quite relevant.

In reason 4.3 of G2/10 (citing G3/89 and G11/91), the Enlarged Board of Appeal of the EPO reiterates the role of the person skilled in the art in the process of assessing whether an amendment fulfils the requirements of Article 123(2) EPC. The enlarged board states: "It follows that any amendment to the parts of a European patent application or of a European patent relating to the disclosure (the description, claims and drawings) is subject to the mandatory prohibition on extension laid down in Article 123(2) EPC and can therefore, irrespective of the context of the amendment made, only be made within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of these documents as filed."

In this reasoning, the Enlarged Board of Appeal seems to proclaim the more liberal reading of Article 123(2) EPC by emphasising the role of the person skilled in the art in assessing the allowance of an amendment.

It will be interesting to monitor whether EPO examiners will broadly adopt the reasoning of G2/10 for assessment of Article 123(2) EPC.

The current practice of the EPO places an increasing demand on the skills of the European patent attorney with respect to these formal issues. In addition, early prosecution costs will dramatically increase since more and more of the description of the patent application is taken up for fallback options and/or more divisional applications may be filed.

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Caroline Pallard joined Nederlandsch Octrooibureau in 2006 after working as a Dutch and European patent attorney at DSM/Gist-brocades in Delft and a postdoctoral fellow at the Dutch Cancer Institute, where she specialised in immunology and biochemistry. She practises in biotechnology and in particular molecular biology, genomics, biochemistry, haematology and microbiology. Pallard has extensive experience of drafting and prosecuting complex patent applications and supporting complex licence negotiations, and she frequently advises biotech startups on their IP strategy.

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