PATENTS

IP developments in Europe and the US

Christian Schlörb, Maurizio Di Stasio and Christian Kilger,
Vossius & Partner, Berlin

A lot has happened since our last IP special was published in 2008. Current developments involving intellectual property in the world of biotechnology and pharma include formal procedural issues when prosecuting patent applications before the European Patent Office (EPO), decisions from the Technical Boards of Appeal of the EPO, pending referrals, and recent decisions in the US.

Two important changes to implementing the EPC regulations will enter into force on April 1st, 2010: a new deadline for filing divisional applications (Rule 36 EPC) and a mandatory response to the Communication pursuant Rule 161 EPC in Euro-PCT applications where the EPO was International Search Authority. It is likely that these changes will have implications on individual prosecution strategies.

New Rule 36(1) EPC distinguishes between voluntary divisional applications which may a) only be filed on the applicant's own initiative within a period of 24 months from the first communication of the Examining Division in any parent application, and b) mandatory divisional applications which may be filed within a period of 24 months after a specific non-unity objection has been raised for the first time.

Prosecuting patent applications before the EPO

After expiry of the respective 24-month periods, applicants will no longer be allowed to file new divisional applications. In any case, divisional applications may only be filed for pending parent applications, i.e. – at the latest the day before the grant of the parent applications is published, even if the 24-month period expires later. New Rule 36 EPC applies for all divisional applications filed on or after April 1st, 2010. As a transitional provision, divisional applications may still be filed until October 1st, 2010 for all pending applications for which the 24-month periods expired before April 1st, 2010. We recommend reviewing all pending EP applications for subject-matter that might have to be prosecuted in a divisional application well before the new provisions enter into force.

According to new Rule 161 EPC, which applies to all Euro-PCT applications for which the Communication pursuant to Rule 161 is issued (i.e. the applicant is invited to correct deficiencies noted in the Written Opinion of the International Search Authority (WO-ISA)) on or after April 1st, 2010, it will be mandatory for the applicant to address all objections raised in the Written Opinion of the International Search Authority (WO-ISA) or – if applicable – the International Preliminary Examination Report (IPER) if they were issued by the EPO. The applicant will be invited to respond to the objections raised during the International Phase and correct all deficiencies mentioned within a period of one month after issuance of the Communication pursuant to Rule 161. If the applicant does not comply with the new requirements, the application will be deemed to be withdrawn. Since said Communication is sent out shortly after entry into the Regional Phase before reaching the EPO, we recommend preparing arguments for the

response to the objections raised and – if necessary – new claims well before the 31-month period.

Decisions and referrals pending

In the biotech realm, industrial applicability of nucleic acid sequences has been a "hobby-horse" for the EPO in the past. Ever since the implementation of the EU Biotech Directive into the European Patent Convention (EPC), an applicant had to lay down the function of a claimed gene in the patent application. The ICOS decision a number of years ago was the first that addressed this legal prerequisite. It outlined that a list in the description of speculative functions of a protein is not in itself a reliable basis for acknowledging industrial application of this protein, and added that a DNA sequence encoding a protein without a credible function is not a patentable invention. It was made clear in T 898/05 that function may lie with a biochemical activity (protease, nuclease etc.), a cellular activity (apoptosis, secretion pathway etc.) or the influence within a multi-cellular organism (cancer, inflammation). One of these levels of function might result in a straightforward industrial application, even though the other levels remained completely unknown. Concerning *in silico* analysis of the gene in question, the Board stated that "the fact that a function is based on computer-assisted methods, rather than on the basis of traditional wet-lab techniques, does not mean that it has to be automatically disregarded or excluded from careful and critical examination. Their probative values have to be examined on a case-by-case basis."

Cases

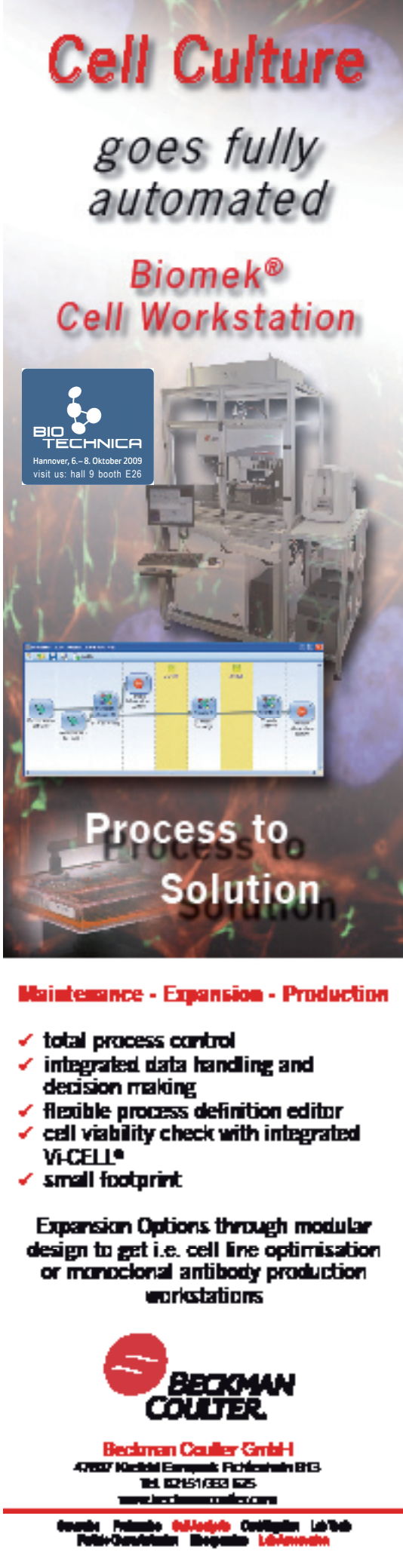
Two recent cases dealt with a similar question "Serine protease/Bayer AG - T 1452/06" and "BDP1 Phosphatase/MAX-PLANCK - T 870/04". In both cases, *in silico* analysis had been used for assigning function to (i) a putative human serine protease and (ii) the BDP1 protein. In T 1452/06, the Board stated that in the absence of experimental evidence in support of polypeptide activity, the application did not provide enough support for the assumption that the claimed polypeptide had serine protease activity.

In "PF4A receptors/GENENTECH-T 604/04" however, industrial applicability was acknowledged. The PF4AR gene had been cloned, and sequence comparison assigned the gene to the G-protein-coupled superfamily. The Board stated that, in the board's judgment, the mentioned structural features make it plausible that this is indeed the case. It is worth noticing that the situation was different from that encountered in T 870/04, where it was not accepted that the polypeptide was a member of the TGF-β superfamily. Industrial application was also acknowledged in "Multimeric receptors/Salk Institute - T 338/00".

In the UK, a recent noteworthy case concerning industrial application of a claim relating to a gene encoding a neutrokine polypeptide is Eli Lilly v. HGS. Here, the nine principles established by the UK court mirror EPO case law. An applicant may use *in silico* analysis to understand the function of a gene, but it is our advice to back this with experimental data.

The other interesting field of decisions is the field of dosage regimens. Here, an invention relates for example to the use of a compound in the preparation of a medication for treating a disease wherein a certain administration pattern is applied. The Technical Board 3.3.4 of the EPO had acknowledged patentability of such claims in "(IGF-i) T 1020/03", and backed that up in the following decisions "Method of administration (II) T 36/04" and "Interferon-/YEDA Reasearch T 836/01".

The German Federal Supreme Court (BGH) in "Carvedilol II" again had a deviating opinion, and stated that if a dosage recommendation was not eligible for patent protection, then one of several dosage features of said patent claim must not be used to assess novelty and inventive steps. The BGH stated that it remained open on whether adopting such a dosage recommendation resulted in the entire patent claim being excluded from protection. In the United Kingdom, in Actavis v. Merck, the Supreme Court of Judicature Court of Appeal held that in the said Finasteride case such dosage regimen



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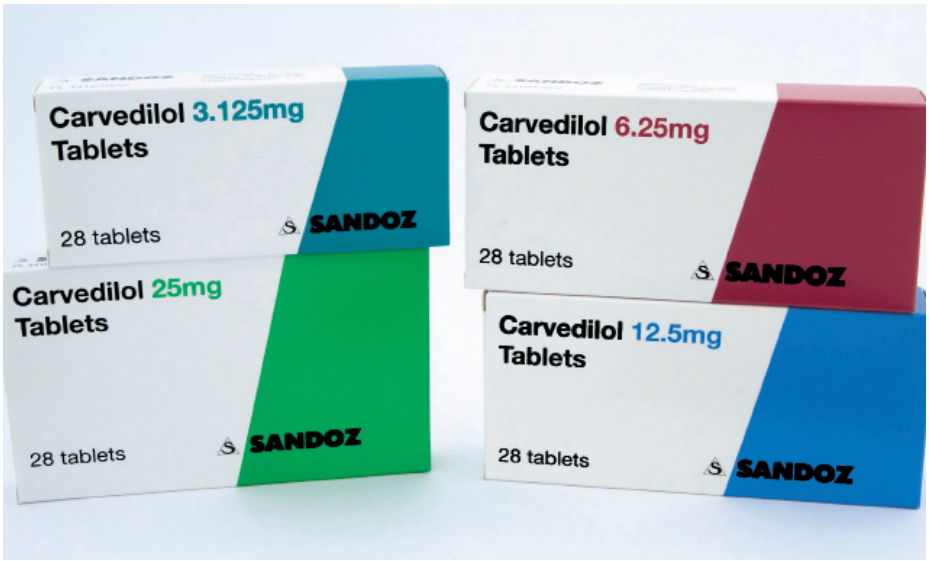

claims were indeed patentable, and pointed in particular to the case law of the EPO. This was before the question went before the EBA at the EPO, where it is now pending as G2/08 as referral under Art. 112 (1) a) EPC by the Technical Board of Appeal - 3.3.02 (Dosage Regimen).

A further important question pending before the EBA is G1/07 (Methods for treatment by surgery). The question to be decided is whether a claimed imaging method for a diagnostic purpose that comprises or encompasses a step consistent with a physical intervention practised on the human or animal body (e.g. an injection of a contrast agent into the heart), is excluded from patent protection as a "method for treatment of the human or animal body by surgery" pursuant to Article 53(c) EPC, if such step does not *per se* aim at maintaining life and health. Oral proceedings are scheduled for November 11th, 2009.

And finally, in the case G1/08, consolidated with G2/07 the EBA must decide on the question of whether a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants falls under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention.

Recent decisions in the US

On May 19th, the US Court of Appeals for the Federal Circuit (CAFC) judged *en banc* on the protection scope of so-called product-by-process claims (Abbott Laboratories et al. v. Sandoz et al.). The question to be decided was whether a claim protecting a "compound X obtainable by a process Y" is infringed by compound X produced by other processes than Y. The court came to the conclusion that "process terms in product-by-process claims serve as limitations in determining infringement." It stated that "[i]n the modern context […] if an inventor invents a product whose structure is either not fully known or too complex to analyze […] that the inventor is absolutely free to use process steps to define this product." However, the court adduced that in such cases the process steps cannot be ignored as "verbiage", as they are the only definition supplied by the inventor. The court also ruled that the use of the "ambiguous" term "obtainable by" does not provide a "free pass". Accordingly, the respective claim has to be viewed extremely narrowly and construed as compound X "obtained by" process Y

Following the logic of the CAFC, a patent on a "blockbuster" drug which at the time of the invention cannot be described without features of the process by which it is obtained is worthless as soon as an alternative process for the production is developed. In our view, the court thereby buried the protection for such compounds and degraded "product-by-process" claims to mere "method of making" claims, which are easy to circumvent in some instances. In view of this decision, care is to be taken when drafting product-by-process claims.

Written description

A case dealing with the so-called "written description" requirement was Ariad Pharmaceuticals v. Eli Lilly. Here, the CAFC invalidated Ariad's claims. The CAFC noted that Ariad's specification identified three classes of molecules potentially capable of reducing NF-κB activity: specific inhibitors, dominantly interfering molecules, and decoy molecules. Regarding the first two classes, the court found that, as of the effective filing date, the specification failed to provide any more than vague functional descriptions of the molecules. Although the CAFC acknowledged "little doubt that [with respect to the decoy molecules] the specification adequately described the actual molecules to one of ordinary skill in the art", the court stated that the specification failed to adequately describe "using those molecules to reduce NF-κB activity". The court went on to state that the disclosure in the specification "is not so much an 'example' as ... a mere mention of a desired outcome" since "there is no descriptive link between the table of decoy molecules and reducing NF-κB activity." Thus, the court concluded "that the jury lacked substantial evidence for its verdict that the asserted claims were supported by adequate written description."

A specification must demonstrate that the applicant possessed the claimed invention that fall within the claimed scope. We advise our clients to draft the specifications in such a manner that the US written description requirement is met, even if an initial filing is before the EPO.

Contact
Christian Kilger
Vossius & Partner
Joachimstaler Strasse 34
10719 Berlin, Germany
Tel: +49-(0)30-340609-501
Fax: +49-(0)30-340609-512
berlin@vossiusandpartner.com