Waking up and smelling the coffee

To the Editor:

As I pointed out recently on the *Patent Docs* weblog (http://www.patentdocs.org/), the editorial 'Sitting up and taking notice' in the May issue[1], announcing Judge Sweet's 29 March decision in favor of the plaintiffs in *Association for Molecular Pathology v. US Patent and Trademark Office*, contains several misstatements and promotes the wrong-headed idea that gene patenting is a problem.

In describing the case, you begin by making factual errors. Judge Sweet's decision (summary judgment) does not indicate that "the judge felt that Myriad had no case to argue." Rather, summary judgment is used when there are no disputed issues of material fact, and the case is decided as a matter of law. I would argue that the prudence of Judge Sweet's judgment is questionable because he chose to make law by deciding that DNA is not patent eligible for being "the physical embodiment of genetic information."

You then state that "[t]he plaintiffs…won on virtually every count." In fact, the court refused to consider the US Constitutional issues raised in the complaint, which formed the basis for the breast cancer victims to have standing in the lawsuit. This is not trivial because the court used these constitutional issues not only to deny defendants' motions to dismiss, but also, politically, to provide the political frisson so attractive to the American Civil Liberties Union (New York) and the Public Patent Foundation (New York).

The editorial goes on to mischaracterize the effects of *BRCA* patents on research, stating that "Myriad's influence has been particularly pernicious. Its lawyers have issued cease-and-desist letters to genetics laboratories in universities, hospitals and clinics that offered diagnostic services based on the *BRCA1* and *BRCA2* genes." Why is enforcing your patent rights pernicious? Use of these patented tests by these institutions constitutes infringement. It doesn't matter whether the infringer is a university, hospital or clinic, they are still liable for infringement owing to their for-profit, commercial activities. There is no evidence that Myriad Genetics (Salt Lake City, UT, USA) or any other gene patent holder has inhibited basic biological research by threatening patent infringement litigation; indeed, there are several thousand basic research papers in scientific journals that have been published since the *BRCA* gene patents were granted.

The piece also attempts to achieve 'truth by association' in citing several groups having "concerns" about gene patents that filed *amicus* briefs, including the International Center for Technology Assessment, Greenpeace, the Indigenous Peoples' Council on Biocolonialism and the Council for Responsible Genetics. Their contribution would be more worthwhile if it did not include incorrect statements regarding gene patenting's consequences, including "the privatization of genetic heritage, the creation of private rights of unknown scope and consequences and the violation of patients' rights."

The editorial was correct in noting that "[t]he alignment of physicians' and patients' groups with what are, in effect, antibiotech lobbyists is a worrying development," albeit ignoring the fact that not only the biotech sector, but also the public should be worried if these groups get their way.

The editorial did supply potentially informative data, that Myriad reported "$326 million in revenue from diagnostic testing against $43 million in costs." Assuming that these numbers are correct, and reflect only BRCA testing, this could be a measure of the profitability of BRCA testing results (perhaps providing motivation for the "universities, hospitals and clinics" to be so keen on getting into the business, infringing or no). But even here, the figures are completely out of context. No indication is provided whether these profits are out of the ordinary for a diagnostics company, traditional or genetic, or whether the 'costs' include ancillary costs like genetic counseling or physician education (both critical in genetic diagnostics due to the consequences for a patient of receiving a genetic diagnosis). If Myriad's profits are significantly higher than those at other diagnostic companies, that fact would be relevant. The absence of any comparisons suggests that the absolute numbers were used because they better supported the editorial's views.

Finally, the editorial departs from reality when it decries the patent system for rewarding "only the last inventive step—the small breakthrough that enables a concept to be realized." Such a statement indicates just how little the writers understand the 'balance of rights' that the patent bargain actually strikes. The patent system rewards inventors who disclose how to make and use an invention that is new, useful and nonobvious. Whether the improvement is groundbreaking or incremental, satisfaction of the statutory requirements governs patentability. Thus, if technology becomes obsolescent, new technology takes its place—because patents expire, as indeed Myriad's patents will begin to expire in 2014. The consistent lack of understanding of innovation and the patent process is illustrated by the suggestion that rights to specific genes in multigene tests be assigned based on "the importance of any specific gene sequence to the utility of the test." This is something the marketplace can be counted on to do without the government's help.

The last sentence of the piece even acknowledges the editorial idea

is "implausible within the current petrified patent system and commercial infrastructure," and then adds that this "doesn't have to stop the dream" or "stop the discussion." I would counter that the dream of better diagnostics and therapies is being, and has been, realized by 30 years of biotech and protection thereof by an invigorated patent system in the United States (and elsewhere). Changing that now, particularly if based on the wooly-headed arguments (really, sentiments) in the editorial, is the fastest and surest way that those hopes and dreams will be dashed.

COMPETING FINANCIAL INTERESTS
The author declares no competing financial interests.

Kevin E Noonan

McDonnell Boehnen Hulbert & Berghoff LLP, Chicago, Illinois, USA.
e-mail: noonan@mbhb.com

1. Anonymous. *Nat. Biotechnol.* **28,** 381 (2010).

***Nature Biotechnology* replies:**

We were not making the case that gene patenting itself was a problem, although it is clear that some DNA patents with overly broad claims are cause for concern. We disagree with the contention that "there is no evidence that Myriad Genetics…or any other gene patent holder has inhibited basic biological research by threatening patent infringement litigation." There are cases where exclusive licensing practices (a particular problem for methods patents) or aggressive license enforcement has stymied research, as is detailed elsewhere in this issue[1]. The problems also reach beyond basic research: a survey of 132 clinical laboratory heads in the United States found that 53% had "decided not to develop or perform a test/service for clinical or research purposes because of a patent"[2]. Indeed, one of the plaintiffs in the *Association for Molecular Pathology v. US Patent and Trademark Office* case is a patient who would like to have their *BRCA1* test from Myriad independently verified by another laboratory, but cannot because of Myriad's aggressive stance that prevents other laboratories performing the test. It might be good business for Myriad, but is it reasonable to enforce intellectual property in such a manner that it is so difficult for a patient to confirm a DNA test in an independent laboratory?

The claim that new technology takes the place of 'obsolescent' technology because "patents expire" is also moot in relation to DNA patents. A point we were trying to make in the editorial is that the fields of molecular diagnostics and sequencing are moving so quickly that they are becoming obsolete along much shorter timelines than patent terms of 20 years. Although it was not trivial to sequence a human gene 20 years ago, it is certainly becoming routine today.

1. Carbone, J. *et al. Nat. Biotechnol.* **28**, 784–791 (2010).
2. Cho, M.K. *et al. J. Mol. Diagnostics* **5**, 3–6 (2003).

Genetic stability in two commercialized transgenic lines (MON810)

To the Editor:

A letter of correspondence by Dany Morisset and his colleagues[1] in the August 2009 issue cites two recent publications[2,3] in which "two commercial seed varieties of the MON810 maize genetically modified event (ARISTIS BT and CGS4540) present genetic variation thus hampering the detection by several methods for MON810 (Monsanto, St. Louis)." As representatives of Monsanto Europe (Brussels), Syngenta Crop Protection (Basel) and Limagrain Services Holding (Chappes, France), we would like to correct the scientific record concerning the claimed "variation" of the transgenic insertion in these transgenic hybrids.

Upon request for further information, Margarita Aguilera and her colleagues at the European Commission, Directorate General Joint Research Center (JRC) in Ispra, Italy, informed us that the seeds tested were among 26 MON810 varieties provided by the Spanish Instituto Nacional de Investigación y Technología Agraria y Alimentaria (INIA; Madrid). The Spanish agency did not provide the JRC with details of the respective batch numbers for each variety.

Our investigation has revealed that the two deviating results were not in fact related to variation of the transgenic insertion, as reported by Aguilera *et al.*[2,3]. Instead, our conclusions are that the two varieties (reported as entry 2 and entry 5) were not MON810 maize hybrids at all.

Variety CGS4540 (entry 5) is a Bt176 maize hybrid and we do not understand why the seed was provided by INIA as MON810. Entry 2, which was designated as Aristis Bt, is most likely Aristis, the conventional counterpart of Aristis Bt (MON810). When we requested INIA to send a sample of Aristis Bt to its official Spanish laboratory CSIC (Consejo Superior de Investigaciones Científicas) for testing, the results were positive for MON810, as expected.

Aguilera and her colleagues were not able to provide a correct chain of custody for the samples used in their analyses, which would have allowed resolution of the origin of these deviating results.

The seed industry has invested significantly to provide quality products to the market place, which includes selling compliant and stable products. Traits are tested for presence and stability for many generations before release to the market place. We are therefore convinced that there is no scientific evidence of instability in MON810 hybrids.

COMPETING FINANCIAL INTERESTS
The authors declare competing financial interests: details accompany the full-text HTML version of the paper at http://www.nature.com/naturebiotechnology/.

Sofia Ben Tahar[1], Isabelle Salva[2]& Ivo O Brants[3]

[1]Limagrain Services Holding, Quality Assurance, Chappes, France. [2]Syngenta Crop Protection AG, Regulatory Affairs, Basel, Switzerland. [3]Monsanto Europe SA, Scientific Affairs, Brussels, Belgium.
e-mail: ivo.o.brants@monsanto.com

1. Morisset, D. *et al. Nat. Biotechnol.* **27**, 700–701 (2009).
2. Aguilera, M. *et al. Food Anal. Methods* **1**, 252–258 (2008).
3. Aguilera, M. *et al. Food Anal. Methods* **2**, 73–79 (2009).