22 Sep 2020

EPO plant patent decision imperils businesses like ours, says Bayer's head of IP

The EPO Enlarged Board of Appeal **caused a stir earlier this year** when it ruled that plant or animals products obtained "exclusively by means of essentially biological processes" are not patentable, contrary to its own previous decisions on the question. This caused controversy not only because of its potential chilling effect on the European agri-tech industry, but also because it followed a **referral** by the agency's president, António Campinos, which many saw as inadmissible and an example of executive overreach.

The EBA decision was the latest development in a series of legal and political disputes about the patentability of biologically produced plant inventions. Contrary to previous EBA decisions, Rule 28(2) of the EPO Guidelines – supported also by the European Commission – excluded these from protection when it was introduced in 2017. But this rule was deemed by the Board of Appeal to be contrary to Article 53(b) of the European Patent Convention in 2018. In their subsequent referral, Campinos and the EPO Administrative Council argued that the further clarification was needed. The EBA then overturned its own case law, finding that the EPC is subject to "dynamic interpretation".

Among the strongest critics of the **decision** has been Joerg Thomaier, head of IP at Bayer, one of the world's largest life sciences companies and agricultural innovators. Speaking exclusively to *IAM*, he shared his views on the EBA opinion's ramifications for businesses in the field and highlighted several legal uncertainties created by the decision that need to be addressed. Thomaier also addressed the difficulties of getting the unified patent system off the ground and spoke about how it could be made to work best for the pharma and biotech sectors.

Living with Rule 28(2)

"I think the decision is not in line with the EU regulations and how it was done was not according to the rules," says Thomaier. "However, this is a final decision and there is no legal remedy available. From that perspective, I would consider it a closed case. We now have to live with Rule 28." The decision could impact the European business of technologically based plant breeding companies, including Bayer, he believes. Furthermore, reduced income could decrease the amount of spending on research and use of new agricultural technologies in Europe.

From a legal point of view, his main concern is that the EBA opinion has not provided as much clarity on the question of plant breeding patents as companies need. The patentability exclusion is based on unclear definitions, Thomaier argues. "What does 'essentially biological process' mean? If a plant is created by one technological step followed by a series of classical breeding steps, is that an essentially biological process? Or does a plant need to be created by an entirely biological process to be excluded?"

The commercial and strategic impact of the exclusion will depend heavily on how broadly it is interpreted. Unless new rules are provided, Thomaier believes, this is likely to be determined in infringement disputes in national courts. "Another problem," he adds, "is that the patented end-product may not have the features which would allow a person to be clear about what the process was behind the invention."

This raises further question about who has the burden of proof when such conflicts occur, Thomaier notes. "Does the alleged non-infringer have to prove that he independently, biologically achieved the same result that we achieved technologically?," he asks. "This is one of the things to work on and discuss."

"It really would be time now to concentrate on clarifying what is patentable to reduce uncertainty for those who want to be active in the field," Thomaier urges. Until this happens, all lawyers and attorneys must be precise in their patent drafting, he comments, before adding: "What companies can do is to call on the EPO and the EU legislature to come up with a clearer definition."

The importance of rewarding innovation

The EBA decision does not have consequences solely for European innovation, Thomaier argues. It has implications in jurisdictions in other parts of the world where patents are not currently available for biologically created plants, or where discussions on this subject are still ongoing. There, the European example can tip the momentum against introducing new protections.

"It is astonishing for people in Asia and Latin America, to see that Europe – which was regarded as a driver of innovation and a model of good IP protection – is now going in a different direction and is setting a negative precedent in this area," he suggests.

More broadly, Thomaier believes, "the ability of science and technological process to solve the problems of society is not honoured enough anymore", while the acceptance that innovative companies should be rewarded with temporary exclusivities is decreasing: "The discussion is framed in the opposite way, as though the company is stealing its inventions from society by seeking a patent."

The future of the UPC

Turning to the unitary patent system and Unified Patent Court, Thomaier is not convinced that things will be up and running any time soon. "The UPC is in limbo," he comments. "It is very clear that the UK will not participate. It would be better if the UK would be with it, because the scope and value of the patents would be greater. But compared to the rest of Europe, the UK is not a large jurisdiction."

While Thomaier is optimistic that the German government will be able to ratify the UPC, despite the country's Constitutional Court recently ruling that the previous ratification had been illegal, problems could be caused by the UK's absence meaning that debates have to be resolved about the distribution of fees and where to locate the life sciences court: "Last time, discussions about money and court locations went on for a very long time. This could push back the UPC for quite some time."

Political disputes are likely to win out over practical solutions, he argues. "**Why not allow the UPC to go ahead provisionally with life sciences cases allocated to Paris and Munich temporarily?," he asks. "This would be very pragmatic. But I seriously doubt it would happen given the nature of politics. Everyone wants to get something and will not allow transitional solutions that take the pressure out of discussions.**"

This would be a shame for the life sciences industry, he thinks, even though pharma and biotech innovators have generally been much more ambivalent about the UPC and UP system than inventors from other sectors, because of fears over the invalidation across Europe of extremely valuable drug patents.

"The bottom line is that innovative pharma companies are in favour of the UP system as long as it is reliable," Thomaier says. "I would support an opt-out period with national patents co-existing with the European patent while the UPC system is in its early stages."

"It is important to have a panel of judges from different member states that decide on a European basis," he adds. "The judges will then be more or less independent of where the court is located. It could be a truly European court. If the court is functioning well and has developed good case law, that will generate more trust in it."



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