PRACTICE UNDER GATT'S URUGUAY ROUND AGREEMENTS ACT

PATENT TERM EXTENSION & DIMINUTION
PROVISIONAL APPLICATION DOMESTIC PRIORITY
NEW ACTS OF INFRINGEMENT
WTO COUNTRY §104 EXEMPTIONS

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URUGUAY ROUND AGREEMENTS ACT - OVERVIEW

(by Professor Irving Kayton)

A. The Principal Provisions

The new statute embodies four major provisions, each having several subsidiary provisions, with various ones of all of these coming into force successively beginning on December 8, 1994, on June 8, 1995, and on January 1, 1996.

1. *On January 1, 1996:*

(a) All World Trade Organization (WTO) countries, i.e., General Agreement on Trade & Tariffs (GATT) signatories which pass enabling legislation, become exempt from the strictures of 35 USC § 104 as did Mexico and Canada earlier under NAFTA. As a consequence, acts outside the United States in a WTO country can be used to prove a date of invention in USPTO or court proceedings in the United States. If, however, the WTO country does not provide for discovery comparable to that which is available in the U.S. proceeding, the tribunal involved "shall draw appropriate inferences . . . in favor of the party that requested the information in the proceeding." 35 USC § 104(a)(3).

(b) Infringement under 35 USC § 271 is to include an "offer to sell," as well as the mere "importation" into the U.S. of: (i) that which is claimed, and (ii) the product of a process that is claimed. However, the offer to sell is an actionable infringement only if the sale is to take place during the patent's term.

2. *On June 8, 1995:*

(a) The term of a patent issuing from an application filed on or after that date, will begin to run on the day of issue and extend for a period of 20 years from the application's effective filing date, which includes the filing date of any § 120, § 121 or international application asserted for priority in the application. The longer the prosecution period, the shorter the patent's life. Prosecution longer than three years, therefore, results in a patent term less than 17 years from issue. However, prosecution delays (up to five years) which are due to interferences, secrecy orders and *successfully* appealed rejections to the Board of Appeals and CAFC are excluded from the 20 year period. 35 USC § 154.

(b) A new form of 12 month domestic priority (analogous to foreign priority under § 119) based upon filing a "provisional application" can be obtained; these 12 months are not included in measuring the 20 year term. 35 USC § 111(b).

3. Effective December 8, 1994, because of activity prior to June 8, 1995:

(a) Every patent in force on June 8, 1995, and every patent which issues directly from an application filed prior to that date, enjoys the longer of two terms -- either 17 years from issue or 20 years from filing.

(b) An opportunity is provided for applications at least two years old that are in being on June 8, 1995, to continue in prosecution after a final rejection as though the rejection were not final (thereby permitting extended prosecution without need for appeal or filing a continuation); and for applications at least three years old to have a close-to-June 8th restriction requirement waived. These two opportunities are in the rule-drafting stage at the PTO, which is nearing completion.

B. The Political and Economic Rationales for the New Patent Term

The above are the major provisions and the date upon which they become effective in our lives. There are many subsidiary provisions, presented and discussed below, which will significantly affect daily practice considerations and actions.

Only the § 104 exemption for WTO countries and the new forms of acts of infringement under § 271 are *required* by GATT. The patent term of 20-years-from-filing-date that comes into effect on June 8, 1995, and which will almost always result in a patent term less than the familiar 17 years from issue (as will be shown below) is a sufficient condition to satisfy GATT. GATT, Article 33, states:

> The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date

Thus, GATT specifies that no *less* a term that 20-years-from-filing is a requirement. To meet GATT's Article 33, a patent term of the *greater* of 17 years from issue or 20-years-from-filing could have been enacted, as many patent practitioners counseled, and continue to counsel. Indeed, that is precisely the provision we *do* have during the "transitional period", i.e., for patents that issue after June 7, 1995, on applications filed before June 8, 1995. This part of the statute is legal because it is just as consistent with Article 33 as is the single 20-years-from-filing patent term.

The Democratic Administration made the new, single, 20-years-from-filing patent term of June 8, 1995, part of its "fast track" legislation for GATT implementation, rather than the dual option terms of the transitional period. Moreover, Commissioner of Patents Lehman had earlier publicly proclaimed "he" would do so as part of an agreement with Japan to induce the

Japanese Patent Office to accept applications from U.S. applicants in English (we had long accepted their s in Japanese) and to end the JPO's sequential pre-issuance opposition proceedings (the patent injustice to patentees of which is something the U.S. never had the temerity to ever consider let alone attempt to institute). And there was no public discussion invited or permitted on what is one of the most philosophically monumental changes in our patent system this century. Yet it is Commissioner Lehman who had earlier been holding public hearings all over the country (to his credit) on half a dozen patent issues of lesser stature.

For the Republicans to have acceded to this Draconian procedure is somewhat strange. In November 1994, they carried out a landslide electoral routing of the Democrats precisely on the issue of the need to get the government out of the lives of its citizens. Yet in December 1994, they accepted a patent term, which is a right of private property, the length of which is now dependent virtually exclusively on a government agency's effectiveness, initiative and the individual training and goodwill of each patent examiner. The USPTO, in these respects, is about average among government agencies -- which is to say, not very good. As a close student of the USPTO for over 40 years, I have witnessed dozens of its institutional defects which would bear significantly negatively on the length of term a conscientious and diligent applicant could obtain under the new regime. One such defect can be described without current embarrassment to anyone in the USPTO because it was rectified years ago. For a period of about two years bracketing 1973, the mail room in the USPTO was in such disarray that it took an average of *three months* for an applicant's communication, *after* it was received in the PTO mail room, to travel from the mail room to the examiner's art unit in the same building. I remember this well because the then Commissioner of Patents took the opportunity PRG had presented him to speak on "Fraud and Inequitable Conduct in Patent Procurement," to speak instead on how he was working on decreasing the mail room pendency time.

In fairness to both the Republicans and the Democrats, the following was reported in *The Wall Street Journal* the day after the bipartisan vote in December 1994. Senate Majority Leader Robert Dole urged, and said he would later submit, an amendment to the Act which would make the dual term option the law not only during the transitional period but for all time. President Clinton was reported to have said that he would not oppose such an amendment in the 104th Congress (which statement was made while he was courting Senator Dole's support for the pending GATT vote).

Do not hold your breath while awaiting passage of such an amendment. (Rep. Dana Rohrbacher (R-Calif.) introduced such a bill (HR359) on January 4, 1995.) The major corporations in the world (especially those in the United States and Japan) are intent on the 20-years-from-filing term remaining the law. Quite understandably, they are disturbed whenever a patent issues after 20 years or more of secret prosecution the invention of which they have used wittingly or unwittingly to establish major product lines or even entire industries. Excessive, but completely legal, use (or abuse in some peoples' view) of continuing application practice can contribute to this result. These "submarine" patents must be eliminated, in the view of many large corporations (at this time there are 673 applications pending that are more than 20 years old, but many of them are of this age because they are under secrecy orders).

Consider, however, the revolutionary inventions which, through no fault of the inventors or their patent practitioners, get bogged down in interferences. The applicant has no choice but to copy claims from later entrants who are trying to claim the pioneer's inventions. The laser is the classic example. It *could not* issue earlier than it did because every Tom, Dick, Harry, Mary and Jane was trying to grab a piece of the action. The laser has revolutionized medicine, computers, communications technology -- it is ubiquitous. Yet the patent took over 30 years to issue. The inventor, Gordon Gould, his investors, and his patent attorneys, finally did get their well-justified but long awaited reward. Under the current 20-years-from-filing regime, with solely a *five* year waiver for interference delays, they would not have gotten a single penny for their magnificent contribution to society's well-being.

Moreover, how genuinely submerged *are* "submarine" patents? In the case of the laser, technical publications and popular newspaper articles abounded with exquisitely detailed descriptions and discussions of the invention for decades; and all patent practitioners knew about the interferences in progress. Despite this knowledge, commercial exploitation of the laser was vigorously instituted in most corporate quarters -- and the only "penalty" to those who have so benefitted from that invention is the payment of a reasonable royalty.

Can such a scenario have really justified changing our patent system to one wherein the life of the patent property is largely in the hands of a government agency wherein private sector type personal and economic incentives to pursue each day's activities with vigor are noteworthy by their absence?

Conventional wisdom's perceived "evils" of submarine patents will, in any event, largely disappear next year *without* the new patent term goad. Legislation will almost surely be enacted in the 104th Congress requiring publication of all U.S. applications 18 months after their filing dates (provisional applications excluded). With such publications, the submarine will always be in view on the ocean's surface. All can contemplate how to torpedo it, or how to take advantage of it -- and, if both wise and honest, how to prepare reasonably to pay for that advantage.

C. Intended and Unintended Consequences of the Act's New Patent Term and Its Subsidiary Provisions

The purposes of this book and the two-day PRG course which it serves, are:

(1) to make clear in detail that which the new amendments to the statute expressly state, and what is thereby required of practitioners by those express statements; and

(2) to make clear in detail what the new amendments require of practitioners that is not expressly stated but which necessarily is implicit in those explicit provisions if practitioners' clients' interests are to be served properly.

In short, both the intended consequences of the law, and the unintended consequences (to the fullest extent discerned by the authors and faculty) will be presented. No doubt the audience at the course, with its wealth of practice and experience will further enrich our perceptions of the unintended consequences. The result should be an exquisitely detailed protocol of optimum daily patent practice which all will likely wish to institute the day after the course ends.

But before going to the specifics and details of the intended and unintended consequences of the Uruguay Rounds Agreement Act, two all-encompassing and unintended consequences should be considered which, unfortunately, will largely vitiate the effectiveness of the U.S. Patent Office and the U.S. Court of Appeals for the Federal Circuit, for at least a decade to come. That two such vital patent institutions will necessarily be so adversely affected by the new patent legislation results from, and informs, how people actually act in response to legislative fiat.

1. First Illustrative Set of Unintended Consequences (the Unsuspecting USPTO)

Every patent that issues from every application filed after June 7, 1995 will no longer enjoy a life of 17 years from issue. Rather its life will be 20-years-from-filing, with filing measured from the date of any domestic priority date asserted in the application. Genuine, effective diligence in prosecution would appear to promise a windfall if the gods smile and the post-June 7th filed application issues earlier than three years after the effective filing date. (Twenty years minus a period briefer than three years provides a patent with a term greater than the traditional 17 years from issue.)

For patentees in technologies in which commercial value of inventions blooms late or lasts for a long time, or in which either *could* occur, the new regime promises a greater return because of the potential for increased life of the patent.

By the same token, a pendency period in excess of three years will result in a patent term less than the heretofore available 17 years from issue.

Can this latter truncated term happen? Not only can it happen, but it most certainly will; it will be the rule rather than the exception. Moreover, the pendency period will be greatly in excess of three years; the term of almost all patents will be considerably shorter than 17 years from issue; and this will be the state of affairs indefinitely for virtually every application filed after June 7, 1995.

The culprit in this unhappy state of affairs is the law of unintended consequences. Recognizing this unintended consequence requires only considering the new patent term in relation to *another* part of the new statute.

Effective this very minute (first breath having been drawn on December 8, 1994) and until midnight June 7, 1995, any patent that issues on *any* and *every* application filed during this officially denominated "transitional period" is entitled to a term of either 17 years from issue or 20-years-from-filing, whichever is *greater* (indeed, this could have been the law even after June 7, 1995, had the Senate and House so drafted the statute, because such a result is completely compatible with Article 33 of GATT).

It behooves patent practitioners to take advantage of such a no-lose situation in every way available to them, economic and financial conditions permitting. Consequently, for every invention disclosure in being during the transitional period on which an application could be filed, one will be filed (or certainly should). Every one of those disclosures with a plurality of patentably distinct inventions therein should be filed (and likely will) as a *plurality* of applications to preclude having to be divided after June 7th. Every application in being prior to June 8, 1995, with restriction requirements outstanding will or should result in a divisional application from every restricted invention defined by the examiner. Every application in being prior to June 8, 1995, with a plurality of patentably distinct inventions either disclosed or claimed or both, will or should have a plurality of divisional applications filed thereon gratuitously even without a restriction requirement in being, *prior* to June 8, 1995. To do otherwise would mean the applications listed above ultimately would be filed after June 7, 1995, with only the problematic 20-years-from-filing term as the sole reward.

The consequence of these two separate patent term parts of the new statute thus guarantees that myriad numbers of patent applications will be filed during the four month period between the start of this course, February 9, 1995, and midnight, June 7, 1995. The only real life constraints on the number of applications are the numbers of working hours patent practitioners can work until June 8th and the willingness and financial capacity of their clients to take advantage of the transitional period's no-lose opportunity.

Realistically, what is the number of applications that can reasonably be expected to be filed before June 8, 1995?

On any given day, approximately 250,000 applications are pending, i.e., are in some state of prosecution in the USPTO. How many of those have restriction requirements to which one or more divisions may yet be filed, and how many not-yet-restricted applications disclose or claim a plurality of patentably distinct inventions? It is not difficult to generate a reasonable quantitative estimate. Since the 1984 amendment to 35 USC § 116, accepted practice strategy properly dictates including as many independent and distinct but related inventions as is feasible in a single application, thereby to provoke a USPTO restriction requirement which, then, provides the protective umbrella of 35 USC § 121. Of the 250,000 pending applications, it is entirely reasonable, therefore, to estimate 125,000 to 175,000 have the potential for having one to four divisions filed from each. A range of 125,000 to 700,000 applications, beyond 1995's regular 180,000 anticipated fillings, will conceivably be dumped upon the largely unsuspecting and oblivious USPTO. The filing of 300,000 to 400,000 previously unanticipated applications is a reasonable prospect. Please recall that filing a division is largely ministerial -- it is not a time consuming activity. Prosecution of the division, however, is a full scale undertaking. And these numbers do *not* include the *multiple* application filings on invention disclosures having multiple patentably distinct inventions which until now would have been filed as a single application. Moreover, as will be seen in the detailed analysis below, there can be good tactical bases, which derive from the new transitional period sections, for filing continuations for a large fraction of the applications now pending; and these also are in addition to the 300,000 to 400,000 applications estimated above.

Average pendency will climb promptly to at least four years and beyond. It will continue that way for a least a decade, absent a massive influx of instantly trained examiners into the USPTO examining corps (which is as likely to occur as is the sun's rising in the west and setting in the east).

The first set of illustrative unintended patent term consequences, therefore is:

(a) Virtually every patent that issues on an application filed *after* June 7, 1995 will have a term significantly shorter than 17 years from issue, despite the utmost conscientious diligence in prosecution on every applicant's part, and this state of affairs will continue for many years;

(b) Virtually every patent that issues on an application filed *during* the transitional period will have a term no greater than 17 years from issue despite utmost conscientious diligence in prosecution (but that is a lot better than a term shorter than 17 years from issue); and

(c) The USPTO, beginning on June 8, 1995, will qualify as a federal disaster area.

2. *Second Illustrative Set of Unintended Consequences (the Unsuspecting CAFC)*

The debacle looming for the U.S. Court of Appeals for the Federal Circuit (and the PTO Board of Appeals) comes not from the hundreds of thousands of additional, unanticipated applications that will be filed by June 8, 1995; at least not as a first magnitude effect. Rather it comes from a third part of the statute which grants, beginning June 8, 1995, an *automatic extension* (but only up to five years) of the 20-years-from-filing term for time spent *successfully* appealing an adverse patentability decision to the Board of Appeals and to the CAFC.

Consider the following fact pattern which illustrates what this term extension potential will mean in every day patent prosecution practice. After a first Office action rejection, the practitioner responds thoroughly and completely to demonstrate the allowability of all claims, or to put them in condition for allowance, or both. There is no serious doubt in the practitioner's mind that the claims as they now stand are patentable. The examiner responds, however, with a final rejection of all claims or of the broadest claims (an extremely common occurrence, as most practitioners will agree). Alerted to the new way of life, the docketing clerk physically hands the practitioner the final rejection on the very day it arrives in the office, and does so within minutes after the mail has been opened and the document has been date stamped. What is the practitioner to do in response to such a final rejection beginning June 8, 1995.

The answer is unambiguously simple and straightforward -- assuming the practitioner wishes to secure the longest patent term available under the 20-years-from-filing regime. He or she must *immediately* prepare a notice of appeal and get it into the mail that very day with a certificate of mailing. By so doing, the patent term diminution clock stops running that day -- at least contingently. Should the appeal be lost and no further appeal taken to the CAFC, then the clock is seen to have actually continued to run *de jure*. Should a *successful* appeal be taken to the CAFC, the clock will be seen to have been stopped from the filing date of the first notice of appeal and can stand still for up to five years.

Had the practitioner engaged in the typical post final rejection prosecution tactics of the past, the life of the patent would have steadily and inexorably diminished to a shortened term, the length of which would have been controlled by the reasonable or unreasonable behavior of the examiner.

It takes little imagination, therefore, to predict that the overwhelming majority of patent practitioners will soon become very adept at taking appeals to the PTO Board of Appeals and to the CAFC.

Consider what will happen after June 7th, 1995, to the backlog of cases at the Board and the CAFC. Under past practice, appeals to the Board were taken in not more than a small fraction of the applications under final rejection. The number that went on to the CAFC was minuscule compared to the total of applications under final. After June 7, 1995, virtually every application under final will be appealed to the Board and, of those, virtually every one in which the examiner is sustained will have to be appealed to the CAFC or the patent term will be severely curtailed.

Barring intervention far too sophisticated for current political institutions, the CAFC and the Board will cease to exist in the forms that we know them.

For patentees, the Court's and Board's backlogs may well be so great that the five year statutory extension period for *successful* appeals will be less than the actual time taken on appeal. For applicants whose appeals fail, the life of whatever patents issue to them could conceivably be measured in months rather than years.

Of course, when those backlogs grow to the dimension estimated above, practitioners may consider going back to taking their chances with the examiner after final rejection, even to the extent of filing a continuation, in the hope of the examiner's goodwill expedition in handling the case. But this would be a practice of dubious value. When practitioners view their claims to be patentable as they stand, a change in even one word of a claim at the request of the examiner creates a prosecution history estoppel which virtually precludes a holding of infringement in litigation against an alert infringer under well established CAFC law. PRG's three-day course, *"Designing Around" Valid U.S. Patents*, has established this truth virtually without cavil.

D. "Eternal Verities" of Patent Practice Which Must Be Kept in Mind While Scrutinizing the Trees in the New Patent Term Forest

1. Validity v. Length of Term

Not Claiming the Earliest Effective Date in a Continuing Application Will Almost Always Be a Serious Mistake

An invalid patent with a 19.5-years-from-issue term is as worthless as an invalid patent with a one month term. One hundred per cent of zero is precisely equal to .00001 per cent of zero. Compromises in prosecution, that are now possible under the new statute, having the problematic promise of a longer term that seriously threaten a future holding of validity in litigation must be eschewed. A good, solid, healthy validity-bird in the hand is worth far more on a rational probability basis than two anemic birds-of-"longer term," the adult potential sizes of which are unknown, scurrying about in the bush. Which is worth more to the client, a valid patent with a 10 year life or an invalid patent with a 16 year term?

In a continuing application, the term of its patent can be lengthened, under the 20-years-from-filing regime, by not asserting the earliest ancestral date possible in a § 120 chain. Were we omniscient (and perhaps clairvoyant) about prior art extant in the world, we could profitably choose the filing date upon which we wish to rely as the earliest one needed to avoid the prior art but which is simultaneously the latest one to give us the longest patent term. In fact, only God is in a position to make such a determination.

We mortal patent practitioners must await patent litigation and the concentrated prior art-seeking efforts of the infringer to know which ancestral filing date was the correct one for us to have asserted years ago in resolving our validity versus length of term dilemma.

I suggest that the correct resolution will always be to elect to assert the earliest filing date -- thereby to opt for the greatest likelihood of validity in future litigation.

Such an approach optimizes the possible economic return to the client.

2. *Infringement v. Length of Term*

Concentrating on Getting Narrow, "Commercial" Claims to Issue Early May be a Relatively Unrewarding Undertaking

Among the considerations presented in this book and course will be techniques to obtain "commercial" claims early in prosecution which "cover" the invention and which will have a longer term than the broader claims.

If the narrow claims are "commercial," the broader claims are commercial *a fortiori*. Moreover, the narrower claims will be the ones most readily "designed around" by the forthcoming infringer.

Based upon well-established lines of CAFC cases, both precedential and non-precedential, unless a claim is infringed *literally*, it will be held not infringed on *summary* judgment in eight times out of nine. PRG's three day course, two volume text and third volume of non-precedential cases, *"Designing Around" Valid U.S. Patents*, demonstrate that a sustained holding of infringement under the doctrine of equivalents is a *rara avis*. Consequently, obtaining allowance of a huge spectrum of claims, starting with the broadest claim that known prior art permits and with each claim spaced in scope narrowly from its next adjacent claim, is the only way to secure a reasonable chance of enforcing patent claims that are admittedly valid.

A long patent term matters not if the patent is invalid. A long termed *valid* patent matters not if an infringer can avoid it with impunity.

To focus prosecution efforts, time and money in getting narrow claims to issue early often will be a feckless undertaking.

IMPLEMENTING GATT/TRIPs:
NEW U.S. PATENT TERM EXTENSION AND DIMINUTION PRACTICE[1]

I. THE CONTROLLING STATUTORY TIME FRAMES

The United States has changed its patent laws in fundamental respects to fulfill its obligations under the General Agreement on Tariffs and Trade ("GATT")[2] and specifically under the accompanying Agreement on Trade-Related Aspects of Intellectual Property Law ("TRIPs"). These changes became U.S. law on December 8, 1994, when President Clinton signed into law the Uruguay Round Agreements Act ("Act").[3] On January 1, 1995, the organization known as the GATT ceased to exist and was succeeded by the new WTO, or World Trade Organization.

The statutory changes take effect on two different effective dates. The provisions relating to patent term and to patent applications (including provisional

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[1] This treatise has been prepared at the behest of and under the auspices of Patent Resources Group, Inc. for educational purposes to contribute to the understanding of American intellectual property law. Thus, the authors and their law firms cannot be bound, either philosophically or as representatives of their various present and future clients, to the comments expressed in this article. Indeed, the co-authors disagree among themselves as to some of the opinions and interpretations presented in this treatise.

The authors express their appreciation to Carol Einaudi, Jean Fordis, Ed Good, Jeffery Karceski, Stephen Kalinchak, Teresa Moton, and Audra Wilson for their help.

[2] During the Uruguay Round of Multilateral Trade Negotiations under GATT, about 115 countries participated in the TRIPs agreement and other trade agreements. The Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, concluded December 15, 1993, was signed by participating countries at the Ministerial Meeting in Marrakesh, Morocco, on April 15, 1994. A copy of the GATT/TRIPs Treaty is included in the Appendix.

[3] Uruguay Round Agreements Act, Pub. L. No. 103-465, tit. V, subtit. C, 108 Stat. 4809, enacted on December 8, 1994 ("Act"). Portions of the Act relevant to patent law are reproduced in Appendix C. Changes to the Patent Statute are shown in Appendix A.

applications) will take effect on June 8, 1995 (six months from the date that President Clinton signed the Act). The remaining provisions will take effect on January 1, 1996.

The GATT/TRIPs agreement obligates the U.S. to make changes in its patent law. The most important changes to U.S. patent law were required to conform to Articles 27, 28, and 33.[4] For example, Article 27 of TRIPs requires that all WTO countries make patents available and patent rights enjoyable without discrimination based on the place of invention. To comply with Article 27 the U.S. has revised 35 U.S.C. § 104, which formerly discriminated *de facto* albeit not *dejure*) against foreign inventors. The U.S. has expanded the definition of patent infringement because Article 28 mandates not only the enforcement rights that were already available in the U.S., but also new rights to prevent others from offering for sale or importing a patented invention, including the product of a patented process.

Numerous changes to the law governing the terms of patents in the U.S. were enacted to comply with Article 33 of the TRIPs, which requires that the term of protection shall not end before the expiration of a period of 20 years, counted from the filing date. Article 70 extended the benefits of TRIPs to protection for existing patents. Therefore, beginning on June 8, 1995, all U.S. patents then in force will be entitled to a term that does not expire before at least 20 years from the filing date of the application. As a result the terms for some existing patents will be reset beyond their current term of 17 years from issue. In addition, a new domestic priority system will become available on June 8, 1995, as part of the new patent term provisions of the Act.

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[4] These Articles of TRIPs are reproduced in Appendix B.

It will be a challenge for patent practioners to determine the best course during the complex transition period when applications filed before June 8, 1995, will have the possibility to issue with a term of 17 years from the date of issue, whereas all applications filed on or after June 8 will be limited to the new 20-year term.

The changes to U.S. patent law will affect owners of existing patents, as well as pending and future patent applicants. Patent owners and applicants should undertake a comprehensive review of pending applications to plan a strategy that will ensure the maximum term of patents that will issue under the new law, and to prevent serious loss of patent term. For many patent applicants, it may be essential to complete this review and to file new patent applications before June 8, 1995, in order to preserve the opportunity to obtain a patent with a term of 17 years from the date of issue.

A. WTO Provisions Taking Effect on January 1, 1996

WTO entered into effect with respect to the United States on January 1, 1995. The Uruguay Rounds Agreement Act, § 531(b), provides that the effective date of the amendment to 35 U.S.C. § 104 and for the expanded definition of infringement is January 1, 1996, one year from the date of entry into force of the WTO Agreement with respect to the United States.

§ 531(b)

EFFECTIVE DATE.—

> (1) IN GENERAL.—Except as provided in paragraph (2), the amendment made by this section shall apply to all patent applications that are filed on or after the date that is 12 months after the date of entry into force of the WTO Agreement with respect to the United States.

> (2) ESTABLISHMENT OF DATE.—An applicant for a patent, or a patentee, may not establish a date of invention for purposes of title 35, United States Code, that is earlier than 12 months after the date of entry into force of the WTO Agreement with respect to the United States by reference to knowledge or use, or other activity, in a WTO member country, except as provided in sections 119 and 365 of such title.

Thus, as of January 1, 1996, inventors in WTO countries will be able, under amended § 104, to begin to rely on inventive activity outside the United States to prove a date of invention earlier than their U.S. or PCT application filing dates.[5] In addition, patentees, as of January 1, 1996, will be able to sue for infringement in the United States based on offers to sell or importation of a patented invention and of the product of a patented process.

The new § 104 will not be retroactive but will apply only to all patent applications filed on or after that date. In other words, the new § 104 will not apply at all to pending applications or patents in force before the effective date. Most significantly, the lack of retroactivity is not just "procedural" but "substantive." That is, the non-U.S. inventive activity, even if it occurred before January 1, 1996, will only establish an invention "date" of January 1, 1996.

The practical consequences of the amendment, therefore, will only be felt later in time, at the earliest approximately January 1, 1997. In particular, consider patent applications filed in 1996 that are based on non-U.S. inventive activity. At least a year or so will likely pass before these applications wind up in interference proceedings or in *ex parte*

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[5] Members of WTO countries will thus join members of NAFTA countries (Canada and Mexico), for whom the effective date was December 8, 1993.

prosecutions where they may need to overcome prior art through the use of a Rule 131 affidavit.

Thus, it will be some time before patent applicants with inventive activity in WTO countries will be able to reap the benefits of the amendment to § 104. In all likelihood, this will begin to occur no earlier than 1997, but only if these potential patent applicants, in the relatively near future, lay the necessary groundwork to take advantage of the new provisions.

B. Patent Term and Application Provisions Taking Effect on June 8, 1995

June 8, 1995, will be a watershed in United States patent law. It is the date on which the 20-year term provisions of the Act take effect. As used here, the "20-year term" is shorthand for the term defined by new 35 U.S.C. § 154(a)(2):

> TERM.—Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

Thus, a "20-year term" is not a term of 20 years, but rather the 20 years is measured from the date of filing, or if the application from which the patent issues is a continuation, from the earliest application for which benefit is claimed under 35 U.S.C. §§ 120, 121, or 365(c). We will refer to the application from which the 20-year term is computed as the "original" U.S. application.[6]

During the transition different classes of patents will be treated differently:

(1) Patents already in force on June 8, 1995, will have their terms reset to 20 years from filing of the original application (subject to terminal disclaimers) if the reset term would be longer than the current 17 years from the date of issue.

(2) All patents issuing directly from applications filed before June 8, 1995, (without filing any subsequent continuing applications after June 8) will be entitled to the longer of a 20-year term from filing or 17 years from issue.

(3) Patents that issue from applications filed on or after June 8, 1995, including those that are continuing applications of parent applications that were filed before June 8, 1995, will have 20-year terms, measured from the original filing. Terms measured as 17 years from issuance will no longer be granted.

On June 8, 1995, the terms of certain patents in force will be reset by operation of law. Because GATT/TRIPs requires that all patents must have a term of at least 20 years,[7] and this provision must be applied to "existing" patents,[8] the term of any U.S. patent which issued in less than three years from its effective filing date will be reset so that the patent will expire no earlier than 20 years from the original filing date. Patents that issue directly from

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[6] As used here, the "original" U.S. application refers to the first regular application, from which benefit under §§ 120, 121, or 365(c) is claimed in the application that issues as a patent, and does *not* include a provisional U.S. application, from which benefit is claimed not under § 120 but rather under § 119.

[7] Article 33.

[8] Article 70.

applications pending on June 8, 1995, will also be accorded the longer of a term of either 17 years from date of issue or 20 years from the first U.S. filing date, taking into account, if applicable, benefit claimed under any of §§ 120, 121, and 365(c) ("earliest effective U.S. filing date").

The term of patents issuing from all **new** applications filed on or after June 8, 1995, (including continuations, divisionals or continuations-in-part of pending applications) will be 20 years from the earliest effective U.S. filing date.[9] The option of 17 years from date of issue will no longer be available.

Beginning on June 8, 1995, a new type of patent application, the provisional application, will come into being. Provisional applications, which will not be examined, will provide applicants with an inexpensive and simplified opportunity to establish "domestic" priority.

C. The Important Transitional Period Between Now and June 7, 1995

Until June 7, 1995, we will be in a transitional period during which applications filed may have benefit of the longer of either the 17-year or 20-year term. Specifically, patents that issue directly from applications filed by June 7, 1995, (including continuations, divisionals, and continuations-in-part of currently pending applications) will be entitled to the longer of a 17-year term from the date of issue or a 20-year term from the date of original U.S. filing. A fundamental purpose of this course is to explore the strategies determining whether patent applications of all kinds, if there is a choice, should be filed either before, or on, or after June 8, 1995.

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[9] But see Section III.A.6.c, *infra*.

D. Interpretation of the Act

The Uruguay Round Agreements Act was hastily drafted, without congressional hearings or meaningful review by the patent bar, and was passed under a fast-track agreement which prevented amendment or correction of the text drafted by the Patent Office and submitted by the Administration. The ambiguities and apparent errors in the statutory text are compounded, particularly with respect to the effective date provisions, by the use of language that departs without explanation from the terminology of the former patent statute.

In the absence of hearings or legislative committee reports on the meaning intended by Congress, interpretation of the Act will depend to an unusual extent on the "plain language" and grammar of the new law. Interpretation of the statutory text will be further complicated by its genesis in the TRIPs agreement and the treaty obligations that are fulfilled by the Act. Where the treaty imposes certain minimum legal obligations, such as the requirement of providing a patent term of at least 20 years, or of affording national treatment to foreign applicants, the courts should attempt to interpret the Act in a manner that avoids violating these requirements.

1. Act § 102(d)

One guide to construction of the Act is specifically provided in § 102(d), which provides:

> STATEMENT OF ADMINISTRATIVE ACTION.—The statement of administrative action approved by the Congress under section 101(a) shall be regarded as an authoritative expression by the United States concerning the interpretation and application of the Uruguay Round Agreements and this Act in any judicial proceeding in which a question arises concerning such interpretation or application.

Under the above-referenced § 102(a) of the Act,[10] Congress approved the statement of administrative action proposed to implement the agreements that were submitted to the Congress on September 27, 1994.

2. Statement of Administrative Action

The portions of the Statement of Administrative Action relating to intellectual property are reproduced in Appendix D. As discussed in the following chapters, the brief explanation provided by the Patent Office and approved by Congress is little more than a paraphrase of the statutory sections. Moreover, the ambiguities and errors in the statutory language, which were overlooked by its drafters, similarly escaped their attention in the statement of administrative intent.

3. Proposed Regulations Implementing 20-year Term

The most comprehensive guide to interpretation of the patent term provisions (except for the present text) is the extensive commentary accompanying the regulations proposed by the Patent Office to implement the new legislation, published at 59 Fed. Reg. 63951 (December 12, 1994). These proposed regulations, which are reproduced in Appendix

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[10] APPROVAL OF AGREEMENTS AND STATEMENT OF ADMINISTRATIVE ACTION.— Pursuant to section 1103 of the Omnibus Trade and Competitiveness Act of 1988 (19 U.S.C. 2903) and section 151 of the Trade Act of 1974 (19 U.S.C. 2191), the Congress approves—

(1) the trade agreements described in subsection (d) resulting from the Uruguay Round of multilateral trade negotiations under the auspices of the General Agreement on Tariffs and Trade, entered into on April 15, 1994, and submitted to the Congress on September 27, 1994; and

(2) the statement of administrative action proposed to implement the agreements that was submitted to the Congress on September 27, 1994.

E, explain the interpretation proposed by the Patent Office in much greater detail than the brief Statement of Administrative Action.

Although the PTO proposed regulations provide extensive guidance with respect to such provisions as the new provisional applications, and the "transitional" provisions permitting continued examination beyond final rejection and examination of more than one invention in certain applications, they do not cover important provisions such as the extension of term provided for patents in force, and the infringement amendments.

4. Plain Statutory Language

In interpreting the meaning of unfamiliar or ambiguous language in the new patent provisions, extreme caution should be exercised in relying on any of the available administrative interpretive materials.

The Federal Circuit has clearly announced its intention to adhere to the literal language of statutory texts, and to ignore any Patent Office interpretation that does not agree with the court's reading of the "plain language" of the statute. In *Glaxo Operations UK, Ltd. v. Quigg*,[11] the Federal Circuit explained that the PTO interpretation of "drug product" was entitled to no deference, since the operative terms of the statute, "individually and as combined in the full definition, have a common and unambiguous meaning, which leaves no gap to be filled in by the administering agency."[12]

Particularly in the context of the regulatory term extension provisions of 35 U.S.C. § 156, the court has repeatedly disagreed with PTO interpretations of the earlier patent

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11 894 F.2d 392, 13 U.S.P.Q.2d 1628 (Fed. Cir. 1990).

12 894 F.2d at 398, 13 U.S.P.Q.2d at 1633.

term provisions, and has adhered to an interpretation divining the plain meaning of the statute. This method of statutory exegesis places principal reliance on dictionary meanings and principles of grammar, and disregards contrary legislative history or administrative interpretation.

For example, in *Hoechst, AG v. Quigg*,[13] the Federal Circuit held that the applicant was entitled to a "windfall" extension of 6.8 years, despite the unquestioned intent of Congress to limit the maximum period of extension to 5 years.[14] Applying rote calculation according to the formula of § 156(g)(1)(B), the court found that it was undisputed that a 9.5-year regulatory review period resulted, which was reduced by § 156(c) to yield a 6.8-year term extension.[15] With respect to the cap imposed under § 156(g)(6), the court determined that Congress had simply overlooked the class of patents that received approval fewer than 60 days before enactment of the Act and for which an exemption had been applied for as of that date, and had neglected to assign any limitation on the length of a term extension for these patents.[16] The PTO construction, under which no "regulatory review period" had occurred,[17] was disregarded on the basis that "this court must reject administrative constructions of the

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13 917 F.2d 522, 16 U.S.P.Q.2d 1549 (Fed. Cir. 1990).

14 917 F.2d at 529, 16 U.S.P.Q.2d at 1554.

15 917 F.2d at 524, 16 U.S.P.Q.2d at 1550-51.

16 917 F.2d at 528, 16 U.S.P.Q.2d at 1554. Each of the circumstances specified in §156(g)(6) was inapplicable to the Hoechst patent, since the patent did not issue after the date of enactment (§156(g)(6)(A)), the exemption had been applied for prior to the date of enactment (§156(g)(6)(B)), and the product had already received regulatory approval at the time of enactment (§156(g)(6)(C)). 917 F.2d at 525, 16 U.S.P.Q.2d at 1551.

17 917 F.2d at 523, 16 U.S.P.Q.2d at 1550.

statute that are inconsistent with the statutory mandate, [and] we give no deference to the agency's interpretations and conclusions."[18]

There is no reason to expect the court to grant any more deference to the PTO interpretation of the new patent term provisions, particularly where there is no clear statement of legislative intent that could support the administrative interpretation.

Moreover, where the language of the statute is hopelessly confused, or even where the language of the statute contradicts the plain and unequivocal intention of Congress, the Federal Circuit has indicated that its job is not to fix what the legislature has broken. In *Hoechst*, the court recognized that the 6.8 year extension was contrary to express legislative intent, but instructed that it is not for the court "to 'fix' what Congress either intentionally or unintentionally failed to anticipate."[19] Similarly in *Asgrow Seed Co. v. Winterboer*,[20] the Federal Circuit adopted an interpretation of the farmer's crop exemption in the Plant Variety Protection Act that eliminates the nominal protection offered to the plant variety certificate owner, by authorizing purchasers of protected seed to go into business as competing seed companies. The court recognized that "without meaningful limitations, the crop exemption could undercut much of the PVPA's incentives."[21] However, construing the statute in accordance with principles of grammar, the Federal Circuit held that this unfortunate result

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[18] 917 F.2d at 526, 16 U.S.P.Q.2d at 1552.

[19] 917 F.2d at 529, 16 U.S.P.Q.2d at 1554 (citations omitted).

[20] 982 F.2d 486, 25 U.S.P.Q.2d 1202 (Fed. Cir. 1992), *reversed*, 63 U.S.L.W. (Jan. 18, 1995).

[21] 982 F.2d at 491, 25 U.S.P.Q.2d at 1206.

followed because the statute "as written . . . contains no ensuing crop limitation" when parsed by the appellate court.[22]

The Supreme Court reversed on the basis that "marketing" is an otherwise undefined term that must be given its ordinary, dictionary meaning, which does not require extensive or coordinated advertising or merchandising activities, but instead is defined by some dictionaries as meaning simply "to sell." The Supreme Court thus applied a different dictionary definition to the statutory language, though it conceded that the meaning of the farmer's crop exemption was far from "plain."

For this reason, it should not be assumed that the courts ultimately will adopt the interpretation set forth either in the Statement of Administrative Action or the PTO regulations as finally adopted. Particularly where the language of the statute as enacted requires or permits a different interpretation, the construction of disputed provisions cannot be resolved until the Federal Circuit rules on the plain meaning of the Act.

II. STATUTORY PROVISIONS THAT WILL TAKE EFFECT ON JANUARY 1, 1996

A. WTO Countries Become Exempt From 35 U.S.C. § 104

The patent system of the United States is unique among the developed countries. In essentially all other countries, whoever is "first to file" a patent application has the superior rights to the invention. In the U.S., the inventor who is "first to invent" has

[22] *Ibid.*

priority rights to an invention. A U.S. patent applicant's ability to prove date of the invention becomes crucial, therefore, in at least two situations:

1. to prove priority of invention in a U.S. patent interference under 35 U.S.C. § 102(g) and

2. to remove references as potential prior art in a patent prosecution under 37 C.F.R. § 1.131 (Rule 131).

A patent interference is an *inter partes* litigation in the PTO to decide which of two or more parties claiming the same patentable invention is entitled to the award of a patent. Whichever party establishes that it invented first will generally prevail. Thus, the ability to prove the earliest date of invention can be crucial to the outcome of a patent interference.

The ability to prove the date of an invention can also spell success or failure in a regular *ex parte* prosecution of a U.S. patent application. If the patent examiner cites prior art (a printed publication or another patent) that anticipates the invention or renders it obvious, it is sometimes possible under Rule 131[23] to remove this prior art by proving that the invention predates the publication date of the article or the filing date of the other patent.[24]

Until GATT/TRIPs, only inventive activity in the United States could be used to prove a date of invention. Activities in other countries were excluded by 35 U.S.C. § 104,[25] which provided that parties could not generally prove a date of invention by relying on inventive activity occurring outside the United States.[26] The restrictive nature of § 104 meant that inventors in other countries generally could only rely on the filing dates of foreign

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[23] In pertinent part, Rule 131 reads:

> When any claim of an application . . . is rejected on reference to a domestic patent . . . or on reference to a foreign patent or a printed publication, and the inventor of the subject matter of the rejected claim . . . shall make oath or declaration as to facts showing a completion of the invention in this country before the filing date of the application on which the domestic patent issued, or before the date of the foreign patent, or before the date of the printed publication, then the patent or publication cited shall not bar the grant of a patent to the inventor . . . .

[24] Generally, Rule 131 can be used to antedate or "swear behind" a reference that is prior art under 35 U.S.C. § 102(a), (d), and (e), as well a reference under, 35 U.S.C. § 103 dated less than one year before the applicants filing date. Rule 131 cannot be used to overcome a reference that is prior art under 35 U.S.C. § 102(b).

[25] In pertinent part, § 104 before the new Act read as follows:

> In proceedings in the United States Patent and Trademark Office, in the courts, and before any other competent authority, an applicant for a patent, or a patentee, may not establish a date of invention by reference to knowledge or use thereof, or other activity with respect thereto, in a foreign country other than a NAFTA country except as provided in sections 119 and 365 of this title . . . .

[26] Under the recently enacted North American Free Trade Agreement (NAFTA), inventive activity in Mexico and Canada is exempted from the prohibition. Also, filing of a convention priority application abroad meeting the requirements of 35 U.S.C. § 119 or § 365 can be a constructive reduction to practice.

priority applications to establish a date of invention in U.S. patent prosecutions and interferences. Earlier inventive activity outside the United States simply would not help. In many of these situations, patent applicants could have proven earlier dates of invention outside the United States.

Similarly, only those facts that show "a completion of invention in this country" can be relied on to remove otherwise fatal prior art under present Rule 131. Thus, although U.S. law allows inventors of any country to file U.S. patent applications under the "first to invent" system, those inventive activities were geographically circumscribed in a *de facto* discriminatory fashion.

The United States has no plans to change its "first to invent" system at this time,[27] and nothing in Article 27 of TRIPs requires the U.S. to abandon its "first to invent" system. However, the *de facto* discrimination against non-U.S. inventive activity traditionally perpetrated by § 104 is unacceptable under GATT/TRIPs, which expressly prohibits discrimination based on place of invention.[28]

To implement GATT/TRIPs, the Act amends § 104 to allow proof of date of invention by showing inventive activity in any WTO nation. As amended, § 104 now reads:

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27 Press Release by the U.S. Secretary for the Department of Commerce Ronald Brown, January 24, 1994. In announcing that the U.S. would not seek to resume negotiations of a treaty harmonizing the world's patent laws, Secretary Brown stated, "While other international negotiations continue, we will maintain our first-to-invent system while keeping open the option of full patent harmonization in the future."

28 Article 27, § 1 of TRIPs provides:

> [P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention.

§ 104. Invention made abroad

(a) IN GENERAL.–

(1) PROCEEDINGS.–In proceedings in the Patent and Trademark Office, in the courts, and before any other competent authority, an applicant for a patent, or a patentee, may not establish a date of invention by reference to knowledge or use thereof, or other activity with respect thereto, in a foreign country other than a NAFTA country or a WTO member country, except as provided in sections 119 and 365 of this title.

(2) RIGHTS - If an invention was made by a person, civil or military–

(A) while domiciled in the United States, and serving in any other country in connection with operations by or on behalf of the United States,
(B) while domiciled in a NAFTA country and serving in another country in connection with operations by or on behalf of that NAFTA country, or
(C) while domiciled in a WTO member country and serving in another country in connection with operations by or on behalf of that WTO member country,

that person shall be entitled to the same rights of priority in the United States with respect to such invention as if such invention had been made in the United States, that NAFTA country, or that WTO member country, as the case may be.

(3) USE OF INFORMATION.–To the extent that any information in a NAFTA country or a WTO member country concerning knowledge, use, or other activity relevant to proving or disproving a date of invention has not been made available for use in a proceeding in the Patent and Trademark Office, a court, or any other competent authority to the same extent as such information could be made available in the United States, the Commissioner, court, or such other authority shall draw appropriate inferences, or take other action permitted by statute, rule, or regulation, in favor of the party that requested the information in the proceeding.

(b) DEFINITIONS.–As used in this section–

(1) the term "NAFTA country" has the meaning given that term in section 2(4) of the North American Free Trade Agreement Implementation Act; and

(2) the term "WTO member country" has the meaning given that term in section 2(10) of the Uruguay Round Agreements Act.

1. Applies to Applications Filed *After* December 31, 1995

The effective date provision that applies to new § 104 reads as follows:

§ 531(b)

(b) EFFECTIVE DATE.–

(1) IN GENERAL.–Except as provided in paragraph (2), the amendment made by this section shall apply to all patent applications that are filed on or after the date that is 12 months after the date of entry into force of the WTO Agreement with respect to the United States.

The effective date for the new § 104 will be January 1, 1996.[29] The new § 104 will not be retroactive but will apply only to all patent applications filed on or after that date. Therefore, the new § 104 will not apply at all to pending applications or patents in force before the effective date.

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29 Members of WTO countries will thus join members of NAFTA countries (Canada and Mexico), for which the effective date was December 8, 1993.

2. Cannot Prove Invention in WTO Countries *Before* January 1, 1996

The lack of retroactivity is not just "procedural" but "substantive," that is, the non-U.S. inventive activity itself will not be recognized as effective for proving a date of invention before January 1, 1996. Section 531(b)(2) of the Act is clear on this point:

> (2) ESTABLISHMENT OF DATE.–An applicant for a patent, or a patentee, may not establish a date of invention for purposes of title 35, United States Code, that is earlier than 12 months after the date of entry into force of the WTO Agreement with respect to the United States by reference to knowledge or use, or other activity, in a WTO member country, except as provided in sections 119 and 365 of such title.

The new § 104 will not recognize any non-U.S. inventive activity occurring before January 1, 1996 as proving a date of invention before January 1, 1996. The practical consequences of the amendment, therefore, will only be felt later in time. Applicants filing U.S. patent applications based on non-U.S. inventive activity will not be able to prove a date of invention earlier than January 1, 1996, and thus, it will not be possible based on such proofs to antedate prior art that has itself an effective date (e.g., is published) before January 1, 1996.

As a practical matter, such rejections will not artise until after January 1, 1996. Even more time will likely pass before the need to prove a date of invention arises in interference proceedings.

Thus, it will be some time before patent applicants with inventive activity in WTO countries will be able to reap the benefits of the amendments to § 104. In all likelihood, this will not begin much before 1997; however, the ability actually to prove a date of invention will only exist if these potential patent applicants, in the relatively near future, lay the necessary groundwork to take advantage of the new provisions.

3. Penalty for Inadequate Discovery in WTO Country

The change in § 104 end discrimination against foreign inventors in proving a date of invention. This change, however, raises the spectre that inventors in countries with restricted or inadequate discovery could actually end up with an advantage over American inventors in interference proceedings and in court. It is conceivable that foreign inventors would be able to use U.S. discovery procedures to obtain the information needed to attack the American inventors' priority proofs, while taking advantage of the limitations on discovery in their own countries to shield their own proofs from similar scrutiny. To prevent this problem, new § 104(a)(3) was added:

> To the extent that any information in a NAFTA or WTO member country concerning knowledge, use, or other activity relevant to proving or disproving a date of invention has not been made available for use in a proceeding in the Patent and Trademark Office, a court, or any other competent authority to the same extent as such information could be made available in the United States, the Commissioner, court, or such other authority shall draw appropriate inferences, or take other action permitted by statute, rule, or regulation, in favor of the party that requested the information in the proceeding.

This discovery language appears to impose a mandatory requirement on the PTO or a court to "draw appropriate inferences" when evidence relevant to the date-of-invention issue cannot be obtained from a party, or perhaps even a third party, in a WTO member country. At this time, the practical implementation of this provision is unclear.[30]

One question that immediately arises is whether the "could be made available" language refers to the scope of discovery allowed in a particular United States forum, or to some general standard of discoverability in the United States. Discovery in interferences before the PTO is generally very limited and bears little resemblance to the much broader scope of discovery available in U.S. district courts.

The authoritative Statement of Administrative Action sheds light on this issue. Specifically, the Statement provides:

> Section 531(a) extends existing safeguards in section 104 of Title 35 to ensure fairness to U.S. inventors. Under the current section 104(a)(3) which was added by the NAFTA Implementation Act, when a party in a proceeding before the Patent and Trademark Office, a court, or another competent authority requests information in Mexico or Canada relevant to the date of invention by an opposing party, and the information is not made available to the same extent as it could be made available in the United States, the adjudicative body must "draw appropriate inferences" or take other action permitted by statute, rule, or regulation in favor of the party that requested but could not obtain the information. The implementing bill makes this provision applicable to information in any WTO member country.

It thus appears that the scope of discovery defining the "could be made available" language should depend directly upon the type of proceeding where the date-of-

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[30] On October 25, 1994, the PTO issued a Notice of Proposed Rulemaking. (Appendix F) Included is new proposed 37 C.F.R. § 1.616 (Rule 616). This Rule suggests that if an administrative patent judge or the Board orders information regarding date of invention to be produced, but it is not, then some rather severe sanctions under Rule 616(a) can be imposed, such as preventing a party from filing any paper. 59 Fed. Reg. 50,181 (1994) (to be codified at 37 C.F.R. § 1.616) (proposed Oct. 3, 1994).

invention issue arises. Thus, in an interference proceeding before the PTO, a narrow scope of discovery would define the type of information that "could be made available." In a U.S. district court, on the other hand, the scope of discovery is much broader, and so therefore would the information that "could be made available" in the United States.

In an interference context, this interpretation seems consistent with proposed Interference Rule 616(c):

> (c) To the extent that any information under the control of an individual or entity located in a NAFTA country concerning knowledge, use or other activity relevant to proving or disproving a date of invention has been ordered to be produced by an administrative patent judge or the Board (§1.671(h)), but has not been produced for use in the interference to the same extent as such information could be made available in the United States, the administrative patent judge or the Board shall draw such adverse inferences as may be appropriate under the circumstances, or take such other action permitted by statute, rule, or regulation, in favor of the party that requested the information in the interference, including imposition of appropriate sanctions under paragraph (a) of this section.

4. Effect in Interferences

Beyond doubt, the change in § 104 should have an enormous impact on interference practice. Heretofore, the foreign applicant was almost always limited to reliance on the foreign priority document as a constructive reduction to practice of the invention. No more!

Now the foreign applicant will be able to prove a date of invention relying on inventive activity occurring outside the United States. In all likelihood this will complicate interference proceedings, since now both parties to the interference will have the potential ability to present priority proofs.

It also seems likely that more interferences will be declared. For example, assume that U.S. patent applicant *A* claims subject matter that interferes with that claimed by German applicant *B*. The U.S. applicant's U.S. filing date is January 10, 1997, and the German applicant's priority date is April 15, 1997.

Under the old law, the PTO would most likely reject the German application over the U.S. application under § 102(g). To provoke an interference, the German applicant would have had to make the rigorous showing required by 37 C.F.R. § 1.608(b), which basically requires a showing of prima facie entitlement to judgment. It would be highly unlikely that such a showing could be made because the German applicant, under the old law, would be precluded from relying on her German activity.

Under the new law, however, assuming the conditions discussed above are met, the German applicant can rely on her German activity to demonstrate prima facie entitlement to judgment. Logically, therefore, more interferences should be declared under the new law.

5. Effect in Antedating References Under Rule 131

a. Changes to Rule 131

Rule 131 provides a procedure for removing otherwise patent-defeating prior art by showing a date of invention before the filing date of the domestic patent or the publication date of a foreign patent or publication. To comply with Article 27 of TRIPs, Rule 131 must be amended to allow a party to rely on inventive activity in any WTO country to prove a date of invention.

The PTO proposed an amendment to Rule 131 in 59 Fed. Reg. 49,876 on September 30, 1994. The changed language will read: "The oath or declaration must include facts showing a completion of the invention in this country or in a NAFTA or WTO Member country . . . ."

For example, assume that a U.S. patent application discloses subject matter that a U.S. patent examiner applies under § 102(e) or § 103 to reject claims by a German applicant. The reference application was filed in the U.S. on January 10, 1997.

The German applicant's priority date is April 15, 1997, and the German's U.S. filing date is April 15, 1998. We further assume that the January 10, 1997, application is issued as a patent on March 10, 1998. We also assume that the German applicant can prove completion of the invention in Germany in July 1996.

Under the old law, there would be virtually no way for the German applicant to antedate the U.S. application's filing date because the applicant was precluded from relying on her inventive activity in Germany. Under the new law, however, assuming the conditions discussed above are met, the German applicant can rely on her 1996 German activity to antedate the U.S. application. Clearly, a foreign applicant's ability to obtain a U.S. patent is enhanced.

6. Proving a Date of Invention

In changing § 104, the amendments provide new opportunities for foreign patent applicants to prove acts of invention based on inventive activity outside the United States. As explained above, the impact from these changes will probably not surface until at least 1997. Nevertheless, foreign applicants need to position themselves **now** so that they may prove inventive acts as of January 1, 1996. These applicants, therefore, must become aware of U.S. practice: the types of proofs and the standards of proof, the concepts of "conception" and "reduction to practice," and the varying rules of practice in interferences and Rule 131 practice.

For example, in the United States, no acts of invention--including conception, diligence, and actual reduction to practice--can be proved in an interference solely by relying on the testimony of the inventor or inventors. Instead, the inventor's acts of invention must generally be corroborated by a noninventor. Therefore, documentary evidence of dates of invention, such as laboratory notebooks, are commonly witnessed by at least one noninventor. Multinational companies should familiarize themselves with the detailed record-keeping procedures and standards of proof generally deemed sufficient for proving and corroborating dates of invention. Armed with such knowledge, beginning on January 1, 1996, applicants with inventive activities outside the United States should be on equal footing with their United States counterparts when trying to prove dates of invention.

7. Effect as § 102(g) Prior Art

a. Interference Estoppel

The language "in this country" also appears in § 102(g), which was not amended by the Act. Section 102(g) provides that a person is entitled to a patent unless "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it."

Some believe that the "in this country" language should be changed to comply with GATT/TRIPs. Otherwise, some strange and unjust results could ensue, particularly in interference proceedings.

Suppose that a party loses a patent interference to another inventor who proved a date of invention by relying on inventive activity outside the U.S. but within another WTO country. That losing party nonetheless might be able to obtain a U.S. patent for the same claims lost in the interference. How could this possibly occur?

After the interference, upon returning to the *ex parte* prosecution before the examiner, the examiner would no doubt reject the lost claims under the doctrine of interference estoppel. The losing party would argue entitlement to a patent unless, under unamended § 102(g), "the invention was made in this country by another who had not abandoned, suppressed, or concealed it" or unless other prior art provided a basis to reject the claims. In particular, § 104, the "invention made abroad" provision, has never been considered to be a prior art section.

If some prior art basis under § 102 is required to deny the losing party the claims, we would be left with an intolerable situation: A party denied a patent under a PTO interference proceeding would be entitled to one because the other invention, which prevailed in the interference under amended § 104, was not "in this country" under unamended § 102(g).

The doctrine of interference estoppel might obviate this problem. The PTO and others likely would argue that interference estoppel precludes this possibility. Specifically, in the authoritative Statement of Administrative Action, one finds the following:

> The implementing bill does not change present practice regarding the effect of a determination that establishes which of two or more inventors was first inventor. This practice precludes the losing party from separately patenting the invention in dispute, even if the invention of the winning party was not made "in this country", pursuant to application of section 102(g) of Title 35, U.S. Code. Thus, a losing party is and will continue to be precluded through interference estoppel from separately patenting the invention in dispute or an invention that is not patently [sic] distinguishable from the invention in dispute (see *In re Deckler*, 24 U.S.P.Q.3d 1448 (Fed. Cir. 1992)).

Is the *Deckler* case really a complete answer? In *Deckler*, the party Deckler, although first to reduce the invention of the count to practice, suppressed the invention until after the other party's priority date, which was obtained by filing a foreign patent application. After return to *ex parte* prosecution, numerous rejections were apparently made, but the only one sustained by the Board was based on the ground that the rejected claims defined the same invention as the interference count.

Deckler, in his opening brief before the Federal Circuit, challenged the Board's conclusion that the rejected claims were not patentably distinct from the subject matter of the lost count. In his reply brief, however, Deckler in effect conceded that the claims were not separately patentable.

The Federal Circuit upheld the Board's rejection, which, it pointed out, relied on principles of res judicata and collateral estoppel. However, a portion of the opinion is telling:

> Since Deckler has in effect conceded that the subject claims in his application are patentably indistinguishable from his claim corresponding to the interference count, the Board properly concluded that the interference judgment barred Deckler from obtaining a patent containing those claims.

24 U.S.P.Q.2d at 1449.

Therefore, and particularly because *Deckler* cites with approval the *McKellin* and *Hilmer* C.C.P.A. cases, one can urge that *Deckler* is limited to a situation where the interference loser admits that the claims are not separately patentable from the lost count. A losing party would be well advised to avoid such an admission upon return to *ex parte* prosecution.

The losing party's position might be even further enhanced if, during the interference, she moved for no interference in fact or for a judgment of separate patentability for the claims in issue under 37 C.F.R. § 1.633(c)(4). Unless § 102(g) is amended before January 1, 1996, the effective date of the amendments to § 104, then the above scenario will probably have to be resolved in the courts.

Congress can still act, however. In light of the inevitable delay in the impact of new § 104, Congress has plenty of time to amend § 102(g) if it finds the arguments in favor of amendment persuasive.

Yet, notwithstanding that § 102(g) was not amended, Congress has approved a bizarre interpretation of the Act that de facto amends § 102(g) as applied against foreign applicants attempting to prove an earlier date of invention in an interference based on foreign activity.

Specifically, the Statement of Administrative Action, which was expressly approved by Congress in § 101(a)(2) of the Act, states:

> As foreign inventive activity may now be considered in a determination of which inventor was the first to invent, fairness to both U.S. and foreign inventors demands a certain identity of treatment with regard to reliance on inventive activity in the

> United States and abroad. Consequently, the inability of an inventor to rely on a date of invention in the United States where the invention has been subsequently abandoned, suppressed or concealed the invention under patentability determinations under Section 102(g) should apply equally to the inventor relying on foreign inventive activity.

The language "the invention under patentability determinations" is unclear and appears to be a typographical error, but the PTO is apparently urged to entertain "abandonment, suppression, and concealment" allegations against a party to an interference that is relying on foreign activity. The possible result, of course, is that the reliant party could contest suppression and concealment allegations based on lack of statutory basis. Again, absent an amendment to § 102(g) before these issues arise, it is likely that this issue will have to be litigated.

b. Third-Party Secret Prior Art

There is yet at least another peculiarity that flows from the failure of Congress to amend § 102(g). Specifically, apart from the context of interferences and any effect of interference estoppel resulting from an interference, it is clear that the ability to prove an earlier date of invention outside the United States has no effect as offensive prior art.

For example, assume that a patent in a U.S. district court patent infringement suit claims a green and red box, the patent having issued from an application filed on January 2, 1999. Further, assume that the alleged infringer takes deposition testimony indisputably showing the actual reduction to practice in Brugges, Belgium of a green and red box on December 24, 1997, i.e., more than one year before the U.S. filing. Assume, however, that no activity associated with the Belgian green and red box falls within any subsection of § 102. Assume it is indisputable that if there were an interference, the Belgian proofs would suffice for proving priority. It is further indisputable that the Belgian box embodies every limitation of every claim of the patent in suit.

Thus, there is no basis under § 102 for invalidating the patent in suit based on the Belgian box, even if the box is the work of the alleged infringer. For sure, § 102(g) does not apply because there is no activity "in this country." Accordingly, even though the Belgian work could have formed the basis for prevailing against the patent in an interference, it has no effect as prior art outside the confines of an interference.

It is believed that this example reveals a major reason why Congress did not amend § 102(g). Simply put, there was concern about exposing U.S. patents to possible invalidity based on "worldwide" secret prior art.

On the other hand, perhaps there was a less restrictive alternative. Congress could have simply amended § 102(g) to remove the "in this country" limitation with respect to interferences. Such an amendment would address the concerns expressed above about what the losing party might do after an interference with respect to claims that during the interference had been designated as corresponding to the count. Further, the amendment would not expose U.S. patents to "worldwide" secret prior art.

In any event, as long as the prevailing policy is not to allow unlimited use of secret prior art to invalidate U.S. patents, there will be a certain lack of symmetry in the law. In other words, foreign activity sufficient to prove an earlier date of invention will not qualify as disabling prior art outside the context of an interference.

B. New Definitions of Infringement are Incorporated Throughout Title 35 of the U.S. Code

Until January 1, 1996, it will not be an act of infringement to offer a patented product for sale, or to import a patented product into the United States. On that date, the law of patent infringement will change to make either of these acts a violation of the patent owner's rights. In accordance with this revision, the patent statute has been generally amended by the Uruguay Round Agreements Act, as illustrated by 35 U.S.C. § 154(a)(1) defining the patent right, and § 271(a) specifying acts that infringe this right:

> **§ 154. Contents and term of patent**
>
> (a) IN GENERAL.–
>
> (1) CONTENTS.–Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, **offering for sale**, or selling the invention throughout the United States **or importing the invention into the United States**, and, if the invention is a process, of the right to exclude others from using, **offering for sale** or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.
>
> **§ 271. Infringement of patent**
>
> (a) Except as otherwise provided in this title, whoever without authority makes, uses, **offers to sell**, or sells any patented invention, within the United States **or imports into the United States any patented invention** during the term of the patent therefor, infringes the patent.

This fundamental revision of U.S. patent law was required by the TRIPs agreement and affects most statutory provisions relating to patent infringement. Article 28 of TRIPs defines the scope of protection a patent must confer. Where the subject matter is a product, the patent must confer the right to exclude others from making, using, offering for sale, selling, or importing the product for these same purposes. Where the subject matter is a process, the patent must confer the right to prevent others from the act of using the process and from the acts of using, offering for sale, selling, or importing for these same purposes at least the product obtained directly by that process.

1. "Offer to Sell" Claimed Invention

Under prior law, it was well settled that neither an offer of sale of a patented product nor promotional activities aimed at such sale constituted an act of patent infringement or provided a jurisdictional basis for a patent infringement action in federal district court. *Laitram Corp. v. Cambridge Wire Cloth Co.*, 919 F.2d 1579, 16 U.S.P.Q.2d 1929 (Fed. Cir. 1990), *cert. denied*, 113 S. Ct. 97 (1992). Under traditional patent law principles, it was not an act of infringement to threaten future infringement, or even to contract to make a patented invention, and to begin its construction, because § 271 did "not cover acts other than an actual making, using or selling of the patented invention" in its completed form. *Eli Lilly & Co. v. Medtronic, Inc.*, 915 F.2d 670, 16 U.S.P.Q.2d 2020 (Fed. Cir. 1990) (*citing Lang v. Pacific Marine & Supply Co.*, 895 F.2d 761, 13 U.S.P.Q.2d 1820 (Fed. Cir. 1990)).

a. When Offer is Made

The new act of infringement resulting from an offer of sale is qualified by an important limitation included in new 35 U.S.C. § 271(i), which provides:

> As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee, or any designee of the patentee, is that in which the **sale will occur before the expiration of the term** of the patent.

For this reason, an offer to sell a patented product, or an offer to sell an unpatented product produced by a patented process, will infringe *only* if the sale will occur before the patent expires. An offer to sell a patented invention that specifies a date of sale after expiration of the patent, or solicitation of orders or advertising of an infringing article, without more, would not constitute infringement under § 271(i).

An interesting issue of subject matter jurisdiction will arise with respect to the question of whether an offer to sell a patented invention, or unauthorized promotion of a patented product, will constitute an act of infringement that may be enjoined prior to its actual sale.

The new act of infringement may ensnare offers for sale, and contracts for production of an infringing article, such as the contract to build a ship's hull at issue in *Lang v. Pacific Marine & Supply Co.*, 895 F.2d 761, 13 U.S.P.Q.2d 1820 (Fed. Cir. 1990), where the contract or offer specifies a date of completion or delivery of the infringing article before the patent term expires.

b. When Sale is Made

For this reason, the central question in determining infringement resulting from an offer of sale will be whether the sale takes place prior to patent expiration. Section 271(i) clearly provides that a sale during the term of the patent is *required* for an offer to sale to infringe, and the requirement of a sale during the term of the patent does not appear to differ in any significant extent from the former requirement for infringement of a sale during the term of a patent.

In analyzing the question of what constitutes a "sale" under the patent laws, it has generally been considered that an infringing sale cannot occur without transfer of title and possession of the infringing article, as extensively discussed in *Ecodyne Corp. v. Croll-*

Reynolds Eng'g Co., 491 F. Supp. 194, 197, 206 U.S.P.Q.2d 601, 603-04 (D. Conn. 1979). For this reason, an infringing offer of sale under the amended statute may require transfer of title during the term of the patent and possibly also delivery of the infringing article.

For this reason, it appears that actual production of the completed infringing article is required under the new infringement provisions, just as under former law. *See Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 223 U.S.P.Q. 591 (Fed. Cir. 1984). If this is the case, an offer of sale under the infringement provisions of the patent statute differs in a significant respect from an offer of sale that will be sufficient to raise a statutory bar under 35 U.S.C. § 102(b).[31] In *UMC Electronics Co. v. United States*,[32] the Federal Circuit held that reduction to practice, by construction of an actual physical embodiment of the claimed invention, is not required for an on-sale bar to arise. Little guidance is provided by the court's instruction that a mere conception is not an invention that can be placed on sale, but that "the on-sale bar does not necessarily turn on whether there was or was not a reduction to practice of the claimed invention."[33]

Based on the conflict in recent Federal Circuit precedent illustrated by *Magna-Graphics* and *UMC Electronics*, it is not possible to predict with reasonable certainty what

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[31] Section 102(b) provides that a person shall be entitled to a patent unless:

> the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States[.]

[32] 816 F.2d 647, 2 U.S.P.Q.2d 1465 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1025 (1988).

[33] 2 U.S.P.Q.2d at 1471-72.

specific activity will be required for a sale to occur before the expiration of the term of patent. In this area as well, litigation will be required to provide an answer.

The main effect of including an offer of sale, coupled with a later sale during the patent term, as an act of infringement appears to be that an infringing act technically occurs as of the date of the original offer. A patentee who can prove loss of sales to customers who accept the offers of sale of a patented invention from an unauthorized source may be entitled to relief, such as interest, from the date of the original offer of sale rather than the eventual delivery date. Further, where an offer of sale specifies a delivery date within the term of an unexpired patent, a declaratory judgment action may be maintained, and injunctive relief awarded, where jurisdiction would have been absent under former law.

2. Mere Importation of Claimed Invention Into the United States

With one exception, treated in the following section, it had not been an act of infringement to import into the United States an article covered by a patent, without "making, using or selling" it in the United States.

For example, in *Genentech, Inc. v. Wellcome Foundation*,[34] the claims related to a cell culture capable of expressing human tissue plasminogen activator (t-PA). The patent owner urged infringement on the basis that defendant had transferred a portion of its master cell bank to the United States, where the imported cells were maintained in a frozen state. The maintenance of this imported cell bank in the United States provided a backup cell

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[34] 14 U.S.P.Q.2d 1363 (D. Del. 1990), *reversed on other grounds*, 29 F.3d 1555, 31 U.S.P.Q.2d 1161 (Fed. Cir. 1994).

culture in the event that the original cells in the United Kingdom were destroyed or contaminated, and further provided an available source of recombinant t-PA for commercial production facilities, when these later became operational. Relying on the absence of any evidence of actual use of the imported cell culture, the district court granted summary judgment of noninfringement based only on the importation and storage of the accused culture in the United States.[35]

This activity would clearly infringe after January 1, 1996, under the amended statutory provisions, without further use or offer of sale. The amendment of the patent statute to provide that importation *per se* of a patented invention constitutes infringement, without making, using, selling, or offering the invention for sale, is a more basic revision than the "offer for sale" provision. It reaches conduct that was completely exempt from infringement prior to the Act.

Although infringement by importation alone is established, the question of the remedy that may be awarded is less clear. Where no sale or other use of the imported infringing article occurs, it is unclear what damages would be adequate to compensate for the infringement under 35 U.S.C. § 284. Indeed, the reasonable royalty floor for damages under the statute is expressly tied to a royalty "for the use made of the invention by the infringer." Under these circumstances, relief may be limited to an injunction prohibiting further use or sale of the patented invention during the term of the patent, or requiring it to be removed from the United States.

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35 *Id.* at 1371-72.

Where the imported article is later used or sold by the importer, the patentee may be able to urge that interest on damages should accrue from the date of importation, rather than the eventual date of sale or use, based on the economic value ultimately derived from infringing use of the patented invention. It would not be necessary to await such eventual use or sale to bring an infringement action, which possibly could be maintained even before the infringing article clears Customs and comes into possession of the defendant.[36]

3. Importation of Product of Patented Process Protected Under Former Law

Even prior to the Uruguay Round Agreements Act, it had been an act of infringement to import into the United States the unpatented product of a process patented in the United States and used abroad. As amended in 1988, 35 U.S.C. §§ 154 and 271(g) made it an act of infringement to import a product that is made abroad using a process patented in the United States.[37]

However, this remedy was circumscribed with numerous qualifications to protect "innocent" infringers, who are persons without notice that a patented process was used to produce the product. For example, liability for infringement is generally limited to manufacturers, wholesalers, or distributors by the provision that "no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there

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[36] *See Bristol-Myers Co. v. Erbamont, Inc.*, 723 F. Supp. 1038, 13 U.S.P.Q.2d 1517 (D. Del. 1989), where the district court held that importation of the product of a patented process occurred on the date when the accused product was physically brought into the United States from outside, without regard to clearing Customs, payment of duties, or sale or use in the United States. *Id.* at 1044, 13 U.S.P.Q.2d at 1522.

[37] The process patent amendments are discussed in Chapter 14 of K.J. Burchfiel, Biotechnology and the Federal Circuit (B.N.A. 1995).

is no adequate remedy under this title for infringement on account of the importation or other use or sale of that product." 35 U.S.C. § 271(g). Further, the statute provides that a product made by a patented process will not infringe after

> (1) it is materially changed by subsequent processes; or
> (2) it becomes a trivial and nonessential component of another product.

The Uruguay Round Agreements Act does not appear to expand the remedy provided by law for importation of an unpatented product of a patented process or to alter the statutory scheme limiting the availability of this remedy.

4. Offer for Sale of Product of Claimed Process Invention

Section 271(g) was amended by the Uruguay Round Agreements Act to specify that an offer of sale of the product of a patented process similarly constitutes an act of infringement, along with § 295, which establishes a presumption that the product offered for sale is made by a patented process, if a substantial likelihood exists that this is the case, and the patent owner made a reasonable effort to determine the process actually used, but was unable to do so.

5. Marking of Goods Offered for Sale or Imported

The Uruguay Round Agreements Act imposes new duties on patent owners as well as infringers, by requiring that patentees and persons offering for sale or importing any patented product mark the product offered for sale or imported in order to sue for infringement damages, unless the infringer received actual notice of infringement under 35 U.S.C. § 287.

A parallel change to 35 U.S.C. § 292 makes it an offense falsely to mark a product that is imported or offered for sale without the authorization of the patentee, with the intent of counterfeiting or imitating the mark of the patentee, or of deceiving the public and inducing them to believe that the thing was offered for sale or imported by or with the consent of the patentee.

6. Intervening Rights

Patent term extensions and revival of expired and invalid patents have been familiar in United States patent law since the early days of the republic. When enacting legislation that extends or revives patent rights, Congress has typically provided for the intervening rights of purchasers or users of the patented technology, whose acts became infringing only as a result of the term extension or restoration of patent rights. The infringement provisions of the Uruguay Round Agreements Act are no exception to this rule, and in extending the patent right to include the right to exclude others from offering for sale or importing a patented invention, Congress amended the reissue and reexamination statutes to provide relief to persons who committed these acts prior to reissue or reexamination.[38]

As amended, the second paragraph of 35 U.S.C. § 252 provides:

> A reissued patent shall not abridge or affect the right of any person or that person's successors in business who, prior to the grant of a reissue, made, purchased, **offered to sell,** or used within the United States, **or imported into the United States,** anything patented by the reissued patent, to continue the use of, **to offer to sell**, or to sell to others to be used, **offered for sale,** or sold, the specific thing so made, purchased, **offered for sale,** used, **or imported** unless the making, using, **offering for sale,** or selling of such thing infringes a valid claim of the reissued patent which was in the original patent. The court before which

[38] Intervening rights under the reissue and reexamination statutes is a separate topic from the intervening rights and compulsory license provided to persons whose acts become infringing as a result of the resetting of patent terms under 35 U.S.C. §154(c)(2), discussed in Section III.A, *infra.*

> such matter is in question may provide for the continued manufacture, use, **offer for sale**, or sale of the thing made, purchased, **offered for sale**, used, **or imported** as specified, or for the manufacture, use, **offer for sale**, or sale in the United States of which substantial preparation was made before the grant of the reissue, and the court may also provide for the continued practice of any process patented by the reissue that is practiced, or for the practice of which substantial preparation was made, before the grant of the reissue, to the extent and under such terms as the court deems equitable for the protection of investments made or business commenced before the grant of the reissue.

The intervening rights provision under the reexamination statute, 35 U.S.C. § 307(b), was amended as follows:

> Any proposed amended or new claim determined to be patentable and incorporated into a patent following a reexamination proceeding will have the same effect as that specified in section 252 of this title for reissued patents on the right of any person who made, purchased, or used within the United States, **or imported into the United States,** anything patented by such proposed amended or new claim, or who made substantial preparation for the same, prior to issuance of a certificate under the provisions of subsection (a) of this section.

A significant distinction is thus created between the intervening rights of the prior user of an invention patented in a reissue patent and a reexamined patent. The reissue provision immunizes prior offers of sale or importation of a patented article, while the reexamination provision is limited to persons who made, purchased, used, or imported the patented invention into the United States.

The further intervening rights provision governing patents revived after lapsing for failure to pay the maintenance fee is amended to provide intervening rights for those who offer for sale or import the invention:

35 U.S.C. § 41(c)(2):

> A patent, the term of which has been maintained as a result of the acceptance of a payment of a maintenance fee under this subsection, shall not abridge or affect the right of any person or that person's successors in business who made, purchased, **offered to sell**, or used anything protected by the patent within the United States, **or imported anything protected** by the patent into the United States after the 6-month grace period but prior to the acceptance of a maintenance fee under this subsection, to continue the use of, **to offer for sale**, or to sell to others to be used, **offered for sale**, or sold, the specific thing so made, purchased, **offered for sale**, used, **or imported**. The court before which such matter is in question may provide for the continued manufacture, use, **offer for sale**, or sale of the thing made, purchased, **offered for sale**, or used within the United States, or **imported into the United States**, as specified, or for the manufacture, use, **offer for sale**, or sale in the United States of which substantial preparation was made after the 6-month grace period but before the acceptance of a maintenance fee under this subsection, and the court may also provide for the continued practice of any process that is practiced, or for the practice of which substantial preparation was made, after the 6-month grace period but before the acceptance of a maintenance fee under this subsection, to the extent and under such terms as the court deems equitable for the protection of investments made or business commenced after the 6-month grace period but before the acceptance of a maintenance fee under this subsection.

This provision, like the reissue provision, distinguishes between the absolute right of a person who made or imported the patented article to continue otherwise infringing acts of sale, offer for sale, or use of articles that came into his possession during the period when such conduct was not infringing, and the right to continue importing the infringing product. In each case, whether intentionally or not, the statute provides only that a court may provide for the continued manufacture, use, offer for sale, or sale of the patented thing after revival or reissue, without similarly stating that the court may authorize continued importation of the patented article to the extent that it is equitable.

The earlier symmetry of the various intervening statutory rights provisions is thus removed by the recent amendments, without explanation of the disparities that are introduced into the statutory language.

7. Applications for Regulatory Approval

The complex statutory provision of 35 U.S.C. § 271(e) exempts from patent infringement clinical trials of drugs or medical devices, where submission of the data obtained is required for federal regulatory approval of an infringing drug, process, or device.[39]

Under the clinical trial exemption from infringement, the submission of an Abbreviated New Drug Application (ANDA) for a generic drug is a highly artificial act of infringement that permits a patent owner to sue for relief that the generic drug may not receive regulatory approval until the expiration date of the patent.

In accordance with the general amendment of the patent infringement provisions, § 271(e)(1) is amended to clarify that it is not an act of infringement to offer to sell or import into the United States a patented drug or medical device solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

Further, with respect to such noncommercial activity, no injunctive or other relief may be granted that would prohibit the offering to sell or importing into the United

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[39] The exemption from infringement under 35 U.S.C. §271 is the subject of chapter 15 of K.J. Burchfiel, Biotechnology and the Federal Circuit (B.N.A. 1995).

States of a patented invention for the purposes specified in § 271(e)(1). 35 U.S.C. § 271(e)(3).[40]

The conforming amendment of § 271(e) does not appear to materially change or broaden the regulatory approval exemption. Even prior to the amendment, it was established that the pre-expiration promotion or offer of sale of a patented drug or medical device was exempted from infringement, and that such pre-commercial promotional activity may be solely for uses reasonably related to the development and submission of regulatory information.

In *Telectronics Pacing Systems v. Ventritex, Inc.*,[41] the Federal Circuit held that extensive promotional activities, including sale and implantation of a defibrillator for clinical trials; demonstration of the defibrillator at medical conferences; and dissemination of clinical data to investors, analysts, and journalists were all activities "solely for uses reasonably related to obtaining FDA approval" under § 271(e)(1).[42]

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40 The commercial offer to sell or importation into the United States of an approved drug is an act of infringement that may be enjoined or form the basis for an award of damages. §271(e)(4)(B)-(C).

41 982 F.2d 1520, 25 U.S.P.Q.2d 1196 (Fed. Cir. 1992).

42 982 F.2d at 1521-22, 25 U.S.P.Q.2d at 1197.

III. PROVISIONS AFFECTING PATENT-TERM BECOME EFFECTIVE ON JUNE 8, 1995

Under traditional United States practice, a patent protects an invention for a term of 17 years, measured from the date of issuance of the patent. The filing date of the application plays no role in measuring the patent's term. Present practice, however, needed to be changed to comply with the provisions of GATT/TRIPs.

Article 33 of GATT/TRIPs requires that the term of patent protection "shall not end before the expiration of a period of twenty years counted from the filing date." The Article permits member countries to provide longer terms, but the minimum allowable term is 20 years from the date of filing.

The United States has now changed the patent term from the former period of 17 years from the date the patent issues to 20 years from the date of filing the original application. The end of the 20-year term under amended 35 U.S.C. § 154(a)(2) is measured from the date of filing of the **original** U.S. application, that is, the first application in a series of continuation, divisional, or continuation-in-part applications. Applications from which priority is claimed under § 119, i.e., foreign priority applications and the provisional U.S. applications created by the Act, are not counted in determining the term of the patent.

The new statute, 35 U.S.C. § 154(a)(2), provides:

> Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the

> date on which the earliest such application was filed.

The patent-term provisions take effect on June 8, 1995,[43] and will apply to **all** U.S. applications filed on or after that date, including continuations, divisionals, and continuations-in-part of applications currently pending.[44] Thus, if a continuation of a pending application is filed on or after June 8, 1995, the patent that issues from that continuation will not have a term of 17 years from the date of issuance, as would have been the case if the continuation had not been filed and the parent application had been successfully prosecuted to issuance. Instead, the term of patent that issues from the continuation filed after June 8, 1995, must be assumed to have a term that is 20 years from the date of the **original** application from which the continuation claims priority under 35 U.S.C. § 120.

Some change in the U.S. system had to occur. After all, some patents issue rather quickly so that the 17 years of protection added to the time required for prosecution would not total the minimum 20-year term mandated by GATT/TRIPs. The United States could have complied simply by amending § 154 to provide a term measured by 17 years from the date of issuance or 20 years from the date of filing, whichever is longer.[45]

But the Act does not adopt this simple approach. Instead, the Act amends § 154 essentially to provide a maximum 20-year term, measured from the date of the filing of

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43 Uruguay Round Act, § 534(b)(1).

44 *Id.* § 534(b)(1); 35 U.S.C. § 154(a)(2) (1995).

45 In fact, on January 4, 1995, 56 members of Congress introduced H.R. 359 which proposes such an amendment to § 154.

the patent application, or, if earlier patent applications are referenced, from the date of the earliest application.

A. Issued Patents

Under the amendments, new § 154(c)(1) covers patents in force on the effective date or patents that result from applications pending on the effective date and states:

> The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of [S. 2467] shall be the greater of the 20-year term as provided [herein], or 17 years from grant, subject to any terminal disclaimers.

As is readily apparent from the face of the statute, in conforming U.S. law to GATT/TRIPs, this provision resets the patent term to any U.S. patent in force as of June 8, 1995, if seventeen years from issue occurs before twenty years from the earliest filing.

1. Resetting of Term of Some Patents in Force

This significant provision will reset the terms of many patents in force. The new legislation resets the term of already-issued U.S. patents to the greater of 17 years from the date of grant or 20 years from the date of filing the original application.[46] In any patent in which prosecution took less than three years from the date of original filing to issuance, the patent term will be automatically reset to expire at the later date.

Apparently, the PTO will not take any action to reset the patent terms of any existing patents. The Uruguay Round Agreements Act is essentially self-executing with respect to patents that are entitled to the longer of the 17-year or 20-year patent term.

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[46] 35 U.S.C. § 154(c)(1) (1995). This term is a maximum and is subject to limitation by terminal disclaimer, as under current law. *Id.*

The statute thus provides a windfall for all patent applications that had a short pendency, and particularly for applications that were allowed on the first action.

To qualify for the new minimum statutory term of 20 years from filing, a previously granted patent must be *in force* on June 8, 1995. There is no statutory definition of "patents in force." It clearly includes all unexpired patents. Several complicating factors exist.

According to § 154(c)(1) the 20-year patent term will be subject to terminal disclaimers. A typical terminal disclaimer disclaims the terminal portion of a patent beyond the date when another patent, referenced in the terminal disclaimer, expires.

The term of a patent in which a terminal disclaimer is filed is thus pegged to the term of the referenced patent. While the date at which the referenced patent expires may be increased by operation of 35 U.S.C. § 154(c)(1), the link between the date of expiration of the referenced patent and the disclaimed patent remains.

Thus, whether the term of a disclaimed patent is reset depends on a three-part determination. First, under § 154(c)(1), is the disclaimed patent eligible to have its term reset? If so, the second determination is whether the term of the referenced patent has been reset and whether the patentee of the disclaimed patent disclaimed to a date certain. If the referenced patent is given a longer term, and if the disclaimer did not use "date certain" language, the disclaimed patent can have its expiration date reset to expire on the same day as the referenced patent.

However, the third determination is whether setting the patent term of the disclaimed patent to the new expiration date of the referenced patent results in a term of the disclaimed patent that exceeds 20 years from filing. If so, the term of the disclaimed patent presumably can only be reset to the 20-year term date.

Most terminal disclaimers are filed to overcome obviousness-type double patenting rejections. Basically, a patent subject to a terminal disclaimer pegged to the expiration of a referenced patent will get a patent term reset depending on the outcome of the three-part determination described above.

What about a patent that otherwise qualifies for a reset term, but the term of which has been disclaimed independently of any other patent?[47] The Statement of Administrative Action states: "A patent whose term has been disclaimed under Section 253 of Title 35 independent of another patent shall be reduced by the length of the originally disclaimed period." Presumably, therefore, unless the disclaimer disclaimed past a date certain, the patent will have its term reset according to the new law, minus the length of the originally disclaimed period.

One way to summarize the effect of a terminal disclaimer when patent terms are reset by operation of 35 U.S.C. § 154(c)(1) is to remember that under the previous 17-year term system the referenced patent would always expire before the disclaimed patent. Otherwise, a terminal disclaimer would make no sense.

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[47] It is possible to disclaim part of a patent term for a reason unrelated to a referenced patent. For example, the patentee could voluntarily dedicate the patent to the public on a specific date before the normal expiration of the patent. In such a situation, the patent would expire on that date, and the term would not be affected by 35 U.S.C. § 154(c)(1).

When the terms are reset, there will be certain basic situations. First, the term of the referenced patent is not increased but remains 17 years from date of issue. In that case, the term of the disclaimed patent does not change either.

Second, the referenced patent was originally filed before the disclaimed patent, and because the complete prosecution of the referenced patent took less than three years, its term is reset to 20 years from the date of its original filing.

In that case, assuming the disclaimer did not use "date certain" language, the term of the disclaimed patent can be reset to expire on the same day as the referenced patent, as long as the reset term of the disclaimed patent is not greater a 20-year term for the disclaimed patent.

Finally, the application for the disclaimed patent may have been filed before the application for the referenced patent, but nevertheless issued later than the referenced patent. If the term of the referenced patent is reset, then the term of the disclaimed patent, assuming absence of "date certain" disclaimer language, can also be reset to as late as the new expiration date of the referenced patent. Here, however, the original filing date of the disclaimed patent must also be considered. It is conceivable that the new expiration date of the referenced patent is later than 20 years from the original filing date of the disclaimed patent.[48] In that case, the term of the disclaimed patent is still reset, but it is not entitled to the full increase, i.e. same expiration date, as the referenced patent. Instead, the term of the disclaimed patent is reset to 20 years from its own original U.S. filing date.

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[48] This hypothetical example assumes that the reference patent does not claim benefit of the earlier-filed original application for the disclaimed patent.

Let's look at a concrete example.

Assume we are dealing with two patents: Patents *A* and *B*. Patent *A* was filed on January 2, 1978, and issued on January 2, 1979. The normal 17-year term would expire on January 2, 1996. Twenty years from filing, however, would be January 2, 1998, so the patent term is reset to expire two years later.

Patent *B* was filed on January 2, 1979, and issued on January 2, 1980. No benefit to an earlier filing date was claimed.

However, a terminal disclaimer was filed in Patent *B*, disclaiming the portion of the term beyond the full statutory term of Patent *A*. Thus, one year of patent term was disclaimed in Patent *B*, and its patent term after grant would be 16 years, i.e., until January 2, 1996, which is 17 years after filing.

Twenty years from filing for Patent *B*, which is January 2, 1999, is later in time than 17 years from issue, which is January 2, 1997, and also later in time than 16 years from issue, which is January 2, 1996, factoring in the terminal disclaimer. Without the terminal disclaimer, the owner of Patent *B* would otherwise have been entitled to a reset term that is three years longer than the disclaimed term. In other words, it appears that Patent *B*, but for the terminal disclaimer, is eligible for a reset term.

However, because of the terminal disclaimer, the term of Patent *B* can only be reset to the reset expiration date of Patent *A*, which is January 2, 1998. Thus, the terminal disclaimer prevents the term of Patent *B* from being reset to a full 20 years from filing.

As mentioned above, terminal disclaimers are filed to overcome obviousness-type double patenting rejections. While the date of expiration of a disclaimed patent is generally determined by the date when a referenced patent expires, the papers filed in the PTO to disclaim a portion of the patent term might refer only to a date certain, i.e., the actual date when the referenced patent was expected to expire.

Let's assume that the terminal disclaimer filed in Patent *B*, referred to in the example above, disclaimed the portion of the term beyond the date certain, January 2, 1996. In other words, the terminal disclaimer used a date certain rather than merely referring to the expiration date of Patent *A*. In this case, it is less clear that the term of Patent *B* would be reset at all.

Where an applicant has already filed a terminal disclaimer in a pending application, the exact wording should be reviewed before the patent is issued to ensure that the disclaimer is linked not to a date certain but to the full statutory term of the underlying patent.

Can a terminal disclaimer in an already-issued patent be affected by any subsequent remedial action? The apparent remedy would be reissue.

On another point, if, as described in the above example, the term of Patent *B* is reset, should the patentee take any affirmative action? Apparently the PTO does not plan to require any action by any patent owner. However, the patentee should consider filing a request for correction to set forth the reset expiration date.

In most cases there would appear to be more advantages than disadvantages to getting the PTO on record as to what the reset term will be. A patent owner might prefer having this matter litigated with the PTO rather than with an adversary in an infringement action in court.

2. Intervening Rights

Along with the reset-term provision, the Act provides intervening rights for persons whose acts become infringing as a result of reset patent terms[49] but requires payment of "equitable remuneration" to the patent owner if such acts are "continued."[50] The statute thus establishes a compulsory license with respect to certain patent rights accruing from reset terms. However, "equitable remuneration" is not defined by the statute and is not necessarily a reasonable royalty.[51] When infringement commenced *before* June 8, 1995, or for which substantial investment was made before then, the *only* remedy is "equitable remuneration," as determined by the courts, which provides essentially a compulsory license.

The relevant statutes read as follows:

35 U.S.C. § 154(c)(2)

> REMEDIES.—The remedies of sections 283, 284, and 285 of this title shall not apply to Acts which—
>
> (A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act; and
>
> (B) became infringing by reason of paragraph (1).

35 U.S.C. § 154(c)(3)

> REMUNERATION.—The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under

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49 35 U.S.C. § 154(c)(2).

50 35 U.S.C. § 154(c)(3).

51 The damages remedy of 35 U.S.C. § 284 is excluded by § 154(c)(2), along with injunctive relief under § 283 and attorney fees under § 285.

> chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)) of this title.

Consequently, when the terms of some patents are reset on June 8, 1995, from 17 years after issuance to 20 years post-filing, there can be an important limitation on the rights of the patentee during the period of the extra "windfall" term. The limitation protects competitors who commenced infringement or made substantial investments based on the belief that the patent would expire on a specific date, only to find belatedly that the term has been increased. However, it also protects opportunistic competitors who will seize upon the Act to obtain an otherwise unobtainable compulsory license.

One of the questions relating to this part of the Act is whether an infringer has commenced commercializing or made a "substantial investment" in commercializing the patented subject matter. Where such commercialization or substantial investment as of the June 8 date has been found to exist, then the rights of the owner of a patent with a reset term will be limited with respect to these "invested infringers."

Such invested infringers are effectively awarded a license. Under § 154(c)(2), the normal remedies a patent owner has under 35 U.S.C. §§ 283, 284, and 285 do not apply. Thus, patent owners will not be entitled to damages, injunctions, or attorney's fees against invested infringers. An invested infringer or licensee of rights will be able to continue otherwise infringing activities upon payment of an "equitable remuneration" to the patentee.

Section 154(c)(3) expressly provides that whether a party has commenced or made the requisite substantial investment, and the measure of the "equitable remuneration," must be determined in an action in federal district court. Presumably, obtaining this relief would require that the alleged infringer prove to the court that the prerequisite conditions of

§ 154(c)(2) exist. Thus, a whole new species of "equitable remuneration" lawsuits will no doubt be spawned.

In view of the possibility of becoming an "invested infringer," it is possible some companies may make strategic decisions between now and June 8 to commence or make substantial investment to commence acts that become infringing as a result of this retroactivity provision of § 154. The benefit of doing so is the ability to obtain a compulsory license and avoid the spectre of an injunction.

The Act provides little or no guidance as to how the equitable remuneration will be determined. The remedies of § 284 that expressly do not apply include "reasonable royalty." There is also very little, if any, guidance in the Statement of Administrative Action as to what an equitable remuneration is intended to be. Courts, therefore, will be left pretty much to their own devices to figure out this remedy. Perhaps some guidance will be obtained from decisions on intervening rights in reissue cases.

When infringement commences on or after June 8, 1995, and there was no substantial investment made before June 8, 1995, all standard remedies are applicable, i.e., damages, injunction, attorney fees.

3. Does this Compulsory Licensing Scheme Contravene the Treaty?

The potential total effect, therefore, of this series of provisions is to provide compulsory licensing with respect to what may be a large group of U.S. patents. Articles 30 and 31 of GATT/TRIPs place limits on compulsory licensing. Article 30 allows for limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. The special considerations of new § 154(c)(2) and (3) may meet this test. If not, the provisions of Article 31 apparently apply and impose stringent conditions on compulsory licenses.

The Statement of Administrative Action points out that U.S. law currently provides for issuance of compulsory licenses under three statutes: the Atomic Energy Act, the Clean Air Act, and the Energy Policy Act. Presumably, therefore, the Administration's position would be that new § 154(c)(2) and (3) are not compulsory licensing provisions, providing additional GATT/TRIPs issues for clarification by future litigation.

4. Effect on Existing Licenses

Patent owners should review their portfolios to determine whether patents issued on or after June 8, 1978, are subject to the term-reset provision and whether existing licenses are affected by the new legislation.[52]

5. Patents in Force Due to Regulatory Extension Under 35 U.S.C. § 156

Some patents that would have expired by June 8, 1995, will still be in force on that date solely because their terms were extended beyond 17 years from the date of issue. For example, under 35 U.S.C. § 156, patents for certain regulated medical products, such as drugs and medical devices, can obtain extensions for delays in the regulatory process.

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[52] Such patents are "in force on" the effective date under 35 U.S.C. § 154(c)(1) and are therefore automatically subject to the new term provision. The status of patents filed on or after June 8, 1975, and issued before June 8, 1978, is unclear. These patents will expire before the effective date of the new legislation, but there is an argument that they might be revived beginning on the effective date, because they resulted from applications filed before the effective date.

These extensions partially restore patent term that was essentially lost because the patent owner could not market the patented product until the product was approved for marketing. A handful of other patents have also received extensions through other mechanisms such as private bills passed by Congress.

The new administrative patent term extensions under 35 U.S.C. § 154(b), which will be discussed later, are "separate from and in addition to" the regulatory patent-term extensions under 35 U.S.C. § 156. Therefore, § 156(a)(2) was amended to make it clear that an administrative extension does not preclude a regulatory extension under § 156.

Both the Statement of Administrative Action and the comments to the proposed PTO rules make it clear that the same patent could be extended under § 154 for up to five years for administrative delays in the PTO and also for an additional five years under § 156 for regulatory delays.[53] (The independence of administrative and regulatory extensions is discussed in detail in Section III.C.4.a., *infra.*)

Both the Act and the legislative history are silent, however, on other important questions about the interactions between the new patent-term provisions and regulatory extensions under § 156. One question is whether and how the term will be reset for existing patents that are entitled to an increase of term under § 154(c)(1) and have had their terms extended under § 156. The notification from the PTO granting an extension under § 156 defines the extension by the number of days added to the patent term and does not specify the expiration date. Thus, there is no guidance as to whether or not these days should be added to the reset expiration date.

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[53] 59 Fed. Reg. 63,952, 63,957; Statement of Administrative Action at 334.

There are thus three possible ways that the expiration date of a patent in force with a regulatory extension could be determined. First, the period of § 156 regulatory extension could be added to the longer of the 17- or 20-year patent term. An argument for this approach is that regulatory extensions under § 156 and the resetting of expiration dates under § 154(c)(1) are independent of each other, and a patentee should be entitled to the full restoration of term afforded by the regulatory extension on top of the full patent term to which it is otherwise entitled.

Second, the period of regulatory extension could be added to the original expiration date of patent based on 17 years from issuance. This is at least a possible interpretation of the words "original expiration date" that appear in § 156(a).

Third, the extension under § 156 could be recalculated and the recalculated extension could be added to the longer of 17 or 20-year patent term. Under this alternative, for example, the patent could remain subject to the limitation in § 156(c)(3) that the extended patent term with the regulatory extension may not exceed 14 years from the date of regulatory approval.

These questions are of enormous practical importance. All patentees with products regulated by the FDA must notify the FDA of the patents that cover approved products, including express notification of the date when those patents will expire. The notice of the expiration dates by the patentee plays a major role in determining whether an ANDA will be approved.

The period near the end of a patent covering a pharmaceutical product is often the most valuable part of the patent-term. Therefore, it seems almost inevitable that there will be litigation to determine when patents with regulatory patent term extensions and resettable terms will actually expire.

6. Revival of Patents

Some patents that are not actually in force on June 8, 1995, may be subsequently brought back to life. Patents that have lapsed for failure to pay a maintenance fee may be revived in some cases. In addition, some patents may have been found by a court to be invalid or unenforceable on June 8 but subsequently determined to be valid and enforceable on appeal.

a. Reversal of Holdings of Invalidity or Unenforceability

Both the Act and the Statement of Administrative Action are silent as to whether patents that are under a judicial holding of invalidity or unenforceability on June 8, 1995, but that are subsequently reversed on appeal or have the basis for unenforceability purged, are "in force" as of June 8.[54] It is conceivable that a court would hold under all these

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[54] As part of the movement toward closer harmonization with the practice in other countries, the U.S. is considering a proposal that U.S. patent applications be published 18 months after filing. Legislation authorizing publication of patent applications was introduced in the 103rd Congress, but did not pass. In anticipation of that similar legislation will be introduced again, the PTO has issued a notice of public hearing and request for comments on the 18-month publication of patent application. This notice is reproduced in Appendix G.

One of the issues to be considered in connection with publication of patent application is whether publication should be coupled with a provisional rights. Under this proposal, if a patent issues from the application, then the pre-grant provisional rights would allow the patentee to recover a reasonable royalty for the use of his invention from the time of publication to the time of grant. This would give the applicant some measure of protection during the period between publication of the application and the day when the patent issues. In Europe and elsewhere where provisional rights exist, this affords a patentee 19½ years of enforceable rights.

circumstances that the patent was not "in force" on June 8. On the other hand, a court might hold that the subsequent reversal or purge places the patent in force as of June 8 *nunc pro tunc*.

One could imagine that a court might determine that a patent is in force *nunc pro tunc* by focusing on whether or not the reason the patent was not in force on June 8 was the fault of the patentee. Under this analysis, patents where a misuse was not purged as of June 8 would not be "in force." On the other hand, a patent not in force on June 8 solely because of an erroneous judicial holding, which is subsequently reversed, should in fairness be found to be in force.

Because the outcome is uncertain, it would behoove patent owners in this situation to take every possible action, before June 8, 1995, to remove any issue of whether or not the patent is "in force" on June 8.

With respect to pending appeals, which will presumably be before the Federal Circuit, the patentee might add to the appeal a request for the Federal Circuit, if it reverses, to rule on the "in force" issue. With respect to a holding of patent misuse and subsequent purge, a patentee would be well advised to try to document that the purge occurred before June 8. Otherwise, subsequent litigation might be required to test the "in force" issue.

Publication of pending applications at 18 months coupled with provisional rights of this type would not, however, eliminate the need for administrative extensions of patent terms for delays during prosecution. This is because the availability of a reasonable royalty is not fully equivalent to the exclusivity provided by a patent, which includes other rights such as the availability of injunctive relief.

b. Failure to Timely Pay Maintenance Fees

A patent that lapses for failure to pay a maintenance fee can be reinstated if the delay in payment was either unavoidable or unintentional. If late payment of the maintenance fee is accepted, the statute requires that the patent shall be considered as not being expired at the end of the grace period, subject to intervening rights set forth in § 41(c)(2). Thus, the revived patent could be considered to be in force on June 8 and treated as any other patent in force on that date.[55]

Under 35 U.S.C. §§ 41(b) and (c) and 37 C.F.R. § 1.378, the Commissioner may accept late payment of maintenance fees for an issued patent if certain conditions are met. First, the applicant must submit the required maintenance fee as set forth in 37 C.F.R. § 1.20(e)-(g). Second, the applicant must submit the surcharge set forth in 37 C.F.R. § 1.20(i).

Finally, the applicant must make a showing that the delay was unintentional or unavoidable since reasonable care was taken to ensure that the maintenance fee would be timely paid. The petition to accept an unintentionally delayed payment of a maintenance fee must be made within 24 months after the six month grace period provided in 37 C.F.R. § 1.362(e). In other words, the petition to accept an unintentionally delayed payment of a maintenance fee must be filed before the conclusion of the 6th, 10th, or 14th anniversary of the issue date of the patent. The 24-month limitation does not apply to petitions to accept an

55 Charles Van Horn, in the videotaped *AIPLA CLE Program: Uruguay Round Agreements Act*, anticipated that this would be the case.

unavoidably delayed payment of a maintenance fee. *Centigram Communications Corp. v. Lehman*, 862 F. Supp. 113, 114-16 (E.D. Va. 1994).

c. Are Expired Patents Revived?

The retroactive patent-term provision applicable to issued patents has two clauses, one applying to patents "in force" on the effective date; the other, to patents that "result from an application filed before" the effective date.[56] It is clear that the "patents in force" provision applies to existing patents that have not expired on June 8, 1995, but this category of patents does not exhaust the class of issued patents that may be subject to recalculation and extension of term under the Act.

(1) Patents Filed on or After June 8, 1975, and Issued Before June 8, 1978

By its plain language, the statute provides that the term provisions apply to patents resulting from applications filed before the effective date, which necessarily includes patents other than those in force on June 8, 1995. Specifically, patents filed on or after June 8, 1975, (the date 20 years before the effective date of the Act) and issued before June 8, 1978, (which therefore expired 17 years after the date of issuance and before the effective date) are included in a first residual category of patents that are expired on the effective date.

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[56] 35 U.S.C. § 154(c)(1):

> DETERMINATION.—The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.

If these patents are indeed subject to the extension of term provided by the Act, on June 8, 1995, they will be revived by operation of law to enjoy a term of potentially three years beginning on the effective date, depending on the time required for prosecution of the original application.

By separately providing for patents "in force" and for a patent that "results" from an application filed before the effective date (using the present tense), the statutory language may exclude a 20-year term for expired patents that "resulted" from applications filed long before the effective date. It is not possible to predict which interpretation will appear more "plain" to the courts, if Congress overlooked the latter category of expired patents. However, this does not end the inquiry, since the scope of patents "in force" must also be considered.

(2) Patents Filed on or After June 8, 1969, and Issued Before June 8, 1972

A second ambiguous provision of § 154(c)(1) is the application of the term provisions to patents "in force" on the effective date. The specific question with respect to this statutory term is whether expired patents can ever be "in force," or whether the class of patents "in force" is completely occupied and exhausted by issued patents that have not expired on June 8, 1995.

The term "patents in force" is not defined in the statute, and there is no indication of what Congress meant in selecting this term to define the class of issued patents subject to extension.

There is a reasonable argument that "patents in force" does not mean the same thing as "unexpired patents," based on the circumstance that a patent is enforceable, *i.e.*, that an action for damages for infringement may be maintained in district court, up to six years after the patent expires. For this reason, a second residual category of patents potentially subject to the extension provisions is the class of patents filed on or after June 8, 1969, (26 years before the effective date) and granted within three years of filing. Normally, the 23-year term of enforceability (17 years plus six years) for patents issued on or before June 7, 1972, would have expired on June 7, 1995. No action for infringement could have been maintained in district court based on these patents on June 8, 1995.

The PTO evidently considers that the term of patents that expire before June 8, 1995, is not affected by the extension provision and that these patents are not subject to revival. One difficulty with this interpretation is that the PTO has no competence with respect to the term extension of issued patents, which automatically occurs by operation of law, as indicated in the proposed regulations. 59 Fed. Reg. 63,957. Because the PTO has no statutory competence with respect to the term of patents in force, its views apparently would not be entitled to significant weight in construing the term-extension provision.

A further and more significant issue of statutory construction is that Congress could easily have specified that the term-extension provisions apply to "an **unexpired** patent" (rather than "a patent that is **in force**") on the effective date or to a patent that "results from an application **pending on**" (rather than one that results from an application **filed before**") the effective date. Congress knew when to specify patent expiration as the operative event in the new statute, as in new § 271(i). By deliberately choosing nonlimiting language with respect to the extension provisions, Congress has provided for an extension that is not limited to the classes of unexpired patents and applications pending on the effective date.

A second argument in favor of interpreting "patent in force" to include a patent that has expired but that can be enforced in a federal district court infringement action is the distinction between reissue and reexamination of expired patents. In *In re Morgan*, 990 F.2d 1230, 26 U.S.P.Q.2d 1392 (Fed. Cir. 1993), the Federal Circuit held that the PTO has no statutory authority to reissue an expired patent, based on the language of 35 U.S.C. § 252, which permits the Commissioner to reissue the patent "for the unexpired part of the term of the original patent." However, the court approved the PTO's practice of conducting reexamination of patents after expiration, since 37 C.F.R. § 1.510(a) provides that reexamination may be requested at any time during the period of enforceability of the patent. A distinction therefore exists between patents that are unexpired and those that are enforceable, a distinction recognized by the PTO regulations and approved by the Federal Circuit.

The statutory interpretation under which the term "patents in force" are not limited to "unexpired" patents is reinforced by the Federal Circuit's definition of the elements required by the patent laws to state a patent infringement claim, including "ownership of a patent still in force, infringement by defendants, and a request for relief." *Kunkel v. Topmaster Int'l, Inc.*, 906 F.2d 693, 15 U.S.P.Q.2d 1367 (Fed. Cir. 1990). *Kunkel* did not involve an expired patent, but based on the circumstance that a patent owner may maintain an infringement action for up to six years after expiration, it appears that patents "in force" need not be limited to unexpired patents.

If the statutory language is interpreted to apply the extension provisions to patents that are "in force" on the effective date, in the sense that an action for infringement can be filed on June 8, 1995, patents that issued before June 8, 1972, and therefore expired before June 8, 1989, may be afforded an extension permitting the patent owner to sue for damages for infringement for up to three more years, depending on the time required for prosecution.

Years of litigation will be required to resolve the meaning of the ambiguous language selected by Congress to define the term extension applicable to issued patents. Undoubtedly, there will be cases where tens or hundreds of millions of dollars in royalties or infringement damages will depend on resolution of this issue. It should not be assumed that the Federal Circuit will either adopt the PTO's restrictive interpretation of these provisions or will narrowly construe the Act to apply only to unexpired patents on the effective date.

Experience has demonstrated that where Congress overlooks a category of patents in providing a statutory term extension, the Federal Circuit will not look beyond the plain language of the statute or restrict the benefit conferred, even where legislative intent is unmistakably clear. *Hoechst, AG v. Quigg*.[57]

The issue of possible revival of expired patents is not trivial, with respect to licenses that specify termination at the end of the patent term, or upon expiration of the last of a number of patents simultaneously licensed, rather than on a specified calendar date. It would be surprising if the equitable remuneration specified for continued practice of such revived patents would differ significantly from the running royalty specified in the license, or a sum otherwise calculated on the basis of the original license fee and term.

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[57] 917 F.2d 522, 16 U.S.P.Q.2d 1549 (Fed. Cir. 1990) ("windfall" extension of 6.8 years under 35 U.S.C. § 156, where Congress intended a maximum five-year extension period).

B. Applications Filed Before June 8, 1995 and Still Pending on June 8, 1995

As explained above, § 154(c)(1) also applies to a patent that results from an application filed before June 8, 1995, and still pending on June 8, 1995. Assume that a U.S. patent application pending on June 8, 1995, then issues as a U.S. patent directly from that application and that no subsequent continuing or divisional application is involved. The term of the patent is also controlled by the substantive provisions of new § 154(c)(1). The patent term should be 20 years from filing or 17 years from grant, whichever is longer.

The special considerations in new § 154(c)(2) (infringing acts) and § 154(c)(3) (payment to continue those acts) also apply literally in this situation if the 20-year term from filing date is later in time than 17 years from issuance date. However, the right to continue the infringing act upon payment of equitable remuneration, (§ 154(c)(3)), would apply only to acts that were commenced, or for which substantial investment was made, before June 8, 1995, and that are infringing in the far-away reset, patent-term period. One has to wonder whether this "protection" is of any practical value.

In particular, there seems to be no reason why the patentee cannot sue for infringement and obtain an injunction during the entire first 17 years from issuance. It would seem to be cold comfort to inform the enjoined infringer that she may recommence infringing, upon payment of an equitable remuneration, at the end of the 17-year period.

C. Future Applications May Lose Patent Term

The harshest impact and greatest threat of the patent-term legislation is its intended effect on future patent applications, including continuations, divisionals, or continuations-in-part of applications now pending, that are filed on or after June 8, 1995.

The genesis of the proposal to measure the 20-year patent term required by TRIPs from the *filing* date of the original patent application, rather than the date of *grant* of the patent, appears to have been a fear of "submarine" patents, filed years or decades earlier, that suddenly issue from concealed continuation applications in the United States to "torpedo" industries that have developed in ignorance of the pending applications. By providing that the term of a U.S. patent is measured from the filing date of the earliest U.S. application for which benefit is claimed under any statutory provision, the patent-term provisions sought to ensure that any such submarine application refiled after the effective date of the Act, claiming benefit of any earlier application filed on or before June 8, 1975, would have no remaining patent term. The menace of other pending submarine applications is proportionately reduced, as their original filing dates approach this 1975 deadline.

However, the effect of this minefield will not be limited to submarine patents but will extend to any U.S. application filed after the effective date that has a pendency of more than three years. Because the PTO calculates its optimistic estimate of median pendency without taking into account claims to benefit of earlier-filed U.S. applications, entire classes of patents that have a total median pendency (including continuations) of more than three years will simply forfeit patent term under the new legislation, with little, if any, effective control of delay in the PTO by applicants. This is the acute problem faced by every practitioner who has on file an application that has been pending for three years or more on June 8, 1995, that will not *certainly* be allowed after the effective date without a further continuation or divisional.

The reduction of patent term will severely affect industries, such as the chemical, pharmaceutical, and biotechnology industries, in which pendency of applications is long, restriction requirements are frequent, and regulatory delay in other agencies reduces the effective patent term. Other industries in which technological advance and obsolescence are rapid may not be as seriously affected by the loss of patent term.

1. Term of 20 Years from Filing for Patents Resulting from all Applications Filed After June 7, 1995

The statute provides that patents resulting from all applications filed in the United States after June 7, 1995, will have a maximum term of 20 years from the date of filing the original U.S. patent application. In the simplest applications originally filed after the effective date, the term of the patent will be limited to 20 years from the filing date, irrespective of the time spent in prosecution before issuance. The patent term begins on the date the patent issues, rather than the date of grant as under present law.

Where an application filed on or after the effective date claims benefit of an earlier U.S. patent application (other than a provisional U.S. application) by making specific reference to an earlier-filed application under 35 U.S.C. § 120, 121, or 365(c), the statute provides that the 20-year term will be measured from the U.S. filing date of the earliest application in the chain of U.S. applications:

35 U.S.C. § 154(a)(2)

> TERM.—Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

2. 20-year Term Measured from Filing First § 120/121/365(c) Continuing Application

In any pending case in which prosecution in an original application or a series of applications has taken more than three years, filing a further continuation or divisional application after June 7, 1995, will be likely to result in a patent term that is shorter than the former 17-year patent term, if benefit of the earlier application under 35 U.S.C. §§ 120, 121, or 365(c) is claimed.[58]

a. 35 U.S.C. § 120

The broadest provision of U.S. law under which "benefit" of the filing date of an earlier U.S. patent application may be obtained in a continuation, divisional, or continuation-in-part application, is 35 U.S.C. § 120. Where a later-filed application is filed before abandonment or termination of an earlier application (continuity of prosecution) disclosing a claimed invention in compliance with 35 U.S.C. § 112, first paragraph (continuity of disclosure), and is filed by at least one inventor named in the earlier application (continuity

[58] 35 U.S.C. § 154(a)(2) (1995). This harsh result is ameliorated by transitional provisions permitting continued examination after final rejection and permitting more than one separate and distinct invention to be examined in a single application, discussed in Section IV, *infra*.

of inventorship), the later-filed application "shall have the same effect, as to such invention, as though filed on the date of the prior application" where benefit of the earlier application is claimed. The only requirement for establishing a claim for benefit is that the continuation application must contain or be amended to contain a specific reference to the earlier-filed application. Benefit under § 120 may be established through an unlimited chain of prior U.S. applications, provided that the statutory requirements of continuity of prosecution, disclosure, and inventorship are met, and a claim for benefit is made with respect to each prior application.

It is this specific reference to the earlier-filed application that restricts the patent term to a 20-year period based on the filing date of the earlier application, under 35 U.S.C. § 154(a)(2).

b. 35 U.S.C. § 121

The statutory provision that permits (but does not require) the PTO to restrict an application to one of two or more independent and distinct inventions, 35 U.S.C. § 121, further incorporates the requirements of § 120 with respect to divisional applications claiming the independent inventions that are not elected for examination in the original application. The statute provides that if the other invention is made the subject of a divisional application that complies with the requirements of § 120, "it shall be entitled to the benefit of the filing date of the original application." Such benefit is effective to overcome any intervening prior art or event.

Apart from this provision, § 121 limits the prior art effect of the original application subject to the restriction requirement, regardless of whether a claim to benefit is made under § 120. A patent issuing on an application subject to a restriction requirement under § 121, or on an application filed as a result of such a requirement, shall not be used as a reference either in the PTO or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. This provision is generally understood to preclude a double-patenting rejection based on a patent claiming subject matter earlier elected in response to a restriction requirement. It further bars the use of the earlier-issued patent as a prior art reference against a divisional application claiming nonelected subject matter subject to the original restriction requirement.

A reference to an earlier-filed application under § 121 in a divisional application is an event that requires the patent term to be measured from the earlier filing date of the application originally subject to the restriction requirement. The consequences of this provision in restriction and divisional practice are discussed *infra*, Section IV.B.

c. 35 U.S.C. § 365(c)

The filing date of a prior PCT application will be effective to limit the term of the U.S. patent issuing from the application, depending on whether benefit is claimed under § 365(a)/(b) or under § 365(c) in the PCT application. The longest U.S. patent term results when a PCT application is used like a prior § 119 priority application and benefit is claimed under § 365(a) or (b) instead of under § 365(c).

3. Foreign Priority Under § 119 and New Provisional Application Filing Are Not Included in 20-Year Term

However, 35 U.S.C. § 154(a)(3) provides that in determining the term of a patent under the new law, "priority under section 119, 365(a), or 365(b) of this title shall not be taken into account." The law makes no distinction between claims to benefit of earlier-filed foreign applications under § 119(a) and earlier-filed U.S. provisional applications under § 111(b), which are entitled to benefit under § 119(e). In either case, the applicant is permitted to establish an earlier effective U.S. filing date up to 12 months before the filing of a § 111(a) U.S. application that *does not limit the patent term* in any way. Enactment of § 111(b), providing for provisional applications to be filed in the United States, was intended to eliminate the disparity between foreign applicants, who are able to claim benefit of a convention application filed up to 12 months before the actual U.S. filing date, and U.S. national applicants. However, in accordance with the national nondiscrimination provisions of TRIPs, the opportunity to file U.S. provisional applications and claim benefit under § 119 is provided both to foreign and U.S. applicants, without limitation based on other foreign priority applications.

The ability to establish an effective U.S. filing date up to 12 months before the filing of a final U.S. patent application under § 111(a) is an important advantage that will be analyzed in detail in the following chapters.

4. Extension of Patent Term Under Limited Circumstances

Realizing the potentially severe impact of the 20-year term measured from the date of original filing, Congress provided relief under certain limited circumstances, where delay results from a secrecy order under 35 U.S.C. § 181, an interference under § 135(a), or a successful appeal to the Board of Patent Appeals and Interferences or a federal court. Under the term-extension provision of 35 U.S.C. § 154(b), the circumstances under which an extension may be available are divided into two distinct categories:

> (1) INTERFERENCE DELAY OR SECRECY ORDERS.–If the issue of an original patent is delayed due to a proceeding under section 135(a) of this title, or because the application for patent is placed under an order pursuant to section 181 of this title, the term of the patent shall be extended for the period of delay, but in no case more than 5 years.
>
> (2) EXTENSION FOR APPELLATE REVIEW.–If the issue of a patent is delayed due to appellate review by the Board of Patent Appeals and Interferences or by a Federal court and the patent is issued pursuant to a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended for a period of time but in no case more than 5 years.

The PTO's interpretation of these provisions is set forth in the commentary on the proposed rules, as follows:

> S. 2467 and H.R. 5110 further provide that the term of a patent may be extended, for a maximum of five years, where the issuance of a patent is delayed because of (1) proceedings under 35 U.S.C. 135(a), (2) placement of the application under a secrecy order pursuant to 35 U.S.C. 181, and/or, under certain circumstances, (3) appellate review by the Board of Patent Appeals and Interferences or by a federal court. The total extension available is limited to five years regardless of whether there were delays due to more than one of the reasons covered by the legislation. This extension is separate from and in

addition to the patent term extension available under 35 U.S.C. 156.

59 Fed. Reg. 63,951.

a. Term Extension Is Independent of and Not Limited by Term Extension under 35 U.S.C. § 156

As noted by the PTO commentary, the extension for prosecution delay under 35 U.S.C. § 154(b) is separate from, and in addition to, the patent-term extension for regulatory delay after issuance of a patent, under 35 U.S.C. § 156. A conforming amendment to § 156(a)(2) clarifies that the term of an unexpired patent shall be extended *from the original expiration date* if "the term of the patent has never been extended **under subsection (e)(1) of this section**" and if the other requirements of § 156 are met.

Accordingly, the grant of an extension of the original term of a patent under § 154(b) to compensate for delay in prosecution does not bar a further grant of term from the original expiration date to compensate for post-issuance regulatory delay.

As explained by the PTO's commentary on the proposed regulations:

> The provisions for patent term extension under proposed § 1.701 are separate from and in addition to the patent term extension provisions of 35 U.S.C. 156. The patent term extension provisions of S. 2467 and H.R. 5110 are designed to compensate the patent owner for delays in issuing a patent, whereas the patent term extension provisions of 35 U.S.C. 156 are designed to restore term lost to premarket regulatory review after the grant of a patent. In order to prevent a term extension under proposed section 1.701 from precluding a term extension under 35 U.S.C. 156, S. 2467 and H.R. 5110 amend 35 U.S.C. 156(a)(2) to provide that the term has never been extended under 35 U.S.C. 156(e)(1).

59 Fed. Reg. 63,957.

Contrary to the general impression that the maximum term of a patent under the new legislation will be limited to 20 years after the original filing date, a patent subject to regulatory delay under § 156 will have a potential term of as long as 30 years from the original filing date, if extended for the full five years permitted for prosecution delay and the full 5 years for delay in regulatory approval after issuance.

b. Term Can Be Extended Cumulatively up to Five Years (in Addition to Extensions Caused by Regulatory Agency Delays)

As noted in the PTO commentary quoted above, the extensions of term for prosecution delay resulting from a secrecy order, an interference, or a successful appeal are limited to a total, cumulative extension of five years. This limit is expressly set forth in 35 U.S.C. § 154(b)(4), which provides that "the total duration of all extensions of a patent **under this subsection** shall not exceed 5 years." Once again, the statutory language is drafted to permit a further regulatory extension under § 156.

(1) Delays Due to Interference Proceedings or Secrecy Orders

The statute mandates an unqualified extension of time up to five years for delay due to an interference under § 135(a) or a secrecy order under § 181:

> **35 U.S.C. § 154(b)**
>
> TERM EXTENSION.—
>
> (1) INTERFERENCE DELAY OR SECRECY ORDERS.—If the issue of an original patent is delayed due to a proceeding under section 135(a) of this title, or because the application for patent is placed under an order pursuant to section 181 of this title, the term of the patent shall be extended for the period of delay, but in no case more than 5 years.

Although the statute specifies the events that start and end the period of appellate-review delay,[59] no similar provision defines when the period of delay "due to" an interference begins or ends. The PTO proposes to fill this statutory void by regulation defining the manner of calculating the period of delay in interferences, in new 37 C.F.R. § 1.701(c)(1), as follows:

> The period of delay under paragraph (a)(1) of this section for an application is the sum of the following periods, to the extent that the periods are not overlapping:
>
> (i) With respect to each interference, if any, in which the application was involved, the number of days in the period beginning on the date the interference was declared or redeclared to involve the application in the interference and ending on the date that the interference was terminated with respect to the application; and
>
> (ii) The number of days, if any, in the period beginning on the date prosecution in the application is suspended by the Patent and Trademark Office due to interference proceedings under 35 U.S.C. 135(a) not involving the application and ending on the date of the next Office communication reopening prosecution.

Certainly, any period of time after prosecution is suspended for consideration of an interference should be included in the automatic and mandatory extension of term "due to" an interference proceeding, up to and including the date of termination of the interference or the reopening of prosecution. However, the statutory extension period is not limited to these periods of delay but expressly includes the period of delay "due to" an interference proceeding, which, under the most restrictive interpretation, must include any period of delay that would not have occurred but for an interference proceeding. Particularly, the period of

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59 35 U.S.C. § 154(b)(3)(A).

PTO delay in deciding whether or not an interference should be declared should include any period of interference-related action in prosecution, beginning on the date on which a requirement to copy claims is first imposed on an applicant in prosecution, whether an interference is ultimately declared or not.

The period of delay with respect to a secrecy order is calculated under proposed 37 C.F.R. § 1.701(c)(2) as follows:

> The period of delay under paragraph (a)(2) of this section for an application is the sum of the following periods, to the extent that the periods are not overlapping:
>
> (i) The number of days, if any, the application is maintained in a sealed condition under 35 U.S.C. 181;
>
> (ii) The number of days, if any, in the period beginning on the date of mailing of an examiner's answer under § 1.193 in the application under secrecy order and ending on the date the secrecy order and any renewal thereof is removed;
>
> (iii) The number of days, if any, in the period beginning on the date applicant is notified that an interference would be declared but for the secrecy order and ending on the date the secrecy order and any renewal thereof is removed; and
>
> (iv) The number of days, if any, in the period beginning on the date of notification under § 5.3(c) and ending on the date of mailing of the notice of allowance under § 1.311.

(2) Period of "Appellate" Review Includes Civil Actions Under 35 U.S.C. § 145

The patent statute distinguishes between *appeals*, which may be taken either to the Board under 35 U.S.C. § 134 or to the Federal Circuit under 35 U.S.C. § 141, and *civil actions* in district court for remedy against the Commissioner under 35 U.S.C. §§ 145 and 146. The prosecution term extension contains an ambiguity, arising from § 154(b)(2), which mandates an extension "due to appellate review . . . by **a Federal court**." The only federal courts having appellate jurisdiction over actions of the PTO are (1) the Federal Circuit, which has appellate jurisdiction over adverse determinations of the Board of Patent Appeals and Interferences (28 U.S.C. § 1295(a)(4)(A)), and (2) the Supreme Court of the United States, which exercises jurisdiction in appeals from the Federal Circuit.

However, the statutory period "due to appellate review" *must* include the period of a civil action under 35 U.S.C. § 145 for remedy against an adverse decision of the Board in an appeal under § 134, because § 154(b)(3) further mandates that the period of extension shall include the period beginning on the date on which "an action is commenced under section 145 of this title."

Evidently, the statutory extension scheme is not limited to appellate review in federal court but includes a period of delay resulting from a civil action in federal district court challenging an adverse determination of the Board.

(3) Are 35 U.S.C. § 146 Delays Included in Proceedings Under 35 U.S.C. § 135(a) or Appeals?

The statute provides that an extension up to five years is mandatory whenever issuance of a patent is delayed "due to a proceeding under section 135(a)," but there is no specific statutory provision indicating whether a civil action under 35 U.S.C. § 146 is included in the period of delay. This omission is explained by the division of prosecution delay into categories of interference/secrecy order, which do not involve appeals to the Board, and delays that result from appellate delay before the Board or "a Federal court."