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(MOSTLY) AGAINST EXCEPTIONALISM

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ABSTRACT

This Essay delves into issues surrounding the relationship between technology and the patent law. Responding to Dan Burk and Mark Lemley's Biotechnology's Uncertainty Principle*, the piece notes that the basic question posed by that article whether the patent law is 'technology specific' is a relatively easy question, given the several doctrines that explicitly link the subject matter context of an invention to the validity and scope of related patents. This sort of technological exceptionalism which the Essay refers to as TYPE I exceptionalism is both extant and easily justifiable for a legal regime directed to technology policy. It is a broader sort of exceptionalism TYPE II that is far more troublesome, implying a role for the patent law in quite detailed policy judgments, such as the optimal breadth for biotechnological patents as Burk and Lemley suggest . The Essay offers a variety of reasons that TYPE II exceptionalism is unwarranted, and indeed, notes that a primary claim of Burk and Lemley's that the Federal Circuit has grossly missed the mark in its purportedly exceptionalist approach previews the sort of problems created by pursuing technological exceptionalism in the patent law.*

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(MOSTLY) AGAINST EXCEPTIONALISM

I

In *Biotechnology's Uncertainty Principle*, Dan Burk and Mark Lemley offer an insightful work that adds to the growing literature on the relationship between the patent law and innovation policy in the biotechnological field. Carefully analyzing the Federal Circuit's jurisprudence relating to this rapidly developing technology, they suggest that the current doctrinal approach is best explained by the court's exceptionalist view of the level of skill in the relevant art a result, they argue, that while perhaps prompted by policy considerations, is in fact "exactly backwards" from an innovation policy perspective.

In the few pages that follow, I suggest an alternative view of Burk and Lemley's findings. I argue that the Federal Circuit's view concerning the "person of ordinary skill in the art" in these technologies is unlikely to be especially troublesome, chiefly because it seems not to doctrinally bind the court in the future from making the typical technological adjustments that the patent law affirmatively requires. Furthermore, even if Burk and Lemley are correct that the concern is more systematic, I question whether the undesirable results they predict will materialize, or whether their suggested changes will address the problems. I conclude that if Burk and Lemley are indeed correct that the Federal Circuit is engaging in wholesale policy laden exceptionalism for biotechnology, then their paper provides, perhaps counterfactually, a strong indictment against such *sui generis* projects within the patent law.

II

It seems important at the outset to decide what one means by "exceptionalism." In the patent context, there are at least two senses of exceptionalism to consider:

TYPE I Exceptionalism: the legal rules applied to innovations are variable across technologies.

TYPE II Exceptionalism: the rules, while distinct across disparate technologies, are similar within closely related technologies. We might call this "industry specific" exceptionalism, but that implies an economic structure coincident within related technologies, which is perhaps but not necessarily the case.

I take the *TYPE I* form to be both a positive description of the patent law, as well as a normatively justifiable position. The chief advantage and challenge of the patent law is its ability to provide a set of clear background *i.e.,* "property" rules upon which private parties can build to invent, invest, and commercialize. Accordingly, the patent law must always retain the flexibility to adapt to new technological developments and economic shifts. As Burk and Lemley note, this *TYPE I* flexibility is significantly realized through the patent law's use of the "person of ordinary skill in the art," or "PHOISTA" in their terminology as the lens through which a number of critical analyses are conducted. As a question of fact that should necessarily vary from particular innovation to particular innovation, the ordinary skill in the art framework grounds the legal abstractions of the patent law to the technological facts in any given case.

It is the *TYPE II* form of exceptionalism, however, that is far more problematic. Here, rather than building flexibility and innovation into the stable backdrop of the law, the project is far broader, typically invoking arguments related to the "nature of the technology" or the "structure of the innovation", or perhaps even the normative profile of the participants to support essentially *sui generis* changes in the patent law. *TYPE II* exceptionalism shifts consideration of the patent law from a general background principle of property rights to a vehicle for particularistic, technology specific innovation policy choices. As I note in Part IV below, there are a number of reasons why it is worth at least challenging the efficacy and appropriateness of this development of the patent law.

III

Whether the patent law is, as Burk and Lemley ask, "technology specific," strikes me, then, as an easy and rather obvious question.[2] Of course it is: among other aspects, the ordinary skill in the art standard implements the *TYPE I* exceptionalism I note above. Other factors, such as explicit carve outs for particular technologies[3], as well as the general factual basis of much of patent law[4] all serve to create *TYPE I* exceptionalism.

Recognizing the fundamental technological specificity of the patent law in the *TYPE I* sense , and yet explicitly distinguishing that aspect from the broader *TYPE II* exceptionalism might yield some important insights.

First, as Burk and Lemley appear to acknowledge[5], if the concern is simply a misunderstanding of the relevant technological principles, then any problem might not be as significant as suggested; the case by case factual nature of the ordinary skill in the art standard should over time result in the correction of such problems. In other words, if the issue is merely due to *TYPE I* exceptionalism yielding dissonant results because of the factual misapplication of otherwise appropriate frameworks then this is worth criticizing, but implies a problem of implementation rather

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[2] They do, of course on page 23 , acknowledge that the patent law is "inherently technology specific." Burk & Lemley, at 23.

[3] *See, e.g.,* 103 b defining special obviousness standard for "biotechnological processes" ; 271 e experimental use exception for technologies covered by the federal food & drug laws ; *Teletronics Pacing Sys., Inc. v. Ventriex, Inc*., 982 F.2d 1520 Fed. Cir. 1992 extending 271 e to medical devices ; 35 U.S.C. § 273 2001 first inventor defense for "methods of doing or conducting business" .

[4] *See, e.g., Markman v. Westview Inst., Inc.,* 517 U.S. 370, 377 1996 noting the factual basis of patent infringement .

[5] *See* Burk & Lemley, at 26. *See also* Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology,* 34 WAKE FOREST L. REV. 827 1999 ; Arti K. Rai, *Addressing the Patent Gold Rush: The Role of Deference to PTO Denials*, 2 WASH. U. J. L. & PUB. POL'Y 199 2000 cited in Burk & Lemley . *See generally* Burk & Lemley, at 24 26 noting technological concerns and collecting sources .

than theory. That any court, but especially the Federal Circuit, may misconstrue key aspects of relevant technology is of course of obvious concern.[6] But such problems are certainly not surprising, nor particularly unlikely given the challenges of evaluating these complex technologies in light of the abstract commands of the patent statute. That is, once we acknowledge and even embrace *TYPE I* exceptionalism, we must also expect to see some variability in the application of law to fact. We can strive to reduce it, yes but eliminating it seems impossible. Indeed, given that virtually all of the cases typically identified by commentators as relevant to this question have been authored by a single Federal Circuit Judge[7] Judge Lourie a strong case can be made that the apparent uniformity of technological views is just that more *apparent* than real.[8] And more to the point, this technological bent is likely to

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[6] I do not know whether the cases evince a misunderstanding of technology. Several thoughtful commentators so suggest. *See, e.g.,* Burk & Lemley at 25 & n. 75, Rai, *supra* note 5 at 839. Given my view more fully explored below that we should be hesitant to reach any general technological conclusions outside of the context of specific innovations, I am content to acknowledge the concern and move on.

[7] Burk & Lemley cite seven cases as representative of the suggested problematic approach to the issue. They are: *Amgen Inc. v. Chugai Pharma Co.,* 927 F.2d 1200 Fed. Cir. 1991 ; *In re Goodman*, 11 F.3d 1046, 1052 Fed. Cir. 1993 ;.*Fiers v. Rivel*, 984 F.2d 1164 Fed. Cir. 1993 ;*In re Bell*, 991 F.2d 781 Fed. Cir. 1993 ; *In re Deuel*, 51 F.3d 1552, 1559 Fed. Cir. 1995 ; *Regents of the University of California v. Eli Lilly & Co.,* 119 F.3d 1559 Fed. Cir. 1997 ; *Enzo Biochem v. Calgene, Inc.,* 188 F.3d 1362, 1371 Fed. Cir. 1999 . To this one might add the April 2, 2002 case styled *Enzo Biochem v. Gen Probe, Inc.,* 2002 WL 417156 Fed. Cir. Apr. 2, 2002 . These cases, or a subset thereof, appear to be the most relevant to the commentators. Of these opinions, only *Goodman* Judge Rader was authored by a judge other than Judge Lourie, through only in *Enzo v. Gen Probe* was there any dissenting opinion.

[8] Again, I do not know whether Judge Lourie is "simply wrong" about aspects of the technology, *see* Burk & Lemley at 25. The point is simply that the uniformity of technological views evidenced in these key cases may have more to do with the consistency of the opinions' author than the development of general Federal Circuit technological understanding.

change as more judges, through normal, case by case determinations, have the opportunity to consider these questions.[9]

A second important point illuminated by clearly distinguishing between *TYPE I* and *TYPE II* exceptionalism is that mistakes or misunderstandings in the *TYPE I* sense are quite unlikely to create doctrinal path dependencies. Here, most commentators appear to assume the future development of this "biotechnological patent doctrine" will continue along the presently observed trajectory. As Burk and Lemley again seem to acknowledge, however, this criticism has an "easy answer": the use of correct technological facts.[10] The excessively factual nature of *TYPE I* exceptionalism provides ample opportunity for later panels of the Federal Circuit to establish their own analysis in any given case. Indeed, an appropriate understanding of the role of the "ordinary skill in the art" in the patent law would seem to virtually preclude the creation and use of categorical rules. The state of the art in such fields is changing rapidly; that one of ordinary skill might have been unable to determine the DNA sequences that would code for EPO from a few examples circa 1984[11] seems nearly irrelevant to the level of knowledge in DNA sequence identification in the late 1990s.[12] Accordingly, the explicit reference to the "ordinary skill in the art" standard in the patent law as a means of implementing *TYPE I* exceptionalism might be said to fundamentally *require* the revisitation of issues of technological fact at each instance[13]

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[9] *See Enzo Biochem v. Gen Probe, Inc.*, 2002 WL 417156, *12 Fed. Cir. Apr. 2, 2002 "*Eli Lilly*, in departing from the general rule for written description and imposing a unique written description requirement in the field of biotechnology, is open to serious question." Dyk, J. dissenting .

[10] Burk & Lemley, at 26.

[11] *U.S. Patent No.* 4,703,008, entitled *DNA sequences encoding erythropoietin*, was filed November 30, 1984. The '008 patent was at issue in *Amgen Inc. v. Chugai Pharma. Co.,* 927 F.3d 1200 Fed. Cir. 1991 .

[12] *See, e.g.,* Burk & Lemley, at 25; John M. Lucas, *The Doctrine of Simultaneous Conception and Reduction to Practice in Biotechnology: A Double Standard for the Double Helix*, 26 AIPLA Q.J. 381, 418 1998 cited in Burk & Lemley .

[13] *See* 35 U.S.C. §§ 103, 112 2001 .

rather than perpetuating imprecise standards, albeit "decoupl ed ,"[14] as substitutes for technological fact. Put simply, the correct rule as a matter of doctrine may also be the correct rule as a matter of policy: the courts may not, and should not, "standardize" the person of ordinary skill in the art.[15]

Burk and Lemley make an interesting point that the court's move in *Eli Lilly* and later cases away from precise notions of technology to a more general doctrine of "structural foreseeability" may be more troubling. That is, they suggest that such a move, while "tidy and doctrinally attractive," cannot be answered by a call for updated technological understandings.[16] This observation is important, for it even more clearly illuminates the Federal Circuit's attempts to standardize the deeply contextual analysis of one of skill in the art. Yet if I am right that the entire exercise of rulemaking related to the knowledge of those of skill in the art is both nonbinding on later decision makers and inappropriate under the patent statute, then the recent cases should not be more problematic.[17]

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[14] *See* Burk & Lemley, at 27 citing Burk & Lemley, *Is Patent Law Technology Specific* draft 2002 .

[15] An anticipated response to this assertion is that the Federal Circuit, at least, seems to consider the prior rulings as having precedential value. *See, e.g., Enzo Biochem v. Gen Probe Inc.*, 2002 WL 487156 *4 5 Fed. Cir. Apr. 2, 2002 citing *Eli Lilly* as precedent . This objection is unsatisfactory. First, the court always acknowledges the factual basis of the analysis. Second, notwithstanding the citations, it is difficult to determine the actual weight given to earlier factual determinations in different cases. And third, I noted above the truly remarkable homogeneity of the relevant Federal Circuit decisions, which suggests that author consistency rather than doctrinal development is at issue. *See supra* note 7 and accompanying text.

[16] *See* Burk & Lemley, at 27.

[17] Perhaps a form of this anti standardization position is what Burk & Lemley argue in the context of "decoupling" the use of one or ordinary skill in the art in the written description and obviousness analyses. If so, however, there would be little need to consider the public policy relating to the appropriate standards for patentability and disclosure. *See* Burk & Lemley, at 28 41.

While in this section I've suggested that the identified "technology specific" aspects of the Federal Circuit are best viewed as the less troublesome *TYPE I* exceptionalism, I acknowledge that reasonable people could disagree on this point. And it appears that Burk and Lemley disagree, arguing that the exceptionalism is deep and systematic that is, a form of *TYPE II*. The next section considers the implications of this argument.

IV

In this section, I take it as given that the biotechnological jurisprudence of the Federal Circuit evinces a form of *TYPE II* exceptionalism: variation in the legal rules across technologies, but strong similarities within groups of related technologies. Here, the claim is that the Federal Circuit has, for essentially policy reasons, developed a *sui generis* approach to biotechnological inventions. Interestingly, Burk and Lemley do not appear to take serious issue with the exceptionalist approach, and instead argue that the Federal Circuit's approach is "exactly backwards" from that suggested by public policy considerations. As in the prior section, I want to gently challenge Burk and Lemley's account, noting that the "narrow and numerous" concern about biotechnological patents may be misplaced, and offering alternative indictments of these sorts of *TYPE II* exceptionalist efforts even beyond biotechnological subject matter.

Burk and Lemley's arguments against the Federal Circuit's "technology specific" approach proceeds from the premise that the court has developed a standard approach whether technological or straightforwardly normative to the application of the ordinary skill in the art analysis to biotechnological inventions. The approach, they suggest, results in relatively stringent disclosure standards especially under the written description requirement , and relatively less stringent obviousness requirements. Hence, the argument goes, biotechnological patents are likely to be more "narrow and numerous" than would be the case absent the exceptionalist approach.

A

The basic insight here the linkage between the disclosure and obviousness requirements within the framework of the person of ordinary skill in the art is important. And yet there is some reason to pause at the outset and consider whether this interplay between disclosure and obviousness they observe will result in "narrow and numerous" biotechnological patents.

As an initial matter, I note a significant, yet unstated, assumption in Burk and Lemley's analysis: that patent scope and, perhaps to a lesser extent, disclosure requirements are innovation neutral. That is, for the "narrow and numerous" premise to be true, the sum total amount of invention in the field would have to remain constant, irrespective of the altered scope and disclosure rules. This assumption is quite troublesome; it is axiomatic that patent scope will influence inventive behavior.[18] Even without deciding whether the reduction in available patent scope in the biotechnological field increases or decreases the total amount of invention produced,[19] it would seem that the *least* plausible scenario would presume few discernible effects.

A second concern about the "narrow and numerous" premise is that the construct depends greatly upon assumptions regarding the relative magnitude of changes in the written description and obviousness standards. Obviousness and disclosure requirements are both affirmative limitations on the scope of patent claims[20]:

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[18] *See, e.g.,* Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 1977 , Merges & Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 1990 ; Eisenberg, *Patents & The Progress of Science*, 50 U. CHI. L. REV. 1017 1989 .

[19] *See, e.g.,* Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 1999 ; Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691 2001 ; Rai, *Evolving Scientific Norms and Intellectual Property Rights: A Reply to Kieff*, 95 NW. U. L. REV. 707 2001 .

[20] *See, e.g.,* Robert M. Hunt, *Nonobviousness and the Incentive to Innovate: An Economic Analysis of Intellectual Property Reform* working paper 1999

two variables in the patent scope equation, so to speak. Altering only one variable yields an easily predictable change; varying both and inversely requires the inclusion of relative magnitudes to allow reasonable suppositions as to overall effect. Burk and Lemley don't address this relative magnitude problem; I note as a matter of patent doctrine, the courts have denied the existence of a quasi proportional relationship between obviousness and disclosure,[21] suggesting a potentially significant obstacle for the "narrow and numerous" presumption.[22]

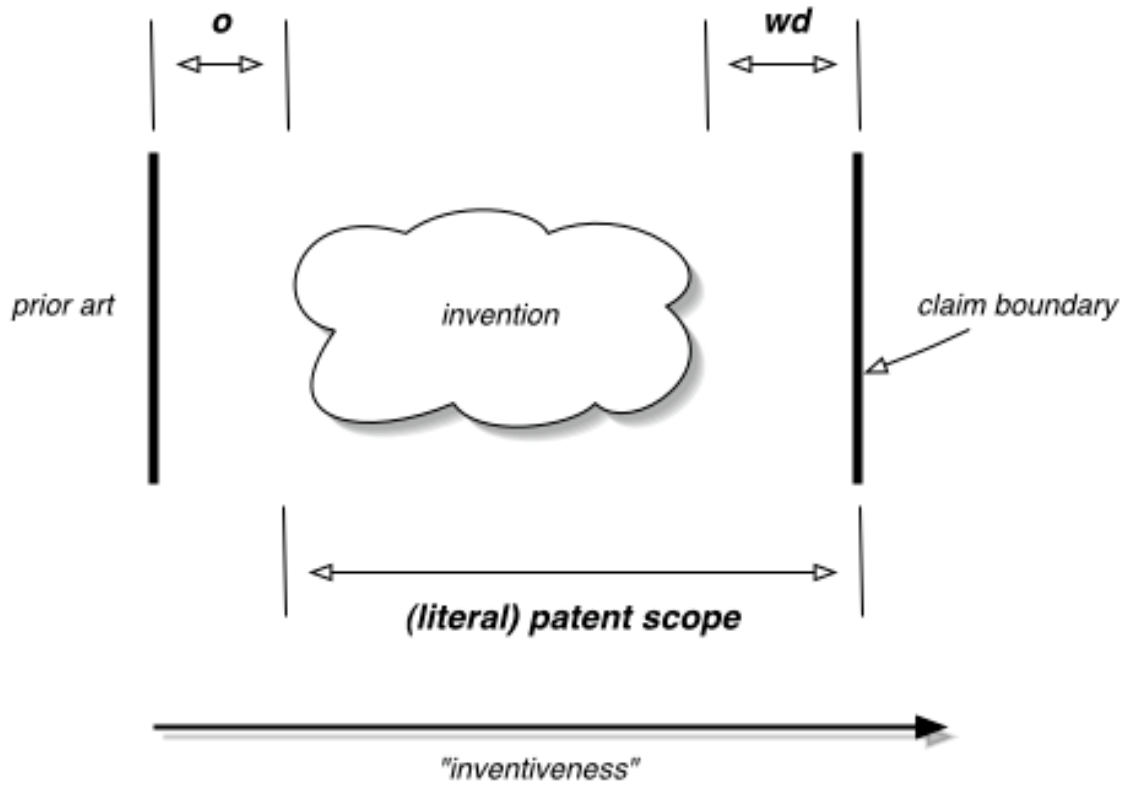
Consider a stylized depiction of patent scope,[23] where new patentable inventions extend from the extant prior art, represented by the figure below.

noting the scope reducing effects of obviousness cited in Burk & Lemley, at 37 n. 110 .

[21] *See, e.g., Eli Lilly,* 119 F.3d at 1566 " A n applicant complies with the written description requirement by describing the invention, with all its claimed limitations, not that which makes it obvious." citing *Lockwood v American Airlines*, 107 F.3d 1565, 1572 Fed. Cir. 1989 .

[22] Potentially, the Burk & Lemley insight about the linking function provided by the person of ordinary skill in the art shows the path to the answer here. But even Burk & Lemley acknowledge at least some differences in the way that standard is applied. In any event, that a common input is approximately constant does not necessarily mean the results will be proportional.

[23] I am aware that this simple drawing does not capture the full complexity of the situation.



Under this depiction, the written description requirement ***wd*** above would define the outer limit of claim scope, given a particular disclosed invention. A stringent written description requirement would limit the patent claim to little more than what is actually and specifically disclosed decreasing ***wd***. The obviousness requirement ***o*** above represents the "distance" required from the prior art: "looser" versions of obviousness decreasing ***o*** would approach anticipation, allowing patentees assuming scope maximizing behavior to claim close to the border of the prior art. Observe the combination of a stringent written description requirement smaller ***wd*** and a loose obviousness requirement smaller ***o*** as Burk and Lemley suggest is the case for biotechnological inventions. These claims will a hew more closely to the prior art; and b be roughly coterminous with the scope of disclosure. Accordingly, I doubt that a meaningful assertion as to the relative scope of the claim can be made, without a series of detailed assumptions regarding the relative scope affecting import of the obviousness and written description changes. Alternatively, one can assume that patentees do not rationally seek the broadest possible claims, meaning that the

"difficulty" of obtaining a patent of set scope is reduced as the obviousness requirement is lessened. But a that's just an argument that narrow claims are easier to obtain, and b requires an assumption contrary to rational behavior.[24]

Burk and Lemley also suggest in what seems to be a break with their "narrow and numerous" premise that the Federal Circuit's exceptionalism will actually result in patents that are broader than expected, because the prior art limitations on the doctrine of equivalents will be less significant in a regime of loose obviousness.[25] This, then raises the question not of "narrow and numerous," but of "broad and numerous" a state of affairs that they argue is "unsustainable," yet suggest in Section IV of the piece that broader patents are likely to comport better with the needs of the biotechnology industry. Burk and Lemley's concern with the use of the doctrine of equivalents appears to stem from the assumption that this will increase the "fragmentation" of the rights to commercial technologies, thus resulting, they say, in the oft cited concern of a "Tragedy of the Anticommons."[26] A full treatment of the problems with this view is well beyond the scope of this essay; I simply note that recent empirical and theoretical work, notably by Ziedonis and Petherbridge, are casting increasing doubt on whether an "anticommons" problem justifies patent policy changes.[27] Furthermore, while I share Burk and Lemley's

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[24] Another possible assumption is that patentees case only about the "outer limit" of their patent claims, meaning that the loss of coverage on the prior art end of the spectrum would be offset by the achievement of a patent that covers even their specifically disclosed embodiment and no more. Perhaps there is something to this, though again, this is an argument about the relative import of obviousness versus written description.

[25] *See* Burk & Lemley at 16. *See also Southwall Techs, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1580 Fed. Cir. 1996 ; *K 2 v. Salomon*, 191 F.3d 1356, 1367 Fed. Cir. 2000 .

[26] *See, e.g.,* Heller & Eisenberg, *Can Patents Deter Innovation? The Anticommons on Biomedical Research*, 280 SCI. 698 1998 .

[27] For recent empirical work, see e.g., Ziedonis, *When the Giants' Shoulders are Crowded: Fragmented Rights and Patent Strategies in Semiconductors* draft manuscript 2002 noting the effectiveness of patenting strategies used by players in the semiconductor industry to overcome fragmented

general concern about situations where the doctrine of equivalents is an increasing component of total patent scope due to the corresponding dramatic increase in uncertainty and associated costs of the patent system , if they are right that biotechnological patents will be literally narrow, then that will unquestionably have a narrowing effect on the doctrine of equivalents as well. The courts *do* strive mightily to maintain some linkage however tenuous between the literal claims and the scope of equivalents.[28] Further, to the extent that the level of skill in the art is an element of equivalents analysis, then a limited view of this factor as identified by Burk and Lemley will of course limit equivalents.[29] If these biotechnological patents are literally narrow as compared to their scope under non exceptional patentability standards,[30]

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rights ; Hall & Ziedonis, *The Patent Paradox Revisited, An Empirical Study of Patenting in the U.S. Semiconductor Industry*, RAND J. OF ECON forthcoming 2002 . *See also* Walsh et al, *The Patenting and Licensing of Research Tools and Biomedical Innovation* working paper 2000 cited in Burk & Lemley, at 34 n.102 .

For recent theoretical work *see, e.g.,* Petherbridge, *Kitch Kiosks, and Kommons: The Myth of a Tragedy of the Anticommons in Intellectual Property* draft manuscript 2002 arguing that the commons expanding nature of intellectual property, *inter alia*, makes the case for anticommons quite weak . Kieff has also done important work in this area. *See, e.g.,* Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 719 727 2001 a commercialization view of patents undermines the anticommons argument .

[28] *See, e.g., Warner Jenkinson, Inc. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 28 30 1997 ; *Sage Products, Inc. v. Devon Inst.,* 126 F.3d 1420 Fed. Cir. 1997 ; *K 2 v. Salomon*, 191 F.3d at 1367.

[29] See, e.g., Burk & Lemley at 19 noting the importance of ordinary skill in the art in equivalence analysis, and citing Graver Tank . See also Sage Prods., 126 F.3d at 1430 "forseeability," according to one of skill in the art, should control equivalents ; Congliaio et al, *Foreseeability in Patent Law*, 16 BERK. TECH. L. J. 1045, 1064 65 2001 arguing that the view of one of skill in the art should determine equivalence scope in cases of prosecution history estoppel, and citing *Sage* .

[30] As I noted above, I have questions as to whether this case has yet been made.

then it follows that they will be relatively narrow under the doctrine of equivalents as well.[31]

B

Setting to one side any potential problems with Burk and Lemley's "narrow and numerous" premise, I am concerned with their move to *TYPE II* exceptionalism in their suggestions that the Federal Circuit's doctrinal development should instead yield "broad and few" patents in these fields. Their argument is that the narrow scope of protection currently available may not yield adequate marketplace returns to induce optimal investment in innovation. Yet they note that the classic model for inducing innovation, set forth by Merges[32], argues for a looser obviousness standard which, they argue, runs counter to arguments in favor of reducing the disclosure requirements. Thus, they conclude that the biotechnology field is perhaps best served by a system that maintains tight obviousness standards, yet also reduces the disclosure requirements which is, they suggest, precisely the opposite of the current regime.

Whether "numerous and narrow" or "broad and few" yields the better mix of individual incentives and societal benefits is, I think, a rather difficult question.[33] Add the idea of *TYPE II* technological exceptionalism to the general analysis and you necessarily factor in a rapidly changing technological, financial, and commercial

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[31] Burk & Lemley suggest that *Festo Corp. v. Shoketsu*, 234 F.3d 558 Fed. Cir. 2000 decision will also significantly limit patent scope. As I've argued elsewhere, *Festo* does not necessarily affect the scope of the doctrine of equivalents for rational patentees, except for patents prosecuted under the pre *Festo* regime, where the effects will be marginal at most. *See* Wagner, *Reconsidering Estoppel: Patent Administration and the Failure of* Festo, 151 U. PENN. L. REV. __ forthcoming 2002 .

[32] Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH L. J. 1 1992 .

[33] *See, e.g.,* Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 1977 , Merges & Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 1990 ; Eisenberg, *Patents & The Progress of Science*, 50 U. CHI. L. REV. 1017 1989 .

environment to this already contestable effort. Indeed, it would seem to me that it is worth serious consideration whether these sorts of *TYPE II* exercises are beneficial over more generalistic approaches to setting standards for patentability enlightened by *TYPE I* exceptionalism, of course .

First a quick logistical point. The same concerns I noted in Section III above with respect to Burk and Lemley's "narrow and numerous" premise will apply equally to their "broad and few" prescriptive offering. That is, Burk and Lemley suggest tightening the obviousness standard while reducing the disclosure requirement. I would think that perhaps reducing the disclosure requirement alone would create the broader patent scope they seek; tightening the obviousness requirement[34] in parallel, however, will likely make any scope change indeterminate. Burk and Lemley's basic insight here is important: either the obviousness or disclosure requirements can be used as a tool for determining patent scope. I'm just not sure you can use both inversely at the same time to do so.

Turning finally to the more general issue of *TYPE II* exceptionalism, note that Burk and Lemley's argument that the Federal Circuit has, through a biotechnology specific approach, yielded precisely the wrong set of rules from a policy perspective should serve assuming they're right as an fairly powerful indictment of this sort of *sui generis* innovation policy program. At least two general objections along this line come to mind:

Institutional factors. There can be little question that locating substantive innovation policy responsibility in the hands of a single federal appeals court is, to say the least, unwise. As the courts themselves have often noted in the patent context, they are simply not equipped to weigh the macro issues involved,[35] especially given the limited case by case nature of doctrinal development. Further, as Rai notes, there are reasons to believe that as between the Federal Circuit and the PTO, the PTO alone has clear technological

[34] Tighter obviousness requirements will yield narrower claims, or in other words make it "harder" to get a patent of the same scope.

[35] *See, e.g., Diamond v. Chakrabarty*, 447 U.S. 303 1980 .

competence advantages, especially in rapidly developing technologies.[36] Accordingly, even if *TYPE II* exceptionalism was justified, jurisprudential alterations would be a disfavored vehicle for such changes.

Uncertainty. A *TYPE II* exceptionalism approach suggests that the general background rules informed by *TYPE I* are inappropriate, from an innovation policy perspective, for a particular technological field. Maybe there are or will be too many patents on upstream biotechnological research. Or too few.[37] Perhaps the allowance of business model patents will curtail innovation in business organizations. Perhaps not. These are important questions, and yet they appear to skip too lightly over the logically anterior analysis: whether ongoing legislative efforts to tailor the patent law to particular technologies can outperform the market, so to speak. I have my doubts. The speed of legislative action in these areas, with many large stakeholders, is positively glacial. The track record of Congressional attempts to enact technology specific innovation policy is not perhaps altogether promising.[38] and such attempts will be subject to judicial interpretation and possible misconstruction or uncertainty.[39] Furthermore, it is likely impossible to *ex ante* predict the long run degree to which a particular fields of innovation will benefit society, or b general patent rules and the market will produce relatively poor results in those fields. For example, Lemley

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[36] *See* Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827 1999 .

[37] Burk & Lemley, at 37.

[38] Consider, for example, the Semiconductor Chip Protection Act, which has been little used., or Hatch Waxman, which has of late developed some pernicious unintended consequences.

[39] *See, e.g., J. E. M. Ag Supply, Inc., v. Pioneer Hi Bred Int'l, Inc.,* 524 U.S. 124 2001 Congressional enactment of plant specific property protections did not preclude patentability ; Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661 1990 exception for "uses reasonably related to FDA approval of pharmaceuticals includes medical devices . *Compare also Funk Bros. v. Kalo Innoculant Co.,* 33 U.S. 127 1948 novel mixture of bacterium that did not occur stably in nature unpatentable *with Diamond v. Chakrabarty,* 447 U.S. 303 1980 novel bacterium engineered from natural beings patentable .

and Burk note that the empirical evidence regarding holdout problems in biotechnology, despite many predictions otherwise, is not especially persuasive.[40] And we have to concern ourselves with more than guessing right at the outset: as the financial, economic, and technological landscape changes, such *TYPE II* projects will have to be repeatedly revisited to ensure ongoing utility.

> This is not to suggest, of course, that the unfettered market is best in all cases. But it does argue, I think, for an aggressively skeptical approach towards *TYPE II* exceptionalism, a viewpoint that seems underrepresented in the current literature. Actual evidence of current and future market failure would seem to be a prerequisite. As is real sensitivity to the effects of changes in the technology or the commercial environment. As between the default condition of relatively clear general standards and the uncertain effects of technology specific rules, there seem to be strong reasons, as the Burk and Lemley work suggests, to conclude that we should be mostly against exceptionalism.

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[40] Burk & Lemley, at 34 & n.102 citing Walsk et al, *The Patenting and Licensing of Research Tools and Biomedical Innovation* working paper 2000 . *See also* Ziedonis, *When the Giants' Shoulders are Crowded: Fragmented Rights and Patent Strategies in Semiconductors* draft manuscript 2002 noting the effectiveness of patenting strategies used by players in the semiconductor industry to address fragmented rights .