WHEN BIOPHARMA MEETS SOFTWARE: BIOINFORMATICS AT THE PATENT OFFICE

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Scholars have spilled much ink questioning patent quality. Complaints encompass concern about incoming applications, examination by the U.S. Patent and Trademark Office ("USPTO"), and the USPTO’s ultimate output. The literature and some empirical data also suggest, however, that applications, examination, and output may differ considerably based on technology. Most notably, although definitions of patent quality are contested, quality in the biopharmaceutical industry is often considered substantially higher than that in information and communications technology (ICT) industries.

This Article presents the first empirical examination of what happens when the two fields are combined. Specifically, it analyzes the creation and early history of a USPTO examination art unit (AU 1631) that reviews interdisciplinary inventions at the intersection of the biological and information sciences. We explore private value and quality metrics in an early cohort of incoming applications assigned to AU 1631, comparing the applications’ performance on these metrics to a group of applications assigned to a related art unit for more traditional software. We then explore the marginal value of the examination process by comparing examination in AU 1631 with that of a matched set of applications assigned to the traditional software art unit.

Our results show that, on almost all conventional measures of patent value and quality, incoming bioinformatics applications were substantially

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different from, and “better” than, traditional software applications. Moreover, when we compared examination of applications in the two art units that had been matched on these dimensions of private value and quality, applications in AU 1631 experienced significantly more rejections, particularly notice-related rejections, than the conventional software applications. The notable exception was in the area of nonobviousness, where the prevailing law at the time made interdisciplinary, or “recombinant,” inventions presumptively nonobvious. Potential causal explanations for the higher rejection rates in areas other than nonobviousness include “biotechnology-specific” guidelines then in place at the USPTO as well as the higher educational attainment of examiners in AU 1631.

Our results contribute to the empirical literature on factors that affect patent examination quality, particularly with respect to notice. They suggest that technology-specific examination guidelines and educational level not only have an impact, but that this impact can “spill over” into other technologies. The results also demonstrate, at the level of the art unit (an important but relatively understudied unit of analysis), the empirical theme of substantial variation in what the USPTO receives and how it processes what it receives. We conclude by discussing potential policy implications, including a link to the literature on how examination should be conducted when (as is increasingly the case) the art in question is an interdisciplinary, team-based field.
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INTRODUCTION

In 1999, nine years after the NIH National Center for Human Genome Research had published its first joint research plan, the project to sequence the human genome was operating at full force. The entire genome of a free living organism, *Haemophilus influenzae*, had already been sequenced, and the first full human chromosome sequence would be published that year. The joint announcement by President Bill Clinton and UK Prime Minister Tony Blair of the so-called rough draft human genome would be made the following year.

This burgeoning body of genomic knowledge required analytical tools for parsing and manipulating it productively. Though such tools had long existed in computer science and had even been applied to research problems in the life sciences under the designation of bioinformatics, they had not yet been systematized into a formal discipline. The specialization of such tools to manage the peculiar scope and scale of genomic information marked the origin of bioinformatics as a distinct discipline.

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4 The White House Office of the Press Secretary, *President Clinton Announces the Completion of the First Survey of the Entire Human Genome: Hails Public And Private Efforts Leading to this Historic Achievement* (June 25, 2000), available at web.ornl.gov/sci/techresources/Human_Genome/project/clinton1.shtml.
5 In 2000, the National Institutes of Health issued the following working definition of bioinformatics that accounted for the importance of that field to the accelerating growth of available biological information:
Research, development, or application of computational tools and approaches for expanding the use of biological, medical, behavioral or health data, including those to acquire, store, organize, archive, analyze, or visualize such data.
Perhaps not surprisingly, the United States Patent and Trademark Office had begun receiving a growing number of patent applications for inventions in the field of bioinformatics. Based on industry input, it projected many more in the coming years.\(^7\) In response, by December of 1999, the USPTO had established a new art unit to examine all bioinformatics applications in a consistent way.\(^8\) The art unit would reside in USPTO Technology Center 1600\(^9\) (the Technology Center that examines inventions in biotechnology and organic chemistry),\(^10\) and would be designated AU 1631.

From its earliest days, the patent examiners in AU 1631 had diverse expertise not only in the biological sciences, but also in physics and electrical engineering and, most importantly, computer science.\(^11\) The USPTO considered the software and data processing patent cases of the late 1990s\(^12\) as directly relevant to patents on computing tools for analyzing biological systems, and accordingly advised bioinformatics inventors to draw lessons from the software invention guidelines in the Manual of Patent Examining Procedure.\(^13\) At the same time, the art unit was located in the biopharmaceutical and chemical Technology Center, a Technology Center for which important new examination guidelines on the so-called written description and utility requirements had just been announced.\(^14\) This latter group of guidelines would presumably also have some impact on the behavior of examiners in AU 1631.

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\(^8\) Id.

\(^9\) Id.


\(^12\) AT&T Corp. v. Excel Communications Inc., 172 F.3d 1352 (Fed. Cir. 1999); State Street Bank & Trust Co. v. Signature Financial Group Inc., 149 F.3d 1368 (Fed. Cir. 1998).

\(^13\) Steinberg, *supra* note 7 (citing MANUAL OF PATENT EXAMINING PROCEDURE [MPEP] §§ 216.01, 216.02).

This Article analyzes these dual influences in an early cohort of patent applications assigned to AU 1631. It first compares the characteristics of these applications with a comparison group of applications from a related, more traditionally software-oriented data processing art unit, AU 2123. Our analysis shows that on all conventional measures of private value and quality, applications in AU 1631 were significantly different from and “better” applications in AU 2123.

The Article then compares the examination of applications from AU 1631 with a matched set of applications from AU 2123. Even on a sample of applications matched on various dimensions of private value and quality, patent prosecution in AU 1631 with its biology-trained examiners looked strikingly different from prosecution in AU 2123. With the notable exception of nonobviousness rejections, applications in AU 1631 experienced more rejections, particularly notice-related rejections, than a matched sample of applications in AU 2123.

As we discuss, these differences in patent examination quality, particularly with respect to notice, appear to result from the biotechnology-specific examination guidelines that applied to examiners in AU 1631 as well as the higher educational attainment of these examiners. Our results therefore have implications for improving patent examination quality. They also reinforce the emerging empirical theme of considerable variation in the manner in which the patent system applies across technologies and art unit. Finally, we link our results to the literature discussing how the growing percentage on patent applications that rely on interdisciplinary and team-based science should be examined.

Part I of the Article summarizes the robust debate surrounding patent quality and introduces the issue of measuring quality. Part II surveys the quality metrics that scholars and policymakers have employed in evaluating the USPTO’s performance as an ex ante guarantor of patent quality. Part III applies the lessons of the patent quality literature to several hundred patent examinations from AU 1631 and AU 2123—employing the quality metrics identified in Part II—and discusses the study’s results as well as its policy implications. Part IV discusses how patent offices should examine applications that increasingly rely on team-based, interdisciplinary science.
I. QUALITY IN THE PATENT OFFICE

Much of the current dissatisfaction with the U.S. patent system stems from concerns about patent quality. Numerous commentators have put forward proposals for quality improvement. Some of these—most notably, enhanced post-grant adjudications at the USPTO—were incorporated into the America Invents Act of 2011. The court system has acted on others. Even so, more remains to be done.

Patent quality failures are perhaps most visible in litigation due to patent litigation’s high costs, often unpredictable outcomes, and potentially unpredictable outcomes.

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18 Both the literature and case law identify a variety of sources for unpredictability in patent litigation. See, e.g., J. Jonas Anderson & Peter S. Menell, Informal Deference: A Historical, Empirical, and Normative Analysis of Patent Claim Construction, 108 NW. U. L. Rev. 1, 4–7 (2014) (discussing uncertainty in claim construction); Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722, 738 (explaining that despite the uncertainty that the doctrine of infringement by equivalents introduces into the patent system, the Court has repeatedly accepted such uncertainty “as the price of ensuring the appropriate incentives for innovation”). See also Alan C. Marco & Saurabh Vishnubhatkar, Certain Patents, 16 Yale J.L. & Tech. 103 (estimating the economic value of the certainty in patent rights that adjudicative resolution brings).
tially lasting dynamic losses to innovation. Yet because many of the more egregious harms from patent litigation are best understood as effects rather than causes of poor patent quality, one important locus of proposed reforms continues to be the USPTO infrastructure for initial patent examination.

When critics bemoan poor quality, they are concerned about several different issues. These include failure to comply with the statutory requirement that patents be granted only to inventions that would not be obvious to the ordinary scientist or technologist working in the area; failure to comply with the statutory requirement that the patent disclose how to make and use the full scope of the invention covered by the claims; and


20 Cf. Mark A. Lemley & A. Douglas Melamed, Missing the Forest for the Trolls, 113 COLUM. L. REV. 2117 (2013) (arguing that the effects of patent assertion by patent trolls, however, defined, are a symptom of broader systemic flaws in the patent system).

21 The situation post-grant appears to be quite different. Not only are the post-grant review procedures set up by the AIA very heavily utilized, but criticisms center around the idea that the procedures are too strict, not too lax.

22 For present purposes, we bracket the question of whether patents on certain types of inventions are inherently “poor quality.” To be sure, the question of whether restrictions should be placed on patent-eligible subject matter has been clearly decided in the affirmative by the Supreme Court. See, e.g., Alice Corp. Pty. Ltd. v. CLS Bank Intern., 134 S. Ct. 2347 (2014); Association for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013); Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289 (2012); Bilski v. Kappos, 561 U.S. 593 (2010). As a normative matter, the issue remains much contested, however.

23 See 35 U.S.C. § 103; KSR Intern. Co. v. Teleflex Inc., 550 U.S. 398 (2007) (finding that a patent on an adjustable automobile pedal assembly would, at the time of invention, have been obvious to one of ordinary skill in the field when considered in light of the available technology).

24 See 35 U.S.C. § 112(a); GlaxoSmithKline LLC v. Banner Pharmacaps, Inc., 744 F.3d 725 (Fed. Cir. 2014) (affirming that a patent on the hormone inhibitor dutasteride and its pharmaceutically acceptable solvates was adequately described under § 112(a) with respect to the term “solvates”); Wyeth and Cordis Corp. v. Abbott Laboratories, 720
violation of the principle that the patent claims must give proper notice as to the boundary of the patent right.\textsuperscript{25}

Given the impossibility of systematically evaluating every patent that issues from the USPTO for compliance with nonobviousness, disclosure, and notice requirements, critics have pointed to various institutional features that would suggest poor quality. One set of institutional features prevents proper application of existing patent law standards. Another set may cause these standards to be too lax. Because both sets of institutional features provide the motivation for our empirical analysis of quality, we discuss them below.

A. IMPROPER APPLICATION OF PATENT LAW STANDARDS

The USPTO operates under a number of institutional constraints that might cause application of existing patent law standards to be too lax. Perhaps most notably, examiners have a very limited amount of time to examine patents. Thus fact-intensive patent law standards that involve significant work, such as thoroughly searching prior art to evaluate nonobviousness or thoroughly evaluating an application’s disclosure, may simply be too burdensome for examiners to implement successfully. Recent empirical work, discussed further in Part II, suggests that these time constraints

\textsuperscript{25} See 35 U.S.C. §§ 112(b), (f); \textit{In re Packard}, 751 F.3d 1307 (Fed. Cir. 2014) (affirming the USPTO’s rejection of a patent application on a coin change holder under § 112(b) for indefiniteness); \textit{Power Integrations, Inc. v. Fairchild Semiconductor Intern., Inc.}, 711 F.3d 1348 (Fed. Cir. 2013) (affirming in pertinent part that patents on techniques for mitigating electromagnetic interference and current flow problems recited sufficient structure with respect to the term “soft start circuit” to satisfy the means-plus-function requirements of § 112(f)). The Federal Circuit has also adopted the view that the written description terminology of Section 112(a) performs a notice function. Moreover, as discussed further below, although the court indicated in 2010 that written description applies to all technologies, during the time of this empirical study the requirement appeared to apply only to biotechnology. \textit{See Ariad Pharmaceuticals et al. v. Eli Lilly and Co.}, 598 F.3d 1336 (Fed. Cir. 2010) \textit{(en banc)}.  

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Another reason for concern is the agency’s funding structure, which is not only entirely fee-based but also heavily based on fees paid only if a patent is granted.\footnote{27}{See, e.g., Arti K. Rai, \textit{Growing Pains in the Administrative State: The Patent Office’s Troubled Quest for Managerial Control}, 157 U. PA. L. REV. 2051, 2062 (2009) (arguing that the USPTO’s fee structure “sets up an obvious financial incentive for the USPTO to grant patents”).} The PTO currently charges $1600 cumulatively for the filing, search, and examination of patent applications—even though the cost of doing this work is more than double that amount.\footnote{28}{The USPTO fee schedule for utility applications charges $280 for filing, $600 for search, and $720 for examination, totaling $1600. U.S. PATENT \\& TRADEMARK OFFICE, USPTO FEE SCHEDULE, \textit{available at} www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule. What these activities cost the USPTO to perform, however, is considerably higher. These costs totaled $3569 in FY 2011, $3906 in FY 2010, and $3284 in FY 2009. U.S. PATENT \\& TRADEMARK OFFICE, USPTO SECTION 10 FEE SETTING – ACTIVITY-BASED INFORMATION AND COSTING METHODOLOGY 18, \textit{available at} www.uspto.gov/sites/default/files/aia_implementation/aia_section_10_cost_supplement.pdf.}

Over half of the USPTO’s operating budget comes from issuance fees that are paid only after an examiner deems a patent application allowable and from maintenance fees that are paid during the post-grant life of the patent, whereas filing, search, and examination fees from new applications account for less than a third of the USPTO’s annual revenue.\footnote{29}{From FY 2001 through FY 2014, annual revenues from maintenance and issue fees have totaled 50% or more whereas annual revenues from filing, search, and examination fees have totaled in the range of 24–31%. U.S. PATENT \\& TRADEMARK OFFICE, USPTO ANNUAL REPORTS, \textit{available at} www.uspto.gov/about-us/performance-and-planning/uspto-annual-reports.}

Moreover, some empirical research suggests that categories of patents from which the USPTO is more likely to receive maintenance fees are also more likely to be granted.\footnote{30}{Michael D. Frakes & Melissa F. Wasserman, \textit{Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the USPTO’s Granting Patterns}, 66 VAND. L. REV. 67, 69–71 (2013).} In the absence of a specifically identified mechanism by
which motivation for future economic gain might influence current USPTO behavior in particular patent areas, these findings should be viewed cautiously. Nonetheless, given the USPTO’s fee structure, applying patentability criteria loosely would have a positive effect on USPTO funding. So would legal or policy decisions that affirmatively relaxed these criteria. In the next section, we examine other institutional pressures that might cause legal standards to be overly lax.31

B. LAX PATENTABILITY STANDARDS

Even absent substantive rulemaking authority, the USPTO has some ability to articulate the contours of patent law.32 Beyond merely exercising its discretion in the interstitial application of patent law to the facts of patent examination, the USPTO also frequently issues legal guidance documents to its examiners to interpret judicial decisions and produces its own substantive precedents in the agency’s internal administrative appeals process.33 Though the Federal Circuit has, thus far, given no deference to these guidance documents or precedents,34 the vanishingly small subset of USPTO actions that come before the Federal Circuit reflects limitations in the court’s inability to actively manage the direction of substantive patent law.35 Moreover, as noted, the USPTO’s funding structure may give it an incentive to relax patentability standards.

Another mechanism by which patentability standards might become too lax relies on the interaction, particularly prior to the passage of the

31 Id. See also Arti K. Rai, Growing Pains in the Administrative State: The Patent Office’s Troubled Quest for Managerial Control, 157 U. PA. L. REV. 2051, 2062 (2009) (arguing that the USPTO’s fee structure “sets up an obvious financial incentive for the USPTO to grant patents”).


33 Wasserman, supra note 32, at 394–98.

34 But see Arti K. Rai, Improving (Software) Patent Quality Through the Administrative Process, 51 HOUS. L. REV. 503 (2013) (arguing that legal determinations made in post-grant review proceedings set up by the AIA may merit Chevron deference).

35 Id. at 398–400.
America Invents Act of 2011, of the USPTO with the Court of Appeals for the Federal Circuit. Prior to the AIA, the major route by which appeals from the USPTO came to the Federal Circuit was through a decision by an applicant to appeal a rejection.\textsuperscript{36} Thus the agency could be reversed only for improper rejections and not improper grants. Under a model where the agency were motivated entirely by the fear of Federal Circuit reversal, it would presumably reject only that small subset of applications that were seen as unpatentable even by the most “pro-patent” members of the Federal Circuit. The result would be a progressive lowering of patent standards.

Although this model probably overstates the extent to which the USPTO is motivated by Federal Circuit reversal, and understates the extent to which it is influenced by the White House and by workload fears, the USPTO has, at times, certainly found itself hostage to Federal Circuit decisions that made it very difficult for the agency to deny patents.\textsuperscript{37} Thus, for example, during the time period covered by our study, the agency operated under a requirement that it show a written teaching, suggestion, or motivation (TSM) to combine prior art when making an obviousness rejection.\textsuperscript{38} As we discuss below, this TSM requirement may have had particular force for AU 1631, where prior art from the life sciences and software would presumably sometimes have to be combined to make an obviousness rejection.

C. Quality and Technology-Specificity

The debate over patent quality also has a technological dimension. This dimension is particularly relevant for purposes of our paper, as we explicitly address not simply a “recombinant” field but a field that combines two areas—biotechnology and software -- historically considered quite different from a quality perspective.

\textsuperscript{38} See id. See also DyStar Textilfarben GmbH v. C.H. Patrick Co., 464 F.3d 1356 (Fed. Cir. 2006); \textit{In re Lee}, 277 F.3d 1338 (Fed. Cir. 2002).
Although the United States has a unitary patent system with few formal exclusions or exceptions,\(^{39}\) the potentially wide-ranging differences among the economic and legal needs of various technology and industry sectors have made it necessary and appropriate for U.S. patent law to adopt doctrines that accommodate those differences.\(^{40}\)

Many substantive criteria for patentability operate by reference to a person having ordinary skill in the art (“PHOSITA”), analogous to tort law’s reasonably prudent person,\(^ {41}\) and so incorporate technology-specific perspectives into nominally technology-agnostic standards.\(^ {42}\) The foundational role of the PHOSITA has, for example, resulted in a doctrine of “unpredictable arts” that tolerates in those arts a greater degree of experimentation for purposes of enablement\(^ {43}\) and more readily accepts unlikely advances over the prior art for purposes of nonobviousness.\(^ {44}\) Indeed, usage of the PHOSITA construct may itself be so fact-intensive as to produce doctrine that is overly technology-specific,\(^ {45}\) raising the normative question of how best to identify the PHOSITA.\(^ {46}\)

Beyond the PHOSITA construct, the Federal Circuit’s historical tendency to apply the written description terminology of Section 112(a) to biotechnology and chemistry, but not necessarily to other arts, had impli-
cations for both notice and scope. In the 1997 case of *University of California v. Eli Lilly*, the Federal Circuit held that, even for originally filed claims, written description was a requirement separate from enablement. The Federal Circuit also held that a genus claim (in that case a functional genus claim to cDNAs that coded for insulin) satisfied written description only to the extent it included the structure of a subset of species representative of the genus. The USPTO’s Written Description Guidelines, issued in draft form in 1999 and finalized in 2001, relied heavily on this precedent, stressing that the structure of a “representative number of species” was necessary to claim the genus.

To the extent that written description has been applied more to biotechnology and chemistry than to other arts, it has arguably generated better boundary notice and more appropriately tailored scope in biotechnology and chemistry. Boundary notice in chemistry (though not necessarily biotechnology) may also reflect the discipline’s well-standardized conventions of nomenclature. In contrast, the relatively imprecise vocabulary of software-related inventions requires greater standardization through bodies such as the Institute of Electrical and Electronics Engineers and others.

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47 See *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).
48 *Id.* at 1566–69 (Fed. Cir. 1997) (invalidating functional genus claim to insulin cDNAs because the written description failed to recite enough species to constitute a “substantial portion of the genus”).
49 *Written Description Guidelines*, 66 FED. REG. at 1106.
50 *Id.*
51 However, the Federal Circuit’s *en banc* decision in *Ariad Pharms. v. Eli Lilly & Co.*, handed down in 2010, does purport to make written description a requirement equally that applies to all technology. 598 F.3d 1336 (Fed. Cir. 2010) (*en banc*).
52 BESSEN & MEURER, PATENT FAILURE, supra note 15, at 152. But see William D. Marsillo, *How Chemical Nomenclature Confused the Courts*, 6 U. BALT. INTELL. PROP. L.J. 29 (1997) (arguing that where a genus of chemical compounds is to be claimed by reference to a few representative species, the rules of chemical nomenclature have created judicial confusion about theoretical permutations of chemical structure and the practical import of actual chemical and physical properties).
53 See Peter S. Menell & Michael J. Meurer, *Notice Failure and Notice Externalities*, 5 J. LEGAL ANALYSIS 1, 36 (2013) (comparing IEEE’s efforts in this regard to similar scientific governance provided by the International Union of Pure and Applied Chemistry).
Additionally, because technology is itself malleable in definition, imposing a priori classifications may compound the already difficult task of comparing patent quality across different arts. One aspect of this problem is that inventions that are truly seminal in a new field pose a challenge for measuring quality because, by their very nature, they are quite broad in scope. Distinguishing broad patents from overbroad patents is difficult. Evaluating the quality of such patents is commensurately difficult as well. Another aspect of the problem is that general-purpose technologies such as software serve as platforms for, or inputs into, a wide variety of other fields, and inventions in these widely adopted arts are not easily identified in objective and replicable ways.

54 The above-discussed line-drawing problem in describing quality and developing reforms in software is an illustration of the same principle. See supra note 64 and accompanying text. 55 For example, what medical researchers may reliably have denoted “oncology” a century ago is now an immensely broad collection of well-developed disciplines defined by affected populations (e.g., pediatric oncology addressing cancer in children and geriatric oncology addressing cancer in the elderly), affected biological systems (e.g., hematology-oncology addressing blood-related cancers), and so on. It is simply not specific enough anymore for modern science to discuss inventions “in the field of oncology.”

56 Matthew J. Conigliaro, Andrew C. Greenberg & Mark A. Lemley, Foreseeability in Patent Law, 16 BERKELEY TECH. L.J. 1045, 1049–53 (describing pioneer inventions as distinct from more incremental technological improvements and proposing a heuristic for according due scope and protection to patents on pioneer inventions). But see Brian J. Love, Interring the Pioneer Invention Doctrine, 90 N.C. L. REV. 379 (2012) (arguing from historical discussion that truly pioneering inventions do not exist and that patent law should formally abrogate the doctrine of giving broad protection to pioneer inventions).


59 For a discussion of the methodological tradeoffs between reaching an accurate definition of software patents that minimizes Type I and Type II errors and reaching a precise definition that is reproducible despite potential errors, see Bronwyn H. Hall & Me-
This general debate over the importance of technology in patent law informs a variety of specific patent quality discussions including proposals for technology-agnostic and explicitly category-based reforms alike. Prominent among these proposals is the desire particularly to assess the quality of software-related patents and, as the case may be, to improve it. These discussions raise a threshold boundary definition problem, inviting general reforms of patent quality that would disproportionately affect patents on software-related inventions in a positive way as well as reforms that are peculiar to software as a practical matter.

More generally, quality concerns have spawned numerous proposals for reform. Some of these proposals such as significantly enhanced post-grant review of issued patents, have already been implemented in the America Invents Act of 2011. Others, particularly with respect to notice, have yet to be attempted or have been implemented only in pilot form.

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60 E.g., Jaffe & Lerner, supra note 15.


64 Colleen V. Chien, *Reforming Software Patents*, 50 HOUS. L. REV. 325, 354 (2012) (discussing the problem of defining software patents and noting some of the foundational legal literature on proposed definitions).

65 See Rai, supra note 34.

We defer discussion of future potential reforms to Part IV, when we turn to policy implications of our empirical findings.

In the next Part, we review efforts to measure patent quality quantitatively. Although these empirical studies do not necessarily lead directly to specific normative conclusions, they provide important background for our own empirical work.

II. MEASURING PATENT QUALITY

The challenge of describing patent quality in qualitative terms is matched by the challenge of describing and estimating patent quality through quantitative measures. Some of the difficulty arises because the empirical literature has not always distinguished carefully between at least three distinct visions of quality: a patent document that is “important” and facilitates diffusion of knowledge; the private value of a patent to the patent owner; and a patent’s conformance with existing legal criteria for patentability. Additionally, an emerging empirical literature views quality through the lens of examiner characteristics and incentives that affect the rigor of examination.

Below we review the quantitative measures in the existing literature, with a focus on those measures that will help us evaluate both incoming patent applications to AU 1631 and AU 2123 and the effects of examination. As we discuss in Part III, we have data on the characteristics of incoming applications and on how those applications were examined. At the art unit level, we also have data on a variety of examiner characteristics.

A. CITATIONS AND KNOWLEDGE TRANSFER

The literature tabulating forward citations of patents stresses the patent’s role in diffusing scientific or technical knowledge in a given community.

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munity. On this view, patents that are highly cited by other patents are likely to be important.\footnote{More formally, a higher degree of citation (adjusted for time lag) should correspond with greater private value in the patent for its owner. We note a recent empirical study that challenges this empirical assumption. \textit{See} David S. Abrams, Ufuk Akcigit & Jillian Popadak, \textit{Patent Value and Citations: Creative Destruction or Strategic Disruption?}, (Penn Inst. Econ. Res., Working Paper 13-065, 2013), \textit{available at} sites.sas.upenn.edu/ufuk-akcigit/files/patentvalue_aap_nber_0.pdf (finding that forward citation rates reflect growing private value only initially, but later correspond to strategic behavior aimed at preserving the returns from past patenting and to an overall decline in value). Though it presents a compelling early criticism of the citation-value literature, its applicability is limited in important respects. The underlying data is based on the patent portfolios of non-practicing entities, whose reliance on licensing is a structurally different use of patent rights than by practicing entities such as manufacturers, who gain more from actually excluding competitors from the market than from merely threatening to exclude as leverage in a licensing negotiation. The underlying data is also proprietary, making it difficult to reproduce or even operationalize the findings into a more complete empirical model. This is not to suggest that the findings themselves are incorrect, but that further, replicable research is needed before the prevailing understanding of citations and value is properly discarded.} One factor that is positively correlated with forward citation rates, and with technological importance more generally, is number of co-inventors.\footnote{\textit{See} Stefan Wuchty, Benjamin F. Jones & Brian Uzzi, \textit{The Increasing Dominance of Teams in Production of Knowledge}, 316 \textit{Science} 1036 (2007); Jasjit Singh & Lee Fleming, \textit{Lone Inventors as Sources of Breakthroughs: Myth or Reality}, 56 \textit{Mgmt. Sci.} 41, 54 (2010) (arguing that a larger team increases the likelihood of a breakthrough and decreases the likelihood of a relatively useless invention).} For this reason, in Part III we use numbers of inventors as one metric for evaluating incoming patent applications.

The citation literature has also generated quality proxies such as technological originality and generality of the invention.\footnote{\textit{See generally} Hall et al., \textit{supra} note 68 (deriving these measures from analysis of time-adjusted citations).} Despite the difficulty of separating out such general-purpose technology patents for analy-
Vishnubhakat, 19 their presence in the background of so many different technologies makes them measurable in their influence and impact. Based on these insights, originality and generality have been discussed as correlate measures of patent quality.  

Recent empirical analysis has shown, however, that examiners have a very significant influence on citations, and this influence is not randomly distributed. Thus the question of how citation data that pools applicant and examiner citations should be interpreted is unclear. Indeed, one study focused on variation among examiners found that examiners whose patents were subsequently invalidated by the Federal Circuit on average issued patents that were more frequently cited.

For our purposes, because we focus on the quality of incoming patent applications and of examination, the forward citation metric is not relevant. On the other hand, as further discussed below, numbers of backward citations to prior art perhaps intuitively address a basic sense of quality. Particularly relevant for our purposes, applicant-provided backward citations may be a proxy for the care with which the applicant drafted the application. In Part III, we use applicant citations to prior art (both patents and non-patent literature) to evaluate incoming applications.

B. Private Value

As for private value, the literature has often proxied for such value by looking at the characteristics of patents that are litigated or for which re-

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72 In the context of software, the definition in most recent growing use relies on a detailed sorting at the level of U.S. patent class and subclass to mitigate over- and under-counting. See Graham & Vishnubhakat, supra note 58, at 75n.7.


76 Mann & Underweiser, supra note 67.
newal fees are paid. In both cases, the assumption has been that rational parties would not incur associated expenditures without some expectation of a return on investment. This literature has determined that litigated and renewed patents generally have higher numbers of claims as well as higher rates of forward and backward citation. Some commentators have therefore used number and complexity of claims not simply as a reflection of private value but also as a proxy for effort expended in obtaining the patent. Similarly, in Part III, we use number of claims at filing as a proxy for effort initially expended by the applicant.

An important variable clearly correlated with private patent value is the size of the patent family—that is, the number of foreign jurisdictions in which the applicant has concurrently sought patent protection for the same invention. We rely on this variable in Part III.


78 Allison et al., supra note 77.


80 Importantly, our use of the number of claims at filing is not a proxy for private value per se. The private value literature considers the number of claims at issuance, and restriction requirements by examiners to divide an application’s claims into separate applications are particularly common in the fields of biotechnology and pharmaceuticals. As a result, the number of claims at filing may not reflect private value because such a number may differ from the number of claims at issuance. Yet the number of claims at filing do reflect an applicant’s expectation, at the time of filing, of future private value in the patent—and so it is a reasonable proxy for applicant effort expended in producing a more detailed, higher-quality application. See Abrams & Wagner, supra note 79, at 551 (including the total number of claims in the empirical analysis, expecting “a higher-quality patent to be more detailed, and thus have more claims”).

C. Legal Validity

A third body of work examines the extent to which particular patent, examiner, or examination characteristics correlate with a subsequent finding of legal validity. For purposes of what the Patent and Trademark Office aims to do, the legal validity question is probably the most important. The validity metric is limited, however, by the very significant selection bias involved in cases that are litigated to a final validity determination by the Federal Circuit. The patent-level characteristics that predict whether the small subset of patents litigated all the way to the Federal Circuit will be found valid or invalid may not necessarily predict outcomes with respect to the much larger pool of issued patents.82

Bearing this caveat in mind, it is nonetheless worth noting that one variable that is positively correlated with a finding of validity is applicant-submitted prior art references.83 Indeed, the importance of applicant-submitted prior art references has been sufficiently recognized that some scholars have thoroughly analyzed applicant behavior across different technology disciplines. The evidence indicates that applications in certain technology areas benefit from much more applicant-supplied prior art than applications in other areas. For example, in a sample of patents issued between January 1, 2001 and December 31, 2003, examiners accounted for all citations in 45% of patents in the computers/communications and electrical/electronic fields. In contrast, only 25% of drug and medical patents, and 30% of chemical patents contained examiner-only citations.84

D. Examiner Characteristics

An emerging body of literature examines the interaction between examiner characteristics and patent quality. Like the role of technology, the

82 That said, there is no reason to believe that the factors that predict validity or invalidity in the subset of patents that reaches the Federal Circuit are strongly correlated with the factors that determine review by the Federal Circuit in the first instance. Mann & Underweiser, supra note 67, at 22–23.
84 Alcacer et al., supra note 74, at 420. The technological field effects were robust to nationality, assignee size, and other factors. Id. For further detailed analysis of prior art supplied by applicants at the time of filing, see generally Bhaven N. Sampat, When Do Applicants Search for Prior Art?, 53 J.L. & ECON. 399 (2010).
role of examiners in patent quality is complex. This is perhaps unsurprising as the defining feature of USPTO examiners is the baseline requirement of training in a science or engineering discipline, so that many aspects of examiner behavior may be technology-specific. Indeed, as we discuss further in Part III, such variation appears to be a key factor in our results.

Beyond subject-matter, however, institutional incentives also result in considerable variation in examiner behavior, variation that has important implications for patent quality. For example, experience level could affect quality, and the correlation might be either positive, because veteran examiners deliver more well-informed review, or negative, because beginning examiners pay greater attention to details than veterans. Experience also affects time allocated to examiners. Under a time allocation grid that has not been significantly revised since 1976, examiners at higher GS-levels within a given art unit are allocated substantially less time to review applications than examiners at lower GS-levels. Time pressure could exacerbate any “burn out” felt by veterans.

Analysis at the individual examiner level is possible because, within an art unit, applications appear to be randomly assigned. One complication, however, is the reality that multiple examiners within an art unit typically work on an application. Primary examiners who have authority to issue actions in their own name supervise and sign off on the work of assistant examiners. Supervisory patent examiners oversee the work of

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85 Examiners in the mechanical engineering field, for example, must be proficient in core subjects including differential and integral calculus, statics and dynamics, fluids mechanics and hydraulics, thermodynamics, electrical fields and circuits, properties and strengths of materials, and optics. See USAJOBS, Job Announcement No. CP-2014-0034 (Mar. 21, 2014), available at www.usajobs.gov/GetJob/ViewDetails/365088500.

86 See generally Cockburn et al., supra note 75.


88 MPEP § 707.01.
entire art units in order to create more uniformity in examiner performance.

Despite this complication, some scholars have looked at individual examiner characteristics. In one study that attributed patent examination to the assistant examiner when there was one and to the primary examiner if there was no assistant examiner, Professors Mark Lemley and Bhaven Sampat found that years of examiner experience at the USPTO at the time of patent examination correlated inversely with number of prior art references added and positively with grant rate. More recently, Professors Michael Frakes and Melissa Wasserman, studying individual examiners as they moved up the GS-level ranks, and finding a similar effect in terms of examiner effort, have argued that it emerges from unduly stringent time constraints placed by the USPTO’s production quota system on higher-level examiners.

III. BIOINFORMATICS AT THE USPTO

This Part applies the quantitative patent quality literature discussed in Part II to an early cohort of patent applications from AU 1631 and a comparison group, AU 2123. We use the patent quality measures identified above to evaluate applications coming into AU 1631 and AU 2123 and to isolate the effects of the examination process on these applications.


90 The effectiveness of these and related efforts at uniformity is the subject of ongoing discussion and improvement. See, e.g., U.S. DEPARTMENT OF COMMERCE OFFICE OF THE INSPECTOR GENERAL, Memorandum for Director David J. Kappos on the USPTO Patent Quality Assurance Process Report No. OIG-11-006-I (Nov. 5, 2010), available at www.oig.doc.gov/OIGPublications/OIG-11-006-I.pdf (summarizing recommendations for improving the agency’s examination quality assurance standards). Notably, although the input of several different examiners into patent examination is a challenge for studies that rely on the individual examiner as the unit of analysis, it poses less of a challenge for our study, which takes the art unit as the unit of analysis.


92 Frakes & Wasserman, supra note 26, at 3–5.
A. TECHNOLOGY AND COMPARISON GROUP

In general, AU 1631 broadly covers inventions combining biology with computer implementation. The unit encompasses algorithms that predict gene function and protein folding and the application of *in silico* screening assays for identifying drug candidates. 93

To understand more precisely what the USPTO does and does not regard as bioinformatics technology, and why AU 2123 is a reasonable comparison group, it is helpful to compare two classification systems that the USPTO employs. One is the United States Patent Classification (USPC) system describing the technological fields to which inventions pertain. 94 The other is the USPTO Technology Center system describing the organizational division of art units that are responsible for patent examination. 95 When the USPTO receives a patent application, the Office of Patent Classification both categorizes it as to the technology class or classes that the claimed invention best represents and assigns it to the art unit best suited to examine it. 96 Not surprisingly, there is a close concordance between the USPC and the USPTO art unit hierarchy. 97 By this concordance, bioinformatics inventions examined in AU 1631 are classified into

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93 The unit excludes biomedical imaging and organ simulation of organ functioning.
94 The USPC is not the only technology classification system maintained by the USPTO: the International Patent Classification (IPC) system has long been in use as well, and the Cooperative Patent Classification (CPC) system is the most recent initiative for a harmonized taxonomy among the major patent systems. See U.S. PATENT & TRADEMARK OFFICE, OFFICE OF PATENT CLASSIFICATION, available at www.uspto.gov/patents/resources/classification/.
96 U.K. INTELLECTUAL PROPERTY OFFICE & U.S. PATENT & TRADEMARK OFFICE, PATENT BACKLOGS, INVENTORIES AND PENDENCY: AN INTERNATIONAL FRAMEWORK 18 (2013), available at www.ipo.gov.uk/ipresearch-uspatlog-201306.pdf (noting that applications received by the patent office first undergo pre-examination formalities such as docketing and allocation according to relevant technology classification systems).
subsets of U.S. patent class 703 pertaining to data processing.\textsuperscript{98} Traditional software informatics inventions examined in AU 2123 are classified similarly.\textsuperscript{99} The two art units do not overlap in the subclasses they cover. Between them, the art units cover class 703, as Table 1 summarizes.


Table 1. U.S. Patent Classes and Subclasses Mapped to AUs 1631, 2123

<table>
<thead>
<tr>
<th>Subclass</th>
<th>Title</th>
<th>AU 1631</th>
<th>AU 2123</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Structural Design</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>2</td>
<td>Modeling by Mathematical Expression</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>3</td>
<td>Electrical Analog Simulator</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>4</td>
<td>Of Electrical Device or System</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>5</td>
<td>Of Physical Phenomenon (e.g., Heat, Wave, Geophysics)</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>6</td>
<td>Simulating Nonelectrical Device or System</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>7</td>
<td>Mechanical</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>8</td>
<td>Vehicle</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>9</td>
<td>Fluid</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>10</td>
<td>Well or Reservoir</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>11</td>
<td>Biological or Biochemical</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>12</td>
<td>Chemical</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>13</td>
<td>Simulating Electronic Device or Electrical System</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>14</td>
<td>Circuit Simulation</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>15</td>
<td>Including Logic</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>16</td>
<td>Event-Driven</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>17</td>
<td>Event-Driven</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>18</td>
<td>Power System</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>19</td>
<td>Timing</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>20</td>
<td>Target Device</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>21</td>
<td>Computer or Peripheral Device</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>22</td>
<td>Software Program (i.e., Performance Prediction)</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>23</td>
<td>Emulation</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>24</td>
<td>Of Peripheral Device</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>25</td>
<td>I/O Adapter (e.g., Port, Controller)</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>26</td>
<td>Of Instruction</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>27</td>
<td>Compatibility Emulation</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>28</td>
<td>In-Circuit Emulator (I.E., ICE)</td>
<td></td>
<td>×</td>
</tr>
</tbody>
</table>

Discussions with USPTO staff familiar with bioinformatics examination confirmed that AU 2123 is a closely complementary art unit to AU 1631. USPTO staff noted, for example, that examiners in the two art units
sometimes share cases.\textsuperscript{100} In addition, because the technology in each of the art units has been assigned the same class by the USPTO, an examiner at a given GS-level in AU 1631 is given the same amount of time to re-view an application as an examiner at the same GS-level in AU 2123.

However, though the technology in the applications allocated to the two art units is comparable, applications received in the two art units may not necessarily have been comparable. As noted in Part II’s discussion of quality, drugs, medicine, and chemistry all represent areas where applicants have historically supplied significantly more prior art than in electronics and communications. Whether or not bioinformatics applications resembled drugs, medicine, and chemistry in this respect was a proposition we tested.

In addition, we tested for differences in patent examination based on examiner characteristics at the level of the art unit. On average, patent examiners in the two art units differ in several ways that may be meaningful. Given AU 1631’s biological sub-focus within informatics, examiners in that art unit are primarily trained in a biological science with additional relevant expertise in computer science, rather than primarily trained in computer science as AU 2123 examiners are.\textsuperscript{101} USPTO staff also indicated that AU 1631 has more examiners who hold advanced degrees than do AU 2123 examiners: approximately 55–60% with Ph.D. degrees and up to 90% have master’s degrees.\textsuperscript{102}

In this regard, personnel data obtained through FOIA requests generously provided to us by Professor Ronald Mann showed differences in the personnel in the respective art units. Specifically, the 13 examiners in AU 1631 in calendar year 2003 had a median GS-level of 13 and had been at the USPTO for a median of 4 years. The 16 examiners in AU 2123 had a median GS-level of 11.5 and had been at the USPTO for a median 2 years.

Finally, for reasons introduced in Part I.C and discussed further below, the particular legal details of examination may have been quite technology-specific. This was true not only because of practical differences in the

\textsuperscript{100} Interview with AU 1631 Supervisory Patent Examiner Marjorie Moran and former Technology Center 1600 Director George Elliott (Oct. 19, 2013) (notes on file with author Arti K. Rai).

\textsuperscript{101} Id.

\textsuperscript{102} Id.
definition of a PHOSITA\textsuperscript{103} and the relative unpredictability of the art but also because of mechanisms by which PTO guidelines and Federal Circuit case law, particularly in 2003, may have applied differentially to bioinformatics and “ordinary” software.\textsuperscript{104}

In all, we were interested both in potentially divergent characteristics of applications as they entered the two art units, and divergent treatment that awaited them there. As to the latter question, even assuming comparable inputs, the literature led us to have several hypotheses about differential examination.

B. HYPOTHESES ABOUT EXAMINATION

First, we expected significant differences in treatment under the written description requirement of 35 U.S.C. § 112(a). Not long after the creation of AU 1631, the USPTO in early 2001 finalized its Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, “Written Description” Requirement.\textsuperscript{105} Although the guidelines did not, on their face, apply only to biotechnology, the relevant Federal Circuit case law at the time as well as examples all came from biotechnology.\textsuperscript{106} Thus we expected more stringent application of the written description requirement to applications assigned to AU 1631. We further hypothesized that this stringent application would spill into the “software” aspects of the invention, with the result that applications would sometimes be rejected for failing to fully describe relevant algorithms and data.

Notably, we expected stricter application of the written description requirement even though the literature on examiner characteristics discussed in Part II might lead us to believe that the higher GS-level examiners in AU 1631 would be less likely to administer a thorough examination. Our prediction was that higher education levels and clear expectations that

\textsuperscript{103} See supra notes 42–46.

\textsuperscript{104} In re Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970) (explaining that the scope of acceptable instruction in the patent varies inversely with the level of scientific or technological unpredictability that is involved). See also supra notes 43–44 and accompanying text (discussing divergent standards of sufficiency as to patentability based on the unpredictability of the field).

\textsuperscript{105} 66 FED. REG. 1099 (Jan. 5, 2001) [“Written Description Guidelines”].

written description should apply strictly to applications involving biotechnology would counteract any effects arising from examiner GS-level. We also predicted that examiners would find it difficult to confine written description rejections to the strictly biological aspects of applications. Rather, requirements for structure would “spill over” into the applications’ informational aspects.

Second, we wanted to examine any differences in other aspects of the patent law—specifically, definiteness, double patenting, and restriction requirements—that police notice. Here we did not have a specific hypothesis but were motivated by the persistent criticism that software patents fail in their notice function.

Third, we expected examination in AU 1631 to more strictly apply the utility requirement of 35 U.S.C. § 101. At the same time it issued its Written Description Guidelines, the USPTO issued its Utility Examination Guidelines. Again, although these guidelines were nominally agnostic as to technology, they were written with biotechnology in mind. Thus we expected more stringent application of the utility requirement to applications that claimed biotechnology-related inventions. Again, our prediction was that higher education levels and clear expectations of how to examine applications touching on biotechnology would counteract any GS-level effects.

Fourth, we expected differences in treatment under both the enablement requirement of § 112(a) and the nonobviousness requirement of 35 U.S.C. § 103. With respect to enablement, we predicted that the greater unpredictability of biotechnological arts and the impact of such unpredictability on what a person of ordinary skill in the art would consider enabled would lead to a higher rejection rate. Again, our prediction was that higher education levels and clear expectations of how to examine applications touching on biotechnology would counteract any GS-level effects.

As for nonobviousness, we expected that the strict (pre-KSR) teaching, suggestion, motivation requirement to combine prior art then in force would lead to a lower nonobviousness rejection rate for interdisciplinary fields like bioinformatics. This effect would arise on top of any lower nonobviousness rejection rate caused by unpredictability in the field. In

this case, GS-level effects might be a third factor leading to lower rates of nonobviousness rejection.

C. RESULTS: APPLICATIONS

To test our hypotheses and describe more fully the contours of USPTO bioinformatics examination early in its history, we reviewed by hand the prosecution histories of patent examinations that were filed between January 1 and December 31, 2003, and were assigned to AU 1631 or AU 2123. These examination records are publicly available from the USPTO Patent Application Information Retrieval (PAIR) system\(^\text{108}\) as well as in bulk through Google\(^\text{109}\) and, more recently, Reed Technology and Information Services.\(^\text{110}\)

We chose calendar year 2003 because it represented the first year for which full prosecution history data on all applications were available on PAIR. Additionally, by 2003, AU 1631 had become reasonably well established. At the same time, the application of software to biology was not yet considered entirely routine. Thus, for example, in 2003, bioinformatician Lincoln Stein famously gave bioinformatics “ten years to live.” He predicted that although informatics would continue to expand and be used, it would, within ten years, be absorbed into biology.\(^\text{111}\)

For each prosecution, we collected information on patent application characteristics that the literature suggests bear on one or more of the following: scientific importance, private value, and legal validity. Specifically, we collected information on: number of inventors (scientific importance), numbers of claims, family size, and application and/or grant in the EPO and JPO (private value) and applicant-cited prior art, including NPL (legal validity).

\(^{108}\) U.S. PATENT & TRADEMARK OFFICE, PUBLIC PAIR, available at portal.uspto.gov/pair/PublicPair.


In total, we gathered data on 565 prosecution histories, 393 from AU 1631 and 172 from AU 2123. Figures 1–6 and Table 2 illustrate the variation in these measures among applications in both art units. Virtually all the differences are highly statistically significant at the mean, as Table 2 shows.

Table 2. Two-Tailed Comparison of Means for Application and Examination Process Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (AU 1631)</th>
<th>Mean (AU 2123)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inventors ***</td>
<td>3.36</td>
<td>2.31</td>
</tr>
<tr>
<td>Claims ***</td>
<td>38.41</td>
<td>26.15</td>
</tr>
<tr>
<td>Applicant Cited Prior Art ***</td>
<td>30.17</td>
<td>8.72</td>
</tr>
<tr>
<td>Applicant Cited NPL ***</td>
<td>20.97</td>
<td>4.41</td>
</tr>
<tr>
<td>Applied in EPO ***</td>
<td>0.48</td>
<td>0.26</td>
</tr>
<tr>
<td>Granted in EPO *</td>
<td>0.12</td>
<td>0.06</td>
</tr>
<tr>
<td>Applied in JPO</td>
<td>0.35</td>
<td>0.30</td>
</tr>
<tr>
<td>Granted in JPO *</td>
<td>0.09</td>
<td>0.17</td>
</tr>
<tr>
<td>Family Size ***</td>
<td>3.05</td>
<td>2.26</td>
</tr>
</tbody>
</table>

* p < 0.05  ** p < 0.01  *** p < 0.001
Figure 1 shows that, at filing, bioinformatics applications in AU 1631 claim co-invented inventions to a higher degree than software informatics applications in AU 2123 claim. For AU 1631, the modal number of inventors is 2 and the distribution is more left-skewed, so that significant proportions of applications have several co-inventors each. By contrast for AU 2123, the modal number of inventors is 1 and the distribution is more right-skewed, so that nearly all applications have 4 co-inventors or fewer. As the number of co-inventors is positively correlated with forward citations and with technological importance generally, the distributions in Figure 1 suggest that bioinformatics applications with their greater co-inventorship are, to that extent, of higher quality than software informatics applications.

Figure 1. Number of Inventors at Filing

![Graph showing the number of inventors for AU 1631 and AU 2123](image)

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112 See supra note 70 and accompanying text.
Figure 2 shows that, at filing, bioinformatics applications in AU 1631 contain more claims than do software informatics applications in AU 2123. For AU 1631, the modal number of claims at filing is 30 and the distribution is more left-skewed, so that significant proportions of applications have scores of claims. By contrast for AU 2123, the modal number of claims at filing is 20 and the distribution is more right-skewed, so that nearly all applications have 50 claims or fewer at filing. This is significant because the USPTO’s standard filing fees allow up to 20 claims, with fees for additional claims. Thus, the revealed preference of applicants in bioinformatics is regularly to seek (and pay for) more claims than are allowed by default. As a greater number of claims is positively correlated not only with the private value of the application to the applicant but also with a greater degree of socially valuable effort expended in crafting and prosecuting the application, the distributions in Figure 2 suggest that bioinformatics applications with their higher numbers of claims are, to that extent, of higher quality than software informatics applications.

Figure 2. Number of Claims at Filing

113 See supra notes 78–79 and accompanying text.
Figure 3 shows that, at filing, bioinformatics applications in AU 1631 contain more applicant-cited prior art references than do software informatics applications in AU 2123. In both cohorts, the modal number of such references is 10 or fewer, but the distribution for AU 1631 is more left-skewed, so that significant proportions of applications have dozens of applicant-cited prior art references at filing. By contrast for AU 2123, the distribution is more right-skewed, so that nearly all applications have 40 applicant-cited prior art references or fewer at filing. As a greater number of applicant-cited prior art references is positively correlated both with greater private value to the applicant and to a greater socially valuable likelihood of legal validity, the distributions in Figure 3 suggest that bioinformatics applications with their much higher numbers of applicant-cited prior art at filing are, to that extent, of higher quality than software informatics applications.

Figure 3. Number of Applicant-Cited Prior Art References at Filing

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114 See supra note 78 and accompanying text.
115 See supra note 83 and accompanying text.
Similarly to Figure 3, Figure 4 shows that, at filing, bioinformatics applications in AU 1631 contain more applicant-cited non-patent prior art references than do software informatics applications in AU 2123. As in Figure 3, in both cohorts, the modal number of such references is 10 or fewer, but the distribution for AU 1631 is more left-skewed, so that significant proportions of applications have dozens of applicant-cited non-patent prior art references at filing. Also as in Figure 3, for AU 2123, the distribution is more right-skewed, so that nearly all applications have 20 applicant-cited non-patent prior art references or fewer at filing. This is significant because patent prior art alone cannot adequately assure a complete review of the state of the art, particularly in software-related industries where much invention goes unpatented. Accordingly, a greater number of applicant-cited non-patent prior art references reinforces the correlation with a greater socially valuable likelihood of legal validity, and the distributions in Figure 4 suggest that bioinformatics applications with their much higher numbers of applicant-cited non-patent prior art at filing are, to that extent, of higher quality than software informatics applications.

Figure 4. Number of Applicant-Cited Non-Patent References at Filing

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116 See supra note 83 and accompanying text.
Figure 5 shows that bioinformatics applications in AU 1631 belong to multi-patent families to only a slightly higher degree than do software informatics applications in AU 2123. In both cohorts, the modal family size is 1 (the U.S. application itself), and both distributions are roughly the same. Related to Figure 5, Figure 6 shows that bioinformatics applications in AU 1631 are concurrently filed in the European Patent Office and are granted in both the EPO and the Japan Patent Office to a greater extent than are software informatics applications in AU 2123. Because patent family size is understood in the literature to reflect only private patent value (with inconclusive evidence about its connection with validity and other indicia of social value), the like distributions in Figure 5 and the comparisons in Figure 6 suggest that bioinformatics applications are at least of comparable quality to software informatics applications. Although the higher grant rate of co-filed bioinformatics applications in the EPO and JPO might invite conclusions about greater quality, we decline to draw that inference because differences in substantive patentability criteria among the USPTO, the EPO, and the JPO likely introduce selection biases that our measures do not disentangle.

Figure 5. Family Size

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117 Mann & Underweiser, supra note 67, at 19
Thus, notwithstanding the fact that both sets of applications involved software used for modeling and simulation, applications in AU 1631 were more scientifically important (number of inventors), privately valuable (numbers of claims, family size, and application and/or grant in the EPO and JPO), and likely to be legally valid (applicant cited prior art, including NPL) than applications in AU 2123.

D. RESULTS: EXAMINATION

Although the disparity in application characteristics was not unexpected, it did indicate to us that we needed to create a new data set for purposes of testing examination results. Specifically, we decided to create a subset that consisted of a matched sample of applications in the two art units. We matched along the criteria of scientific importance, private value, and legal validity listed in Table 2. This matched sample consisted of
61 applications in each art unit. The relatively small size of this matched sample may cause certain examination disparities between the samples to fail to reach statistical significance. Thus to the extent we discuss only disparities that have statistical significance, we probably underestimate disparities.

With respect to the substance of examination, we collected information on the statutory grounds for rejections, the source of the prior art that the examiner cited in support of such rejections, and the examiner’s imposition of a restriction requirement, if any, through the first round of examination. 118 Figures 7 and 8 illustrate our findings.

**Figure 7: Grounds for Rejection During Prosecution**

![Pie Chart](chart.png)

118 A restriction requirement is an enforcement by the examiner of the single-invention rule and consists of a finding by an examiner that a patent application claims “two or more independent and distinct inventions,” so that the applicant must restrict the application to one of them. 35 U.S.C. § 121. The applicant may then claim each remaining invention in a divisional application that otherwise satisfies the criteria for patentability. *See generally* 37 C.F.R. § 1.142; MPEP Ch. 0800.
E. DISCUSSION

1. The Coarse Filter

Bioinformatics applications in AU 1631 received rejections for subject matter ineligibility under § 101 at approximately the same rate (36.87%) as did software applications in AU 2123 (42.62%). Given that bioinformatics and other informatics bear a general taxonomic similarity and differ only in their technological details, it is notable that the requirements of subject matter eligibility could not “tell them apart.” This finding reinforces the view that subject matter eligibility is a rather coarse filter for evaluating inventions. Indeed, this view appears in the case law, the literature, and even legal guidance that the USPTO has issued in response to the Supreme Court’s interpretation of § 101. As for novelty,

119 See supra Figure 7 (finding no statistically significant difference at the 95% confidence interval).
120 See supra Part III.A.
121 E.g., Research Corp. Techs., Inc. v. Microsoft Corp., 627 F.3d 859, 869 (Fed. Cir. 2010) (referring to § 101 as “the coarse eligibility filter”).
122 E.g., Michael W. Carroll, One for All: The Problem of Uniformity Cost in Intellectual Property Law, 55 AM. U. L. REV. 845, 892–93 (observing that “use of standards along the subject matter dimension permits only coarse-grained exercise of interpretive discretion because an adjudicator can choose only between applying all or no rights to a particular innovation or class of innovations”).
the difference between rejections received for applications in AU 1631 (49.18%) and AU 2123 (55.74%) was also not statistically significant.\textsuperscript{124}

For a more fine-grained comparison, we turn to various patentability requirements under § 112 and § 103.

2. Written Description: Impacts on Notice

Supporting our first hypothesis, bioinformatics applications in AU 1631 received rejections for inadequate written description under § 112 to a much greater extent (21.3%), more than threefold, than did software applications in AU 2123 (6.56%).\textsuperscript{125} Moreover, as we predicted, use of written description was not limited to the biological aspects of the invention. To the contrary, a check of the first 15 written description rejections in AU 1631 for which we coded showed that 13 of the 15 rejections involved examiner arguments that the applicants had failed to describe adequately either an algorithm or relevant data.\textsuperscript{126}

As previously discussed, adequate written description requires disclosure of structure commensurate with the scope of what is claimed.\textsuperscript{127} As a result, it may somewhat limit scope, perhaps unduly. The written description requirement’s chief virtue is its promotion of boundary notice. In turn, certainty about patent boundaries offers a number of benefits including the ability to assess the value of patent rights for transaction and commercialization,\textsuperscript{128} to “distinguish the invention or discovery from other

\textsuperscript{124} Id. (finding no statistically significant difference at the 95% confidence interval).
\textsuperscript{125} See supra Figure 7.
\textsuperscript{126} The written description rejections we examined arose in application numbers 10/204849, 10/304496, 10/309152, 10/309391, 10/332999, 10/345905, 10/350341, 10352246, 10/359439, 10/360747, 10/360796, 10/363727, 10/432932, 10/430685, and 10/378866. Of these, only two (10/304496 and 10/359439) applied written description to the biological aspect of the invention.
\textsuperscript{127} See supra note 24 and accompanying text.
\textsuperscript{128} See generally Craig Allen Nard, Certainty, Fence Building, and the Useful Arts, 74 IND. L.J. 759 (1999). In advocating for opposition proceedings to test closely the validity of patents and provide early certainty, Professor Nard argues that such clarity with “facilitate greater accuracy in private valuation because, as the prior art picture becomes more complete during prosecution, the more informed the parties will be with respect to the boundaries.” Id. at 765–66. Such arguments regarding the value, certainty, and clear delineability of patent rights did ultimately drive the creation of USPTO post-grant review proceedings under the AIA. See Pub. L. No. 112-29 § 6.
things before known and used”\(^{129}\) in determining freedom to operate, and, most simply, to avoid infringement of a competitor’s patents and coexist in the market.\(^{130}\)

Taken in historical context, this finding as to bioinformatics inventions in AU 1631 and more conventional informatics inventions in AU 2123 suggests that the structural specificity that already existed for biological and biochemical inventions invited more robust examiner scrutiny of the relatively unstructured software elements of applications in AU 1631. The alternative inference—that applications on conventional software informatics inventions in AU 2123 received fewer written description rejections because they were already better described under § 112—is inconsistent with the widely accepted view, discussed in Part I.C, that conventional software patents pose substantial challenges for notice. Moreover, as we discuss further in Part IV, current patent notice reform efforts aimed at improving the correspondence between functional claiming and corresponding structure also focus heavily on software.\(^{131}\)

3. Other Indicia of Notice

Three other measures in our results—definiteness, double patenting, and restriction—shed further light on the extent to which examination of bioinformatics and software informatics applications enhanced notice. The definiteness requirement promotes boundary notice by requiring that patent claim terms clearly delineate \textit{ex ante} the metes and bounds of an invention as claimed in the patent.\(^{132}\) The double patenting rule furthers this goal by exerting downward pressure on the sheer quantity of rights that a market actor must navigate and clear, particularly because the existence of duplicative patent rights injures the public’s expectation that the

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\(^{131}\) \textit{See infra} Part IV.

Expiration of a patent on an invention will leave that invention free for public use.133 This rule recognizes that even if individual patent rights were perfectly clear *ex ante* (an assumption that is far from realistic), the discovery costs of identifying relevant rights134 are also a function of scale. Put another way, if the capacity to search effectively does not survive increasing size and complexity in the set of all patent rights, then search bottlenecks may still cause notice failures.135

Unlike definiteness and double patenting, which clearly promote notice, the single invention rule has more complex effects. On the one hand, it furthers notice by mitigating the complexity of patent rights in somewhat the same way that the definiteness requirement seeks to do. Whereas definiteness offers clarity in evaluating claims within a patent, restriction offers clarity in evaluating inventions within a patent. Examiners commonly impose restriction requirements in pharmaceutical- and biotechnology-related applications because it is common for applications in those fields to claim numerous related chemical compounds or processes that turn out to be patentably distinct.136

That said, there is evidence that divisional applications occur not only among the least valuable patents, where applicant ignorance might be the cause, but also among the most valuable patents, suggesting that sophisticated applicants sometimes draft claims calculated to provoke restriction by the examiner.137 This evidence may mean that applicants who draft claims calculated to provoke restriction sometimes intend to produce strategic delay in examination, and that this practice is particularly common in

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133 *Longi*, 759 F.2d at 892–93 (explaining that “[t]he public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also [obvious] modifications or variants”).


biotechnology. If so, the net effect of restriction may be to pose additional challenges for public notice in creating market uncertainty about whether sunk investments may become encumbered by later-issued patent rights. In any case, the paradox of the restriction requirement’s notice benefit is that, by carving up multi-invention applications into patentably distinct sets of rights, the single invention rule actually increases the total set of rights to be searched and cleared, but it does so by reducing the patent-to-invention relationship to a simple one-to-one correspondence.

With respect to all three rejection grounds, applications in AU 1631 received more rejections. First, with respect to indefiniteness, applications in AU 1631 received more rejections (62.30%) than did applications in AU 2123 (40.98%). Second, with respect to the double-patenting rule, applications in AU 1631 received more than twice as many rejections (13.11%) than did applications in AU 2123 (4.92%). Although this second result did not rise to statistical significance, lack of significance is probably a consequence of small sample size. Third, with respect to the single invention requirement of § 121 to manage the complexity of patent rights by limiting each patent to one invention, applications in AU 1631 received an order of magnitude more rejections (70.49%) than did applications in AU 2123 (6.56%).

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139 Id. at 72–73 (discussing the relationship between examination delay and market uncertainty). Professors Lemley and Moore argue further that 18-month publication of pending applications after the 1999 AIPA may not meaningfully have improved transparency about pending applications, as publication is required only for applications that will also be filed abroad, where 18-month publication is the norm, meaning that U.S. publication reveals only what would have become publicly available regardless. Id. at 88–89.
140 Supra notes 134–135 and accompanying text.
141 Notably, the professed purpose of restriction practice is usually administrative convenience in patent examination. E.g., Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc., 98 F.3d 1563, 1568–69 (Fed. Cir. 1996). The extent to which restriction practice actually strikes an efficient balance in patent notice is an open empirical question.
142 See supra Figure 7.
143 See supra Figure 7.
144 See supra note 118.
145 See supra Figure 7.
Unlike with written description, we had no a priori reason to believe that these other notice requirements would be applied with greater vigor in AU 1631. Thus the inference to draw from our results is somewhat less clear. However, assuming that the matched set of applications coming into the two art units had roughly similar attributes with respect to notice (an assumption that seems likely except that applications in AU 1631 may have been likely to have more problems with respect to multiple inventions in the same patent), the inference would be that examiners in AU 1631, while more time-constrained on average than examiners in AU 2123, nonetheless policed notice more vigilantly. Utility

Supporting our third hypothesis, bioinformatics applications in AU 1631 received rejections for inadequate utility under § 101 much more frequently (8.2%) than the traditional software informatics applications in AU 2123 (0%). This finding is consonant with the aims of the Utility Guidelines that the USPTO issued in 2001, to provide a more specific assertion by the applicant of the utility of the claimed invention.

To satisfy the utility requirement, the patent specification must disclose some substantial utility from which the public may receive some specific benefit. This requirement may have particular force for biotechnology inventions because the unpredictable nature of biological and chemical arts increases the likelihood that a field of invention may offer a variety of unforeseen benefits, and the public interest favors leaving those benefits free for later discovery and development rather than granting rights over them to an inventor who has not yet actualized those benefits. Starting in 1995, the USPTO had begun requiring a showing by the applicant that an invention has a specific utility that would be credible to one of ordinary skill in the art or else has a generally well-established utility. Adopting Brenner, the USPTO in 1999 proposed to raise the

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146 See supra Figure 7.
147 66 FED. REG. 1092.
149 See id. at 534 (explaining that patents on inventions whose utility is not sufficiently described “may engross a vast, unknown, and perhaps unknowable area” to the detriment of the public interest).
150 60 FED. REG. 36263 (July 14, 1995) (‘‘1995 Utility Guidelines’’).
standard so that credible utility alone was no longer enough, and the 2001 Utility Guidelines did so with a requirement for a specific, substantial, and credible utility. Thus, given the greater potential for unforeseen utility in biotechnology-related inventions, applications in AU 1631 should, indeed, receive rejections for inadequate utility at a higher rate than applications in AU 2123.

4. Enablement and Nonobviousness

The results did not support our hypothesis that bioinformatics applications in AU 1631 would receive significantly more rejections for inadequate enablement under § 112(a) than would traditional software informatics applications in AU 2123. Arguably, the most notable feature of the enablement results was the low frequency of these rejections across both art units. This low frequency is consistent with the view that enablement rejections are complex, fact- and prior art-intensive inquiries that time- and resource-constrained examiners are unlikely to favor.

Consistent with our hypothesis, applications in AU 2123 did receive significantly more rejections for obviousness (78.69%) than did applications in AU 1631 (39.34%). Moreover, both sets of applications received rejections for obviousness at a level inverse to the level at which they received rejections for inadequate enablement. Applications in AU 1631 received more than twice as many obviousness rejections (39.34%) as enablement rejections (16.39%). Applications in AU 2123 received nearly seven times as many obviousness rejections (78.69%) as enablement rejections (11.48%). Indeed, this is to be expected given the conceptual symmetry between nonobviousness and enablement. Nonobviousness requires that a given invention represent a sufficiently large inventive leap from the current state of knowledge, whereas enablement requires that the

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152 2001 Utility Guidelines, 66 Fed. Reg. at 1098–99. The current practice redefines the formerly separate “well established utility” standard in the same terms of a “specific, substantial, and credible utility that must be readily apparent to one skilled in the art.” Id. at 1097.

153 See supra Figure 7.

154 Id.
applicant’s disclosure sufficiently bridges that inventive leap so that others may follow. As a result, the applicant who downplays the scope of the prior art in order to trumpet the inventive quality of an invention for non-obviousness purposes has that much less prior art to rely on later when demonstrating that the application provides sufficiently enabling disclosure. Conversely, the applicant who makes much of the prior art in order to demonstrate that a disclosure would enable one of ordinary skill thereby also expands the body of knowledge that her own invention must overcome to be regarded as nonobvious.

In general, across all 393 AU 1631 prosecution histories that we analyzed, examiners conducted prior art searches in both biology and software in the majority of cases. However, given that bioinformatics was still an emerging interdisciplinary field as of 2003, and given that the relevant pre-KSR law that was in force at the time required a very specific teaching, suggestion, or motivation in the art in order to combine prior art references, examiners were apparently quite reluctant to combine life science and software prior art. This reluctance appeared even though the applications in question, which had an average of 3.36 inventors, presumably often included both inventors with biological skills and software skills.

In Part IV, we discuss further the normative question of how, in view of these empirical findings, patent applications on interdisciplinary, team-based inventions should be examined. We propose that the answer turns in part on when the interdisciplinarity of the field in question itself be-

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155 This is not to say, however, that the actual requirements for nonobviousness and enablement are identical in practice. As Jeffrey Lefstin has observed:

Most notably, the judicial standard for enablement, that the ordinary artisan ought to be able to make and use the invention without “undue experimentation,” invokes the effort required to produce the invention given the state of the art. In contrast, the statutory standard for nonobviousness under section 103 explicitly discourages inquiry into the inventive effort, declaring that “[p]atentability shall not be negatived by the manner in which the invention [would be] made.”


157 Id.
comes relatively routine. In the case of bioinformatics, this may have occurred before 2003. However, given the Federal Circuit’s pre-KSR demand of a written teaching, suggestion, or motivation requirement, examiners may have been reluctant to combine life science and software references.

IV. POLICY IMPLICATIONS

Given our relatively specific empirical focus on two art units, we tread carefully when it comes to normative implications for the patent system as a whole. However, our results do indicate that some combination of examiner training and advanced educational background can have an impact on patent quality, particularly with respect to notice. Thus, efforts to train examiners, particularly on the use of the written description requirement, and on mechanisms by which patent applicants can be forced to specify the meaning of potentially problematic claim terms, are likely to prove fruitful. Moreover, while the PTO is unlikely to attract significant numbers of individuals with advanced degrees in most art units, training examiners in basic principles of scientific peer review may prove useful as well.

Our inquiry also has implications for patent examination in an era of team-based, interdisciplinary science. As various empirical studies have now made clear, scientific knowledge production is increasingly team-based. In fact, team sizes have, at the mean, risen at a rate of 15–20% per decade, and this increase appears in nearly all subfields of research and invention. Patent applications have mirrored this shift. All areas of patenting have shown increases in team size over the past 25 years across all countries. By 2005, over 60% of patents had more than one inventor.

The recognition that knowledge production is increasingly team based has prompted some scholars to call for an explicit doctrinal shift away from the familiar legal reference point of a “person having ordinary skill

\[^{158}\text{See Menell \& Meurer, supra note 53.}\]
\[^{159}\text{Benjamin Jones, As Science Evolves, How Can Science Policy?, in 11 Innovation Policy and the Economy (Josh Lerner \& Scott Stern, eds., 2011).}\]
\[^{161}\text{Ma \& Lee, supra note 160, at 388.}\]
in the art” to a “team having ordinary skill in the art.” In a 2002 article, Joseph Meara proposed that in fields where advances are typically made in interdisciplinary teams, a “TOSITA” standard would be appropriate. Meara gave the example of implementing a Dutch auction on the Internet. In that example, a team consisting of a software engineer and a businessperson with MBA training would presumably have found the idea obvious, even though either individual alone might not have.

Although Meara’s TOSITA proposal was promulgated prior to the 2007 Supreme Court decision in *KSR v. Teleflex*, which eased the burden of combining prior art references to show obviousness, the principles of that proposal apply with even greater force after *KSR*. In a 2011 article advocating an “inducement based” standard for nonobviousness (under which patents would be granted only on those inventions that “would not be disclosed or devised but for the inducement of a patent”), Michael Abramowicz and John Duffy endorsed making the inducement determination at the level of the inventive team.

We build upon this earlier work, but propose a slightly different approach. In our view, a team-based approach should be used when a field has become *routinely* interdisciplinary. This is because the very act of creating a team may be innovative when it brings two previously disparate fields together into a new combinatorial space. Moreover, although (for the reasons we have discussed at length) a patent grant may not always be a sign of true invention, at least some of these patents were presumably granted at a time when the interdisciplinarity in question was quite nascent.

Recent empirical work has begun to quantify this combinatorial process of invention. Notably, a new study of U.S. patent and technology classification records from 1790 to 2010 demonstrates that patenting over that time has been characterized not only (or even primarily) by the creation of new technological capabilities but by the increasingly complex

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combination of existing technological building blocks. Because the USPTO assigns relevant USPC classifications to each patent, a patent’s classes identify the distinct technologies that the inventor combined to produce the invention—and the combination of classes that are reflected in a patent identifies the particular interdisciplinarity at work in that instance of inventive activity. Historically, the rate at which new inventions have introduced new technological capabilities, representing new technological classes, has slowed considerably. Yet surprisingly, the rate at which new combinations of technological classes have emerged has systematically kept pace with the number of new patents.

These results suggest that whereas some inventions represent new combinations of technological capabilities, other inventions represent merely existing combinations of technological capabilities to improve and refine current knowledge. The former shows emerging interdisciplinarity; the latter, routine investigation within an increasingly well-defined field. Empirically, the split between these two phenomena is roughly 60-40, i.e., for each new patent, there is a 60% likelihood that the invention augurs a new technological combination and only a 40% likelihood that it relies on an existing technological combination. Thus, interdisciplinarity is, and historically has been, the prevailing mode of innovation.

To be sure, our proposed doctrinal inquiry of routine interdisciplinarity may sometimes prove difficult to implement. Beyond the ordinary line-drawing problems that inform all such taxonomic determinations, there is the added temporal difficulty of determining when previously unrelated disciplines should be regarded as solidly linked.

In the particular case of bioinformatics, we proceed with the benefit of a historical record. The systematic collection and analysis of biological sequence data has commanded the collaborative efforts of “computer sci-

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165 See supra note 94 and accompanying text.
166 Youn et al., supra note 164, at *3–4.
167 Id. at *4.
168 Id.
169 Id.
entists, statisticians, and biologists” for over four decades,170 and the term “bioinformatics” itself dates from 1970.171 The idea of a bioinformatician proper, however, is of more recent vintage, dating between the mid-1990s172 and the early 2000s.173 During this time, public accounts began referring to bioinformatics as its own field.174 Moreover, universities like the University of Michigan175 and the University of California San Diego176 began establishing training and degree programs in bioinformatics.177

For its part, the PTO kept squarely abreast of scientific change. The agency established its art unit in bioinformatics precisely as the fields of biology and software were becoming solidly linked. Indeed, as previously noted, by the year 2003 (the year that we studied), the role of computer science in biology was sufficiently well-established that Lincoln Stein predicted bioinformatics had only “ten years to live” as a field that could be considered interdisciplinary in the first instance. However, the shadow of the Federal Circuit’s requirement for combining prior art may have kept AU 1631 from fully assimilating team-based research norms and practices.

172 See Contreras, supra note 6 and accompanying text.
173 See Charles Vorndran & Robert L. Florence, Bioinformatics: Patenting the Bridge Between Information Technology and the Life Sciences, 42 IDEA 93, 126 (2002) (noting that “bioinformatics is a multidisciplinary field” and “that the field, itself, is fairly new, yet developing rapidly”).
174 E.g., Brad Stone, Wanted: Hot Industry Seeks Supergeeks; To Build Better Drugs, the Exploding Field of Bioinformatics is Looking for Highly Trained Workers Comfortable with Supercomputing and Biology, NEWSWEEK 54, 55 (Apr. 30, 2001).
175 UNIVERSITY OF MICHIGAN, DEPARTMENT OF COMPUTATIONAL MEDICINE & BIOINFOMATICS, available at www.ccmb.med.umich.edu/graduate-program (dating the first class to 2001).
177 Stone, supra note 174 (additionally relating that, as of 2001, schools including UC Davis, UC Berkeley, and Cornell University had established bioinformatics programs or were planning to do so).
CONCLUSION

The history of bioinformatics examination that this Article has traced offers important lessons for the empirical literature on patent quality as a function of human capital and institutional design. We have shown that patent applications in bioinformatics generally received more stringent examiner scrutiny and more rejections, particularly on notice-related grounds, than did applications in conventional software informatics. Bioinformatics examiners paid significant attention to notice not only in the biological aspects of the inventions that they examined but also in the inventions’ strictly informational aspects. Our results suggest that institutional investment in human capital at the level of the art unit can, and did, make a difference.

Our results did not hold, however, for application of the nonobviousness requirement before the KSR decision. KSR may therefore have been a particularly important precedent for proper evaluation of interdisciplinary and team-based science.

Our Article also offers the first empirical account of patent quality at the juxtaposition of two fields generally believed to be wholly opposed with respect to patent quality, particularly boundary notice. At the stage of incoming application, we found significant evidence that bioinformatics applications were “better” than conventional informatics applications.

Finally, our results invite further study of invention conducted in collaborative environments and that draws on expertise in a variety of disciplines, as bioinformatics does. A richer empirical account of these inventive activities would do much to align the U.S. patent system with the modern realities of team-based innovation.