Northwestern Journal of Technology and Intellectual Property

Volume 6	Article 2
Issue 1 Fall	

Fall 2007

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Recommended Citation

Richard M. Lebovitz, *The Duty to Disclose Patent Rights*, 6 Nw. J. TECH. & INTELL. PROP. 36 (2007). https://scholarlycommons.law.northwestern.edu/njtip/vol6/iss1/2

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N O R T H W E S T E R N JOURNAL OF TECHNOLOGY AND INTELLECTUAL PROPERTY

The Duty to Disclose Patent Rights

Richard M. Lebovitz



Fall 2007

VOL. 6, NO. 1

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The Duty to Disclose Patent Rights

By Richard M. Lebovitz*

I. INTRODUCTION

Scientific research publications do not, as a rule, disclose the existence of patent rights associated with the subject matter of the publication. Disclosure of patents and patent applications is typically required only when they constitute a competing financial interest that could bias authors in reporting their results and compromise their objectivity.¹ However, there are other reasons to require patent disclosure in scientific literature.

Scientific journal publications are one of the key channels through which scientists communicate and exchange information with each other. The purpose of disseminating knowledge among scientists is to stimulate further research and discovery, as well as to promote practical applications of their work. In furtherance of this goal, the scientific literature is generally considered to belong to the public domain, available to any scientist to read, implement, or improve upon. The concept of scientific literature as a public resource is challenged when the technology it describes is the subject of a patent application.² The publication literally puts the technology into the public's possession, but the fact that a patent application has been filed manifests a clear intent to control its use. When such restriction is not openly disclosed to the public, the publication contains a potentially deceptive message about the availability of the technology. A patent application that is not disclosed in a scientific report, but later discovered by the public, may give the author the appearance of impropriety, even if no financial conflict exists. Thus, the failure to disclose patent rights can harm the integrity of the individual scientist, as well as the public image of the scientific community as a whole.

A new duty to disclose patent rights is proposed here that would require the listing of all pertinent patents and patent applications in scientific publications. Full disclosure promotes candor and truth telling, encouraging scientists to reveal all facts that could possibly have relevance to the objectivity of their work and the public image of the scientific community. Finally, notice of patent rights also informs potential users of the technology that the authors intend to patent certain aspects of it, which may later restrict its use.

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¹ Philip Campbell, *Declaration of Financial Interests*, 412 NATURE 751 (2001). For information for authors listing patents and patents applications as an interest which might be a source of bias, see SCIENCE, Conflict-of-Interest Disclosure, http://www.sciencemag.org/about/authors/prep/coi.dtl (last visited Nov. 17, 2007).

² Rebecca S. Eisenberg & Richard R. Nelson, *Public vs. Proprietary Science: A Fruitful Tension?*, 77 ACAD. MED. 1392 (2002).

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Because many journals already require the disclosure of patent rights when they constitute a competing financial interest with the subject matter of the publication, we determined the extent to which patent rights are disclosed in the scientific literature and how effective the existing rules are in encouraging patent disclosure.³ Other studies have examined whether authors disclose patents as financial interests, but did not suggest an absolute ethical duty to disclose patent rights in the absence of competing financial interests.⁴

II. METHODS

Research articles were surveyed from two leading journals, *Nature* and *Science*. Only research articles related to biomedical research were selected.⁵ Both journals had conflict-of-interest disclosure requirements.⁶ *Nature* specifically identified patent applications as a potential conflict, but *Science* did not (although the policy has subsequently changed).⁷

All author names were searched in a freely available patent database maintained by the European Patent Office for applications that related to the research described in the article.⁸ The patent database contains published worldwide patents and patent applications, including published European, United States, and Patent Cooperation Treaty (PCT) applications.⁹ Since it can take as long as 18 months from the time of filing for a patent application to be published, the analysis was performed retrospectively on research articles which had been in the public domain for at least 30 months (selected from the period of January 2002-June 2002) to account for any errors or delays in the patent publication. United States applications have been published since March 15, 2001 (for those filed after November 29, 2000);¹⁰ so if an application was only filed in the United States, it should have been detected by the search methods utilized here, unless the applicant specifically requested non-publication.¹¹

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³ Scientific journals may require authors to declare competing financial interests that could bias an author's judgment and objectivity in reporting his results. Personal interest in patents and patent applications is considered a competing financial interest because its value may be affected by publication.

⁴ Sheldon Krimsky et al., *Financial Interests of Authors in Scientific Journals: A Pilot Study of 14 Publications*, 2 SCI. ENGINEERING ETHICS 395 (1996); see also S. Mayer, *Declaration of Patent Applications as Financial Interests: A Survey of Practice Among Authors of Papers on Molecular Biology in Nature*, 32 J. MED. ETHICS 658 (2006).

⁵ Publications relating to ecology, evolution, neuropsychology, and psychology were not considered in this analysis. However, all other biomedical and biological science-related publications were considered, including publications related to bioengineering.

⁶ See http://www.nature.com/authors/editorial_policies/competing.html for NATURE (last visited Oct. 26, 2007) and http://sciencemag.org/feature/contribinfo/prep/coi.dtl for SCIENCE conflict-of-interest disclosures (last visited Oct. 26, 2007).

⁷ Since 2004, SCIENCE has asked authors specifically about patents in their conflict-of-interest policy (personal communication from SCIENCE editorial staff).

⁸ *Esp@cenet* Portal, http://www.espacenet.com (last visited Oct. 26, 2007).

⁹ See Patent Cooperation Treaty art. 8, 11, 62, June 19, 1970.

¹⁰ Patent Full-Text and Full-Page Image Databases, http://www.uspto.gov/patft/index.html (last visited Oct. 26, 2007).

¹¹ In the United States, a patent applicant can request non-publication of her application to preserve its secrecy only if such request is made on the day the application is filed and if no other corresponding application has or will be filed in another country. 37 C.F.R. § 1.213 (2000).

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17 Patent applications having claims to the main experimental subject matter described in the publication were scored as positive. The results are listed in Table 1. In all of these cases, working examples, figures, and data from the publication could be clearly identified in the corresponding patent application. Patent applications which described materials or technology that would be needed to conduct the research described in the article were also identified in the searches. These are referred to as "enabling technologies" because they are not the direct subject of the article, but are necessary to carry out the experiments described in the article.¹² This category is listed in Table 1. A material or technology was only counted as an enabling technology if there was at least one author of the journal article in common with the inventors listed on the patent or patent application.

III. RESULTS AND DISCUSSION

The results of this study are summarized in Table 1. Almost one-third (32.7 percent) of the biomedical research articles surveyed in this study were associated with underlying patent applications. Of all the applications, 17.9 percent directly covered the research disclosed in the scientific publication, and 11.7 percent were related to an enabling technology that was utilized in conducting the research. In 3.1 percent of the cases, the authors filed for patent protection, but only after the publication had been published. Despite the high number of patent applications associated with journal articles, disclosure was very low; 87.5 percent of patent rights were not disclosed to the public. In another study, Mayer found two-thirds of the publications surveyed did not disclose patent applications or company affiliations.¹³

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Of the publications, 17.9 percent contained subject matter that was a direct topic of the application. This number is comparable to the 22 percent value identified earlier by Krimsky et al., whose data was collected from 1992, 10 years before this study period.¹⁴ While there was not a considerable difference (about 18 percent versus 22 percent) in publications associated with patent application filings from the previous decade, this current study was not designed to evaluate this issue, and the sampling methods differed between the two studies.

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Of the scientific publications, 11.7 percent did not disclose patent applications that related to an enabling technology, a category not identified by Krimsky. This category is defined as technology that was not the primary subject of the publication, but which was necessary to perform the research reported in it and for which a patent application was filed by at least one co-author of the journal article. For example, several publications described experiments in which genes or transgenic animals were utilized that were themselves the subject of undisclosed patents or patent applications filed previously by at least one coauthor of the publication. If these experiments established a significant new utility for the patented or patent pending application, the publication would increase the

¹² Examples of enabling technology included proteins, genes, transgenic animals, purification procedures, and compounds which were used in the research article.

¹³ Mayer, *supra* note 4, at 658.

¹⁴ Krimsky, *supra* note 4, at 395. Krimsky examined university authors from Massachusetts institutions who appeared in 14 scientific and medical journals. In contrast, this study compiled data from two journals during a specific period of time, without consideration of the authors' affiliations or geographic locations.

value of the previously filed patent, creating a clear financial conflict of interest. It does not appear that journal policies have adequately addressed this type of financial conflict.

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With about one-third of the articles associated with patent rights, these results show the close intertwining of private intellectual property interests with published scientific literature. The high frequency of this intertwining is not unexpected. In the United States, federal policy under the Bayh-Dole Act of 1980 has encouraged academic institutions to commercialize discoveries made with federal funds.¹⁵ Patents are a strong component of the commercialization process. They enable the patent owner to restrict competitors from copying patented products, to carve a niche in the marketplace, and to use the patent as a source of revenue through patent licensing. In 2004, there were two academic institutions in the top 15 holders of U.S. deoxyribonucleic acid patents.¹⁶

	SCIENCE		NATURE		TOTAL	
	Number	Percent	Number	Percent	Number	Percent
Total number of publications	81		81		162	
1. Patent application discloses research in article	14	17.3	15	18.5	29	17.9
2. Patent applications on related and earlier technology ("enabling technology")	9	11.1	10	12.3	19	11.7
Total of patent applications related to research article and filed prior to publication	23	28.4	25	30.9	48	29.6
3. Patent applications filed <i>after</i> publication	2	2.5	3	3.7	5	3.1
Total of all application categories	25	30.9	28	34.6	53	32.7
Application is disclosed in article	1	4.3 (1/23)	5	20.0 (5/25)	6	12.5
Patent non-disclosure	22		20		42	87.5
At least one author in the research group is listed as an inventor of a patent or patent application	62	76.5	67	82.7	129	79.6

TABLE 1.

In addition to the findings about patent stakes in the particular articles reviewed, a search was conducted of all article authors to determine whether they were listed as an inventor of any patent or patent application. For the purpose of this analysis, all the authors of a single article are referred to as a "research group." The results presented here show a high proportion (79.6 percent) of research groups (Table 1) with at least one member who also files patent applications, suggest the success of the Bayh-Dole Act in promoting commercialization of government-funded research.¹⁷

¹⁵ 35 U.S.C. § 200 (2000).

¹⁶ David Malakoff, *NIH Roils Academe with Advice on Licensing DNA Patents*, SCIENCE., Mar. 19, 2004, at 1757 (identifying the University of California and The Johns Hopkins University).

¹⁷ Presently, there is no universal rule in the European Community (EC) about patent ownership,

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- ¶13 Although a high number of scientists pursue patent protection for their scientific work, this is not transparent to the scientific community in the journals in which they publish. In *Science*, for the period of time surveyed, where patent applications were not expressly described as a potential conflict-of-interest, no authors disclosed that their publication was the subject of a patent application. On the other hand, in *Nature*, where patent applications were listed as a possible financial conflict of interest, some authors did disclose their patent filing, but the number was low, with only 20 percent (5 of 25) disclosing the existence of a filed patent application. In total from both journals, only 12.5 percent of patent rights were disclosed to the public.
- This low frequency leads to several conclusions. First, scientists do not perceive the existence of patent rights as requiring disclosure. Secondly, patents are not considered by scientists as a per se financial conflict of interest. Thus, financial disclosure rules are insufficient to ensure complete patent disclosure in the scientific literature.
- The rare disclosure of a patent application when there is no perceived financial interest indicates that scientists, on their own, do not recognize any duty to disclose patent rights to the public. This fact is not surprising. The three major patent systems in the United States, Europe, and Japan each have a period during which patent applications are kept secret. Europe and Japan publish patent applications 18 months after filing, giving patent applicants a limited period during which their application is shielded from discovery. The U.S. adopted this pre-grant publication period in 2000, but before this time, applications were kept secret until the patent was granted by the Patent Office. Consequently, the patent system does not encourage disclosure of applications, but protects their secrecy.

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Despite the patent's system strong commitment to a limited period of secrecy, should this secrecy be protected when patent applications are the subject of a scientific publication? Conflict-of-interest rules utilized by at least some scientific journals require that the secrecy be waived when there is a financial conflict of interest. The results of this study indicate that these rules elicit disclosure of only 20 percent of journal publications associated with patent rights.

A. Should There Be a Duty to Disclose Patent Applications, apart from Competing Financial Interest Rules?

¶17 The juxtaposition of patents and scientific literature creates an inherent conflict between the public nature of scientific literature and the proprietary rights of patents. Patents are primarily for the purpose of controlling the use of a technology, while the function of scientific literature is to fully disclose the technology and make it freely available to the public. When a patent is granted, the patented subject matter cannot be practiced freely without a license from the patent owner. In contrast, the unfettered practice of a technology described in a journal publication is important for others to validate and build on the scientific work. Thus, the act of patenting and publishing

http://europa.eu.int/comm/research/era/pdf/iprmanagementguidelines-report.pdf.

although several European countries have adopted intellectual property provisions that mirror the Bayh-Dole Act, and it has been suggested that the EC as a whole enact similar legislation. *See* EC, *Management of Intellectual Property in Publicly-Funded Search Organizations: Towards European Guidelines* (Expert group report, Working Paper EUR 20915 EN, 2004), *available at*

creates a conflict of purpose. As explained in more detail below, when the conflict of purpose is not disclosed, there are harmful consequences to the scientific process and community.

B. Harm to Integrity

The failure to disclose the existence of patent rights in a journal publication can give the appearance of impropriety when the rights later become discovered. In a journal that requires disclosure of competing financial interests, it can raise suspicion that there is a financial interest at stake and that the author intentionally decided not to disclose it. The author may have determined that the value of the patent rights would be unaffected by publication, and therefore, did not constitute a competing financial interest. However, while this determination may be perfectly valid at the time, it may not be perceived so by the public. This is detrimental to not only the scientist's reputation, but it could also suggest to the public that the work is tainted or biased, when it is not.

Moreover, even when there is no actual competing financial interest necessitating disclosure of a patent application, non-disclosure — when it becomes known to the public — can lead to public mistrust of the scientific community. The Canavan dispute is a good example of this. In 1997, a patients' advocacy group for Canavan disease discovered that scientists, with whom they had been cooperating by providing patient samples, had filed and obtained a patent on the disease gene and a diagnostic test for it, although at no time — either to the patient group or in journal articles reporting the gene's discovery — had this been disclosed.¹⁸ A lawsuit was brought on behalf of children afflicted with the disease in which it was alleged that the scientists intentionally concealed their plan to patent the disease gene in order to reap all financial benefit for themselves.¹⁹ The case eventually settled, but not without acrimony between the scientific community and patient advocacy groups.²⁰ With publicity of this kind, scientists as a community have had to contend with mistrust and lack of confidence in the scientific community.

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A failure to disclose patent rights can also reflect a scientist's desire to distance himself from commercial applications for fear that either he or the work will be taken less seriously. This is disingenuous. Scientific research furthers our understanding of the world and how it works, but also, when translated into commercial products, has the potential to transform and improve lives. Viewing science as either a quest for knowledge for knowledge's sake or a commercial endeavor aimed at making money, is a false dichotomy when a single discovery can satisfy both aims. The Bayh-Dole Act recognizes this duality — encouraging commercialization of the applied aspects of the research, while the scientists continue to pursue their independent research goals.

¹⁸ Rajinder Kaul et al., *Cloning of the Human Aspartoacylase cDNA and a Common Missense Mutation in Canavan Disease*, 5 NATURE GENETICS 118 (1993); U.S. Patent No. 5,679,635 (filed Sept. 9, 1994).

¹⁹ Greenburg v. Miami Children's Hosp. Res. Inst., Inc., 264 F.Supp.2d 1064 (S.D.Fla. 2003).

²⁰ Canavan Foundation, Gene Patent Lawsuit May Radically Affect Research,

http://www.canavanfoundation.org/news/09-03_miami.php (last visited Nov. 28, 2007).

C. Harm to Objectivity

¶21 Even when patent rights have no personal financial value that would require their declaration in a journal article, they may still compromise the perceived or true objectivity of the publication, one of the driving forces behind the conflict-of-interest guidelines.²¹ Companies that sponsor research may review employee and grantee manuscripts prior to editorial submission and publication to cleanse them of statements that could be construed as inconsistent with a patent position or that could adversely affect future patent filings. For example, the author may be a salaried employee and not consider himself to have any financial interest in the patent application, but in "clearing" the publication with the company's patent counsel, the counsel may insist on substantive changes that he believes would impact the company's patent position. In such cases, the publication content may not be a neutral reflection of the data, but may be shaped by considerations outside the scope of its scientific purpose.

D. Harm to Data Sharing

This conflict of purpose between patenting and publishing in the scientific literature has serious consequences for data sharing in the scientific community. Patents have been characterized as a means to protect the commercial potential of scientific discoveries while continuing to disseminate the results of the research.²² However, patents — by requiring a license to practice the patented subject matter — have the potential to block the use of materials utilized in the research findings, hampering the goal of data and material sharing.

There has been continued emphasis on procedures ensuring that information is shared among scientists. After publication, scientific journals may require that data and research materials be shared upon request. *Nature* requires as a condition of publication that authors "make materials, data and associated protocols available . . . to readers promptly on request."²³ Deoxyribonucleic acid sequencing projects have given the same attention to public access to gene sequencing information. In guidelines published by the first International Strategy Meeting on Human Genome Sequencing, participants issued a statement that "all genomic sequence information should be 'freely available and in the public domain in order to encourage research and development and to maximize its benefit to society."²⁴

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United States funding agencies have also placed an emphasis on making research results freely accessible to the public. Beginning May 2, 2005, the National Institutes of Health (NIH) has requested that NIH-funded investigators provide electronic copies of final manuscripts to the NIH Library of Medicine for archiving purposes. This policy is

²¹ See Krimsky, supra note 4, at 397; Frank Davidoff et al., Sponsorship, Authorship, and Accountability, 345 New Eng. J. Med. 825, 826-27 (2001).

²² Committee on the Conduct of Science, National Academy of Sciences of the U.S.A., *On Being a Scientist*, 86 PROC. NAT'L ACAD. SCI. 9053 (1989), *available at*

http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=2594750. ²³ See Nature, Availability of Data and Materials,

http://www.nature.com/authors/editorial_policies/availability.html (last visited Nov. 30, 2007).

²⁴ David R. Bentley, *Genomic Sequence Information Should Be Released Immediately and Freely in the Public Domain*, SCIENCE, Oct. 25, 1996, at 533 (quoting from The Bermuda Statement, 7 Human Genome News 19 (1996)).

to ensure that research results and accomplishments of NIH-funded investigators are freely "available to the research community and public at large."²⁵

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Because patent rights can undermine these data-sharing goals, scientists should have an independent duty to put the public on notice that the content of a published article is associated with patent rights that have the potential to restrict the free sharing of materials.

E. Misrepresentation

¶26 When a new technology is described in a scientific journal, its authors will often boast about it, describing its advantages over pre-existing technology. One evident reason for these statements may be self-serving, to convince the reviewers and readers that the technology is good and merited publication. But a scientific publication that describes the advantages of a new technology may intentionally be doing more than merely exercising its deserved bragging rights; it may be persuading other scientists to use the technology in their own research programs. For academia, this is within the intended purpose of scientific publications: to trade ideas and discoveries freely with other scientists in order to advance knowledge. But, when the scientists and their institutions have filed patent applications on the technology, the intent becomes less clear. Once a patent application matures into a granted patent, the owners of it have the right to exclude all others from using the patented technology. The scientific publication assumes a dual purpose: to disseminate information, but also to promote the technology to potential licensees. Not putting the public on notice that the technology is the subject of patent rights risks misrepresenting the inventors' intent to control the practice of the invention and potentially elicits reliance on the fact that it is free to use, when it may not remain so.

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With almost 80 percent of the journal articles having at least one author who has filed a patent application, it is clear that the scientific community is familiar with the patent system. Consequently, although there is a potential for a party to detrimentally rely on the free availability of a technology in a published journal article, when it may not remain so, it can be assumed that most parties are aware that a published technology may also be pending patent. Nonetheless, because patent applications are published 18 months after filing, there is at least an 18-month gap before even the most diligent party can determine the existence of a patent application. This leaves a period of time where the technology is apparently in the public domain, but with no "user beware" sign to warn of inchoate patent rights.

F. Inadequacy of Financial Conflict Rule

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Disclosure of financial conflict-of-interest is an obvious necessity to avoid bias and compromising objectivity when conducting scientific research. It is a mistake to leave it to the authors to decide for themselves whether the patent or patent application is a financial interest that requires disclosure. First, an unintentionally wrong decision defeats the purpose of the rule: a financial interest that could bias the author's published

²⁵ Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html (last visited Oct. 26, 2007).

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results is left unreported. Secondly, there are no clear rules on when a patent right is a competing financial interest. For example, is an unlicensed patent application, which is filed on the same day that a manuscript is submitted to a journal, a financial conflict of interest when the author is an employee of a major pharmaceutical company who owns none of the company stock? Is the situation different if the author is an academic who, through university patent policy, receives 50 percent of the licensing income from the patent application? These ambiguities leave a loophole in the rule, opening the door for rule-bending. An author who may want to keep the application secret can use the imprecision built into the rule to justify non-disclosure.

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Disclosure rules need to go deeper than the typical financial conflict of interest rules to ensure that scientific research is conducted in an atmosphere of full disclosure. Patent rights should not be excluded from this realm of openness. A patent right is a finger of the private sector in the public information cookie jar, and the scientist has the social duty to let the public know. Science and technology have important societal ramifications — for example, in genetic engineering, cloning, stem cell technology, and new drug development. Full disclosure allows the public to police the scientific community and engage in meaningful dialogues about the relationship between science, commerce, and ethics.

G. Is the Public Harm Significant Enough to Sacrifice the Secrecy Period?

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A pertinent consideration in adopting a universal disclosure rule is whether there is any harm to patent owners. The patent system gives inventors a period of exclusivity in which to use their inventions in return for publicly disclosing how to make and use the invention.²⁶ This encourages inventors to share their results with the public rather than keeping them a trade secret. The exclusivity period has two forms. First, once a patent is granted on an invention, the owners have a period in which they can exclude others from practicing the invention. Thus, although the inventor is required to fully describe how to make and use his invention to the public, the fact is that it cannot be practiced without a license to the patent. Second, the application has a period in which its content and Europe and Japan have long published applications existence is kept secret. automatically 18 months after the filing date. The United States has only recently adopted this practice. The 18-month pre-grant publication rule gives inventors a limited period in which to keep all details of the application in confidence, avoiding tipping off competitors and giving inventors a leading edge. However, once the application is published, the veil is lifted. Requiring scientists to disclose the existence of a patent in a publication clearly could impact the length of the limited period during which the application is kept secret.

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Intellectual property rights are not harmed by disclosure of the existence of a patent application in the first publication of the technology. Once a patent application has been filed, the inventors have secured their patent rights as of the day of filing and subsequent disclosure, even of the entire application content, does not injure these inchoate rights. The requirement that a patent application be disclosed to the public has the potential to infringe upon the 18-month publication rule that gives inventors a limited period of secrecy during which they can develop and exploit their invention without the

²⁶ 35 U.S.C. §§ 112, 154 (2000).

knowledge of competitors. However, by making their invention public in a scientific journal, the inventors have already surrendered this period of secret exclusivity.

Moreover, the application itself is confidential, so any information and technology not disclosed in the publication can be kept from public view. Unless complete transparency required authors to provide copies of the patent application, they would still retain control over its dissemination. Accordingly, a universal patent disclosure rule should not deter inventors from publishing their work.

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What does full disclosure require? The minimum is to inform the reader that a patent application has been filed on subject matter described in the publication, or the intent to do so.²⁷ This puts the reader on notice that the technology described in the article is not being placed in the public domain, but that certain rights are being reserved in it. In addition to knowing the existence of the application, a reader might also want to know details of the filing, such as application type and country of filing, the application contents, whether the technology is available for licensing, and even the technology licensing terms. However, if the point is to make the reader aware that intellectual property rights have been retained, then to satisfy this requirement it should only be necessary to tell the public that an application has been filed and to provide a point of contact where further inquiries can be made. Contact information seems reasonable to facilitate further inquiry about the application status.

 $^{^{27}}$ In most countries, except the U.S., a prior publication by the inventors is a bar to patentability. 35 U.S.C. § 102(a) (2000). To protect worldwide patent rights, a patent application is generally filed before publication. However, in circumstances where the authors publish prior to filing, they should disclose their intent to file a patent application.