Important Role of Patents

- Patents are an essential reward for the inventor of a new product.
- Patents can be obtained for any new and useful process, machine, article of manufacture, composition of matter (*e.g.* chemical compositions), and any new and useful improvement to any of these.
- The invention must be useful, novel, and non-obvious.

The Patentee's Exclusive Rights

- The patentee can exclude others from making, using, selling, offering for sale in the United States or importing the claimed subject matter into the United States. 35 USC 271(a).
- Use, sale, or importation of an article made by a patented method is infringement irrespective of where the invention was made. 35 USC 271(g).

The Patentee's Remedies

- Injunction to prevent infringement until the patent expires; and
- Damages for lost profits/sales due to infringement; or
- Damages set at a reasonable royalty.

Importance of Patents to Research Institutions

- The indirect importance of patents to academic research institutions is, at least, as important as their direct benefits.
- Patents have important direct benefits for academic research institutions, enabling them both to recoup the costs of their basic research and to fund further research.
- Patents also indirectly support this research by enabling commercial entities to make the enormous investments essential for the R&D needed to bring new treatments and cures to market.

9

Importance of Patents to Commercial Pharmaceutical Innovation

- Existing patent protections are critical to commercial development of new treatments and cures because of the enormous risks and costs and the many years of R&D and regulatory review required.
- Estimated average cost for a commercial entity to develop a new pharmaceutical treatment or cure is over $800 million.
- Only 20 in 5,000 compounds that are screened enter preclinical testing, and only 1 drug in 5 that enters human clinical trials is approved by the FDA as being both safe and effective.
- Effective patent life is unusually short relative to other research-intensive fields both because commercial entities must seek patents early due to the high degree of competition within therapeutic classes, and because of lengthy regulatory review periods.
- Patents enable the full range of innovation, including sequential innovation, essential to refinement and to discovery of entirely new treatments and cures.

The Hatch-Waxman Act

- In the Drug Price Competition & Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act"), Congress attempted to pursue two goals:
  - Making low cost generic drugs more rapidly available;
  - Maintaining incentives for pioneering pharmaceutical research.

Approval of Generic Drugs

- To speed and reduce the cost of generic drug approval, the Hatch-Waxman Act allowed generic companies to rely upon the safety and efficacy data submitted in support of the branded drugs they wish to copy, so long as the generic can show that its product is bioequivalent to the branded original.
- To enable generic companies to perform the required bioequivalence testing, the Act grants generic companies an exception from patent infringement so that they can use approved branded drugs to test the bioequivalence of their copies.

12

Patent Protection for Pioneer Companies

- To maintain incentives for pioneer companies to innovate, Congress had to ensure that they could still protect their patent rights.
- The Hatch-Waxman Act requires generic drug applicants to certify for patents listed in the "Orange Book": (1) that patent information has not been filed; (2) that the original patent has expired; (3) the date on which the patent will expire; or (4) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug (Paragraph IV Certification).
- If the generic applicant files a paragraph IV certification, and the patent owner brings suit for patent infringement within 45 day of receipt of notice of the certification, FDA will stay final approval of the ANDA for 30 months.

Operation of the Hatch-Waxman Act

- Since 1984, the generic industry's share of the prescription-drug market has jumped from less than 20 percent to almost 50 percent.
- Pioneer R & D investment has increased from $3.6 billion in 1984 to more than $30 billion in 2001.
- Few patent disputes have arisen.

Yet, changes have been contemplated through legislation in response to lobbying efforts by the generic drug industry.

14

Contemplated Legislative Changes to Hatch-Waxman that Affect the Rights of Patent Holders

- Essentially identical legislation has been proposed in the Senate and House, S. 812 / HR 5311/HR 1862 (McCain-Schumer/Thune-Emerson-Gutknecht/Brown).
- If enacted, this legislation would undermine intellectual property rights, threatening economic incentives for commercial entities to develop new treatments and cures, and adversely effecting the value of research institution developments and opportunities for research support.

Undermining Intellectual Property Rights

Limitations on Enforcement of Patent Rights

- Bar on Infringement Actions for Unlisted Patents:
  - Under the proposed legislation, if the NDA applicant fails to file patent information with FDA before the required date, then the owner of the patent is ***barred*** from bringing an infringement action against a generic applicant or any person that makes, uses, or sells an approved generic product.
- Bar on Infringement Actions After 45 Days
  - If the patent owner fails to bring an infringement action with 45 days of receiving a Paragraph IV certification notice, the patent owner is ***barred*** from bringing an infringement case "in connection with the development, manufacture, use, offer to sell, or sale of the [generic] drug.
- Limitations on Scope of the 30-Month Stay:
  - The proposed legislation would limit the 30-month stay to only those patents filed with FDA within 30 days of NDA approval.

16

Effects of Potential Hatch-Waxman Legislative Changes for Research Institutions

- By weakening patent rights, the proposed legislation would undermine the certainty of investments made by commercial entities.
- Loss of rights to bring patent infringement claims for failure to meet an arbitrary, short filing deadline could jeopardize the patents of research institutions that license rights to these patents to pharmaceutical companies.
- The benefits of patents obtained by research institutions under the Bayh-Dole Act would be reduced, because the economic incentives of commercial entities to license the rights to these patents would be diminished.
- Limitation of 30-month stay rights would reduce incentives for commercial entities to perform and support sequential innovation to develop improved treatments and cures.
- The proposals will jeopardize the economic incentives necessary for commercial entities to develop the technologies of research institutions for patients.

From: Norman Latker
To: cohn@warf.ws; gglover@ropesgray.com; John Kelly; kphillips@cogr.edu; Michael.Remington@dbr.com; Missy Jenkins; Rachel Kerestes; rhardy@cogr.edu; rharpel@nasulgc.org; richard_turman@aau.edu; Sara Radcliffe; sheinig@aamc.org; sheldon_steinbach@ace.nche.edu; Valerie Volpe
Date: 10/11/02 2:12PM
Subject: Re: Sept.26 Meeting Follow-Up

Valerie
I would like to be on the planning committee to celebrate Bayh-Dole. I iimagine that a first consideration is how to fund the celebration which will determine its size. If it is determined to somehow include in the celebration those who made contributions to the development and passage of the Act, I would hope no one is overlooked. At this point given the short time available, I don't know how that can be done unless planning starts very soon.

Regards-------Norm Latker

>>> "Valerie Volpe" <wolpe@phrma.org> 10/03/02 12:08PM >>>
On behalf of John Kelly and myself, once again I thank you for taking the time from your demanding schedules to participate in the September 26th meeting. As agreed, Greg Glover's slide presentation is attached. Also attached are the meeting notes. Please feel free to make comments or changes regarding the notes and I will resend a new version to reflect those changes. In addition, in order to follow up on the suggestions made at the meeting, I would appreciate feedback on the following:

1) Frequency of subsequent meetings - quarterly, etc?
2) A December event to celebrate the successes of Bayh-Dole. Should we decide to move forward on this, please indicate whether or not you would like to be part of a "committee" of sorts to plan the event.
3) Dissemination of information on priority issues for the university/academic community.

All of us at PhRMA look forward to working with you to protect the work we all do to bring treatments to patients. Thank you again.

From: "Remington, Michael J." <Michael.Remington@dbr.com>
To: "'Valerie Volpe'" <wolpe@phrma.org>, <sheinig@aamc.org>, <richard_turman@aau.edu>, <sheldon_steinbach@ace.nche.edu>, <njl@browdyneimark.com>, <kphillips@cogr.edu>, <rhardy@cogr.edu>, <rharpel@nasulgc.org>, "John Kelly" <JKELLY@phrma.org>, "Missy Jenkins" <MJENKINS@phrma.org>, "Rachel Kerestes" <RKERESTES@phrma.org>, "Sara Radcliffe" <SRADCLIF@phrma.org>, <gglover@ropesgray.com>, <cohn@warf.ws>
Date: Fri, Oct 11, 2002 2:49 PM
Subject: RE: Sept.26 Meeting Follow-Up

Dear Valerie,

Thanks for your email and for distributing the notes taken by Chris Wilson. I see that Norm Latker just weighed-in. Hopefully, others will too.

For others on this email, please note that we attempted to identify consensus items (see below) (I would very much like to know whether I captured the items appropriately or missed anything).

As regards your questions,

1. I would favor quarterly meetings.

2. A would favor a December event to celebrate the successes of Bayh-Dole, and would be interested in being part of a "committee" to plan the event. I would also propose that we use the December event to launch planning for 3-4 regional events in 2003 (one in the Northeast, one in the Midwest, one in the South, and one in the West).

3. I would defer to the university/research community on the distribution of information about priority issues.

SUMMARY OF CONSENSUS ITEMS

* Dr. Glover's Power Point presentation would be distributed electronically to all participants.
* Informal meetings to discuss legislative proposals that impact on the pharmaceutical industry and universities are productive and should occur periodically.
* The "success" of the Bayh-Dole Act is critical to the future of collaborative research and the ability of universities and pharmaceutical companies to engage in inventive activities and to bring new products and processes to the market. However, because the Bayh-Dole is under criticism, its success should not be taken for granted.
* The parties should consider a 22nd birthday celebration on December 12 for the Bayh-Dole Act, as enacted on December 12, 1980.
* The parties should consider a grass-roots approach to Bayh-Dole programs to occur at a handful of universities where successful collaborative research and technology transfer have occurred.
* Patent law is necessary not only for inventive activities on university campuses and in pharmaceutical companies but also for collaborative activities between and amongst these entities. As a general proposition, legislative efforts to decrease patent protections should be seriously scrutinized by the respective parties which, based on their own priorities, should express opposition.

programs to occur at a handful of universities where successful collaborative research and technology transfer have occurred.
* Patent law is necessary not only for inventive activities on university campuses and in pharmaceutical companies but also for collaborative activities between and amongst these entities. As a general proposition, legislative efforts to decrease patent protections should be seriously scrutinized by the respective parties which, based on their own priorities, should express opposition.

Sincerely,

Mike

-----Original Message-----
From: Valerie Volpe [mailto:wolpe@phrma.org]
Sent: Thursday, October 03, 2002 12:08 PM
To: sheinig@aamc.org; richard_turman@aau.edu; sheldon_steinbach@ace.nche.edu; njl@browdyneimark.com; kphillips@cogr.edu; rhardy@cogr.edu; Remington, Michael J.; rharpel@nasulgc.org; John Kelly; Missy Jenkins; Rachel Kerestes; Sara Radcliffe; gglover@ropesgray.com; cohn@warf.ws
Subject: Sept.26 Meeting Follow-Up

On behalf of John Kelly and myself, once again I thank you for taking the time from your demanding schedules to participate in the September 26th meeting. As agreed, Greg Glover's slide presentation is attached. Also attached are the meeting notes. Please feel free to make comments or changes regarding the notes and I will resend a new version to reflect those changes. In addition, in order to follow up on the suggestions made at the meeting, I would appreciate feedback on the following:

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3) Dissemination of information on priority issues for the university/academic community.

All of us at PhRMA look forward to working with you to protect the work we all do to bring treatments to patients. Thank you again.

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Thank you very much

From: <abajournalereport@ABANET.ORG>
To: <ABA_JOURNAL_GROUP1@MAIL.ABANET.ORG>
Date: Fri, Mar 7, 2003 11:37 AM
Subject: Judicial watchdog at a standstill

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Friday, March 7, 2003
Volume 2, Issue 9

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THE NATIONAL PULSE

NEW YORK JUDGE <http://www.abanet.org/journal/ereport/m7speech.html> WINS SPEECH CASE
A judge who gave potential voters pizzas and doughnut coupons brings the state judicial conduct commission to a standstill. (More...)
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IN A BUSY WEEK, THE U.S. SUPREME COURT:
* Writes <http://www.abanet.org/journal/ereport/m7lockyer.html> federalism into its three-strikes opinions. (More...)
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* <http://www.abanet.org/journal/ereport/m7secret.html> Adopts some of the ABA's analysis in the Victoria's Secret case. (More...)
<http://www.abanet.org/journal/ereport/m7secret.html>
* Says <http://www.abanet.org/journal/ereport/m7megan.html> online sex-offender registries are not punitive. (More...)
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VIRGINIA BAR <http://www.abanet.org/journal/ereport/m7best.html> RETREATS IN BATTLE OVER 'THE BEST'
Can a law firm say its lawyers are among the best? A state bar revises its ethics opinion on the issue. (More...)
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PLEDGE <http://www.abanet.org/journal/ereport/m7pledge.html> PLAINTIFF HOPES FOR HIGH COURT REVIEW
The California physician who challenged the Pledge of Allegiance says the amended appeals court decision stands a better chance of winning affirmance. (More...) <http://www.abanet.org/journal/ereport/m7pledge.html>

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IDEAS THAT WORK

WHAT'S MY BID <http://www.abanet.org/journal/ereport/m7bidlaw.html> FOR THIS CASE?
A small Texas start-up hopes that Internet auctions will provide a better way to connect lawyers and clients.
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<http://www.abanet.org/journal/ereport/m7solo.html>
<http://www.abanet.org/journal/ereport/m7solo.html> WHEN SOLOS JOIN AN ALLIANCE
Make sure you do your homework before merging with a bigger law firm.
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ANSWERS OF THE <http://www.abanet.org/journal/ereport/m7answers.html> WEEK
PINK SLIP: Last week, we asked you to tell us your experiences-whether they were sad, funny or outrageous-with firing an employee or getting fired yourself. Here are our favorite answers.
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BIG <http://www.abanet.org/journal/ereport/m7career.html> RISK
We recently asked you to tell us about the biggest career risk you've taken. Here is another batch of our favorite answers.
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From: Roger Browdy
To: Broder, Mike; Browdy, Craig (home); Browdy, Dan (work); Browdy, Jonathan; Cohn, Ilan; Cooper, Iver; Einav, Henry; Finkelstein, Jay; Kornbau, Anne; Latker, Norman; Lommel, Jim; Neimark, Sheridan; Rubin, Tad; Schlosser, Steve; Segerman, Alan; Struse, Heidi; Yun, Allen
Date: Fri, Mar 7, 2003 2:10 PM
Subject: Engineering Conversions

With today's rapid advance in technology, we thought it important to bring to our readers' attention some new engineering conversions:

Ratio of an igloo's circumference to its diameter: Eskimo Pi

2000 pounds of Chinese soup: Won ton

1 millionth of a mouthwash: 1 microscope

Time between slipping on a peel and smacking the pavement: 1bananosecond

Time it takes to sail 220 yards at 1 nautical mile per hour: Knot-furlong

365.25 days of drinking low-calorie beer: 1 lite-year

Half of a large intestine: 1 semicolon

Shortest distance between two jokes: A straight line.
(think about it for a moment)

1000 aches: 1 kilohurtz

Basic unit of laryngitis: 1 hoarsepower

453.6 graham crackers: 1 pound cake

1 million microphones: 1 megaphone

10 cards: 1 decacards

1 kilogram of falling figs: 1 Fig Newton

1000 cubic centimeters of wet socks: 1 literhosen

2 monograms: 1 diagram

8 nickels: 2 paradigms

3 statute miles of intravenous surgical tubing at Yale University Hospital: 1 I.V. League

2000 mockingbirds: 2 kilomockingbird

From: Sheridan Neimark
To: Browdy, Roger; Epstein, Barry; Finkelstein, Jay; Goldberg, Mickey; Herman, Esther; Hoffman, Martin; Kamphuijs, Jesse; Kamphuijs, Naomi; Kaufman, Jean; Kessler, Brian; Latker, Norman; Lattner, Sam & Harley; Lewis, George; Mellk, Harlan; Neimark, Matt; Neimark, Rebecca; Scottrabbi@aol.com; Sobo, Diana Michelle; Stein, Leonard; Yun, Allen
Date: Fri, Mar 7, 2003 10:15 AM
Subject: Petition against Belgian Supreme Court

What appears below was forwarded to me.
SN

Dear friend,
Cher Amis,

Please enter the site below and sign the "Belgian petition"- No politics!

Kindly forward to all contacts in your address book, since it is of utmost importance for Israel and, whether we agree with P.M. Sharon's current political Policies or not, is certainly irrelevant at this point, the travesty of justice must be prevented, and now!

http://www.petitiononline.com/FRAN002H/petition.html
<http://www.petitiononline.com/FRAN002H/petition.html>

We the undersigned, express our outrage, ridicule and opposition to the ILLEGAL decision of the Belgian Supreme Court, which has arrogantly appointed itself as the world's highest authority on War Crimes .....

The distinguished Lebanese dignitary Mr. Nagi N. Najjar – Director of the Lebanon Foundation for Peace, recently published an article just prior to the elimination of Elie Hobeika at the behest of the Syrians....
http://www.free-lebanon.com/LFPNews/Belgium/belgium.html& nbsp;&

http://www.israeltodamascus.com/thebook.htm#CHAPTER7

One wonders, on what grounds the Belgian Justice system dares to posture as the Moral Superiors of the World!? See; http://search.
yahoo.com/search?p=belgium++massacre+africa+congo+history
<http://search.yahoo.com/search?p=belgium++massacre+africa+congo+history%0D%0A>
<http://search.yahoo.com/search?p=belgium++massacre+africa+congo+history%0D%0A>

In view of Belgium's own ignominious history, justice like charity, should certainly start at home. It should also be applied equally rather than selectively.

Further information about this petition is available through Hyperlink http://www.hasbara.us <http://www.hasbara.us/> or by contacting the undersigned at NAZARIAN@HASBARA.US <mailto:NAZARIAN@HASBARA.US>

Prepared & presented Respectfully by Director-Hasbara.us, Francois Nazarian

Please CLICK at above site for the on-line Petition. Sign the petition & your Assistance in helping us grow is greatly appreciated. Please take, a

Further information about this petition is available through Hyperlink http://www.hasbara.us <http://www.hasbara.us/> or by contacting the undersigned at NAZARIAN@HASBARA.US <mailto:NAZARIAN@HASBARA.US>

Prepared & presented Respectfully by Director-Hasbara.us, Francois Nazarian

Please CLICK at above site for the on-line Petition. Sign the petition & your Assistance in helping us grow is greatly appreciated. Please take, a

From: Rabbi Ethan Seidel <eseidel@TIFERETH-ISRAEL.ORG>
To: <TIFERETH_ISRAEL@HOME.EASE.LSOFT.COM>
Date: Thu, Mar 6, 2003 9:01 AM
Subject: [TI] ANN: Excellent play at DCJCC Theatre

Rachel and I went to the DCJCC Theatre last night and saw "Jump/Cut". It is excellent (and there is a very postive review in today's Post). Though the play has nothing really to do with Judaism, the health of the DCJCC theatre does, so I urge you to go and see the show. It's playing through March 30th.

Rabbi Seidel

From: INTA <Communications@inta.org>
To: <sneimark@browdyneimark.com>
Date: Wed, Mar 5, 2003 9:43 AM
Subject: U.S. Supreme Court Issues Decision in Victoria Secret Dilution Case

On March 4, 2003, the U.S. Supreme Court issued its decision in the matter of VICTOR MOSELEY and CATHY MOSELEY, dba VICTOR'S LITTLE SECRET, PETITIONERS v.V SECRET CATALOGUE, INC., et al. In its decision, the Court ruled that the Federal Trademark Dilution Act requires proof of actual dilution.
For more information on this ruling, please visit: www.inta.org.

Attend INTA's Trademark Dilution Forum tomorrow to learn from the experts more about this important Supreme Court decision and other major Dilution topics. Increase your effectiveness and value to your employer and clients. Don't be left behind, register onsite!
http://www.inta.org/forums/2003/dilution/index.html

- Location: Arlington, Virginia
- Date: March 6 & 7, 2003 (Onsite Registration Begins at 8 a.m.)
- Venue: Crystal Gateway Marriott

Featured Topics include:
- More insights on the recent Victoria Secret ruling by the Supreme Court
- Qualifying for Dilution Protection: Establishing the Definition
- What is Dilution?
- Remedies: Jurisprudence and the Scope of Injunctive Relief
- Real World Effects of Dilution
- Many more!

For more information on all INTA meetings and forums, please visit: http://www.inta.org/meetings

From: "Shelly Glaser" <shelly@glaser.co.il>
To: "Roger Browdy (E-mail)" <RLBrowdy@browdyneimark.com>
Date: Fri, Mar 7, 2003 8:38 AM
Subject: If Pfizer owns a patent, it's valid. If Pfizer does not own a patent, it's not valid. Simple, no?

You may find this http://www.forbes.com/2003/03/06/cx_mh_0306pfe_print.html interesting...

FYI,

Shelly

From: <Membership@ABANET.ORG>
To: <ABA-MEMBERSHIP@MAIL.ABANET.ORG>
Date: Tue, Mar 4, 2003 4:10 PM
Subject: Re: McElhaney on Litigation - no-cost CLE from ABA Connection

Don't Forget! The ABA Connection 1 hour CLE teleconference
McELHANEY ON LITIGATION: UNDERSTANDING HEARSAY
- - Wed. March 19, 2003 1 PM E.T. Space is limited! - -

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1. Register online or call 1.800.285.2221.
2. Read the article on page 50 of the February ABA Journal before the teleconference seminar.
3. By Monday, March 17 , you should receive a confirmation FAX: a toll-free number to call for the program, a Personal Identification Number (PIN), a certificate of attendance, and an evaluation form.
4. Call the toll free number a few minutes before 1:00 p.m. E.T. on March 19. An operator will ask for your PIN.
5. If you want CLE credit for the program, FAX back your "Teleconference Attendance Confirmation Form" and evaluation form at 1.312.988.5250.

QUESTIONS?
Please contact the ABA Service Center at 1.800.285.2221 for call-in information or your pin number. Please call ABA-CLE FaxInfo Service at 1.800.995.1253 if you have not received your fax by the Monday before the conference; or to get a copy of the ABA Journal article, certificate of attendance, or evaluation form.

ALREADY REGISTERED?
If you already registered for this seminar, this e-mail is just a reminder for you to look for your confirmation fax, read the ABA Journal article on page 50 before March 19, and follow steps 4 and 5 above!

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TELEFAX CONTROL SHEET

SENT TO: Neil MacDonald

DATE SENT: 4/15/03

SUBJECT: Tech. Trans. History

No. of pages (including this cover sheet): 20

FROM: Norm Latker

Remarks: Neil

Enclosed are the history presentation I mentioned and my C.V.

I'm enclosing the C.V. because it highlights most of the policy, regulatory and legislative actions resulting in the body of law governing federal tech. trans. Also you may see something of interest in the list of presentations I made over time most of which are not easily found.

Norm

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1ST Slide

HIGHLIGHTS Of FEDERAL TECHNOLOGY TRANSFER

- 1964 - DHEW inventions not reaching the marketplace.
- 1968 -Disputes over Federally funded inventions
- 1968 - G.A.O. Report.
- 1969 - DHEW patent policy changed.
- 1973 - First technology transfer Association formed
- 1976 - First gene splicing patent licensed

2ND Slide

TECHNOLOGY TRANSFER LEGISLATION

- 1977 - DHEW reassesses 1969 patent policy changes.
- 1977 - Universities press for legislation.
- 1980 - Bayh-Dole enacted.
- 1983 - Executive order extends Bayh-Dole.
- 1986 - Federal Technology Transfer Act enacted.

3 RD
Slide

RESULTS OF BAYH-DOLE

- Royalty returns
- Industrial Research Support

Brief History of Federal Technology Transfer

Norman J. Latker

September 24, 2000

Before the Advisory Committee of the

National Institute for General Medical Sciences

First Slide

As early as 1964, the failure to attract industry development of Government funded life science inventions was well known.

Dr. Shannon, then NIH director, characterized the source of the problem before Congress by emphasizing that NIH grantees do not engage in the direct development and manufacture of inventions and it is industry that must bring grantee inventions to the marketplace. But in doing so, an industry developer must decide that the patent rights offered are sufficient to protect the risk investment involved not only for the invention offered, but for the huge number that fail in development compared to few successes. He concluded by saying that NIH's research effort was complementary to that of other elements of society and that it was in the best interests of the American people to assure that the various interests of the

development compared to few successes. He concluded by saying that NIH's research effort was complementary to that of other elements of society and that it was in the best interests of the American people to assure that the various interests of the

medical research community can interact. The Department's policy to own all such inventions for non-exclusive licensing at most clearly precluded the cooperation Dr. Shannon suggested.

By 1968, while factions in the Department continued to argue policy, the problem had been dramatized by increasing numbers of invention ownership disputes involving inventions assigned to industrial developers by NIH grantee investigators without notice to NIH.

In the case of Gatorade, Mr. Cade of the University of Florida, frustrated by the Department's failure to timely respond to his good faith request for the patent rights to Gatorade, assigned the invention to Stokely-VanCamp, who thereafter sued the Department for clear title. Under this threat, the Department negotiated leaving the invention to the University of Florida under conditions which were later adopted in Department Institutional Patent Agreements (IPA's) and then later in the Bayh-Dole Act.

Earlier, in another notorious situation, Dr. Heidelburger and the University of Wisconsin, after being publicly accused by Sen. Long's staff of confiscating ownership

Earlier, in another notorious situation, Dr. Heidelburger and the University of Wisconsin, after being publicly accused by Sen. Long's staff of confiscating ownership

of 5FU, a breakthrough cancer chemotherapy drug and licensing it to an industry developer, successfully convinced the Department that minimal government funds were involved in its conception.

Further, Dr. Guthrie, a Department grantee and the inventor of the then preferred test for PKU being marketed by an industrial developer under license, after being publicly pilloried by Sen. Long's staff for confiscating the invention, assigned ownership to the Department.

These cases had a further chilling effect on industry involvement as they surmised that any amount of government funding touching an industry invention could result in similar a claim of rights by the Government.

Thereafter, the G.A.O. added additional urgency to resolving the problem, by reporting that due to Department Patent Policy precluding transfer of any exclusive rights, inventions resulting from all of NIH's medicinal chemistry grants could not find the necessary industry support to continue development.

grants could not find the necessary industry support to continue development.

Finally, in 1969, in direct response to these situations, the Department relented and changed its patent policy by establishing a uniform IPA policy that left ownership to grantee institutions who agreed to staff a technology transfer office to manage and license these rights. The changes also included administrative authority that permitted the Department to grant exclusive licenses to industry in inventions made by DHEW employees. NSF followed with similar changes in 1972.

In 1973, the newly established IPA holders formed the Society of Patent Administrators to enhance outreach to industry so as to overcome industry's continuing resistance to development of government funded inventions because they were not made in the company's laboratories. (Ironically, this impediment was called the NIH or not-invented-here syndrome).

By 1976, 75 IPA's had been negotiated and executed with institutions who received well over 50% of the annual DHEW extramural funding.

Also in 1976, Dr. Frederickson, then Director of NIH, agreed with the consent of other Federal research agencies to

extramural funding.

Also in 1976, Dr. Frederickson, then Director of NIH, agreed with the consent of other Federal research agencies to

permit the University of California and Stanford to administer the Cohen-Boyer gene splicing patent under their IPA's. Stanford's non-exclusive licensing of Cohen-Boyer to dozens of commercial concerns sparked the biotech industry.

Second Slide

Notwithstanding the clear record of increasing licensing by IPA holders, the secretary of the Department, instituted in 1977 a "reassessment" of the IPA policy which stopped further invention processing on the ground that the introduction of new technology into the marketplace was escalating the price of healthcare which required Department oversight. Legislation was introduced in the Senate to provide the Department with this oversight authority at the same time. Simultaneously, Sen. Nelson of Wisconsin conducted hearings as to the legality of IPA's.

Frustrated, organizations having IPA's (led by the University of Wisconsin, Stanford University, the University of California, and Purdue) responded by pressing for legislation to assure continuance of the 1969 Department policies and its further expansion to other federal agencies having conflicting

California, and Purdue) responded by pressing for legislation to assure continuance of the 1969 Department policies and its further expansion to other federal agencies having conflicting

policies. This resulted in Senators Bayh and Dole introducing what became the Bayh-Dole Act.

In December 1980, in a lame duck session of Congress, Bayh-Dole was enacted with no executive support, establishing for the first time a uniform government patent policy guaranteeing ownership of all federally funded inventions to non-profit organizations and small business but with a limitation on the life of exclusive licenses granted to industry. In addition it created for the first time, statutory authority for exclusive licensing of all other Government owned inventions, the bulk of which were generated by intramural Federal Employees. The Act repealed 22 conflicting agency statutes, many of which were a result of amendments by Sen. Long to Agency Appropriation Acts. Enactment was achieved against formidable opponents including the Attorney General, Sens. Long and Nelson, Ralph Nader, Ad. Rickover of Atomic submarine fame, the Agency administrators of the Acts to be repealed and others.

In 1983, the ownership principles of Bayh-Dole were extended to all other recipients of Federal funding not otherwise precluded by statute by Executive order, which received little notice other than from its opponents. This

In 1983, the ownership principles of Bayh-Dole were extended to all other recipients of Federal funding not otherwise precluded by statute by Executive order, which received little notice other than from its opponents. This

established for the first time a uniform government patent policy covering all federal agencies conducting research and ended 40 years of the Government requirement for ownership of grantee and contractor inventions as a condition for funding.

In 1984, Bayh-Dole was amended to permit exclusive licenses for the life of the patent.

Finally, in 1986 with strong White House support, the Federal Technology Transfer Act of 1986 was enacted, which required decentralizing the statutory licensing authority for government owned inventions created in Bayh-Dole to the Federal laboratories at which they were made. This was intended to put the Federal laboratories on an equal basis with the laboratories covered by Bayh-Dole. The Act also extended the Bayh-Dole principles of an option to future invention rights to industrial concerns in return for their funding a cooperative research and development agreement (CRADA) at a federal laboratory.

Third Slide

The success of Bayh-Dole can be easily measured by the royalty return to grantees and the increase in research funding

Third Slide

The success of Bayh-Dole can be easily measured by the royalty return to grantees and the increase in research funding

to grantees from industry in return for an option to exclusivity in future inventions made by the grantee.

With regard to royalties:

The Unv. of California earned 67M in royalties in '97

Stanford Unv. 52M,

Columbia Unv. 50M,

Sloan-Kettering 30M,

N.Y. Blood Center 32M,

Unv Wisc. (WARF) 17M

The grand total in royalties in '97 for all federally funded institutions was 700M.

With regard to research funding to grantees from industry and others, the total reached 2.2 billion in 1997.

All of the 700mil in royalty income is required by Bayh-Dole to be returned to research minus expenses and a percentage to the inventors.

But more important are unseen successes such as:

percentage to the inventors.

But more important are unseen successes such as:

1. Greater interest in government research, resulting in,

2. Increased collaboration between industry and government research organizations as foreseen by Dr. Shannon and movement of personnel between them resulting in:

3. Expedited delivery of important life science inventions to the public, resulting in

4. Increased Congressional support encouraged by citizen belief in science and technology.

Hopefully all in a never ending cycle.

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SENT TO: Jennifer Washburn

DATE SENT: 3/11/03

SUBJECT: Tech. Trans.

No. of pages (including this cover sheet):

FROM: Norm Latker

Remarks: Jennifer

Enclosed are the Science article I mentioned, and my C.V. Economist article

I'm enclosing the C.V. since it highlights most of the policy, regulatory and legislative actions that comprise the body of law governing federal technology transfer. Also you might find something of interest in the list of presentations I made over time, most of which are not easily found.

NJL

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From: <Michael.Remington@dbr.com>
To: <rhardy@cogr.edu>, <cohn@warf.ws>, <richard_turman@aau.edu>, <rharpel@nasulgc.org>, <sheinig@aamc.org>, <njl@browdyneimark.com>, <kphillips@cogr.edu>, <sheldon_steinbach@ace.nche.edu>, <jon.soderstrom@yale.edu>, <p_harsche@fccc.edu>
Date: Mon, Mar 3, 2003 11:34 AM
Subject: FW: Packet on Hatch Waxman

Attached you will find materials relating to Bruce Kuhlik's comments on Hatch-Waxman. Please insert into your notebook under Tab E.

Mike

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CC: <vvolpe@phrma.org>, <bruce.kuhlick@phrma.org>

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December 23, 2002

BY HAND DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0417

Dear Dockets Management Branch:

Enclosed please find two copies of the Comments of the Pharmaceutical Research and Manufacturers of America (PhRMA) on FDA's proposed rule on "Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug is Invalid or Will Not be Infringed" (Docket No. 02N-0417).

Thank you for your assistance.

Best regards,

Michael S. Labson

Counsel for Pharmaceutical Research and Manufacturers of America

Enclosures

Comments of the

Pharmaceutical Research and Manufacturers of America (PhRMA)

on

FDA's Proposed Rule:

"Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug is Invalid or Will not be Infringed"

[Docket No. 02N-0417]

Of Counsel:

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Counsel for the Pharmaceutical Research and Manufacturers of America

December 23, 2002

and Manufacturers of America

December 23, 2002

Introduction

The Pharmaceutical Research and Manufacturers of America ("PhRMA") submits these comments in response to the proposed rule FDA published on October 24, 2002 regarding the agency's implementation of the patent listing and 30-month stay provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the "Hatch-Waxman Amendments").[1] PhRMA is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA's member companies invested more than $30 billion in 2001 alone in discovering and developing new medicines. PhRMA companies are the source of nearly all new drugs that are discovered and marketed throughout the world.

As the leaders in the search for innovative new cures, PhRMA's members hold the overwhelming majority of the new drug applications ("NDAs") filed with FDA. The financial health of these companies, and their ability to continue to invest in future drug research and development, depend in critical part on the intellectual property that protects their inventions, including in particular patents. Accordingly, PhRMA and its members have a unique stake in the patent listing and stay provisions that are the subject of FDA's proposed rule.

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1 67 Fed. Reg. 65448 (October 24, 2002).

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1 67 Fed. Reg. 65448 (October 24, 2002).

FDA's proposed regulation would make significant changes to current law. Since 1984, NDA and patent holders have had the opportunity to obtain a 30-month stay on FDA approval of an abbreviated new drug application ("ANDA") or 505(b)(2) application whenever the ANDA or 505(b)(2) applicant makes a paragraph IV certification challenging a listed patent. The proposed rule would eliminate this opportunity in certain circumstances. Generic drugs could be approved and enter the market without the innovator company's having had a fair opportunity to litigate the patent infringement issues raised by the generic product. FDA's proposal would also make several categories of patents ineligible for listing in the Orange Book. In short, the proposed regulation in its current form would have a substantial impact on the innovator drug industry that PhRMA represents.

The 30-month stay provisions are intended to give NDA and patent holders an opportunity to enforce their intellectual property rights prior to the approval and market entry of generic drugs, and are at the heart of the Hatch-Waxman scheme. FDA's stated intent is to ensure that innovator companies always have the opportunity for one 30-month stay on approval of an ANDA or 505(b)(2) application. As formulated, however, in some situations the proposed regulation could be manipulated by generic applicants to deprive NDA and patent holders of the opportunity to obtain even a single 30-month stay when their patents are challenged. As explained below, this apparently unintended consequence can be corrected by FDA in a final rule, without a significant adjustment to the legal theory put forward in the preamble to the proposed rule. The corrections are necessary, however, to effectuate the purpose of the statute, to be consistent with FDA's own stated goals, and to ensure that there

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remains a meaningful opportunity to obtain an appropriate 30-month stay during the pendency of patent litigation.[2]

Detailed comments on these needed technical changes and other issues raised by the proposed rule follow. The 30-month stay provisions are addressed first.

I. How Many Times Can an Application's Approval Date Be Subject to a 30-Month Stay Period? [Proposed §§ 314.94(a) and 314.52(a)]

The proposed regulation should be modified to ensure that NDA and patent holders have one meaningful opportunity to obtain a 30-month stay. The Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act") states that ANDA and 505(b)(2) applicants must provide notice to NDA and patent holders when an application is "amended to include" a paragraph IV certification. FDCA §§ 505(b)(3)(C) & 505(j)(2)(B)(iii). Under FDA's new proposed interpretation of this language, if an ANDA or 505(b)(2) application contains one paragraph IV certification and is amended subsequently to add another paragraph IV certification, the amendment would not be considered one to "include" a paragraph IV certification, because the application already contained a prior paragraph IV certification. No notice would therefore be required for the new paragraph IV certification, and no 30-month stay could arise based on the certification.

FDA's discussion of these issues focuses exclusively on amendments to ANDAs and 505(b)(2) applications that arise because of patents that are newly listed by

---

[2] PhRMA supports FDA's attempt to establish clearer rules on the operation of these complex provisions. Nonetheless, without the modifications described in these comments FDA's regulation could be manipulated to erode the opportunity to obtain any 30-month stay. However unintended this consequence might be, PhRMA would necessarily consider a legal challenge to prevent that outcome.

However unintended this consequence might be, PhRMA would necessarily consider a legal challenge to prevent that outcome.

NDA holders. Indeed, FDA's entire proposal on 30-month stays is rooted in the concern that NDA holders should not be able to obtain multiple 30-month stays when litigation is brought on newly issued and listed patents. 67 Fed. Reg. at 65449. Nowhere does FDA address amended patent certifications that an ANDA or 505(b)(2) applicant makes on its own accord. These types of amendments are distinct, and present unique legal and policy concerns that FDA must address in a final rule.

If FDA does not clarify its approach to these and other related circumstances, ANDA and 505(b)(2) applicants may be able to game FDA's proposed rules to deprive NDA and patent holders of a meaningful opportunity to obtain even a single 30-month stay. The agency's change in interpretation of the Act itself shifts the balance of the Hatch-Waxman law. It deprives NDA and patent holders of a reasonable time period to adjudicate patent rights prior to agency approval for patents that do not issue before the filing of an ANDA. FDA must take care to ensure that it does not permit even further unintended erosion of the opportunity to obtain a 30-month stay. Such a result would be at clear odds with the Hatch-Waxman Amendments.

The importance of the stay provisions to the Hatch-Waxman scheme is clear from the face of the statute, as well as from the legislative history. A House of Representatives Report from 1984 explains that the stay

> permits the commencement of a legal action for patent infringement before the generic drug maker has begun marketing. The Committee believes this procedure fairly balances the rights of a patent owner to prevent others from making, using, or selling its patented product and the rights of third parties to contest the validity of a patent or to market a product which they believe is not claimed by the patent.

> third parties to contest the validity of a patent or to market a product which they believe is not claimed by the patent.

4

H. Rep. 98-857, Part 1, 98th Cong., 2d Sess. at 28 (June 21, 1984). Senator Hatch recently explained:

> a pioneer drug patent holder, whose patents are under challenge by a generic drug manufacturer, is accorded an automatic 30-month stay. This was not some giveaway to the innovator pharmaceutical industry. We inserted this mechanism to protect the intellectual property of companies that develop patented medications, companies, I might add, that were going to be afforded less intellectual property protections than any other industry as part of the 1984 law. . . . The public policy purpose for this stay is to allow time for the courts to determine the status of validity of drug patents and/or to decide whether valid patents are, or are not, infringed by a generic drug challenger.

148 Cong. Rec. S27342, S7344 (July 25, 2002) (remarks Sen. Hatch).[3] The 30-month stay provisions are thus a key component of the careful compromise embodied in the law, and FDA must ensure that any regulatory actions it takes do not go too far in upsetting that legislative compromise.

FDA asserts in this rulemaking that its intent is to ensure that "the opportunity for one 30-month stay in the abbreviated application's effective date always exists." *Id.* at 65456. Indeed, FDA cites in the preamble to the proposed rule the agency's prior acknowledgement that any result that would deprive NDA and patent holders of an opportunity to obtain a single 30-month stay "could not be reconciled with the Hatch-Waxman amendments' intent to strike a balance between generic drug approval and

---

[3] Senator Hatch further explained that "any discussion of the 30-month stay is incomplete if it does not include the fact that, under Hatch-Waxman, generic drug firms are given a unique advantage under the patent code that allows them to get a head start toward the market by allowing them to make and use the patented drug product for the commercial and ordinarily patent infringing purpose of securing FDA approval and scaling up production." 148 Cong. Rec. at S7344.

the market by allowing them to make and use the patented drug product for the commercial and ordinarily patent infringing purpose of securing FDA approval and scaling up production." 148 Cong. Rec. at S7344.

5

encouraging future innovation." 67 Fed. Reg. at 65455. The following sections discuss technical changes that must be made to the new proposed rules in order for FDA's stated intent to be met.

A. Notice Should be Given when ANDA and 505(b)(2) Applicants Change Previous Patent Certifications.

Under the proposed rule, there is a serious potential for ANDA and 505(b)(2) applicants to avoid any 30-month stay. Assume, for example, that two patents are listed for Drug X, a patent on the drug substance in Drug X and a narrow formulation patent. Under the proposed regulation, an ANDA applicant could file a paragraph III certification on the drug substance patent and a paragraph IV certification of non-infringement on the formulation patent. The ANDA applicant would only have to provide notice to the NDA and patent holder on the formulation patent. If the NDA holder determines that the ANDA formulation does not infringe, it could not sue.

The proposed regulation would then permit the ANDA applicant to convert its earlier paragraph III certification to the drug substance patent to a paragraph IV certification without providing notice to the NDA or patent holder. No notice would be required because, under FDA's new interpretation, the ANDA already "included" a prior paragraph IV certification. No 30-month stay could arise from the new paragraph IV certification, because there would be no notice and no way to trigger the statutory stay provisions. No 30-month stay would exist from the original paragraph IV certification, because the NDA and patent holders had not sued. Thus, no 30-month stay would apply, even though there was no prior stay on the approval of that ANDA. This result conflicts with FDA's stated intent of ensuring that NDA holders have a *meaningful* opportunity to obtain one 30-month stay. At a

stay on the approval of that ANDA. This result conflicts with FDA's stated intent of ensuring that NDA holders have a *meaningful* opportunity to obtain one 30-month stay. At a

minimum, this must mean that NDA holders can litigate under a 30-month stay with respect to the patents listed at the time the ANDA is filed.

A similar situation might exist where two listed patents have substantially different expiration dates. The ANDA applicant could file a paragraph IV certification against a patent with an imminent expiration date, and a paragraph III certification against the second patent with a later expiration date. The applicant could then subsequently amend the paragraph III certification to a paragraph IV and circumvent the notice requirement, since the ANDA would already have included a paragraph IV certification.

This potential for abuse is real. Under FDA's proposal, there would be little reason for an ANDA or 505(b)(2) applicant ever to make more than one paragraph IV certification in an initial application. The applicant would have every incentive to select a single patent for a paragraph IV certification, make paragraph III certifications to the other patents, and later amend those paragraph III certifications to paragraph IV certifications for which no notice would be required and no stay could apply. NDA holders could do nothing to prevent such gamesmanship, because the law makes patent listing mandatory. NDA holders must list eligible patents and would have no discretion to forego the listing of narrow formulation or other patents that would be targets for initial paragraph IV certifications.

FDA must address this serious loophole in its proposed rule, and it can do so within the new statutory interpretation framework it has set forth. Specifically, FDA should provide that amendments to ANDA and 505(b)(2) applications that are made to change a patent certification that the applicant had already made relate back to, and substitute for, the original patent certification. That is, if an ANDA initially contains a paragraph IV

original patent certification. That is, if an ANDA initially contains a paragraph IV

7

certification to one listed patent and a paragraph III certification to another, a later amendment to change the paragraph III certification to a paragraph IV would be considered to have been made with the initial application. Notice to the NDA and patent holders therefore would be required, just as it is for any paragraph IV certification made as part of an initial ANDA submission under FDCA § 505(j)(2)(B)(i).[4] Under the statute (FDCA §§ 505(b)(3)(C) & 505(j)(2)(B)(iii)), notice is given when the application is amended (even if the amendment relates back to the earlier submission of the application), and receipt of the notice would start the 45-day period during which the NDA or patent holder could bring an infringement action and trigger a 30-month stay in connection with the patent that is the subject of the notice.

This approach is supported by FDA's existing regulations. FDA's current regulations provide that when an ANDA or 505(b)(2) applicant amends a previous patent certification, the new certification substitutes for the prior certification, and "the application will no longer be considered to contain the prior certification." 21 C.F.R. § 314.94(a)(12)(viii). When an ANDA or 505(b)(2) applicant converts a paragraph III certification to a paragraph IV certification, the amended certification should be deemed to relate back to and substitute for the original certification and trigger a new notice obligation.

This proposed "fix" would not prejudice generic applicants. It applies only when an ANDA or 505(b)(2) applicant itself changes a patent certification it previously

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[4] Alternatively, the change in patent certification could be viewed as an amendment to "include" a paragraph IV certification under FDCA § 505(j)(2)(B)(iii), since it would be treated as if it were made when the application was first submitted and no prior paragraph IV certification would exist. Again, notice would trigger a 45-day period to bring suit.

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made. The fix would not affect FDA's proposed treatment of patents that are newly listed by NDA holders. In those instances, the ANDA or 505(b)(2) applicant would amend its application to add a new certification, not to change a prior certification. The new certification would not relate back and thus could not trigger a new notice requirement or a new stay, where there had not been an earlier paragraph IV certification. NDA holders could not abuse the approach described here, because the decision to *change* a prior patent certification would rest solely in the hands of ANDA and 505(b)(2) applicants.

PhRMA's proposed approach meets FDA's stated intent of ensuring that there remains one real opportunity for innovator companies to obtain a 30-month stay, while retaining FDA's proposed measures to address the concerns about operation of the 30-month stay provisions that the Federal Trade Commission raised in its report on *Generic Drug Entry Prior to Patent Expiration* (July 2002). Without modification along the lines described here, FDA's proposed regulation could be manipulated to erode the opportunity to obtain any meaningful 30-month stay.

B. Notice Should Be Given When ANDA and 505(b)(2) Applicants Change the Formulation of a Product.

A similar issue and potential for abuse can be presented when an ANDA or 505(b)(2) applicant amends the formulation covered by the application. Suppose, for example, that an ANDA is filed for a drug product formulation that does not infringe, and the applicant files a paragraph IV certification on that basis. If the NDA or patent holder agrees that there is no infringement and does not sue, the ANDA applicant could then amend the application to use a drug product formulation that does infringe without having to give notice or risk a 30-month stay.

application to use a drug product formulation that does infringe without having to give notice or risk a 30-month stay.

In order to avoid the potential for such gamesmanship, FDA should require that ANDA and 505(b)(2) applicants provide amended patent certifications whenever they make changes to the chemistry, manufacturing, and controls section of an application.[5] As in the circumstances described in the preceding section, these would be amendments wholly of the ANDA or 505(b)(2) applicant's own doing, and unrelated to any patents being newly listed by the NDA holder. The amended patent certifications would substitute for and relate back to the prior patent certifications, and could trigger a new notice obligation in accordance with the approach proposed in the preceding section. In that way, the NDA and patent holder would retain one bona fide opportunity to obtain a 30-month stay.

C. A Single ANDA or 505(b)(2) Application May not be Used to Seek Approval of More than One Distinct Drug Product.

A further potential for abuse could occur under the proposed rule if the holders of ANDA and 505(b)(2) applications are permitted to file supplemental applications when they should instead be submitting new applications. For example, if an NDA holder develops a new patented dosage form that would be listed separately in the Orange Book, an ANDA applicant should be required to file a new ANDA for that dosage form, as opposed to a supplemental ANDA. Otherwise the applicant could avoid providing notice and becoming subject to a stay by amending an application that already "includes" a paragraph IV certification. FDA can ensure that this will not occur by making clear that separate ANDAs

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[5] This issue is the subject of a citizen petition currently pending before the FDA. *See* Docket No. 02P-0001, Citizen Petition Submitted by John B. Dubeck, Esq. on behalf of Biovail Corporation, January 2, 2002.

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or 505(b)(2) applications are required for every drug product listed separately in the Orange Book.[6]

D. NDA and Patent Holders Should be Able to Learn About New Patent Certifications Even Where No 30-Month Stay Is Available.

When an ANDA or 505(b)(2) applicant amends an application to make a paragraph IV certification that does not trigger a notice requirement, NDA and patent holders should be able to learn about the paragraph IV certification even if it does not trigger the opportunity to obtain a 30-month stay. This would arise, for example, where an ANDA applicant makes a paragraph IV certification to a newly listed patent and had already made a prior paragraph IV certification. FDA assumes in the preamble to the proposed rule that NDA and patent holders will somehow learn about all subsequent paragraph IV certifications, even when no notice is provided, and will be able to enforce their rights by seeking a court injunction and/or damages. 67 Fed. Reg. at 65455. This is not accurate. For example, if the first paragraph IV certification did not trigger litigation, or if that litigation is over, there may be no mechanism for an NDA or patent holder to learn about the subsequent paragraph IV certification until a generic product has already entered the market.

FDA should prevent such stealth paragraph IV certifications by posting paragraph IV certifications on its Web site, or otherwise making the information public. This approach would be entirely consistent with FDA's implementation of the Freedom of

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[6] While ANDA applicants may be permitted to include, for example, several strengths in a single *initial* ANDA submission, they should not be permitted to file originally for one strength and then amend to add another, if the result would be to deprive the NDA and patent holders of an opportunity to sue under a 30-month stay with respect to the new strengths. FDA therefore must require that new strengths be submitted through a separate ANDA, or otherwise ensure an opportunity for a 30-month stay on the new strengths.

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Information Act ("FOIA"). When an ANDA or 505(b)(2) applicant makes an initial paragraph IV certification, it must provide notice to the NDA and patent holders, even under FDA's proposed regulation. That notice is a form of public disclosure of the existence of the ANDA or 505(b)(2) application. Accordingly, there is no basis under FDA's FOIA regulations to exempt from public disclosure the fact that a subsequent paragraph IV certification has been made. Disclosure of the subsequent paragraph IV certification – for example, on FDA's Web site – merely indicates what was already publicly disclosed when notice was given of the earlier paragraph IV certification, namely that a particular ANDA has been filed. Moreover, under its existing rules, FDA has required ANDA filers to provide notice of all paragraph IV certifications and hence has not deemed the filing of such notices to be confidential as to the affected NDA and patent holders.

FDA's FOIA regulations state that the agency "will not publicly disclose the existence of an application or abbreviated application before an approvable letter is sent . . . *unless the existence of the application or abbreviated application has been previously publicly disclosed or acknowledged.*" 21 C.F.R. § 314.40(b) (emphasis added). In the case of an ANDA or 505(b)(2) application with a prior paragraph IV certification, the applicant did previously disclose or acknowledge the existence of the application. Accordingly, there is no bar on FDA's publication of any subsequent paragraph IV certifications for such applications.

This proposed approach of FDA publication of subsequent paragraph IV certifications is one way of addressing the concern that NDA and patent holders should be able to learn about all paragraph IV certifications challenging listed patents. Other

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approaches would no doubt work as well. PhRMA is supportive of other approaches that would effectively address this issue.

II. What Patents Must Be Listed in the Orange Book? [Proposed § 314.53(b)]

Proposed § 314.53(b) would delineate what patents must and must not be listed in the Orange Book. PhRMA agrees that it is beneficial to establish clearer rules regarding patent listing. The proposed rule provides helpful guidance in this regard for NDA, ANDA, and 505(b)(2) sponsors alike, and, if adopted, should reduce considerably the number of disputes that will arise with the agency or between private parties over the listing of patents.

At the same time, PhRMA has concerns regarding three issues under the new proposed rules for patent listing: the listing of patents that claim different forms of a drug substance; the listing of patents that claim integrated drug delivery systems; and the listing of patents that claim a method of using an approved drug product to administer a metabolite. Comments on these issues follow. FDA specifically requested comments on the listing of product-by-process patents, and that topic is also addressed below.

A. FDA Should Clarify in its Preamble that Patents Claiming a Form of a Drug Substance that is the "Same" as the Active Ingredient in the NDA Are and Always Have Been Listable.

The proposed rule would require the listing of patents that claim the form of the drug substance that is the subject of a pending or approved NDA, or that claim a different form of the drug substance where the different form is the "same" as the active ingredient that is the subject of the NDA within the meaning of section 505(j)(2)(A)(ii) of the FDCA. The proposal reflects a reasonable and sensible reading of the statute. Indeed, it would be improper for FDA to consider different forms of a drug substance to be the "same" active

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ingredient under the ANDA approval provisions of the Act, and yet somehow not to be the same for determining whether a patent may be listed under the Act's closely related patent listing provisions. The proposal is also consistent with court decisions holding that patents on different drug forms may be listed, court decisions which FDA has cited with approval in the past.[7] The agency's past reliance on these decisions belies its contention in the preamble (67 Fed. Reg. at 65450) that it "implicitly" did not accept the reasoning in those cases.

FDA is incorrect when it suggests at several points in the preamble (67 Fed. Reg. at 65449, 65451, 65452, 65453) that the proposal reflects a change in prior FDA policy. The proposal would at most confirm prior agency policy and cannot fairly be characterized as a substantive change.[8]

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[7] *See Zenith Labs., Inc. v. Abbott Labs.*, Civ. No. 96-1661, 1996 WL 33344963 (D.N.J. Aug. 7, 1996); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 10 F. Supp. 2d 446 (D.N.J. 1998)); Response from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, to Hugh L. Moore et al., Lord, Bissell & Brook, dated November 21, 2000 ("Woodcock Letter"), at 5 n.13 (denying citizen petition that sought to delist patents claiming a different form of paroxetine hydrochloride than the form in Paxil, as marketed, and citing these two court cases with approval).

[8] FDA's policy is best shown in its denial of a citizen petition regarding two patents claiming anhydrate forms of paroxetine hydrochloride, listed by SmithKline Beecham Corporation ("SmithKline") (now GlaxoSmithKline) for its drug Paxil (paroxetine hydrochloride). Apotex, Inc. sought to de-list the patents on the ground that Paxil, as marketed, contains only the hemihydrate form of paroxetine hydrochloride. SmithKline supported the listing of the patents, among other reasons, on the ground that the hemihydrate and anhydrate forms of the drug were asserted by Apotex and considered by FDA to be the same. Letter from Bruce N. Kuhlik, Covington & Burling, Counsel for SmithKline, to Docket No. 00P-0499, dated June 13, 2000, at 6-8. FDA denied the Apotex citizen petition. Woodcock Letter, *supra* note 7, at 1. The only possible reading of this decision is that it was FDA's policy at the time to permit the listing of patents claiming different forms of a drug substance. FDA denied the citizen petition with full knowledge that the patents at issue claimed forms of the drug substance not present in the marketed NDA formulation. If it were FDA's policy at the time that patents are listable only if they claim the form of the drug substance actually present in the marketed drug product, the agency surely would have clarified the applicable standards for patent listing and requested that the NDA holder re-
(continued...)

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(continued...)

FDA must clarify this point in the preamble to its final regulation, both to correct the administrative record and to avoid raising inappropriate implications about patents on different drug forms that were listed previously based on perceived agency policy and prevailing court decisions.

B. No Further Rules are Necessary to Identify Listing Criteria for Product-by-Process Patents.

The proposed rule appropriately provides that product-by-process patents must be listed. As FDA recognizes in the preamble, product-by-process patents are properly classified as product, not process, patents. 67 Fed. Reg. at 65452 (citing *In re Bridgeford*, 357 F.2d 679, 682 (CCPA 1966)). It would be improper to treat a product-by-process patent as an unlistable process patent. *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834, 845 (Fed. Cir. 1992) ("Though using only process terms, a product-by-process applicant sought rights to a product, not a process.").

In the preamble, the Agency invited comment "on ways to ensure that only appropriate product by process patents are listed, while maintaining the act's restriction against listing process patents." 67 Fed. Reg. at 65452. The same listing criteria used for other product patents should be used for product-by-process patents. The pertinent inquiry is whether or not the patent claims the approved drug product (in the case of product-by-process patents claiming drug products) or a form of the drug substance that is the "same" as the approved drug (in the case of product-by-process patents claiming drug substances). *See id.* at 65464 (proposed 21 C.F.R. § 314.53(b)). If a product patent claims a drug – whether

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certify against those standards, precisely as FDA did in the Biovail and Pfizer cases discussed in the preamble.

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