BIOTECHNOLOGY IN THE FEDERAL CIRCUIT: A CLOCKWORK LEMON[†]

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In this short presentation I will attempt to accomplish a couple of different goals. First, I will discuss a series of recent cases that set out the doctrine for biotechnology patenting. Judge Lourie of the Federal Circuit has written most of the opinions, and recently one or two other judges have joined in. Looking at these cases is much like looking at a wonderful machine, as the cases progress in a very deterministic and Euclidean manner. Judge Lourie and, to some extent, his colleagues started out with some axiomatic propositions about patent law and biotechnology. They then worked in a syllogistic manner to reach a number of conclusions. Consequently, the case law forms a very intellectually beautiful, very internally consistent, very precise framework for thinking about biotechnology patents in the Federal Circuit.

These cases fit together doctrinally like a beautiful precision instrument, which explains the "clockwork" metaphor in the title of my presentation. But, of course, when looking at a beautiful piece of machinery that functions like a clock or like clockwork, the next question might be whether this wonderful precision instrument bears any relation to reality. And it very well may be that the clock actually does not tell time particularly well, or was set to tell the time in some other time zone. It might work some part of the time; as the saying goes, even a broken clock is right twice a day. But most of the time such a clock would not be especially helpful in keeping people on schedule.

That is where the "lemon" part of the title emerges. The case law developed by the Federal Circuit may constitute a wonderfully intricate and very precise axiomatic framework, but it may not be useful if it bears no relationship to the actual needs of the biotechnology industry. I am going to suggest that it does not. Although it is internally consistent and intellectually fascinating and quite intellectually compelling, the legal framework does not fit very well with what innovation theory tells us society would want to construct for the biotechnology industry. The framework does not work with the innovation profile of the biotechnology industry, and probably does not provide the necessary incentives for

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innovation in the biotechnology industry. Finally, I am going to suggest some ways society might fix the clock or think about fixing the axiomatic system that the Federal Circuit has developed.

I. THE STRUCTURAL PARADIGM

Now, this axiomatic system starts out with some postulates in sort of a classic Euclidean manner. It begins with the definition of conception, the fundamental legal requirement of the inventive process. Some of these definitional cases date back from the mid-1980s to the early 1990s. This is the language the court uses to define the nature of conception for biotechnology: "conception of a DNA, like conception of any chemical substance, requires a definition of that substance other than by its functional utility."[1] So axiomatically, knowing a molecule's function is not enough for conception. What is needed for conception? Judge Lourie states that conception of a molecule "requires conception of its structure, name, formula, or definitive chemical or physical properties."[2] And that aphorism, the sort of slogan suitable for bumper stickers and T-shirts, has become the core concept of biotechnology cases from the early 1990s to the *University of Rochester v. G.D. Searle & Co., Inc.* decision handed down just a few weeks ago.[3]

After defining conception as the axiomatic postulate or fundamental premise of this framework that the Federal Circuit created for biotechnology patenting, the court then applies that axiom to a number of cases dealing with gene patents, where the court generates or derives the definition of obviousness in biotechnology. The court's definition of obviousness flows directly from the definition of conception. If conception requires detailed knowledge and revelation about the structure or detailed physical qualities of the molecule, then in order for a molecule to be "obvious," it needs to meet the same criteria—the same degree of detail within the prior art is required for obviousness that is needed in the mind of the inventor for conception.

Obviousness is not judged with reference to the inventor, rather, it is judged by reference to an imaginary legal construct, the person having ordinary skill in the art, or PHOSITA, who is imagined to know all the relevant prior art. But these cases create a reciprocal relationship between these two patent doctrines: in order to conceive, the cases imply that the invention has become obvious in the mind of the inventor. And, under this Federal Circuit formulation we can, in a sense, think about obviousness as a kind of conception—in essence, we might consider obviousness a sort of *constructive* conception, not in the mind of an inventor, but in the prior art, in the hypothetical mind of the hypothetical person having ordinary skill in the art.

In cases like *In re Bell*[4] and *In re Deuel*,[5] the court applies this relationship to DNA sequences that code for a protein whose sequence was known

1. Fiers v. Revel, 984 F.2d 1164, 1169 (Fed. Cir. 1993).
2. *Id.*
3. Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916 (Fed. Cir. 2004).
4. 991 F.2d 781, 783–84 (Fed. Cir. 1993).
5. 51 F.3d 1552, 1558–59 (Fed. Cir. 1995).

in the prior art. There is a relationship between the DNA sequence and protein sequence, but the correspondence between codes is not one-to-one; there is redundancy or degeneracy. Because of the degeneracy of the genetic code, the court held that the prior art lacked the degree of detail necessary for obviousness until actual discovery of the molecule—that is, the degree of detail necessary for conception.[6] And so the cases produce a very stringent view of obviousness, what we might call obviousness in detail. The cases sum this up in more slogans for T-shirts and bumper stickers: "What cannot be contemplated or conceived cannot be obvious."[7] Similarly, knowledge of a protein does not give one a conception of a particular DNA encoding it, because it does not provide the detailed structure of the genetic code.[8]

So, the court's first step past the initial axiom or postulate is to define obviousness in terms of that axiom or postulate—to define obviousness in terms of the definition of conception. Its next step in extending the framework was to think about the disclosure requirements required by the patent statute: enablement and written description. The Federal Circuit produced opinions following that logical progression to the next step, to define the requirements of disclosure, again relating those requirements back to the postulate about detailed conception. In essence, the court states that disclosure is the inverse of the obviousness requirement. By defining an invention as non-obvious unless disclosed in detail in the prior art, then it also is not properly disclosed in the patent unless it has been revealed in similar detail by the patentee in specification of a patent. The degree of detail required for conception is the degree of detail required for obviousness, and it is also the degree of detail required for enablement and written description.[9]

For DNA, then, the court requires a very detailed disclosure, preferably a structural disclosure. Once again, when defining disclosure in terms of conception, the court states that "[i]f a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity."[10] A conceived method of preparing some undefined DNA, Judge Lourie told us, does not define that DNA with the precision necessary to render it obvious over the protein it encodes.[11] Similarly, disclosing a method for preparing a DNA molecule is not enough to satisfy the written description requirement. Again, the patent requires this detailed structural description, the same kind of disclosure that we want to have for conception, the same kind of disclosure that if it were in prior art would render the molecule obvious.

This emphasis on structural detail to satisfy the written description requirement creates problems in a case like *Regents of the University of California*

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6. *Id.*; *In re Bell*, 991 F.2d at 784.
7. *In re Deuel*, 51 F.3d at 1558.
8. *Id.*
9. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1208–09 (Fed. Cir. 1991).
10. Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993).
11. *In re Bell*, 991 F.2d at 785.

v. Eli Lilly & Co. where the claims are drawn to homologous DNA sequences.[12] The genome actually varies surprisingly little from species to species, and if one isolates a gene in one species, it is likely that there are analogous genes in other species, with similar functions and gene products, but slightly different sequences. These homologous DNAs essentially form a genus of similar molecules. The inventor would want to get genus claims because finding a similar DNA in another species might be trivial, allowing easy circumvention of the patent. However, given the degree of structural precision contemplated in these cases, the inventor may be limited to the exact sequence or sequences conceived, and to the exact sequence or sequences disclosed. Without disclosing a very large number of sequences, the inventor may not have disclosed enough examples to claim the entire genus.

So starting with conception, we have now derived obviousness and have derived the disclosure requirements in terms of the structural paradigm—the requirement that detailed DNA structure is necessary to satisfy each of these doctrinal definitions. And there are some second order corollaries that follow from these first-order derivations. One is that degree of predictability or unpredictability of the structure will determine the scope and availability of the patent.

In the obviousness cases, even though a method was available that was certain to isolate the claimed molecule, due to genetic code degeneracy, one could not predict with certainty the structure of that molecule. It is structural certainty, not methodological certainty, that counts in these cases. If we can predict the DNA structure with a lot of certainty from the prior art, that sequence might be obvious. The court offers the example of a DNA sequence so short that degeneracy of the code introduces no real uncertainty as to the predicted structure. This rule has a real impact on the availability of a patent: the inventor will be hampered by homologous sequences in the prior art only if the prior art allows definite prediction of the new molecule's structure.

By the same token, predictability of structure is the key to DNA genus claiming. If it is possible to predict with certainty, from the disclosure of the patent, the structure of homologous DNAs, then the inventor might be able to claim a whole genus or claim related homologs. But if there is uncertainty as to structure, or anything unexpected that might happen in the homologs, the inventor will not be able to claim them under this standard.

If we consider the history of the wet sciences, it quickly becomes apparent that a lot of this structural emphasis comes from old chemical cases about small molecules and dealing with the structural definition of small molecules. Cases like *In re Papecsh* and its progeny discuss the predictability or unpredictability of characteristics among isomers and families of related molecules.[13] If we start with a known molecule and systematically vary the side

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12. *Eli Lilly*, 119 F.3d at 1562–64.

13. *In re* Papecsh, 315 F.2d 381, 387–88 (C.C.P.A. 1963); *see also* Helmuth A. Wegner, *Prima Facie Obviousness of Chemical Compounds*, 6 APLA Q.J. 271, 271 (1978) (discussing *In re Papesch*).

chains in a predictable way, or if we change the configuration of the molecule in a particular way, will the result be a molecule with predictable function or predictable qualities? If so, that new molecule is probably obvious. If the result is something unexpected, then perhaps the new molecule is not obvious. If the molecule is disclosed in a patent, and from that disclosure other related molecules prove to be predictable, can the inventor claim them? Probably. But if the inventor discloses the molecule and there remains some unpredictability to the expected structure of related molecules, then probably not.

Consequently, this doctrine on the quality of surprising properties and predictability goes all the way back to the small molecule cases, and we have seen the resurgence of that doctrinal application in the recent *University of Rochester*, in which Judge Lourie brought the law full circle, deals once again with the written description requirement in the context of small molecules.[14] And the court in this case seems to say that it has refined this doctrine in the DNA area, but is going to apply the doctrine to small molecule chemistry the same as we applied it to macromolecules.[15] So the doctrine is really ending up back where it began.

II. EXTENDING THE PARADIGM

Now, this factual application of the predictability principle reflects the nature of the legal framework in which it is embedded. Just as we can make predictions about molecular structure based upon extension of known principles, we can also make predictions about legal outcomes based upon the postulates and corollaries derived within this system of biotechnology patenting. The very logical progression of these cases, starting with a definition of conception and then moving in sequence through a definition of obviousness and a definition of disclosure, means that we can make some predictions about how those principles might be extended. For example, Judge Lourie did just that in *University of Rochester*, a case decided earlier this year.[16]

We could make some predictions as to whether certain macromolecules will render others obvious. The cases discussed above involving DNA obviousness are cases addressing whether complementary DNAs (cDNA) would be obvious in light of a corresponding protein amino acid sequence; the cases tell us that the redundancy in the genetic code between nucleic acid and amino acids means the structure of a given cDNA is not predictable. Under the rules that produced this outcome, will genomic DNA (gDNA) be obvious in light of a messenger RNA (mRNA)? That will possibly depend on whether we are talking about eukaryotic or prokaryotic DNA. Recall that prokaryotic genomic DNA will look a lot like mRNA—there will be a very predictable correspondence between the two sequences, as the one sequence is transcribed from the other with a one-to-one correspondence—no redundancy there. So, as Judge Lourie has indicated,[17] the

14. Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 917–18 (Fed. Cir. 2004).
15. *Id.* at 925.
16. *Id.*
17. *Id.*

compatibility and the relationship between RNA and DNA in that case might render that genomic DNA obvious. We can typically predict the structure of the one from the structure of the other.

On the other hand, if we are considering DNA from a eukaryotic organism, the gDNA will tend to have intervening sequences, or introns, that are edited out of the mRNA transcript. The gDNA will be considerably longer than the mRNA, and contain sequences that do not correspond to anything in the mRNA. In that case, the gDNA sequence will not match up closely with the mRNA, and the answer to the obviousness question might be "no," because there is no structural predictability between the two molecules.

It is also important to remember that one of the lessons of the *Papesch* line of cases is that the three-dimensional molecular structure is not always predictable based on flat, two-dimensional representations of a molecule on paper. So molecules sometimes surprise us even when we think we can predict their characteristics from a two-dimensional depiction. This will be even more the case for macromolecules that fold into complex three-dimensional structures. The characteristics of nucleic acid or protein cannot always be predicted based on its primary sequence in the prior art. This will affect the determination of obviousness under the Federal Circuit framework.

For example, several years ago, molecular biologists were surprised to discover an unusual regulatory mechanism for mRNA. They found this was due to an unusual coding sequence, called a "terminator," which has nothing to do with the new governor of California. Instead, it is a sequence that sometimes loops out, forming a hairpin secondary structure as the bases in the RNA strand associate with themselves.[18] When this looping happens, it interrupts the translation of the RNA, blocking the enzyme RNA polymerase from completing the RNA transcript.[19] Similar kinds of hairpin sequences sometimes allow a single RNA to code for two proteins, by essentially knocking the ribosomes off of the RNA transcript, and producing a short truncated version of the protein.[20] Other times, the strand stays linear, with no loop to disrupt the translation process, and the ribosomes read all the way down the strand, producing a longer and different protein.[21] Little molecular tricks of this sort might make the structure of a protein unpredictable, and hence patentable, over a prior art mRNA or cDNA.

Similarly, we might initially think that mRNA might not be patentable over a corresponding prior art cDNA, as Judge Lourie has hinted in his most recent opinion.[22] Because cDNA is reverse transcribed from mRNA, the sequence correspondence between the molecules seems highly predictable. So it seems unlikely that Judge Lourie would let an inventor have a claim to the mRNA

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18. *See* JAMES D. WATSON ET AL., MOLECULAR BIOLOGY OF THE GENE 377–78 (4th ed. 1987) (describing RNA terminator control sequences).

19. *Id.*

20. DAVID FRIEFELDER & GEORGE M. MALACINSKI, ESSENTIALS OF MOLECULAR BIOLOGY 376–79 (2d ed. 1993).

21. *Id.*

22. *Univ. of Rochester*, 358 F.2d at 925.

because the relationship between the two molecules is very straightforward. But some years ago biologists discovered to everyone's great surprise that some RNA transcripts had catalytic activity—they can mediate chemical reactions because of the way that they fold up into secondary and tertiary structures.[23] No one expected these "ribozymes" to have this activity, based on their primary sequence. That kind of a surprising result would surely be non-obvious, even if the primary sequence of the RNA were obvious from a cDNA in the prior art.

In addition to subject matter outcomes, we can also extend the principles of this framework in terms of doctrines or patentability standards that the court has not touched on yet. For example, to date there is very little case law about the doctrine of equivalents in biotechnology. But starting with this very axiomatic system that has been created, we can make some predictions about how that doctrine would be applied in biotechnology. The court provides a definition of conception that in turn allows us to derive a particular definition of obviousness, which could be expanded to new doctrines such as the doctrine of equivalents. We know from *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, for example, that there is a relationship between the obviousness doctrine and the doctrine of equivalents.[24] That case and those following it establish that the range of equivalents is bounded by what would have been obvious at the time the patent was filed.

So having defined obviousness in a particular way, as requiring this sort of very detailed structural disclosure in the prior art, then that is going to dictate certain parameters of the range of equivalents available for a particular set of biotechnology claims. The range of equivalents cannot impinge on prior art that would have been obvious at the time of patenting, and obviousness will be tested by reference to the presence or absence of detailed structural disclosure in the prior art. The presence or absence of such disclosures will thus define the range of equivalents. Equivalents ultimately relate back to the conception axiom, because equivalence has been defined in terms of the definition of obviousness, which, in turn, was defined by the definition of conception.

The same prognostication holds with the doctrine of reverse equivalents. That doctrine first appears in *Westinghouse v. Boyden Power-Brake Co.*,[25] the classic reverse equivalents case, dealing with locomotive air brakes.[26] There the Court suggests that there is a relationship between reverse equivalents and non-obviousness. In essence, an accused device that ostensibly reads on a patent claim, but is in practice so far changed in principle that it yields a different function, in a different way, with a different result than that of the claimed invention, is really a different invention.[27] An accused device with those characteristics is pretty much by definition non-obvious over the claimed invention.

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23. WATSON, *supra* note 18, at 402.

24. Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677, 684–85 (Fed. Cir. 1990).

25. Westinghouse v. Boyden Power-Brake Co., 170 U.S. 537, 562 (1898).

26. *Id.* at 548–49.

27. *Id.* at 569.

So, in biotechnology, having defined obviousness as a structural place in the prior art can extend that structural criterion to define reverse equivalents. Imagine, for example, a claim that reads on a nucleic acid sequence containing the "terminator" element described above. Someone discovers the "terminator" regulatory property and uses the gene to produce the truncated protein—not the full length protein that would be obvious from the disclosure. That person is using a sequence that reads on the claimed invention, but is using it to yield a different result, in a different way, with a different function than what would be expected by reading the claims. That may very well be a reverse equivalent of the claimed sequence.

Or, imagine that a claimed sequence produces different gene products, and so different proteins, by means of a frame shift. Nucleic acid sequences are read in triplets; if you start reading one or two bases down from the usual starting point, you get a different series of triplet groupings, and consequently a different gene product. Some viruses use this arrangement to get triple-duty out of their limited genomic complements, and it was a big surprise when first discovered. Once again, if someone were the first to discover this property in a nucleic acid that had already been claimed in a patent, he might have a reverse equivalents defense to infringement: he would be using the same structure, but with an unpredictable and non-obvious new function, way, and result.

Of course, this frame-shift trick and the terminator trick are already well known, but they illustrate that macromolecules can surprise us, and are not always predictable. Under the Federal Circuit's jurisprudence, unpredictability will affect the range of equivalents and reverse equivalents. Such cases have not yet been decided, but undoubtedly will be as research progresses and we discover new structural tricks in the genomes of various organisms. The axiomatic framework developed by the Federal Circuit can be predictably extended to cover them.

III. EFFECTS ON THE INDUSTRY

So the framework is intellectually elegant, internally consistent, and very predictable. We can plug in different kinds of inventions, and figure out how they are going to come out the other end when we apply these doctrines. We can figure out how the doctrine might be extended to new areas as new cases arise. But we need to think, as mentioned in the introduction, about the actual effect that this framework might have on the industry. However logically consistent it may be, does the framework take the industry in a direction that we would want it to go in the real world? Does the framework offer the right incentives in terms of industry needs and wants? Just what kind of effects does this wonderfully precise doctrinal mechanism have on the biotechnology industry?

Well, one implication of the way the court has defined the framework is that firms are likely to obtain numerous patents. Why? Because the court has set the obviousness standard relatively low. A detailed disclosure of a molecular structure must be found in the prior art before Judge Lourie wants to call that molecule "obvious." That standard is going to make it easier to get patents because the necessary quantum of information is quite high to render a molecule unpatentably obvious. The higher information requirement actually lowers the obviousness barrier. But at the same time, it will be hard to get a broad patent

because the disclosure requirements that the court has developed in this clockwork structure require a very detailed disclosure. And without that detailed disclosure, an inventor will be limited to what she can claim, because the claims must be commensurate with the disclosure. So it is harder to get genus claims. It is harder to get broad claims. Consequently, the industry will end up with lots of patents—lots of narrow patents.

A number of scholars, including Rebecca Eisenberg at the University of Michigan, have become concerned with the creation of a so-called "anticommons."[28] The term is based on the old story about the "tragedy of the commons," where everybody in the village would put their sheep out on the village green, a common area that became overgrazed. Because nobody owned the village green, nobody had the responsibility for it; because nobody had responsibility for it, everybody over-used it. And so the result was overgrazing, since everybody had free access to it. The usual solution for the "tragedy of the commons" is to assign private property rights. We give the land to somebody so that somebody will have a selfish interest in managing it and making sure it is grazed in the proper fashion. Private property creates incentives to make certain the "green" does not get overgrazed.

Michael Heller, Rebecca Eisenberg, and some other scholars have suggested that we can take that solution too far.[29] They have found some examples where society granted too many property rights, and the rights to a particular resource became too fragmented. In that situation, it becomes difficult to accomplish any large project due to the number of owners you must deal with. If there are too many landowners with small parcels of land, it is hard to build a bridge or a road or anything at all because of the cost to contact all of them and obtain lots of different permissions to get access to their land. Or, there may be the cost of contacting and negotiating with all of them to acquire the various parcels of land. Some owners may hold out or refuse to sell their land. So the transaction costs and holdout problems become very pronounced, and result in the tragedy of the *anti*commons where we have given too many property rights, rather than too few, and it is too expensive to get permissions and licenses from all those people.

Because of the biotechnology obviousness and disclosure doctrines that the Federal Circuit has generated, many commentators are concerned that an anticommons situation will develop, where firms hold numerous narrow patents—everyone gets a DNA patent, but no one gets claims to more than the particular molecule they have isolated. To accomplish any large project in that environment,

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28. *See, e.g.*, Arti K. Rai & Rebecca Eisenberg, *Bayh-Dole Reform & the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 297 (2003); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698–99 (1998); *see also* Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. ILL. L. REV. 173, 192–94.

29. *See*, Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 675–76 (1998); Heller & Eisenberg, *supra* note 28, at 698.

one would have to get so many licenses and so many permissions that it becomes prohibitive to do so. So there is considerable concern that the industry may be poorly served by a low obviousness standard coupled with a high disclosure standard.

At the same time, it is clear that when we consider other technologies, these standards are not the same being applied elsewhere. Judge Lourie has told us in the *University of Rochester* opinion that his axiomatic derivation of written description applies to all technologies;[30] it is not specific to DNA. But that proposition is demonstrably wrong. This idea of having negligible obviousness and very stringent disclosure is not the case, for example, in the case of software where the Federal Circuit has said in effect, "no, the disclosure necessary is negligible. You don't need to disclose actual code to us. You don't even need to give us a flow chart. Just tell us the function of the software." As is apparent from the biotechnology cases, negligible disclosure is the worst thing an inventor can do under Judge Lourie's conception of biotechnology. Merely disclosing the function of a molecule is not enough; the inventor must disclose the code sequence or make a similarly detailed disclosure. But in software, disclosing code would be more than enough.

At the same time, the court has suggested that the obviousness barrier in software will be quite high because once you have disclosed what the software is supposed to do—be it to function as a compiler or as a spreadsheet or whatever it is—any person of ordinary skill in the art can write the code.[31] That implies that the majority of implementations are obvious over the prior art, if anyone of skill in the art can create them. So the software situation is essentially the exact opposite of the biotechnology situation. And this demonstrates a very technology-specific application of these doctrines. Even if Judge Lourie believes the standards are uniform, other judges in the Federal Circuit have begun to recognize that technology specificity is the direction in which things are progressing.[32]

IV. CUSTOMIZING PATENT DOCTRINE

What levels of obviousness and disclosure would we optimally want to have? Is the situation described above, with regard to obviousness and disclosure, the situation that we would want to have in biotechnology, as opposed to the situation that we seem to have for computer software? If we were guided by innovation theory in setting the levels for patentability, we would be thinking about the profiles of the industries involved. Innovation theory directs us to consider the costs of innovation, the foreseeable costs of developing and bringing a

30. Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 925 (Fed. Cir. 2004).

31. *See, e.g.*, N. Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 941 (Fed. Cir. 1990).

32. *See* Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1325–27 (Fed. Cir. 2003) (Rader, J., concurring) (noting the industry-specific nature of the written description doctrine); *Id.* at 1327–28 (Bryson, J., concurring) (acknowledging idiosyncratic biotechnology standard).

product to market, and whether in software or semiconductors or biotechnology or any other industry. The patent is supposed to give an incentive for such innovation—an incentive to create products and bring them to market. And we would want to modulate patents in order to encourage that outcome in different industries.

So if there are, for example, very expensive development costs and high innovation costs, we would want to make it easier to get a patent and easier to get a big patent, as to offer a big reward and big incentive to invest in innovation. Considering biotechnology in particular, one of the things that characterizes the biotechnology industry is that it is diverse and includes agricultural products, human pharmaceutical products, and a wide variety of other economic sectors. Some of these sectors are quite different from the others. But in general, when talking about biotechnology in any sector, most products have rather long development times, in part because biology is complex. These systems are quirky, and sometimes it is hard to get these inventions to work the way the inventor wants them to work.

Additionally, biotech products have long development times because of very stringent regulatory oversight. It could be oversight by the Environmental Protection Agency, it could be oversight by the Food and Drug Administration, or it could be oversight by the U.S. Department of Agriculture, depending on the area of biotechnology under consideration. But wherever the regulatory oversight comes from, there will be increased costs for development, testing, and preparing products to go to market. Incentives in biotech need to be set in such a way that people will be willing to make that investment in a very long-term product development process that is going to be very expensive. That suggests that we ought to make it easier to get broader patents, which means we probably want to adjust the disclosure and obviousness requirements in such a way to make that happen.

The doctrines discussed so far are exactly the doctrines used to modulate patent availability and patent scope. There are essentially two choices in creating patent incentives for a particular industry. First, we can modulate the scope of the patent. We can offer the developer a bigger reward—a bigger, broader patent. We can then patent by adjusting the way we look at the claims, both literally and by equivalence. Since claims must be supported by disclosure, we can also adjust the breadth of the patent by adjusting the amount of support an applicant must have in the specification. The less disclosure needed to support the claim, the more claim you can get for a given quantum of disclosure.

And at the same time, we can also fiddle with the availability of the patents and the frequency of getting the patents. If the system produces too many patents, it may also produce the anticommons problem discussed above. Or, it may create the closely related probem of "patent thickets."[33] Patent thickets block follow-on innovation; an innovator must metaphorically cut her way through the

33. Carl Shapiro, *Navigating the Patent Thicket: Cross Licensing, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POL'Y AND THE ECON. 119, 121 (2001).

underbrush in order to complete a project that she wants to accomplish. Blocking patents can overlap to form patent thickets if an art has become crowded with many patents. So patent policy must take into consideration such problems and the availability of patents for people. But at the same time, it must make patents available enough that the proper incentive is there.

And this a specific application of a general problem in the development of new technologies and the proper reward structure for those technologies. As technologies are developed, and as they grow and as they change, how do we want to manage the incentives? How will we manage the development of innovation?

We have got a couple of institutional choices that we could make. One is to rely on the legislature to pass a new statute that is tailored to each new industry or to each new technology that arises. Such "*sui generis*" statutes attempt to address the needs and characteristics of each technology. This approach typically does not work terribly well—legislatures are big and ponderous and move slowly. It takes a great deal of political capital to muster the votes for a new technological statute, and that is unlikely to happen very often. The legislature typically has other things to worry about, such as collecting campaign contributions, getting re-elected, posturing for constituents, and so on.

Even when the legislature does muster the political will to pass an industry-specific statute, we may wish that it had not. The poster child for badly tailored statutes in this country is the Semiconductor Chip Protection Act passed by Congress in the 1980s.[34] The industry lobbied for such a statute for many years. Finally it got Congress to pass this very specific type of intellectual property legislation just for semiconductors, but it has only been enforced in one reported case since it was enacted.[35] And why? Because it was very tailored, very specific to the technology of that time, but the technology changed and nobody uses that kind of mask work technology that the statute was designed for anymore. So the statute is essentially irrelevant to the industry. It instead relies on utility patents and negotiations between its members to get its products to market, and this statute was not terribly helpful. So there is a danger of immediate obsolescence in passing these very specific kinds of statutes.

The other approach we could take, which as a society we more often decide to use, is to create a comprehensive system like the patent system or the copyright system. These are general statutes that are intended to cover a wide range of technologies. Rather than attempting to enact new legislation for every change in technology, the legislature puts a lot of flexibility into the general statute, makes it very adaptable, and then leaves it to the courts to change the doctrine and make the statute fit the technology as the technology changes.

This is a variation on the general problem of rules versus standards where society could choose to adopt a very specific, bright line rule or society could choose to adopt a vague but flexible standard. The former tends to be inflexible

34. Pub. L. No. 98-620, 98 Stat. 335 (1986) (codified at 17 U.S.C. §§ 901–914).

35. Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1561 (Fed. Cir. 1992).

and imposes the costs of formulation by the legislature up front, *ex ante*. The latter is applied on a case-by-case basis, and imposes costs *ex post*, after the fact, by the court or adjudicator that is applying them to each particular situation. The latter approach seems to be the better approach where the technological situation is changing rapidly.

In this particular case, as the biotechnology industry grows and changes, we have adopted a statute of general application—the patent statute—that we would want the Federal Circuit to modulate and adjust in order to fit the needs of the industry. The statutory standards like obviousness and disclosure can be modulated in just this way. In fact, the court has been doing that to create this framework discussed earlier. Unfortunately, it has not been doing it with an eye towards the industry. Rather, it has been doing it with regard to legal coherence and consistency, but not external consistency.

V. OPTIMIZING PATENTS FOR BIOTECHNOLOGY

So what is the diagnosis here? What needs to happen to properly adapt patent law to this industry? One problem may be the lag in patent enforcement. It appears, as you read these cases, that the Federal Circuit may have misunderstood the state of the technology, as the cases look in hindsight back at patents filed during the 1970s and 1980s. The court is also disadvantaged because it takes time for cases to percolate up from the district courts. The delay may prevent the Federal Circuit from adapting the doctrine to current industry needs.

The court may also be pursuing a certain misplaced sense of judicial economy. A conservative approach to legal doctrine is at least in part the source of this wonderfully coherent clockwork system that may not actually meet the needs of the industry. The court has taken existing doctrines and essentially recycled them from small molecule chemistry, extending them to macromolecules, rather than making up entirely new doctrine. Making the law very consistent and predictable is very sensible from the standpoint of judicial economy, as long as the result has some external relevance—but it is not clear that in this instance the external relevance is there.

In particular, the doctrine regarding the person of the ordinary skill in the art is something that is key to this system and to what the Federal Circuit has been developing. The person having ordinary skill in the art—the so-called PHOSITA—shows up in the obviousness standard, as the legal construct against which obviousness is measured. The PHOSITA is also the metric for disclosure. And one way to view these standards, as developed by the Federal Circuit, is to conclude that the Federal Circuit seems to think that a person of ordinary skill in the art in biotechnology is not very bright and requires a very detailed disclosure in order to be able to understand the invention and be able to find a particular molecule. And the court seems to believe that this person of ordinary skill in the art who apparently is not very bright would be unable to look at the prior art and figure out what was obvious without a very detailed and specific disclosure in the prior art. Of course, contrasting this biotech PHOSITA with that in the software situation, the software PHOSITA seems to be extremely intelligent—he does not need much disclosure and can figure out on his own how to write the code.

The PHOSITA is core both to the obviousness and to the disclosure doctrines. And there are, in fact, other extensions of the PHOSITA that show up elsewhere, in the doctrine of equivalents and other areas. So we would expect the construction of the PHOSITA to have a key role in adapting the patent statute to different industries. But the Federal Circuit needs to think about the characteristics of the PHOSITA and perhaps then decouple the obviousness PHOSITA from the disclosure PHOSITA, because there is a kind of inverse relationship between the two.[36] If the PHOSITA in biotechnology is not too bright, it needs a lot of disclosure in the specification in order to practice the invention. That also means that that PHOSITA, if we assume it is the same PHOSITA, is going to have a hard time figuring out what is obvious from the prior art.

But those PHOSITAs do not necessarily have to be the same person. We could separate the obviousness PHOSITA from the disclosure PHOSITA since they are actually doing different things. One PHOSITA is trying to figure out what is obvious and the other PHOSITA is actually trying to implement something—make and use something from the specification. So the level of skill in the art and the knowledge of the PHOSITA is actually measured at different times for the two different doctrines and has different purposes. Each PHOSITA is focused on something separate; we could treat them differently and we would not end up with this reciprocal relationship between obviousness and disclosure. We can calibrate those two doctrines independently to the needs of the industry. So we can keep the PHOSITA as one of these flexible standards that is specific to the art and decide what an industry needs.

Additionally, if we consider the innovation needs of an industry, the necessary incentives, and the uncertainty that a technology such as biotechnology is going to face in developing new products, we can also work into the obviousness discussion a new secondary factor such as those found in the obviousness determination from *Graham v. John Deere*.[37] Courts already look at secondary factors, such as the number of units sold, to determine the invention's commercial success. Or they look at whether other people tried to invent something similar and failed. Another objective factor that we might introduce could be an inquiry into how expensive it is in a given industry to get a product to market. That might be a secondary factor that would affect the level of obviousness that the new framework would end up setting.

We can then modulate the availability of the patents in an industry like biotechnology by independently tweaking those two doctrines of disclosure and obviousness. Additionally, other doctrines might be used to modulate the breadth and availability of patents, as well: for example, the utility doctrine or the doctrine of equivalents.[38] But the overall goal should be to change and modulate those criteria to meet the innovation needs of the industry, rather then to simply have a

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36. Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?* 17 BERKELEY TECH. L.J. 1155, 1202 (2002).

37. 383 U.S. 1, 17–18 (1966).

38. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1645–46, 1654–55 (2003).

beautiful and internally consistent set of doctrines that do not have any relationship to what is actually required for innovation.

VI. CONCLUSION

So I have argued that we need to re-calibrate the mechanism developed by the Federal Circuit for biotechnology. The patent framework we have now for biotechnology has the virtues of consistency and doctrinal predictability. Unfortunately, the outcomes we can predict from the framework do not match the needs of the industry terribly well. There is nothing wrong with special treatment for biotechnology, or for any other industry under patent law—that kind of customization is what our patent statute is designed for. But the special treatment should be the treatment needed to produce innovation, not merely that needed to produce a clockwork lemon.

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