

## **JOHN P. WALSH**

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John received his BA in Sociology from the University of Cincinnati, his MA in Sociology from Northwestern University and his PhD in Sociology from Northwestern University in the United States. His research focuses on the sociology of technical change. He has written extensively on the uses and effects of the Internet on scientific work. His current research is on the relations between patenting and innovation in the United States and Japan, with a particular focus on the biotech-related industries and on university-industry relations. This work is funded by the National Science Foundation and the National Academy of Sciences' Board on Science, Technology and Economic Policy.

John is co-author of the following forthcoming publications: "R&D Spillovers, Appropriability and Patenting: A Comparative Study of the Japanese and United States Manufacturing Sectors" Research Policy; "Links and Impacts: Survey Results on the Influence of Public Research on Industrial R&D" Management Science; "Computer Network Use, Collaboration Structures and Productivity." In P. Hinds & S. Kiesler, eds. Distributed Work. Cambridge, MA: MIT Press; and "Public Research, Patents and Implications for Industrial R&D in the Drug, Biotechnology, Semiconductor and Computer Industries." In Government-Industry Partnerships in Biotechnology and Information Technologies: New Needs and New Opportunities. Washington, DC: NAS Press.

## **THE PATENTING OF RESEARCH TOOLS AND BIOMEDICAL INNOVATION**

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Over the last two decades changes in technology and policy have altered the landscape of drug discovery. These changes have led to concerns that the patent system may be creating difficulties for those trying to do research in biomedical fields. Based on interviews and archival data, we examine the changes in patenting in recent years and how these have affected innovation in pharmaceuticals and related biotech industries.

We find that there has in fact been an increase in patents on the inputs to drug discover (“research tools”). However, we find drug discovery has not been substantially impeded by these changes. There is some evidence of delays associated with negotiating access to patented research tools, and there are areas where patents over targets limit access. There are also cases where research is redirected to areas with more IP freedom. However, the vast majority of respondents say that there are no cases where valuable research projects were stopped due to IP problems.

We do not observe as much breakdown as one might expect because firms have been able to develop “working solutions” that allows their research to proceed. These working solutions combine taking licenses, inventing around patents, infringement (often informally invoking a research exemption), developing and using public databases and challenging patents in court. In addition, changes in the institutional environment, particularly new PTO guidelines and some shift in the courts' views toward research tool patents, appear to have further reduced the threat of breakdown. Finally, the very high technological opportunity in this industry means that firms have a surplus of potential targets for drug development, so that the walling off of some by patent holders, while shifting the focus, does not prevent firms from discovering drugs.

We conclude with a discussion of the potential social welfare effects of these changes in the industry and the adoption of these working solutions for dealing with a complex patent landscape. While there are social costs associated with these changes, there are also important benefits. Overall, we are optimistic about the industry's ability to accommodate the increased complexity of intellectual property.