2008-1352

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

TRIANTAFYLLOS TAFAS,
Plaintiff-Appellee,

and

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline), SMITHKLINE BEECHAM PLC, and GLAXO GROUP LIMITED (doing business as GlaxoSmithKline),
Plaintiffs-Appellees,

v.

JON DUDAS, Undersecretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and UNITED STATES PATENT AND TRADEMARK OFFICE,
Defendants-Appellants.

Appeal from the United States District Court for the Eastern District of Virginia in consolidated case nos. 1:07-CV-846 and 1:07-CV-1008, Senior Judge James C. Cacheris

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BRIEF OF *AMICUS CURIAE* MONSANTO COMPANY IN SUPPORT OF APPELLEES AND IN SUPPORT OF AFFIRMANCE

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October 3, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Tafas v. Dudas

No. 2008-1352

CERTIFICATE OF INTEREST

Counsel for the ~~(petitioner) (appellant) (respondent) (appellee)~~ (amicus) ~~(name of party)~~ Monsanto Company certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Monsanto Company

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Ronald A. Schechter, David R. Marsh, Matthew M. Shultz and Kristan L. Lansbery
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October 3, 2008
Date

Signature of counsel

Ronald A. Schechter
Printed name of counsel

Please Note: All questions must be answered

cc: _____

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INTEREST OF *AMICUS CURIAE*

Monsanto Company ("Monsanto") is a leading global provider of agricultural products. The seeds, biotechnology trait products, and herbicides that Monsanto researches, develops, and brings to market improve agricultural productivity, reduce farming costs, produce better animal feed, and produce better foods for consumers. Monsanto spends over $2 million per day in research and development to support and improve its businesses. Patents are a critical component of Monsanto's research and development activities and a significant factor in Monsanto's willingness to devote substantial resources to these activities.

The final rules at issue in this case will severely restrict the ability of patent applicants like Monsanto to claim the full scope of their inventions. 72 Fed. Reg. 46,716 (Aug. 21, 2007) ["Final Rules"]. For example, Final Rules 75 and 265, which limit applicants to five independent claims and twenty-five total claims unless the applicant files an "examination support document" ("ESD") [the "5/25 Rule"], will have irreparable adverse effects on important types of Monsanto inventions. The Final Rules, if allowed to go into effect, will result in the forfeiture of substantive patent rights, particularly for those inventions that are generated in an organized program of progressive research and development, such as that used by Monsanto.

SUMMARY OF ARGUMENT

The District Court correctly held that the Patent and Trademark Office ("PTO") does not have the statutory authority to issue the Final Rules because, as this Court affirmed in *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008), the PTO lacks the authority to issue substantive rules. For research-based companies like Monsanto, an egregious aspect of the Final Rules is the 5/25 Rule. If implemented, that Rule, alone and in combination with other provisions of the Final Rules, will deny Monsanto's statutory right to fully claim what it regards as its inventions. The Final Rules also compromise other statutory rights, including Monsanto's rights under 35 U.S.C. § 103(c) and, because the 5/25 Rule prejudicially interacts with limiting principles of patent law such as prosecution history estoppel and intervening rights, Monsanto's right to enforce its patents. Thus, the Final Rules are substantive rules—those that change existing law—that are beyond the PTO's rulemaking authority.

ARGUMENT

I. Introduction

Monsanto is a leading global provider of agricultural products. Monsanto's Seeds and Genomics segment produces leading seed brands, develops biotechnology seed traits that assist farmers in controlling insects and weeds, and provides other seed companies with genetic material and biotechnology traits for

their seed brands. Through its Agricultural Productivity segment, Monsanto manufactures herbicide products for the residential and commercial markets. Monsanto invests heavily in the development and implementation of chemical manufacturing processes for the production of herbicides, including its *Roundup*® brand herbicides.

Biological and chemical products such as these typically involve progressive stages of research, with intervals of months often passing between significant developments. Once the initial invention is made, a patent application claiming it is filed. Additional research, however, often leads to new data, improvements, modifications, and a better understanding of the invention or of its important properties and the principles on which it functions. New patent claims are necessary to protect improvements to the developing technology with a scope commensurate with the inventor's contribution to the art. This is particularly important with respect to biological or chemical inventions because, by their nature, they are subject to infinite variation within the scope of the inventive concept.

Early in the development process, it is difficult to determine the significance of certain descriptions of the invention or the importance of alternative ways of describing the same or similar inventions. At the time the initial application is filed, the inventor may not fully appreciate which specific combination of features

will form the product or process that ultimately will be brought to market, often many years later, or what regulatory hurdles will be faced in bringing the invention to the market. Moreover, during litigation, which may occur years after prosecution, the courts may interpret the claims differently from what the inventor intended, adding to the importance of presenting many alternative claims.

Each claim in a patent application defines inventive subject matter that differs from every other claim. All of the claims together define the subject matter to which the inventor is entitled. Applicants must present all patentable claims during original prosecution because claims cannot be added or amended in litigation, and adding or amending claims after the patent has issued is problematic and constricted by law. Accordingly, selection of which claims to present in prosecution determines the inventor's rights in the invention.

The key flaw in the 5/25 Rule is that it assumes that all inventions can be adequately claimed within that number of claims and disregards certain inventions that cannot be described so precisely and, therefore, improperly limits an inventor's ability to protect the full scope of the invention by preventing the inventor from submitting an appropriate combination of independent and dependent claims. With intricate inventions in a crowded field, the use of broad independent claims may be vulnerable to assertions that they are not novel, or that they are obvious from prior art. Narrower dependent claims—which are more

specific and contain more limitations—may avoid these issues, but are unlikely to cover all embodiments of an invention to which an inventor is entitled.

Applicants properly seek to address these concerns by submitting multiple independent (*i.e.*, broader) claims to provide breadth of coverage and multiple dependent (*i.e.*, narrower) claims to provide both depth of coverage and a graduated scope of protection. As development of an invention progresses, applicants need the ability to claim additional embodiments of the invention disclosed in the initial application, as well as improvements and new uses that are patentable over prior art. A properly structured series of claims is important to avoid gaps in patent coverage that would undermine the patent holder's legitimate interests (and investment). Such gaps may enable a competitor to appropriate the essence of the invention by designing around the claims without having invested in the original research, because subject matter disclosed in a patent application but not claimed is in the public domain. In a complex technology, such gaps likely are unavoidable if the claim structure of a single application is limited to twenty-five claims.

II. The District Court Correctly Held that the Final Rules Are Substantive Rules Beyond the PTO's Rulemaking Authority

The District Court correctly held that the PTO does not have the authority to issue the Final Rules, because the PTO's rulemaking authority is limited and does not extend to substantive rules. *Tafas v. Dudas*, 541 F. Supp. 805, 811-13 (E.D.

Va. 2008); *see also Cooper Techs.*, 536 F.3d at 1336; *Brand v. Miller*, 487 F.3d 862, 869 n.3 (Fed. Cir. 2007) (stating that "the Board does not earn *Chevron* deference on questions of substantive patent law"); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996); *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991). The Final Rules are substantive because, in the District Court's words, they "change existing law and alter the rights of applicants." *Tafas*, 541 F. Supp. at 814; *see Cooper Techs.*, 536 F.3d at 1336 ("A rule is 'substantive' when it 'effects a change in existing law or policy' which 'affect[s] individual rights and obligations.'") (quoting *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991)) (internal quotations omitted); *see also Chamber of Commerce v. United States Dep't of Labor*, 174 F.3d 206, 211-12 (D.C. Cir. 1999).

The Government's brief ignores the real issue with the Final Rules. The issue is not whether applicants have a right to file an unlimited number of continuations and RCEs or make as many claims as they want. The real, substantive harm of the Final Rules is that they will deny applicants their right to "claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112.

The Government characterizes the Final Rules as merely "regulat[ing] the timing and availability of procedural mechanisms" and "setting filing and documentation requirements," not governing "the substantive criteria that will be

applied in the proceedings." Appellants' Br. 14, 24. It claims that any infringement on applicants' substantive rights is merely incidental to the exercise of the PTO's rulemaking authority. *See id.* at 31-32, 37-38. Further, the Government repeatedly claims that the Final Rules do not place any real restrictions on applicants. However, an honest evaluation of the impact of the Final Rules shows that they will prevent applicants from obtaining patent protection for inventions that they would receive under the current patent laws and rules—precisely the type of "change in existing law" that this Court's *Cooper Technologies* decision held was beyond the PTO's limited rulemaking authority. The best way to see this effect is through a specific example although any number of complicated inventions that develop over time, with important details being determined over time, will suffer this same problem.

A. Monsanto's Oxidation Catalyst Technology

A catalyst is a substance that increases the rate of a chemical reaction without itself being consumed. While different catalyst structures often have similar compositions, they can have vastly different molecular mechanisms of action.[1] Catalysts are important during manufacture of many chemical products,

[1] For example, one mechanism that increases the rate of a chemical reaction involves bringing the reactants in closer proximity to each other by having them both bind to "active sites" of the catalyst.

such as methanol, ammonia, and sulfuric acid. Through its research, Monsanto looks for better and more economical ways to produce chemical products by developing new catalysts.

Monsanto has been conducting research to reduce the expense of producing an important herbicide for farmers. Production of the herbicide uses an oxidation catalyst comprising a composition on a carbon support. This is an expensive ongoing research project and, so far, there have been at least three generations of progressive inventive development.

Because describing the composition of a catalyst generally is not the best way of enabling others to practice the invention, the patent specification of a novel catalyst usually describes a method of its preparation and its physical properties. In fact, when a catalyst is first developed, many of its detailed characteristics remain unknown, and the exact composition of the active sites may defy precise analysis for a long period of time. Thus, from necessity, novel catalysts often are redefined over time based upon the identification of physical properties that are associated with the catalyst's performance. These physical properties relate to such complex subjects as specific surface area, sorption and desorption characteristics of the catalyst surface, solid-state phase relationships at active sites, physical microstructure of the catalyst, and electronic configuration of the catalyst. While there are many ways to assess a catalyst, in the early stages of development

it is difficult to know which properties are important or even the most effective way to define the catalyst's relevant properties.

An application claiming priority only to the first generation of Monsanto's oxidation catalyst technology is still pending.[2] It includes claims directed to catalysts comprising various transition metal and nitrogen compositions on a carbon support. Included are claims that define the transition metal composition as a cobalt nitride, cobalt carbide nitride, iron nitride, or iron carbide nitride.[3]

The second generation applications also claim a process that uses oxidation catalysts on carbon supports. But the oxidation catalyst is described in terms of various specific surface area parameters and combinations thereof that are also based on generally less expensive non-noble metals,[4] thereby enabling millions of dollars to be saved in making the herbicide.

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[2] U.S. Patent Application Publication No. 2006/0068988 (published Mar. 30, 2006). One first generation patent has issued, U.S. Patent No. 7,129,373 (issued Oct. 31, 2006) (the '373 patent), and another patent related to this catalyst technology also has issued, U.S. Patent No. 7,390,920 (issued Jun. 24, 2008) (the '920 patent).

[3] The '373 patent also includes claims to a catalyst comprising a noble metal deposited over a modified carbon support having a transition metal/nitrogen composition thereon. Noble metals are resistant to corrosion or oxidation. They include precious metals, such as gold, silver, tantalum, platinum, palladium, and rhodium.

[4] The first pending independent claim (Claim 302) recites a process for the oxidation of an organic substrate where the oxidation catalyst comprises "a carbon support having formed thereon a transition metal composition . . . wherein the total

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The third generation application[5] claims a novel method for preparing further improved catalysts, and contains multiple independent claims separately characterizing the improved catalyst in terms of physical properties different from the properties claimed in the second generation application.[6] The third generation claims more finely define the invention by including in the claims a list of preferred transition metals for the carbon support.[7]

These three generations of applications currently have pending at least 41 independent claims and 256 total claims. The total is relatively low because many of the pending independent claims have not yet been further detailed with a full

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Langmuir surface area of said catalyst is at least about 60% of the total Langmuir surface area of said carbon support prior to formation of said transition metal composition thereon." Amendment submitted August 19, 2008 in U.S. Patent Application No. 10/919,028 (the '028 application).

[5] U.S. Patent Application Publication No. 2006/0229466 (published Oct. 12, 2006)(the '466 publication).

[6] These include: (i) time of flight secondary ion mass spectrometry ("ToF SIMS"); (ii) particle size of the transition metal/nitrogen composition on the carbon support; (iii) x-ray photoelectron spectroscopy ("XPS"); and (iv) electron paramagnetic resonance ("EPR").

[7] The first independent claim of the '466 publication recites "a catalyst, wherein the catalyst comprises a carbon support having formed thereon a transition metal composition comprising a transition metal (M) and nitrogen, the transition metal being selected from the group consisting of copper, silver, vanadium, chromium, molybdenum, tungsten, manganese, cobalt, nickel, cerium, and combinations thereof, wherein the catalyst is characterized as generating ions corresponding to the formula $MN_xC_y^+$ when the catalyst is analyzed by ToF SIMS as described in Protocol A and the relative abundance of ions in which x is 1 is at least 20%."

series of appropriate dependent claims. To adequately cover this technology through the first three generations may ultimately require 500 to 1,000 claims. Because the 5/25 Rule was not in force when the patents issued, the first patent to issue in the family, the '373 patent, had a total of 106 claims pending in its application at one time; these were reduced to a total of 92 claims in the final patent. This strategy allows the '373 patent and the '920 patent to serve as early notice to competitors and would-be infringers of Monsanto's rights while additional claims are prosecuted in the PTO.

As explained below, Monsanto's strategy for patenting this catalyst technology would be foreclosed under the 5/25 Rule. Absent the limitations of the 5/25 Rule, Monsanto could fully protect its catalyst technology as it is currently doing. This change in existing law is the type of substantive regulation that the PTO is forbidden from implementing.

B. The Loss of Substantive Patent Rights Is Amplified by the Final Rules' Limits on Continuations Practice

The forfeiture of claims arising from the 5/25 Rule is amplified by the Final Rules' limit of no more than two continuation or CIP applications. Under the 5/25 Rule and current continuation practice, an applicant could, at least in theory, pursue all of its patentable claims by filing a series of twenty-five-claim continuation applications—albeit at exorbitant expense, after extended delay, and with significant loss of patent term. But under the Final Rule's limitations on

continuation practice, even this unattractive alternative is not available, because only two continuation or CIP applications are allowed.

Thus, the combination of these two rules limits an applicant to a maximum of fifteen independent and seventy-five total claims, in an original application and its two permitted continuation or CIP applications, and then only if there are no patentably indistinct claims in copending continuing applications. If there is even one patentably indistinct claim in a copending continuing application, all of the claims in that continuation or CIP application and in the original application must be within the 5/25 Rule. This combination of rules clearly represents a change in existing patent law or policy that affects an inventor's patent rights. As such, this combination of rules represents substantive rulemaking that is beyond the authority of the PTO.

The only way to get more than twenty-five claims examined at one time, other than filing an ESD, is to file a divisional application. Divisional applications can be filed in parallel with a continuation or CIP application, but can only contain claims that the PTO previously has found to be patentably distinct from all other claims in another application. Because under the Final Rules only the PTO can find the claims patentably distinct for purposes of a divisional application, divisional applications would be permitted only for claims previously presented in an initial application or one of the two continuation or CIP applications.

By limiting the divisional applications to previously presented claims, the 5/25 Rule limits the subject matter that can ever be presented to subject matter within the scope of only the patentably distinct claims filed in the original application and its two continuation or CIP applications. There is no way to have claims examined in a separate application, even if they are patentably distinct, without the PTO first confirming that they are patentably distinct. This hobbles the presentation of new claims directed to different aspects of an invention as continued research determines that such aspects are important to a commercial embodiment of the invention. Applicants are forced to guess which claims will be commercially relevant, patentably distinct, and patentable without the necessary feedback from the Patent Office, since only 25 claims can be presented at one time, rather than let the commercial embodiments or discovery of prior art guide the strategy over time.

If even one of any of a set of new claims is found patentably indistinct from even one copending claim, and twenty-five claims are already present among the pending applications, an applicant would have to cancel a pending claim to compensate for each claim added, or wait to file a continuing application until one of the copending applications is allowed or abandoned. Under the Final Rules, a divisional application is allowed two continuation applications, provided the claims remain within the same scope as the claims originally presented in the

divisional application. But any such divisional application and any continuation applications thereof would also be limited to five independent claims and twenty-five total claims among them such that the divisional application and its continuation applications will likely be prosecuted serially with consequent sacrifice in term.

The Government attempts to justify its restrictions on an applicant's right to file continuations to claim what he regards as his invention by relying on *In re Bogese II*, 303 F.3d 1362 (Fed. Cir. 2002). Appellants' Br. 44-47. But, *Bogese II* is not inconsistent with the District Court's finding that Final Rule 78 violates 35 U.S.C. § 120. *Tafas*, 541 F. Supp. 2d at 815. That decision merely extends the equitable doctrine of prosecution history laches found in *Symbol Technologies, Inc. v. Lemelson Medical., Education & Research Foundation*, 277 F.3d 1361 (Fed. Cir. 2002), to proceedings in the PTO. *Bogese II* applies established judicial precedent that allows a court to render unenforceable a patent that issued after unreasonable and unexplained delay. 303 F.3d at 1367, 1369. It does not authorize the PTO to promulgate new, substantive rules to deny all applicants, regardless of the reasonableness of their approach to prosecution and without any individualized review, the right freely to file more than two continuations.

The Government relies on the statement in *Bogese II*, 303 F.3d at 1368, that "[t]he PTO has inherent authority to govern procedure before the PTO, and that

authority allows it to set reasonable deadlines and requirements for the prosecution of applications" to justify Final Rule 78. Appellants' Br. 45-47. However, the scope of the PTO's rulemaking authority is a completely separate issue from the Court's specific holding that prosecution history laches, an equitable remedy, applies to proceedings before the PTO. Equitable remedies by their nature require case-by-case consideration and balancing of all relevant facts and circumstances. *See Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1387, 1385 (Fed. Cir. 2005) ("[T]there are no strict time limitations for determining whether continued refiling of patent applications is a legitimate utilization of statutory provisions or an abuse of those provisions. The matter is to be decided as a matter of equity, subject to the discretion of a district court before which the issue is raised. . . . The doctrine [of prosecution laches] should be applied only in egregious cases of misuse of the statutory patent system."); *see also A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1032 (Fed. Cir. 1992) ("With its origins in equity, a determination of laches is not made upon the application of 'mechanical rules.' The defense, being personal to the particular party and equitable in nature, must have flexibility in its application. A court must look at all of the particular facts and circumstances of each case and weigh the equities of the parties." (citations omitted)). Accordingly, it is not appropriate to

codify an equitable remedy in a blanket legal rule as the PTO purports to have attempted here.

Furthermore, Final Rule 78 fails to meet even *Bogese II*'s reasonableness standard. In light of the above discussions, the PTO cannot establish that the Final Rules' "could not have been submitted" standard is reasonable, that it is reasonable to apply this standard after two continuations and one request for continued examination ("RCE"), and that it is reasonable to apply this standard to all applications in all circumstances.[8]

In defense of the limitation on continuations, the Government also cites the applicant's opportunity to submit an adequate set of claims at the outset as justification for curtailing the right to refile. In effect, it contends that the applicant should exercise foresight to initially file whatever claims he will ultimately require, and thus obviate any need for continuations. But this argument ignores the fact that 5/25 Rule frustrates the very practice that the continuation rule is purportedly intended to encourage. Under the 5/25 Rule, the diligent applicant is precluded from presenting the full complement of claims that the continuation rule compels him to foresee. One rule demands uncommon prescience, the other thwarts it.

[8] Because the District Court did not reach the question of whether the Final Rules were reasonable under *Bogese II* or the Administrative Procedure Act's arbitrary and capricious standard, if the Court reverses the District Court's decision, these issues should be decided on remand.

C. Monsanto Would Be Unable to Adequately Claim This Catalyst Technology Under the Final Rules

As the preceding discussion demonstrates, to fully protect novel catalysts, the patent applicant must be able to claim each of the catalyst's properties that is associated with favorable or commercially important catalytic performance. But the relationship of performance to composition, microstructure, or properties must be determined by expensive and time-consuming research. The inventor can completely protect the invention only through separate claims covering various properties associated with performance and details of the catalyst's microstructure. Only when many broad and narrow claims are presented to claim properties separately and in different combinations will the patentee derive an appropriate scope of protection to reward his or her investment in the invention. The ability to fully claim novel catalysts is essential to reliable patent protection of catalyst technology, but will be frustrated by the Final Rules.

The application of the Final Rules will likely restrict Monsanto's ability to fully define and claim its novel oxidation catalyst in a manner consistent with Monsanto's contribution and investment.[9] For example, if continuation

[9] If the Final Rules are given effect, the PTO will apparently apply the 5/25 Rule to applications filed before November 1, 2007, in which a first Office action on the merits was not mailed before that date. 72 Fed. Reg. at 46,716. The 5/25 Rule therefore would apply to all three generations of these Monsanto applications, despite the fact that they were filed before the Final Rules were published and that

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applications were to be used to patent 25 claims at a time, then the new subject matter of U.S. Application No. 10/923,416 ("the '416 application") could not be filed until after the last of the 75 claims were allowed (still fewer than the 92 patented in the '373 patent). Worse yet, the parent '373 patent would be prior art to the '416 application because the two continuations allowed as a matter of right under the Final Rules have been used up getting the 75 claims so that the '416 application could not claim priority back to the first generation provisional—a huge loss of substantive rights.

Under the patent laws, competitors that choose not to invest in research can legitimately try to appropriate the value of patented inventions by designing around valid claims or finding additional prior art. Because a catalyst is relatively inexpensive to make, parasitical competitors can frequently follow the teaching of the patent application while designing around all of the claimed properties and details. This is also true for other types of research-intensive inventions, such as transgenic plants. In anticipation of such competitive activity, inventors seek to develop an adequately graduated claim structure and, where possible, to add claims supported by their pending applications that read on competitors' products as they

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there are now more than 25 total claims after a first Office action on the merits in the '028 application.

emerge in the market place. The Final Rules would thwart such a strategy, thereby significantly impinging on inventors' substantive patent rights. Once the meager 5/25 allotment is used up, the Final Rules would prevent Monsanto from claiming any further embodiments of its novel catalyst. Thus, to the extent that the number of claims it can make is arbitrarily restricted, Monsanto will incur increased risk of leaving a gap and not covering an invention that it is otherwise entitled to claim—again, a significant restriction of Monsanto's substantive patent rights. As noted, a competitor that has not made the investment in research may exploit this gap to Monsanto's detriment.

The Final Rules as applied among claims of different applications containing patentably indistinct claims is especially prejudicial, with the greatest prejudice suffered by research-based companies like Monsanto. As described above, progressive research requires a series of successive patent applications. Many narrower subgeneric and species claims in Monsanto's second generation application include limitations not present in the first generation, but fit within a broader genus claim in the earlier application. Monsanto's third generation application includes additional subgeneric claims, as well as species claims, within the scope of both of the earlier applications. In these circumstances, regardless of whether each of the second and third generation applications is patentable over its predecessor application, the 5/25 Rule will be applied against the entire family of

copending applications, thereby limiting the inventor to a sum of five independent claims and twenty-five total claims to be allocated among the several applications.[10]

The Government's brief condemns the above-described strategies for fully protecting inventions as misuse and abuse. *See* Appellants' Br. 5-6; 26. The Government must discredit such practices because it cannot avoid the reality that the Final Rules violate applicants' right to claim what they regard as their invention. Instead of using the accepted and well-established practices described above, the Government would require applicants to foresee the progress of their invention, the ways in which it might be appropriated by others, and what claims—but no more than 15 independent and 75 dependent claims—would be needed to fully protect the invention. *See id.* at 25; 43.

[10] Under 35 U.S.C. § 103(c), the earlier generation applications are often disqualified as prior art to later generation applications for purposes of obviousness under 35 U.S.C. § 103(a). But as discussed below, the benefit of § 103(c) is nullified by the 5/25 Rule. Even in later generation applications that qualify as patentable over earlier applications under § 103(a) as applied by the Supreme Court in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), and *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), there is no relief from the 5/25 Rule. In the Monsanto example, the PTO cannot apply the first generation applications as prior art against the second, nor the second against the third under § 103(c). The third generation application is believed to be patentable as non-obvious over the first under § 103(a), but that does not avoid the 5/25 Rule since claims of the first generation applications read on or are obvious from the third.

The Government's attack on the legitimacy of these practices is also contrary to this Court's binding precedent, and the admitted intent of the Final Rules to preclude them is an admission that the Final Rules run contrary to existing law. In *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 869 (Fed. Cir. 1988), Kingsdown, during prosecution of its patent application for a medical device, became aware of a similar, competing device manufactured by Hollister. *Id.* at 870. Kingsdown filed a continuation application to obtain more quickly claims that read on Hollister's device. *See id.* The continuation application presented an unamended, previously rejected version of a claim instead of the amended, allowed version of the claim. *Id.* at 871. A patent ultimately issued with this claim, and Kingsdown sued Hollister for infringement. *See id.* at 869. The district court held Kingsdown's patent unenforceable, accepting Hollister's defense of inequitable conduct based on a misstatement and prosecution of the earlier rejected claim in the continuation application. *Id.* In reversing the district court, this Court held that Kingsdown's strategy of filing a continuation application to add claims to cover Hollister's device was not evidence of deceitful intent. *Id.* at 874. This Court stated,

> It should be made clear at the outset of the present discussion that there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a

> competitor's product the applicant's attorney has learned about during the prosecution of a patent application.

Id.

In *In re Wakefield*, 422 F.2d 897, 961-62 (CCPA 1970), the examiner rejected several claims for undue multiplicity and the Patent Office Board of Appeals affirmed on the basis that the claims were unnecessary and confusing. In overturning the rejections, the CCPA affirmed an applicant's right to claim his invention as he sees fit. The CCPA stated,

> It is rarely possible to determine necessity for narrower claims at the time of prosecution. An applicant often does not know all the prior art which may be asserted against his broader claims when he litigates his patent. Further, he is never sure that the broader claims will not be successfully attacked on other grounds when litigated in the courts.

Id. at 962. Thus, the CCPA concluded, "an applicant should be allowed to determine the necessary number and scope of his claims, provided he pays the required fees and otherwise complies with the statute." *Id*. As explained above, the Final Rules will prevent research-based companies like Monsanto from presenting patent claims in a manner expressly authorized by *Wakefield*.

Of course, according to the Government, all of these problems with the Final Rules disappear if the applicant files an ESD. *See* Appellants' Br. 10; 54. However, the Final Rules' ESD requirements are impractical, burdensome, and

risky for applicants. The Government largely ignores or dismisses these significant issues. *See id.* at 16; 27.

The ESD protocol requires that the applicant search all U.S. patents and patent application publications, all foreign patent documents, and all non-patent literature, covering all claim limitations. Final Rule 265(b). For each material reference, the applicant must identify all the limitations of each claim that are shown by the reference and explain how each claim is patentable over the reference. Final Rule 265(a)(3)-(4). And, there must be a further showing of where each limitation of each claim finds support in the applicant's specification. Final Rule 265(a)(5). The cost of all of this will be prohibitive.

The Government's brief analogizes the ESD requirements with PTO Rules 56 and 105, which require applicants to supply information to the PTO. *See* Appellants' Br. 57-59. This analogy misses the mark because these rules do not require applicants to search out references and then characterize their effect on the application. Under 35 U.S.C. §§ 131 and 132, the PTO performs these tasks. Shifting these responsibilities to applicants effectively relieves the PTO of its examination obligations and its burden to show that an applicant is not entitled to a patent. As the District Court correctly concluded, by shifting this burden to

applicants, the Final Rules alter existing patent law and practice—which is beyond the scope of the PTO's rulemaking authority. *Tafas*, 541 F. Supp. 2d at 816-17.[11]

An attempt to comply with Final Rule 265 requires applicants to make statements in a vacuum, which could lead the applicant to characterize both the claims and the prior art in a manner that is at best unhelpful to the examiner and at worst could lead to unwarranted fraud allegations in litigation, expanding the current plague of such allegations. Indeed, if the examiner finds the applicant's ESD unhelpful or if the claims change after submission of the ESD, the examiner could ask the applicant any number of times to supplement the record, increasing the cost to the applicant and the time spent by both the applicant and the examiner

[11] The cases the Government relies on do not support the PTO's imposition of the ESD requirement. In *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1282 (Fed. Cir. 2005), this Court affirmed the PTO's interpretation that Rule 105 allowed it to request information from the applicant beyond that which is directly material to patentability. However, the differences between Rule 105 and the ESD requirement are stark. Rule 105 allows the examiner to request information that "may be reasonably necessary to properly examine or treat the matter" after the examiner has begun examination. The ESD requirement will require applicants to supply information before examination. Thus, while Rule 105 allows for targeted requests for information relevant to the issues the examiner has identified, the ESD requirement will require an applicant to perform a wide ranging, burdensome, and expensive search without the benefit of the examiner's input. *In re Epstein*, 32 F.3d 1559 (Fed. Cir. 1994), does not permit the PTO to take whatever action it deems necessary to relieve its burden of establishing unpatentability. The concurring opinion in *Epstein*, cited by the Government, warns that rules shifting the burden of patentability onto applicants may be subject to abuse and puts the onus on the PTO and this Court to keep such abuse in check. By attempting to impose the ESD requirement on applicants, the PTO has failed in this duty.

in prosecution. Thus, the applicant is faced with a Hobson's choice: either undertake the expense and untoward risks of submitting an ESD; or be relegated to the restrictions of the 5/25 Rule. Each of these impositions is contrary to statute.

III. Other Principles of Patent Law Amplify the Harm Caused by the Final Rules

A. Evisceration of the Protection of 35 U.S.C. § 103(c)

Congress enacted § 103(c) of the Patent Act in 1984 and expanded it in 1999 to overrule the adverse effect on organized research of the decision of the Court of Customs and Patent Appeals in *In re Bass*, 474 F.2d 1276 (1973). *See Oddzon Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1402-03 (Fed. Cir. 1997) (discussing history and purpose of 35 U.S.C. § 103(c)); *Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co.*, 973 F.2d 911, 917 (Fed. Cir. 1992) (same). Section 103(c) prevents inventions made in the course of organized research from being held unpatentable as obvious from earlier inventions, disclosures and patent applications produced in the same organization that qualify as prior art only under § 102(e), § 102(f), or § 102(g). Congress recognized that applying such art for purposes of obviousness under § 103(a) would disqualify meritorious inventions arising from the typically progressive nature of organized research, while discouraging the communication and collaboration among co-workers that is the lifeblood of a research organization.

The 5/25 Rule as applied among multiple applications effectively defeats the purpose of § 103(c). In a series of commonly owned applications respectively directed to successive generations of development in a given technology, § 103(c) cannot afford relief where the 5/25 Rule imposes a drastic limit on the number and scope of claims that can be filed. If multiple generations of applications remain copending, the inventor will have difficulty in presenting any claims at all in a fifth, fourth, or even third generation application without exceeding the 5/25 limit. Thus, the benefits otherwise available from § 103(c) are rendered nugatory.

B. Doctrine of Equivalents

If a competitor takes advantage of a gap in patent coverage caused by the 5/25 Rule and the competitor's design-around reflects only an "insubstantial change" compared to one or more elements of the claimed invention, the patent holder can argue that there is infringement even if the design-around does not fall within the express terms of a patent claim. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39-40 (1997). However, in recent years, the courts have progressively constricted this doctrine, referred to as the doctrine of equivalents, and the 5/25 Rule would exacerbate the effects of these restrictions.

Under the landmark *Festo* decisions,[12] essentially any amendment during prosecution that adds a claim element or narrows an existing element, and that relates to a substantial issue of patentability, creates a risk of an estoppel against the enforcement of the claim under the doctrine of equivalents with respect to that element.[13] If the competitor offers a product or uses a process that substitutes an equivalent for the added or narrowed element, the claim cannot be enforced under the doctrine of equivalents if the substitution would have been "foreseeable" at the time the application was filed.

Thus, instead of relying on the doctrine of equivalents, it is critical for the patentee to have claims in the original patent that can be literally read on any foreseeable competitive product or process. According to longstanding patent practice in complex technologies, this need typically is met by presenting a relatively large number of claims, including parallel claims that may omit the narrowed element of the amended claim, while distinguishing the prior art in other ways that a competitor may not ultimately avoid.

The 5/25 Rule will severely limit the number of claims of varying scope that can be prosecuted, even where the impact is not compounded by applying the Rule

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[12] *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002) and its Federal Circuit progeny.

[13] Moreover, there is a presumption that any narrowing amendment does relate to a substantial issue of patentability. *See Festo*, 535 U.S. at 739-41.

against the sum of claims in related applications. Moreover, if a claim that would literally cover the accused product or process is present in the application as filed, or in a foreign counterpart or PCT application, "foreseeability" will be conclusively established and enforcement under the doctrine of equivalents barred by *Festo*.

Even in the absence of an estoppel, application of the doctrine of equivalents can be barred by inadvertent dedication of subject matter that is disclosed but not claimed. *See Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). For example, if the broadest claim is found unpatentable over previously unidentified prior art, the 5/25 Rule may leave gaps in coverage that may enable a competitor to resort to the patentee's own teachings in developing a competing technology that avoids the remaining valid claims.

C. Inadequate Post-Issue Remedies and Intervening Rights

After all applications based on a given disclosure have issued, the only alternative currently available for changing or adding claims to remedy any discovered gaps involves returning to the PTO for remedial prosecution, either re-examination under 35 U.S.C. § 302 or re-issue under 35 U.S.C. § 251. If a change or addition is pursued at that time, the patent holder can suffer significant prejudice against enforcement and further time delay. For example, unless an original claim that reads on a competitor's product or process is upheld during remedial

prosecution, the patent holder cannot recover damages for the period prior to the date that a revised patent or certificate issues.[14] This is so even if a claim added in the remedial PTO proceeding covers the infringer's product and is determined to be valid by a court. *See BIC Leisure Prods.*, 1 F.3d at 1220-21. Also, if the claims are amended, the court can allow a competitor to continue infringing activity in certain circumstances where the competitor relied on an error in the original claims. 35 U.S.C. § 252.

To avoid these problems in litigation, longstanding patent practice in complex technologies involves presenting a comprehensive claim structure that distinguishes the prior art yet prevents a competitor from copying the invention. However, as discussed above, the 5/25 Rule, alone and in combination with other provisions of the Final Rules, will severely limit the ability of patent applicants to prosecute a claim structure adequate to provide insurance against these types of risk.

[14] This legal principle is referred to as intervening rights. *See BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1220-21 (Fed. Cir. 1993); *Fortel Corp. v. Phone-Mate, Inc.*, 825 F.2d 1577, 1579-80 (Fed. Cir. 1987).

CONCLUSION

For the foregoing reasons, the Court should affirm the District Court's decision in this case.

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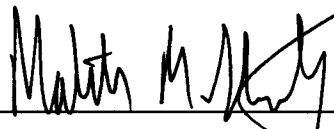
(s) 

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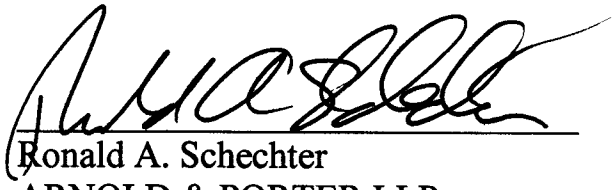

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